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Abstract

This document reports the results of the mapping and review of RRI keys and dimensions in one research conducting organization (the University of Padova) and in one research funding organization (Fondazione Telethon). The review process explored their organisational structure, culture and operational environment to identify barriers and drivers for RRI. Furthermore, the review identified any best practices for RRI already established in the organisation.

This RRI Review process was a preliminary step to write an Outlook, which defined a list of priority actions to develop RRI in the organizations and to strengthen the organisations' commitment to RRI implementation.

A brief analysis of the Italian science system and of the Italian public debate on responsibility in science and technology, illustrates the national context of the two organizational case studies. Finally, selected outcomes of the case studies are referred to in recommendations for national and European policy-makers.

Contents

1. Executive summary	4
2. Introduction: about the report	6
3. Methodology	6
4. The context for RRI: the national science policy system	8
4.1 General country information.....	8
4.2 Legal and other binding normative frameworks.....	11
4.3 Political and cultural values and discussions related to STI.....	12
5. Aspects of responsibility in national science policy	14
5.1 The conceptualization of responsibility in national science policy.....	14
5.2 The notion of 'RRI' in national science policy discussions.....	17
5.3 Ethics in the national science system.....	20
5.4 Societal engagement strategies in research.....	21
5.5 Gender equality and diversity strategies in the science system.....	22
5.6 Open access and open science strategies in the national science system.....	22
5.7 Science education as integrated in research.....	23
5.8 Incorporation of AIRR dimensions into science policy discussions.....	23
5.9 The integrated or fragmented nature of different responsibility related aspects.....	24
6. Organizational reviews and outlooks: Research conducting organisation	25
6.1 Mapping of the organization.....	25
6.2 Aspects of responsibility in organisational policy and practice.....	26
6.2.1 The conceptualisations of responsibility in the organisation.....	26
6.2.2 Ethics.....	28
6.2.3 Societal engagement strategies in organisation.....	31
6.2.4 Gender equality and diversity strategies in the organisation.....	36
6.2.5 Open access and open science strategies in the organisation.....	39
6.2.6 Science education as integrated in research.....	41
6.2.7 Incorporation of AIRR dimensions into policies.....	42
6.2.8 Other concepts used to characterise responsibility in the organisation.....	44
6.3 Reflection on Review findings, Outlooks developed and ways forward.....	45
6.3.1 The integrated or fragmented nature of different responsibility related dimensions.....	46
6.3.2 Common barriers or drivers.....	46
6.3.3 Final reflections and plan for follow-up.....	47
6.3.3.1 <i>Ethics: directions of improvement and action points</i>	48
6.3.3.2 <i>Societal engagement: directions of improvement and action points</i>	49
6.3.3.3 <i>Gender equality: directions of improvement and action points</i>	49
6.3.3.4 <i>Open access: directions of improvement and action points</i>	50
6.3.3.5 <i>Science education: directions of improvement and action points</i>	51
7. Organizational reviews and outlooks: Research funder	51
7.1 Mapping of the organization.....	52
7.2 Aspects of responsibility in organisational policy and practice.....	54
7.2.1 The conceptualisations of responsibility in the organisation.....	54
7.2.2 Ethics.....	56
7.2.3 Societal engagement strategies in organisation.....	58

7.2.4 Gender equality and diversity strategies in the organisation.....	62
7.2.5 Open access and open science strategies in the organisation.....	64
7.2.6 Science education as integrated in research.....	66
7.2.7 Incorporation of AIRR dimensions into policies.....	68
7.2.8 Other concepts used to characterise responsibility in the organisation.....	71
7.3 Reflection on Review findings, Outlooks developed and ways forward.....	72
7.3.1 The integrated or fragmented nature of different responsibility related dimensions.....	72
7.3.2 Common barriers or drivers.....	72
7.3.3 Final reflections and plan for follow-up.....	73
7.3.3.1 Ethics: directions of improvement and action points.....	73
7.3.3.2 Societal engagement: directions of improvement and action points.....	74
7.3.3.3 Gender equality: directions of improvement and action points.....	75
7.3.3.4 Open access: directions of improvement and action points.....	76
7.3.3.5 Science education: directions of improvement and action points.....	76
8. Summary of findings on each responsibility dimension.....	77
8.1 The concept of responsibility.....	77
8.2 The notion of 'RRI'.....	78
8.3 Ethics.....	78
8.4 Societal engagement.....	79
8.5 Gender equality and diversity strategies.....	79
8.6 Open access and open science strategies.....	80
8.7 The inclusion of science education into research.....	80
8.8 Incorporation of AIRR dimensions.....	81
8.8.1 Diversity and inclusion.....	81
8.8.2. Anticipation and reflexivity.....	81
8.8.3 Openness and transparency.....	81
8.8.4 Responsiveness and adaptation.....	82
8.9 The integrated or fragmented nature of different responsibility related dimensions.....	82
9. Discussion of findings.....	83
10. Conclusions.....	84
10.1 Policy recommendations to national policy makers.....	84
10.2 Policy recommendations to European policy makers.....	84
10.3 Recommendations to research conducting and funding organisations.....	84
10.4 Best practices scalable to European or national level.....	85
Annex 1 Summary matrixes for each RRI key, University of Padova.....	86
Annex 2 Summary matrixes for each RRI key, Fondazione Telethon.....	92
Annex 3 Participants in individual interviews and in focus groups.....	98

1. Executive summary

This document reports the results of the mapping and review of Responsible Research and Innovation (RRI) keys and dimensions in one Research Performing Organization (RPO) (the University of Padova) and in one Research Funding Organization (RFO) (Fondazione Telethon). The review process explored their organisational structure, culture and operational environment to identify barriers and drivers for RRI. Furthermore, the review identified any best practices for RRI already established in the organisation. This RRI Review process was a preliminary step to write an Outlook, which defined a list of priority actions to develop RRI in the organizations and to strengthen the organisations' commitment to RRI implementation. A brief analysis of the Italian science system and of the Italian public debate on responsibility in science and technology, illustrates the national context of the two organizational case studies. Finally, selected outcomes of the case studies are referred to in recommendations for national and European policy-makers.

The national mapping and analysis shows that RRI has a limited presence in the Italian science policy debate. The absence of a specific national policy framework on this matter does not prevent, however, the implementation of individual, sophisticated initiatives in regional policy (e.g. the Lombardy Regional Law on research and innovation), or industry (e.g. the UNI Reference Practice on responsible innovation). On the other hand, many aspects of RRI Keys are the subject matter of regulation and policies of more general validity, such as the laws on the prevention of gender discrimination, or the national evaluation framework of the Universities' Third Mission activities made by the Italian National Agency for the Evaluation of University and Research Systems (ANVUR).

The University of Padova is the case study of RPO presented in this report. A large, research intensive higher education institution, the University of Padova sees knowledge production and research quality as two fundamental dimensions of the University's social responsibility. RRI as such has a limited diffusion and seems mostly confined to the individuals, groups, and structures more involved in EU programs. Otherwise, national and EU sectoral regulations and policies shape rules, targets, and behaviours in the domains identified by RRI Keys and create opportunities to introduce elements of anticipation, reflection and responsiveness into the University planning and decision-making processes. From this point of view, the ANVUR assessment of Third Mission activities and the Triennial Performance Plans each University has the legal obligation to prepare, are significant examples of these entry points. The analysis showed also the importance of leadership role in steering policy actions, as it happens, for instance, for gender equality policies. In general, the Action points proposed in the RRI Outlook of the University referred to: (1) measures to align individual priorities and organizational ones, by way of ad hoc incentive systems and training opportunities; (2) changes in the reporting structure of the University to gain a more precise understanding of resources invested and of their actual returns (for instance, by introducing a specific heading on public engagement in the University budget).

Fondazione Telethon is the case study of RFO presented in this report. Telethon is a private foundation performing and funding research on rare genetic diseases. Research excellence and impact on patients are the chief criteria Telethon has set to deliver its mission and, therefore, to be responsive to the community and to its stakeholders, such as donors, individuals affected by genetic diseases, and their families. Similarly to the University of Padova, Telethon was new to RRI, too. However, policies, programs and practices are in place and cover all RRI Keys. Interactions with European peers and US leading research and research funding organizations were crucial in developing the Foundation's policies, for instance on Open Access. In gender equality, organizational culture and leadership clearly emerged as a key driver for Telethon's remarkable performance. The analysis showed also the importance of Telethon's links with

organizations and practices of the corporate world, which are an important reference for its own initiatives and activities. These tight connections are also a consequence of the Foundation's reliance on industry to recruit its officers and managers, including its director general. The Action points proposed in Telethon's RRI Outlook fall in three broad categories: (1) training of researchers and staff, for instance in ethics/regulatory issues and in public engagement rationale and techniques; (2) publication of official guidelines on sector policies (e.g. Open access, research integrity), in order to strengthen clarity and transparency; (3) extension of the indicators used for organizational analysis and reporting, in order to gain a more precise understanding of the return on investment of policies and initiatives (e.g. public engagement, Open access), but also to have a more sophisticated picture of women's participation and role in research.

Despite their differences, the two case studies illustrated the importance of the international context to shape RRI-related practices and policies. This influence is not limited to the obvious significance of EU policies and programs for national initiatives, but it is extended to the influential role of an international community of peers on organizational learning. The national framework is much more compelling for public institutions, such as universities, rather than private foundations, which are not mandated to observe pre-determined sets of indicators in assessing their policies. Common to both organizations is the situation of researchers, which are caught between two opposite forces: on the one hand, organizations are increasingly aware of and committed to RRI-related aspects such as public engagement, Open access. On the other hand, these emerging organizational priorities are not reflected in individual career advancement criteria. This misalignment of incentives reinforces a deep rooted attitude of many researchers to consider these aspects as 'distractions' from their real work. If this analysis is correct, the design and implementation of organizational solutions aligning individual interests and preferences with organizational and systemic orientations is required.

The report finally highlights policy recommendations and good practices on the organizational, national and European levels. Training on RRI is suggested as an important activity to encourage researchers and administrative officers alike to go beyond single RRI-related policy domains (ethics, social engagement, etc.) and think of responsible innovation as an integrated whole. Nationally, the broadening of ANVUR indicators for the Third Mission assessment is considered essential to strengthen the commitment of universities to public engagement. On the European level, including RRI in FP9 and integrating the same approach in other funding programs is seen as an important condition to further diffuse and consolidate RRI as an object of policy and practice. Smart Specialization Strategies and, in general, regional policy seem the best candidate for enabling this consolidation, for their systemic character (they address territories, not organizations) and their importance in funding applied research and technology development in a variety of domains.

The report emphasises two scalable best practices, one for each type of organizations. For Research Conducting and Higher Education Organizations, it is suggested to make explicit the link between teaching/research activities and their contribution to solve societal challenges. In 2018, the University of Padova has made mandatory for the academic staff to explain the contribution of their courses to the achievement of the UN Sustainable Development Goals. In this way, academic staff can be encouraged to reflect on the societal implications of their teaching. If extended to research activities, this approach might prove effective to gradually orient scientific research and knowledge transfer to reach "societally desirable" goals. For Research Funding Organizations, Fondazione Telethon has institutionalized a number of instruments through which patient organizations interact with researchers and can influence the Telethon's operations and mission. Creating similar mechanisms to integrate issue-based civil society organizations into organizations' decisions might prove instrumental to build structures, and to make funding choices and, subsequently, research activities closer to societal expectations and needs.

2. Introduction: about the report

The report collects the results of the investigation conducted by the research team of the Centre for environmental, ethical, legal and social decisions on emerging technologies (CIGA) of the University of Padova as part of WP6 of the project Responsible Research and Innovation in Practice (RRI Practice).

The research explored and assessed the positioning vis-a-vis Responsible Research and Innovation (RRI), its keys (science education, open access, ethics, gender equality, public engagement) and dimensions (anticipation, reflexivity, inclusion, responsiveness) in two Italian organizations: the University of Padova and the Telethon Foundation. This RRI Review was preliminary to the elaboration of an RRI Outlook, which defined a list of priorities and actions for the implementation of RRI in these organizations.

The context of this analysis is provided by way of a “national mapping” exercise on the significance and characterization of RRI in the Italian public debate and policy. This work followed a national workshop which was convened in February 2017 in Padova for eliciting stakeholder opinions on RRI as a way to orient the subsequent data collection and analysis.

The research is based on a qualitative analysis of policy and legal documents, as well as interviews and focus groups of key informants in both organizations (see below the Methodology section for further details).

In the last paragraph of this section, we would like to acknowledge the many contributors to this report. Firstly, the Authors are grateful to all the participants in the interviews and in the focus groups for contributing to this research. Secondly, we would like to thank Professor Marcella Bonchio, Vice Rector for Research and Professor of Organic chemistry, Dr. Barbara Mantelli, Research Manager in the Life Science Cluster at the International Research Office, and Dr. Lucia Monaco, Head of Research Impact and Strategic Analysis. They were our contact persons in the University of Padova (Professor Bonchio and Dr. Mantelli) and in Fondazione Telethon (Dr. Monaco). In this role, they suggested documents to review, helped us identify informants to be interviewed, and provided detailed feedback on the preliminary results of this research. In particular, we are thankful to Lucia Monaco for her careful reading of and detailed feedback on Section 7 of this report, which helped us refine our understanding of Fondazione Telethon and its operations. Barbara Mantelli and Dr. Leopoldo Laricchia-Robbio, formerly Head of Research Analysis & External Grants of Fondazione Telethon, are to be thanked for participating in the RRI-Practice International Workshop held in Berlin on September 20-21, 2017. Dr. Laricchia-Robbio was also our liaison person in Fondazione Telethon until October 2017 and, as such, his help was essential in setting up and starting data collection in Telethon. In the RRI-Practice team, special thanks are due to Alexei Grinbaum, Marko Monteiro, Paolo Magaudda, Maël Pégny for their insightful comments on earlier drafts of this report. Stefano Crabu and Paolo Magaudda are to be thanked for their help in organizing and conducting the organizational focus groups, too. All these contributions improved the quality of this report. However, the Authors are solely responsible for the views expressed and for any remaining error or omission.

3. Methodology

Following the research protocol of RRI-Practice, this work is based on a qualitative documentary analysis, as well as interviews of and focus groups with key informants in both organizations.

The initial description of the national RRI landscape relies also on the country profile realized by the University of Padova as part of the RRI Trends research in the FP7 ResAgorA Project (<https://rritrends.res-agera.eu/>). This description is complemented with 3 interviews to key informants, which were selected to cover the three broad stakeholder groups of academia, civil society and industry. A small number of recent policy documents was identified and examined to provide information on some RRI-related initiative in the country.

The organizational studies of the University of Padova and Fondazione Telethon included:

- the retrieval, collection and analysis of documents, such as bylaws, strategic planning documents, codes of conduct, applicable legal provisions, press releases and other communication documents (e.g. website contents);
- the administration of individual semistructured interviews with key informants in the University of Padova (7 interviews) and Fondazione Telethon (7 interviews) in the months from April to September 2017;
- the organization of two focus groups in Milan (February 26th, 2018) and Padova (March 28th, 2018), respectively joined by 8 Telethon and 7 University representatives.

The pool of respondents was identified and contacted according to a judgement sampling strategy.

In the case of Fondazione Telethon, the respondents were selected cooperatively with the main contact in the organization, who determined the contacts most suitable to provide relevant information regarding RRI, its keys and dimensions. In the case of the University of Padova, the research unit defined an initial set of potential respondents and the initial group was broadened by way of a snowball approach, through suggestions from other respondents. The initial list of interviewees was based on existing collaborations of the research group on RRI. The same procedure was repeated for individual interviews and the focus group. Individual interviews and the documentary analysis were instrumental to draft the RRI Reviews. The RRI Outlook is based on the results of the focus groups. Part of the interviewees were invited to participate in the focus group, as their familiarity with the project was considered an asset to ensure a more robust assessment. Table 1 presents an overview of the location of respondents in the case study organizations, for both the interviews and the focus groups.

Regarding the questioning route, RRI keys (ethics, societal engagement, gender equality, open access, science education) were used as the primary entry point for eliciting respondents' opinions on RRI and the predominant topic of the interviews. AIRR dimensions (anticipation, inclusion, reflexivity and responsiveness) were highly unfamiliar to interviewees and barely mentioned during the interviews and the focus groups. It was the researchers' task to isolate elements in the interviews and in the analysed documents which were relevant to describe and assess this second aspect.

The analysis of the interviews and of the focus group was based on a deductive approach, combining the matrix of organizational dimensions affecting the uptake of RRI (structural issues, cultural issues, organization-environment interchanges), as well as the indicators identified in the relevant RRI Practice Guidance document¹.

¹ To preserve anonymity, respondents are identified by a serial number with a prefix (e.g. R#1). The prefix "NM#" distinguishes respondents interviewed for the national mapping section of this report. The prefix "R#" marks the participants in the organizational interviews and "FG#" identifies the participants in the organizational focus groups. Quotes are followed by the serial identifier of respondents and the *approximate* start and end times of the corresponding passages in the interview.

Tab. 1. Location of respondents in the case study organizations

	University of Padova		Fondazione Telethon	
	Interviews	Focus group	Interviews	Focus group
Top management (Rector, Vice rector, Director, Board Chairman, etc.)	1			1
Middle management (Department director, Division manager, Office manager, Branch manager, Area manager, Committee Chair o Member, etc.)	2	1	3	2
Administrative Officers (project coordinators, program coordinators, specialized staff, etc.)	2	2	4	4
Senior researcher (Full professor, Group leader, Laboratory manager, Program leader, etc.)	1	3		
Junior researcher (post-doc, temporary post-holder, research group members, etc.)	1	1		1

4. The context for RRI: the national science policy system

4.1 General country information

Italy is a parliamentary Republic and a Member of the European Union. The Italian Constitution, which was signed into Law on 27 December 1947, assigned to the Republic the duty “to promote the development of culture and of scientific and technical research” (art. 9)².

Until the 2000s, the implementation of this constitutional provision was a responsibility of the national government and of the Ministry in charge of research and university (over the years, the exact scope of the Ministry’s mandate have changed). The Constitutional Law No. 3 of 18 October 2001 redistributed legislative powers between the national government and the Regions. Namely, art. 117 of the Constitution, as modified by the Constitutional Law, establishes that legislative powers “are vested in the State and the Regions in compliance with the Constitution and with the constraints deriving from EU-legislation and international obligations”. The same article includes “scientific and technological research and innovation” among the subject matters on which both Regions and the State have legislative competences.

Moreover, art. 117 grants to Regions a concurring legislative competence also in “international and EU relations”. This aspect is important as Regions are therefore entitled to participate in the preparatory decision-making processes of EU legislative acts, which concern the legislative matters they are responsible for. Regions are also responsible for the implementation of international agreements and EU measures, in compliance with the rules established by national law.

These brief comments show that the Constitutional reform assigned to Regions important

² Quotes from the Italian Constitution are from the official English translation. The translation is available on the website of the Presidency of the Italian Republic at the following URL: <http://www.quirinale.it/page/costituzione>. Translations of documents and interview excerpts are by S. Arnaldi if not stated otherwise.

competences in research and innovation matters. Furthermore, their responsibilities in the implementation of EU laws give to Regions significant resources for funding the innovation system, especially through EU Cohesion Funds, although regional funding programs are defined and implemented in the framework of a national development strategy (see <https://opencoesione.gov.it/it/>).

Constitutional norms set the fundamental principles of research and higher education, too. Article 33 grants freedom of research and teaching in “the arts and sciences”. As a dimension of this freedom, “[i]nstitutions of higher learning, universities and academies, have the right to adopt autonomous bylaws within the limits laid down by the laws of the State”. Article 34 affirms that “education is open to everyone” and that “capable and deserving pupils, including those without adequate financial resources, shall have the right to attain the highest levels of education”. Education and vocational training are a “right” for “disabled and handicapped persons”, too. Inclusion policies in higher education institutions are based primarily on these legal grounds.

The political and legal bond between Italy and the European Union dates back at least to 1951. In that year, the Treaty establishing the European Coal and Steel Community (ECSC Treaty) was signed in Paris. The Treaty brought together Belgium, France, Germany, Italy, Luxembourg and the Netherlands to organise the free movement of coal and steel and to free up access to sources of production (see <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:xy0022>). In 1957, the same countries signed in Rome the Treaty establishing the European Economic Community (EEC) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=legisum:xy0023>) and the Treaty establishing the European Atomic Energy Community (Euratom) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:xy0024>). Today, the EEC Treaty has become the Treaty on the Functioning of the European Union.

Italy was therefore among the founding EU countries, and the unwavering support of European integration was a constant of the Italian foreign policy over more than five decades. However, the current status of Italian relations with the Union looks increasingly frail. Public opinion has become more negative on the Union and its policies. Looking at Eurobarometer data (Eurobarometer Interactive), we can see that 59% of Italian citizens declared to be very or fairly attached to the European Union in January 2002. In March 2018, the percentage of Italians who have the same view of the EU is just 48%. In a mirror image, Italian citizens who are not at all or not very attached to the EU are 50% in March 2018, up 14 points from January 2002.

This cooler attitude of Italians is reflected in the political positions of the Government and of the main political parties. After the general elections of March 4, 2018, the new parliamentary majority was formed by the (formerly Northern) League and the Five Star Movement. These two parties are vocal critics of the current institutional set-up of the European Union and their policy priorities deviate significantly from the current EU policy and regulatory framework on a number of matters, e.g. on migration, State budget, common currency, labour market.

However, these political ambition and this more negative public opinion are still to be translated in irreversible fissures between Italy and EU. The functional interdependences between the EU Member States, and between them and the EU institutions are still formidably strong. The EU regulatory and policy framework is still overwhelmingly influential on many policy domains.

This influence is reflected, of course, in the domain of science, technology and innovation, too. Yet, influence does not mean that all the aspects of EU policy are effectively translated into national laws or programs. Unfortunately, this is the case of RRI, whose status in Italy is well described by a quote from one of the respondents:

there's not so much about this, nationally. (R#10, 45:00-45:30)

The results of the national workshop, the national mapping interviews, and the documentary analysis, all confirm this assessment. Yet, as we will describe below, there are indications of a growing interest for responsible innovation, and examples of best practices and policy initiatives are available.

This interest in RRI emerges against the backdrop of a research and innovation system characterized by endemic underfunding (according to Eurostat, the R&D expenditure per inhabitants is significantly lower than the EU average³) and by a tendency to increase the national regulation and control of the higher education system. This latter aspect has known the most important (and contested) manifestation with the creation of the Italian National Agency for the Evaluation of the University and Research Systems (ANVUR – Agenzia Nazionale di Valutazione del Sistema Universitario e della Ricerca, www.anvur.it), a public body created in 2006. According to the Law establishing the Agency (Law 286/2006), ANVUR is an independent, public body, whose functioning is overseen by the Ministry of University and research. ANVUR which started its operations five years later in 2011, has a broad mandate, which includes the following tasks: (1) evaluating processes, results and outputs of education and research activities (including technology transfer); (2) defining criteria and methods for the evaluation of research institutions and universities, and of universities' teaching activities; (3) drafting the guidelines for self-evaluation exercises performed by universities and research institutions; (4) determining, upon request of the Ministry, the parameters for allocating public funds to the higher education and research system..

ANVUR has been tasked to organize and perform a wide array of evaluation exercises for individual academics, such as the national scientific qualification (ASN – Abilitazione Scientifica Nazionale, the procedures that grant academics the qualification to compete for associate and full professorships), departments, such as the research product quality assessment of their members (VQR – Valutazione della qualità della ricerca), and universities as a whole, such as the accreditation of degree courses. In 2017, ANVUR has introduced a specific monitoring of the University Third Mission, including all the activities performed by universities to the direct benefit of their communities, regions, and, in general, of society. Until now, the result of this assessment does not affect the distribution of funds from the Ministry, but it is expected that, like VQR, Third Mission assessment will enter the set of indicators on which decisions on the assignment of performance-related additional funds will be taken (see section 6 for further details on the current indicators for the Third Mission assessment).

As a brief overview of the Italian higher education and research system, there are currently more than 90 universities in Italy recognized by the Ministry (Source: Ministry of Education, University and Research, <http://ustat.miur.it/dati/didattica/italia/atenei>), variably distributed in the Country. The National Research Council (CNR – www.cnr.it) is the alternative “pole” of public research, with 8.400 researchers and 102 research institutes (Source: www.cnr.it/it/cnr-in-numeri). Other 12 public research institutes (e.g. the Italian Space Agency or the National Institute of Oceanography and Applied Geophysics) are controlled by the Ministry (<http://www.miur.gov.it/enti-pubblici-di-ricerca1>).

While it is far beyond the scope of this report to provide a comprehensive picture of the Italia R&D system, we would like to add a few comments on the specific sector which is related to one of the case studies illustrated in this report, Fondazione Telethon, an Italian private charity whose mission is to fund and perform research activities.

Indeed, foundations are an important actor in the Italian landscape of research funders and research management organizations⁴. Foundations have been used by regional governments or, in general, public

³ http://ec.europa.eu/eurostat/product?code=rd_e_gerdtot&language=en&mode=view (accessed June 16, 2018).

⁴ The following paragraphs are based on the RRI Trends 2nd Round Country Reports on Italy. The report is available at: <http://rritrends.res-agera.eu/reports/second/>.

administration to coalesce local public and private partners around research and technology transfer ventures. For instance, the Tuscany regional government co-founded the Toscana Life Sciences Foundation in 2004. The three Tuscan universities (Florence, Pisa, and Siena) and the Sant'Anna, Pisa Normale and Lucca IMT Schools for Advanced Studies are among the founding partners, in addition to the Region of Tuscany, the MPS Bank and Foundation and all of the Sienese local authorities co-founded Toscana Life Sciences.

Moreover, bank foundations dominate the scene of private funding agencies in Italy. It is important to say that these foundations are not bodies depending from private banks, but they are independent, non-profit foundations created in the beginning of the 1990s as a result of the privatization process of Italian "Casse di Risparmio" (Savings Banks). The Law No. 218/1990 and the Legislative Degree No. 153/1999 mandate the Foundations to invest the profits they have from their financial assets in projects and investments to benefit their local and regional communities. Their nature of independent, private bodies give Foundations complete latitude to decide the allocation of their funds, though they usually (but not always) grant funds for scientific research through competitive calls for proposals, whose evaluation is performed by expert committees. As offsprings of local saving banks, Foundations focus their funding initiatives on the local areas where they have their roots, with the partial exception of the largest ones, which have a national presence. The Associazione di Fondazioni e Casse di Risparmio Spa (Association of Foundations and Savings Banks) has 88 full members, whose assets totalled Euro 39,7 billion Euro in 2016 and in the period 2000-2016 member organizations awarded a total of Euro 20.6 billion in grants across a highly diversified set of sectors, from social policies to scientific research (for further details see <http://www.acri.it>).

Fondazione Telethon, which is the case study of research funder we analyse in this report, is instead an example of funding agencies, whose assets and revenues are more traditionally linked to raising funds from the general public. Since 1990, Fondazione Telethon was active performing and funding excellent biomedical research to cure rare genetic diseases. The keystone of its activity is civil society's contribution: through volunteers, partnerships with companies, and media campaigns, Fondazione Telethon invested more than 450 million Euro in genetic research (for further details see Section 7 of this report). Telethon is one of several third sector organizations (foundations and associations) which play an important role in the biomedical research field and which promote research, education, awareness raising activities targeting one specific disease or group of diseases, such as cancer. For instance, Fondazione FIRC, created in 1977 and acknowledged as a Foundation by law in 1980, is an operating body of the AIRC (Italian Association for Cancer Research), the leading private, non-profit funder of cancer research, and collected more than 266 million Euro in donations and gifts bequeathed in wills (for further details see www.fondazionefirc.it).

4.2 Legal and other binding normative frameworks

There is no national legal or regulatory framework for RRI in Italy. Nonetheless, aspects that are relevant to RRI are covered by legal initiatives and frameworks of more general validity, whose vastness and intricacy makes impossible to review them in this report.

Exemplary cases of these broader normative frameworks are regulations about gender equality. As part of the public administration, universities have to comply with a set of regulation designed for the whole perimeter of the State's direct intervention in society. For instance, the Central Committee for the promotion of equal opportunities, workers' welfare and non-discrimination (Comitato Unico di Garanzia) is mandated by national law (art. 16, Law No. 183/2010). Similarly, in cases of discrimination, employees of

universities can appeal the Ombudsman (Difensore civico), which is not a University body but an independent office appointed by the Regional Parliaments, according to Law 142/90.

Nonetheless, a few, inductive considerations can be done, starting from the indications we obtained from the analysis. For Italian universities, a key normative reference is the Legislative Decree 33/2013 and later modifications about the “Reorganization of the regulation regarding citizens' right to access to information and public administration's obligation to ensure information's public availability, transparency and diffusion”. The Law require public bodies, including universities, to make available online and with other means of communication, information about a whole set of domains and activities, including about staff and consultants, public works, and companies owned, etc. While many of these aspects are not directly related to research and knowledge transfer activities, data regarding dimensions such as staff and performance are significantly linked to research, and are informative about how research activities are planned, organized and implemented.

A second key reference is the so called “Brunetta Reform”, from the name of the Public Administration Minister who was responsible for the adoption of this legal text (Legislative Decree No. 150/2009, implementing Law No. 15/2009). The Reform implemented a system of planning and performance assessment on a triennial basis for all public organizations, including universities. This “Performance cycle” is now the main programming, monitoring and assessment instrument for the management of universities as a whole. From the perspective of this report, the Performance Plan has been identified as a key way to plan and implement RRI-related actions and initiatives in Universities.

4.3 Political and cultural values and discussions related to STI

Scientific literacy in Italy seems closely associated to school education. 54% of Italians have studies science and technology at school, while only 9% at college or university. These values are respectively 10 points higher and 7 points lower than the EU28 average.⁵ Job creation (30%) and health (16%) are the clear priorities for science and technological innovation which are identified by Italian citizens. Interestingly, only 4% of Italians considers skills and education a priority, the lowest percentage in the EU.

In terms of the impact of S&T on these policy areas, Italians seem moderately optimistic. 37% think that science and technology will positively impact job creation over the next 15 years; 24% think they will make things worse. 43% believe that health and medical care will be improved, and 19% believe they will not (this is the lowest percentage of all EU28 Member states).

In the recent years, the single, most important debate on science-related issues has likely been the public controversy on compulsory children's vaccination. In 2017, the Government pushed a law to make vaccines compulsory (Law No. 119/2017). The law makes compulsory to vaccinate infants against ten diseases: *Haemophilus influenzae* type b, measles, mumps, rubella, varicella and whooping cough (pertussis), as well as those that were already mandated (diphtheria, tetanus, polio and hepatitis B) before the law was approved. The law was highly controversial and polarized an existing public debate on the risks of vaccination. The law prohibited kindergarten attendance to children who are not vaccinated and imposes fines to parents of primary and secondary school students who did not complete all the compulsory vaccinations.⁶

⁵ Data are from Special Eurobarometer 419, “Public Perceptions of Science, Research and Innovation”, 2014.

⁶ Ministry of Health, “Il Decreto vaccini è legge, tutte le novità”, available at: http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?menu=notizie&p=dalministero&id=3027 (Accessed July 20, 2018).

At a first glance, the public debate developed according to two main themes. The first one was about risk. Regarding this theme, the prevalent dynamic of the controversy was one of contestation of the expert knowledge claiming that vaccines bring negligible risks. The second one concerned freedom of choice and children's rights. From this second perspective, the controversy revolved around the instrument chosen by the government to reverse the decline in immunization coverage (making vaccination mandatory by law), which "had decreased alarmingly over the previous 5 years: a fall of 5.3% in 2011–15 for the measles vaccine, for example"⁷. The solution of mandatory vaccinations was proposed by the Ministry of Health, and was widely supported by medical associations, such as the Italian Society of Paediatrics (Sip), the Italian Federation of Paediatricians (Fimp), the Italian Society of work medicine and industrial hygiene (Simlii), the Italian society of public health (Siti), the Italian Federation of general practitioners (Fimmg).⁸ The critics of the law considered the compulsory nature of vaccination as a threat to children's right to education and parents' right to nurture their children according to their values. The opposition to the law was mainly composed by a number of parents' associations (e.g. Comilva – Coordination of the Italian movement for the freedom of vaccination, <http://www.comilva.org/>). Opposing opinions to vaccines and the law had wide circulation among grassroots groups promoting a natural life style and taking a more general anti-capitalist stance (e.g. <https://www.terranuova.it/content/search?SearchText=vaccini>). The mandatory nature of vaccination was targeted also by important consumer associations (Codacons – Associations for the protection of the environment and of users and consumers rights), which attacked what they see as a conflict of interest stemming from the relationship between the medical doctors advocating vaccines and the pharmaceutical companies selling them.⁹ While the official position of medical associations was in favour of the Law, a minority of medical doctors expressed personal reservations on the mandatory vaccination imposed by the Government in 2017. The range of positions varied, from scientific and technical reservations on the necessity of establishing a legal obligation for 10 vaccines¹⁰ to a critique of the law as a threat to individual freedoms and rights¹¹

Politically, the Law was opposed by the then opposition parties the Five Star Movement (M5S) and the (then) Northern League. The two parties have gained a parliamentary majority after the latest general elections on March 4th, 2018, and they formed a coalition government afterwards. The current Health Minister, Giulia Grillo (M5S), has declared that she supports vaccines, but that the Government will scrap the law establishing the compulsory nature of vaccination.¹²

As a final comment, it is interesting to notice how this debate is framed in terms of responsibility. On

⁷ Burioni R, Odone A, Signorelli C. Lessons from Italy's policy shift on immunization. *Nature*. 2018 Mar 1;555(7694):30.

⁸ See, for instance, the press release by the Italian Society of Paediatrics (SIP): "Vaccini, Villani: Bene la legge sull'obbligo". Alberto Villani, MD, is the President of SIP. The release can be accessed at: <https://www.sip.it/2017/07/28/vaccini-villani-bene-legge-su-obbligo/> (as of July 20, 2018).

⁹ This controversy continues today. See, for instance: "Vaccines: Codacons replies to Burioni and attacks again the immunologist", Codacons Press Release, June 23, 2018. Available at: <https://codacons.it/vaccini-codacons-risponde-a-burioni-e-torna-ad-attaccare-immunologo/> (Accessed July 20, 2018). Roberto Burioni is a virologist at the San Raffaele Hospital in Milan and he is a prominent public figure supporting the Vaccines Law and mandatory vaccination.

¹⁰ "Un'alternativa all'attuale decreto vaccini? Ecco la nostra proposta [An alternative to the vaccination decree? Here is our proposal]", Available at http://www.quotidianosanita.it/lettere-al-direttore/articolo.php?articolo_id=52451 (Accessed July 20, 2018).

¹¹ "Emergenza vaccinazioni? No, emergenza democrazia" [Vaccination emergency? No, it is a democratic emergency], available at <https://www.medicinademocratica.org/wp/?p=4747> (Accessed July 20, 2018).

¹² "Giulia Grillo: 'Vaccini, a scuola con autocertificazione. L'obbligo cambierà. Io incinta, vaccinerò mio figlio'" [Giulia Grillo: Vaccination, with a self-certification children will attend school. The obligation will change. I am pregnant and I will vaccinate my child'. *Corriere della Sera*, July 5, 2018. https://www.corriere.it/salute/18_luglio_05/giulia-grillo-a-breve-proposta-legge-modificare-l-obbligo-vaccinale-4ed0d75c-8047-11e8-841c-47290107a48c.shtml.

the one hand, critics of the law and critics of vaccines claim that parents have a responsibility for the wellbeing of their children, including the right to refuse medical treatments that (are believed to) imperil their health. Hence, this responsibility comes with the freedom of choice, a constitutional right the Law is said to threaten. On the other hand, advocates of the law maintain that the parents who do not vaccinate their children fail their social responsibility to society, as they negatively affect herd immunity. A recurrent argument is that their refusal to contribute to herd immunity threatens the health of those children who cannot be vaccinated for health reasons (for instance, because of their weak immune system). Social responsibility trumps individual choice and compulsoriness is justified on these grounds. On the contrary, mistrust in science and medical research, pharmaceutical industry, and regulators is frequently cited as a reason to doubt the safety of vaccines, and apparently influences the subjective perception of risk. While a comprehensive review of the controversy is not possible, two aspects can be relevant to this report. Firstly, the contrast seems to be related to the individual or collective views of responsibility, with the assumed opposition of parental responsibility and social responsibility. Secondly, social responsibility has a collective dimension, but it is without the reference to reciprocity which is characteristic of RRI. On the one hand, the public debate was heavily adversarial and the controversy was evidently politicised.¹³ On the other hand, the decision-making process had no trace of the inclusive and dialogic procedures which RRI advocates, and the mutual positioning was squarely built on expert authority on the one side, while mistrust of experts and industry, together with the defence of unrestrained freedom of choice were the grounds on which opposition to the vaccines law was based.

5. Aspects of responsibility in national science policy

5.1 The conceptualization of responsibility in national science policy

Economic growth features prominently in the national discourse on science and innovation policy. A manufacturing and export-oriented country, Italy is pushing hard towards Industry 4.0, automation and the digital integration of value chains.

Yet, the political discourse on innovation has made room to the awareness that technological transformation has to be governed and that consequences on society can be negative, too. For instance, the former Economic Development Minister, Carlo Calenda, repeatedly affirmed that digitalization and innovation processes are not positive by default¹⁴. The President of the Republic, Sergio Mattarella, introduced the same theme in his 2017 New Year's Eve address to the Country, which is one of the most

¹³ For instance, some of the regions governed by the then opposition parties threatened to disapply the law. See, for example: "Viale: «Questo è fascismo». E la Regione Liguria boicottterà la legge sui vaccini" [Viale: 'This is fascism! And the Liguria Region will boycott the Vaccines Law], *Il Secolo XIX*, July 28, 2017. http://www.ilsecoloxix.it/p/genova/2017/07/28/ASgVb5al-boicotttera_liguria_fascismo.shtml. Roberta Viale is the Liguria Regional Minister of Health. See also: Cuzzocrea A., "L'accusa a Grillo 'Tesi pericolose sui vaccini'. M5S: 'Falso, per noi sono essenziali'" [Grillo is accused: 'She has dangerous beliefs on vaccination'. 5SM: 'It is false, we believe they are essential'], *La Repubblica*, May 4, 2017, Available at: <http://ricerca.repubblica.it/repubblica/archivio/repubblica/2017/05/04/laccusa-a-grillo-tesi-pericolose-sui-vaccini-m5s-falso-essenziali01.html?ref=search>. Giulia Grillo is a 5SM Member of Parliament and the current Minister of Health.

¹⁴ "Calenda: sul digitale l'Italia si gioca tutto", available at: http://www.aidr.it/archivio10_notizie-e-comunicati_0_501_2253_8.html (Accessed June 17, 2018).

solemn speeches of the Presidency. Mattarella said:

*In our time, the word “future” recalls uncertainties and concerns. In the past, it did not. In history, scientific discoveries and technological evolution accompanied a positive idea of progress. Nonetheless, transformations need to be governed to avoid that they create injustices and new exclusions. The authentic mission of politics consists exactly in the capacity to tackle these novelties and to direct these change processes. To make this new era more just and sustainable.*¹⁵

In the background, there is the awareness of the political upheaval that these disruptive transformations are producing. This concern brings clarity to the “mission” (or responsibility) of politics. However, the ways in which this awareness is translated into policies are far from clear.

Interviews are useful to bring some clarity, but they suggest a broader view encompassing public policy and private activities. For higher education institutions, the attention and commitment to the social implications of knowledge production is formalized in their “Third mission” evaluation performed by the National Evaluation Agency. The “Third mission” has two components: (1) creating value from research (valorizzazione della ricerca); (2) producing public goods of social, cultural and educational nature.¹⁶ Corporate Social Responsibility (CSR) is the reference framework for firms, especially the large ones. CSR covers many aspects overlapping with RRI keys, though it does not provide a structure to integrate these concerns in corporate R&D activities (NM#1, 8:30-11:20).

In terms of public policies, the “forerunner” of responsibility in innovation policy (NM#2, 14:45-21:00) has been the national system of Chambers of Commerce. In Italy, Chambers of Commerce are public bodies, but their governance is participated by industry/commercial representative associations. The key signature of this effort was the choice of certifications and standards development as the instrument for introducing responsibility in corporate processes. This choice was based on the assumption that firms should be addressed using languages and tools they are familiar with. According to this perspective, the Emilia-Romagna Region’s Chambers of Commerce started in the late 2000s the preparation of a “Certification of responsible innovation - UGO” (<http://www.ugocertification.org/index.htm?lang=ENG>). UGO was developed by the Centre for Innovation and economic development (CISE) of the Forlì-Cesena Chamber of Commerce (now Romagna Chamber of Commerce). UGO is a voluntary standard that can be applied by any Organization spending at least 5% of their added value in R&D and willing to direct innovation both towards the development and the improvement of human living standards. Certified companies agree to apply the “precautionary principle” to their innovative activities and products if their characteristics, on the basis on the current knowledge, could be harmful both to the health and to the safeguard of people and environment. If the precautionary principle is applied, certified companies are requested to invest annually at least 1% of their turnover in research activities aimed at eliminating the possible damages and anticipating the adoption of preventive measures in respect to the effective risks. Certified companies agree to foster innovations that allow the maximization of the value and of the quality of life of the stakeholders, by applying a transparent method which is defined in the standard.

UGO was tested by a limited number of companies and evolved into a Reference Practice (Prassi di riferimento) of the National Standards Body (UNI – Ente Italiano di Normazione), which was drafted by CISE

¹⁵ The full speech is available at: <http://www.quirinale.it/elementi/Continua.aspx?tipo=Discorso&key=769> (Accessed June 17, 2018). The Authors thank Francesco Samorè for pointing at this passage of the speech.

¹⁶ Bonaccorsi A. “Verso un’università responsabile: la valutazione della terza missione”, Workshop “La valutazione delle terza missione nella Sua-Rd” (Verona, Italy, March 4th, 2015). Available at: <https://dilive.univr.it/videos/video/331/download/Intervento%20Prof%20Bonaccorsi.pdf> (Accessed June 17th, 2018).

in collaboration with the Italian Association of Industrial Research (AIRI). The “Guidelines for management and processes development for responsible innovation” (UNI/PdR 27:2017) define:

the criteria to ensure that the innovation process implemented by the organizations take place in a responsible way, i.e. in such a way that the latter is finalized to the progress and improvement of quality of life, according to the expectations of different parties concerned and which is sustainable overall on an environmental, social and economic level.

(catalogo.uni.com/pdr/pub/uni_pdr_27_2017.pdf)

The Practice is not a norm or a certification, but it is a sort of preliminary step towards that direction. A corresponding norm will be adopted if widespread interest in the practice is demonstrated over time.

The growing diffusion of the logic of responsibility in the private sector, is proved by the “Confindustria’s manifesto for changing firms in a transforming county” named “Social responsibility in Industry 4.0” (cf. <https://bit.ly/2naspVO>). The document is promoted by the National Industrialists Association (Confindustria) and it is aimed to encourage Confindustria’s members to embrace social responsibility and sustainability as key dimensions of economic activities. The UN Sustainable Development Goals are mentioned as a framework for sustainability policies and actions, and firms are viewed as a key contributor to achieving these goals.

The document starts identifying environmental degradation, climate change and income inequalities as challenges to global economic growth and calls firms to address these challenges. Reversing these trends is seen as a condition for the long term sustainability and prosperity of industrial activity itself, as well as for the competitiveness of Italian firms.

Firms are encouraged to adopt the sustainable and responsible behaviours that fit best with their business sectors, although the document emphasizes that this type of engagement should remain a voluntary choice of individual companies. Firms are also urged to reduce the social and environmental impacts of their products. In doing so, they should not limit their attention to their own productive processes and they should consider their whole value chain.

These two examples show the importance of Corporate Social Responsibility (CSR) in shaping innovation activities. CSR is certainly significant in industry, yet it is debatable to what extent it represents a valid framework for responsibility in industrial research and in the higher education sector. Firstly, it is quite rare that CSR covers research activities as such. Secondly, this happens not only in firms, but also in Universities. Where social reporting is available, the missions of the University are accounted for their process indicators, rather than their outcomes and impacts.¹⁷ Moreover, social reporting still has a limited diffusion among higher education institutions and only a handful of universities are regularly publishing a social report.¹⁸ This narrow diffusion in the academic, public and corporate and research worlds, suggests that CSR and its instruments are not a shared or generally valid framework for defining and implementing responsibility in research and innovation.

RRI is not such a framework, either. As we will show, there is not a single, overarching framework for responsible innovation, and sectoral legislations, individual policy initiatives, and distinct programs contribute instead to model the meaning of responsibility and to shape the concrete forms which RRI, its keys, and dimensions take.

¹⁷ For an example: Carlesi A. (ed.). *Bilancio sociale dell’Università di Pisa*. Pisa: Pisa university press, 2013.

¹⁸ Verde M., “La rendicontazione sociale nelle Università: il bilancio sociale”, Presented at the Conference “Autonomia e responsabilità sociale dell’Università: governance ed accountability nel processo di riforma” (Vercelli, Italy, March 2, 2012). Available at: <http://www.econometrica.it/events/2012/Verde.ppt.pdf> (Accessed July 20, 2018).

5.2 The notion of 'RRI' in national science policy discussions

There is little on RRI in the Italian public discourse and policy. The Rome Declaration on Responsible Research and Innovation in Europe signed in 2014 had little or no consequence in the country. A likely and potentially important effect of this political involvement in SiS-RRI is the inclusion of RRI in the Piano Nazionale della Ricerca (National Research Program, <https://www.researchitaly.it/il-programma-nazionale-della-ricerca/>).

The National Research Program is the framework document for national science and technology policy. It is a governmental act, which is issued by the Ministry of Education, University and Research, with the collaboration of other ministries (e.g. Economic Development). The current Program covers five years (2015-2020) and identifies twelve “specialization areas” of applied research, which are considered a national priority and which are supported by the funds allocated by the program. These areas are identified by matching H2020 Societal challenges and Key enabling technologies with the national priorities in science, technology and innovation.

The Program has six broad directions: (1) fostering internationalisation, including aligning the national R&D programs to the EU funding and policy, especially H2020; (2) developing the human capital of the Italian research system; (3) strengthening and rationalizing research infrastructures; (4) promoted public-private partnerships in industrial research; (5) advancing the potential of Southern Italy in research and innovation; (6) improving the efficiency and quality of funds management.

The topic of Responsible Research and Innovation (“Ricerca e innovazione socialmente responsabile”) is included in the funding line on public-private partnership, as part of a broader emphasis on “Society, research and social innovation”. The funds are targeted to the creation of a national coordination platform for RRI-related activities, with the goal to strengthen the Italian participation to the SWAFS program (p. 65).

The composition of this coordination platform will include both private and public body and it is expected to elaborate a national framework and vision for RRI, in order to define also a National Roadmap for RRI-related policy implementation. The platform is expected to prepare policy recommendations to the Government, connect the national research system with international experiences in RRI, define an ethical-scientific framework for the elaboration of guidelines on this topic, apply and mainstream RRI principles in research evaluation.

There is no reference to keys in the section of the document dealing with RRI. The document takes a more systemic approach which follows closely the original von Schomberg’s definition of Responsible Research and Innovation.¹⁹ According to the Program, the three essential elements of RRI are: (1) “Norms”, that are the values shaping the understanding of responsibility; (2) “Activities”, that are the tools and methods to match these values (e.g., life cycle analysis, corporate social responsibility, public engagement, technology assessment, foresight, etc.); (3) “Actors”, that are the interactions and mutual responsibilities between stakeholders.

However, it is unclear how such an ambitious plan can be implemented, considering the very limited financial investment available for its implementation (€ 300,000/year for three years). To date and to our knowledge, this coordination activity has not been started, yet.

¹⁹ Von Schomberg R (2013) A vision of responsible innovation. In: Owen R, Heintz M, Bessant J (eds) Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society. Wiley, Chichester, UK, pp 51– 73

Though with a subnational geographical target, a more comprehensive approach is adopted by the Lombardy regional government. Lombardy is the most populated Italian region, with more than 10 million residents, and had an annual GDP of 350 Billion Euros in 2015 (Source: Eurostat, Regional gross domestic product by NUTS 2 regions). Regional Law 29/2016 defines the framework of regional science and innovation policies of Lombardy and introduces responsible innovation as an official goal of regional science and innovation policy and funding (<http://normelombardia.consiglio.regione.lombardia.it/NormeLombardia/Accessibile/main.aspx?iddoc=lr002016112300029&view=showdoc>). The Law commits the Regional Government to promote “the culture of responsible research and innovation”, including among Lombard firms (art. 1, paragraph 2, letter a). The main tool of this policy is a “Three-years Strategic Plan” defined by the Regional Government and approved by the Regional parliamentary assembly (Consiglio regionale). Among the goals of the Program, the Law lists “open science for the public sharing of research data and publications” (art. 2, paragraph 3, letter k) and “[the support to] social innovations that meet social needs and create new collaborations and relations” (art. 2, paragraph 3, letter p).

The Law creates also a Regional Forum for research and innovation (art. 3) as an advisory board to the Regional government and assembly. The 10 members of the Forum have been selected through an international tender and are “highly qualified experts” in the relationship “science/innovation/technology and society” at large. The Forum’s mandate has begun in 2018. The Forum is expected to: (1) define topics and methods of public participation in decisions about science, technology and innovation; (2) examine the public’s opinion on techno-scientific themes and present the results; (3) elaborates targeted projects to support applied research in SMEs “that invest in responsible and sustainable development”.

The Regional Law is the only legislative document in Italy that mentions RRI as an explicit goal of public policy, to the best of our knowledge. The Law mentions explicitly some of the RRI keys, such as social engagement and open access/open science. Ethics is indirectly referred to in the mandate of the Forum. The Forum itself is probably the most interesting point is the creation of the Regional Forum as a multidisciplinary advisory body to the Regional Government, involving also social sciences and humanities as part of a comprehensive approach to technology assessment. If fully implemented, this architecture of the Law could lead to the systematic integration of societal issues in the regional policy agenda on science, technology and innovation, in a reflexive and anticipatory way.

The Lombardy Regional Government tasked the Fondazione Giannino Bassetti of selecting the candidates to join the Regional Forum, as well as of steering and coordinating its activities, also since the Foundation strongly promoted the inclusion of RRI in the Law and the creation of the Forum itself. This mandate acknowledges the public role that the Fondazione has played in the diffusion of responsible innovation and, later, RRI in the Italian public discourse. Established in 1994, the Fondazione has the mission “to promote responsibility in innovation within both the national and international setting, helping institutional, private and associational actors to orient their aims and goals, in considering them a factor of interest for the entire society; both in the techno-scientific field and regarding governance models” (https://www.fondazionebassetti.org/en/pages/2016/05/fondazione_giannino_bassetti.html). Among other activities, the Fondazione contributed to the establishment of VIRI, the “Virtual Institute of Responsible Innovation”, which is housed by the Center for Nanotechnology in Society at Arizona State University. Since 2016, the Lombardy Region participates in the Foundation and has a stake in the Foundation’s governance. The Fondazione Bassetti is an example of the few private, not-for-profit, actors who have played an important role in fostering the debate on responsible innovation in Italy and abroad thanks to its established and broad network in Europe and in the US, promoting Responsible Innovation since more than 20 years, thus years before the academic discussion and the inclusion of RRI in the European Commission’s

policies and funding programs.

Another example of private organization involved in RRI is AIRI – Associazione Italiana per la Ricerca Industriale (Italian Association for Industrial Research). AIRI is a not-for-profit organization, which represents a national network of industries (large firms and SMEs) and public research institutions, with the mission to promote research and innovation (R&I). AIRI network's members cover sectors such as ICT, nano-microelectronics, biotechnologies, advanced materials, chemistry, energy, transportation, aeronautics, space. Its division AIRI/Nanotec.IT has been a key actor in the European debate on the governance of nanotechnologies and is now deeply involved in the EU RRI community. AIRI has been involved in a number of EU projects related to RRI, such as FramingNano, NanoCode, ObservatoryNANO, Responsible Industry, SATORI. With the Chamber of Commerce of the Romagna Region, AIRI has drafted the Reference Practice on Responsible innovation which was commented above.

Among research funders, a key role is played by Fondazione Cariplo.²⁰ Fondazione Cariplo is the largest private donor in the country and the biggest bank foundation in Italy. Fondazione Cariplo originated from the Cassa di Risparmio delle Provincie Lombarde (Savings Bank of the Lombard Provinces). Based in Milan, Fondazione Cariplo was officially set up in December 1991, following the reorganization of the Italian banking system resulting from Law No. 218/1990. Fondazione Cariplo organizes its activity around a Multi-year Framework Plan and specific, sectoral Action Plans. Action Plans set out specific project objectives, outlining the role the Foundation can play in a given area, the specific objectives it pursues, as well as the strategies and means it can use to achieve them. All these activities fall within four broad thematic areas: environment, arts and culture, scientific research and technology transfer, and social services.

The Fondazione joined international collaborative projects on RRI, as part of its commitment to the European philanthropic community and the ongoing discussions on RRI in that context (e.g. the EFC Research Forum Statement on Responsible Research and Innovation in October 2014). Fondazione Cariplo was part of the RRI Tools Project (<http://www.rri-tools.eu/>) and acted as the leader of the Italy-Switzerland project hub.

More importantly, the Fondazione has incorporated RRI in its call for proposals. The language of the calls now includes references to Responsible Research and Innovation and scientists competing for the Foundation's resources are requested to structure "their communication plan in a dialogic way complying with the RRI Approach" (see e.g. the 2018 call on biomedical research, p. 5; available at <http://www.fondazionecariplo.it/static/upload/bio/biomedical-research-on-ageing-related-diseases.pdf>). The same call text provides a definition of RRI: "[i]n light of the available literature, it is possible to describe RRI as a dynamic and iterative process which intends to match research and innovation to values, needs and expectations of the society. Moreover, RRI aims at actively involving all the stakeholders taking part to activities of research and innovation, making them mutually responsible with respect to both the research process and its results" (p. 5).

These brief considerations highlight some of the leading initiatives and actors on RRI in Italy. However, it is apparent that RRI as such has a limited diffusion and significance. This implies that the regulation of and policy about the keys mostly depends on sources and initiatives which are unrelated to the RRI debate. This report cannot provide a comprehensive overview of these sources. As we have done in other sections of this deliverable, we will draw from our case studies and from this 'national mapping' exercise to illustrate some of the national reference policies which are relevant to the RRI keys.

²⁰ The following paragraphs are based on the RRI Trends 2nd Round Country Reports on Italy. The report is available at: <http://rritrends.res-agera.eu/reports/second/>.

5.3 Ethics in the national science system

In Italy there are national and local Ethics Committees. On the national level, the Italian National Ethics Committee (Comitato Nazionale di Bioetica – CNB) acts as a consultative body of the President of the Council of Ministers, who heads the national government. The Committee issues opinions on the ethical and legal aspects of scientific research and technological development. The Committee can initiate the work on an opinion in an autonomous manner, or it can reply to a request from another government body or social actor.

A second advisory body to the Presidency of the Council of Ministers is the “National Committee on Biosecurity, Biotechnologies and Life Sciences” (Comitato Nazionale per la Biosicurezza, le Biotechnologie e le Scienze della Vita – CNBBSV). This second Committee has the task to advise the Government on the scientific, economic and social issues related to life sciences and biotechnologies. Among other tasks, the Committee: “(1) assesses the risks arising from the use of biological agents, and to this end identifies the risk factors and conditions for their classifications; (2) develops criteria for the definition of safety standards in relation to the applicative areas of biotechnology, biosafety and life sciences; (3) cooperates in drafting the regulations transposing European directives that in any way implicate the involvement of biotechnology, biosafety and life sciences; (4) as direct support of the President of the Council of Ministers: ensures, after considering the respective and specific competences, the coordination, harmonisation and integration of programs, initiatives and activities of ministries, institutions and organisations, both public and private, operating within the biotechnology, biosafety and life sciences sectors” (http://presidenza.governo.it/biotechnologie/eng/Institutional_responsibilities.html). The CNB and the CNBBSV can organize joint meetings and can issue joint opinions and guidelines, such as the joint opinions on genetic testing of 15 July 2010 and on robotics of 17 July 2017.

On the local level, Ethics Committees are involved in the authorization procedures of clinical trials. Local Ethics Committees are established by the administration of the public health local authorities in which clinical trials are conducted. The Regional Governments are responsible for the accreditation of the Ethics Committees working within their regions and for the transmission of the list of them to the Italian Medicines Agency.

Regional bioethics committees may act as coordinators for local ethics committees and also as a link between them and the National Bioethics Committee. In some regions where there is only a Regional bioethics committee, it will act as a local ethics committee and review research proposals. In January 2018, the Parliament delegated the Government to review and reorganize the clinical trials of pharmaceuticals and medical devices (Delegating Law No. 3/2018), in order to coordinate the national regulation with the new EU Regulation No. 536/2014 on clinical trials. Among other things, the delegating law established a National Coordination Centre of the local ethics committees for clinical trials of medicinals and medical devices. The Centre is housed by the Italian National Medicines Agency (AIFA) and has the tasks of coordinating, monitoring, and steering the ethics assessments of clinical trials performed by the local ethics committees.

Ethical aspects of animal experimentation are assessed by OBAs, the Animal-Welfare Bodies (OBA – Organismo per il Benessere Animale), which have been created following Directive 2010/63/EU on the protection of animals used for scientific purposes. In universities, OBAs replace Ethics Committees on Animal Research established by internal regulations. Before the Directive, there was no legal requirement to have such a body, while they were widespread due to the fact that an opinion by the Ethics Committee on Animal Research was generally a requirement for publication. The OBA’s mandate is to ensure the

welfare of animals used for scientific purposes in research projects.

There is no legally mandatory provision to create Ethics committees in domains different from experimentation on human subjects or on animals. Ethics committees in psychological research are widespread and research projects must be reviewed by a Local Ethics Committee before they start. However, this obligation rests on the Ethics Code of the Italian Psychology Association, whose General Assembly approved the Code in 2015 (cf. <https://www.aipass.org/node/11560>). To our knowledge, there are no ethics committees to review research in other domains, such as the social sciences or computer sciences.

5.4 Societal engagement strategies in research

For higher education institutions, the attention and commitment to the social implications of knowledge production is formalized in their “Third mission” evaluation, as performed by the Italian National Agency for the Evaluation of the University and Research Systems (ANVUR).²¹ The evaluation of the Third Mission is established by the Ministry of University, with the Ministerial Decree No. 47/2013, as part of the self-evaluation and accreditation procedures of universities and their courses. The same decree establishes a set of quantitative indicators to be monitored as part of the universities’ annual reporting (Annex E):

- scientific and cultural dissemination activities;
- number of patents in ten years;
- income from contract research and externally funded research projects;
- number of spin-off in ten years.

The “Third mission” has two components: (1) creating value from research (valorizzazione della ricerca); (2) producing public goods of social, cultural and educational nature. The former involves aspects such as: intellectual property management (patents), spin-offs, contract research, collaborations with innovation intermediaries. The latter includes activities such as; production and management of the cultural heritage, participation in clinical trials, creation and maintenance of medical research infrastructures, medical training, adult and continuous education, public engagement.

Public engagement refers here to a wide array of heterogeneous activities, ranging from publications for the general public, to concerts and theatrical pieces, to dissemination activities for the youth, to participation in policy-making, to seminars and lessons. It is evident that this very broad definition groups in a single category public engagement, science communication and science education activities, thus making them virtually indistinguishable from the perspective of university evaluation. This wide characterization disincentives universities to refine their understanding of public engagement and to start activities which could be properly defined as ‘engagement’. Moreover, the list of indicators presented above clearly shows how this evaluation framework creates incentives to focus more on the commercialization of knowledge over the production of public goods, including public engagement initiatives.

Finally, it is interesting to examine how the National Evaluation Agency differentiated teaching and

²¹ This description is based on the official definitions and instructions provided by the National Evaluation Agency as presented by: Bonaccorsi A. “Verso un’università responsabile: la valutazione della terza missione”, Workshop “La valutazione delle terza missione nella Sua-Rd” (Verona, Italy, March 4th, 2015). Available at: <https://dilive.univr.it/videos/video/331/download/Intervento%20Pro%20Bonaccorsi.pdf> (Accessed June 17th, 2018).

research activities, on the one hand, and Third Mission activities, on the other hand. The former are individual activities of academic staff, and defines their legal status. As such, they are constitutionally protected (Art. 33 of the Italian Constitution, stating the freedom of research and teaching). Third Mission activities are not seen as individual responsibilities of academics, but as an organizational responsibility of academic structures (universities and departments). This different allocation of responsibility influences also the levels on which evaluation is performed: individual, for teaching and research; organizational, for the third mission.

5.5 Gender equality and diversity strategies in the science system

Gender equality is a highly regulated area, which goes beyond research and innovation. One of the most direct influence this regulation has on science and innovation, concerns the type, mandate, and procedures of the public bodies and organizations whose task is to protect and promote equal opportunities in the public administration, including universities and public research institutions.

For instance, the Central Committee for the promotion of equal opportunities, workers' welfare and non-discrimination (Comitato Unico di Garanzia – CUG) is a mandatory body according to the National Law 183/2010 and has advisory and monitoring tasks in matters of equal opportunities concerning the administrative staff of the University. Similarly, the Ombudsman (Difensore civico) is not a University body. It is instead an independent office appointed by all Regional Parliaments, according to Law 142/90. The Ombudsman action is limited to ensuring the transparency, fairness and timeliness of public administration. The Ombudsman can be therefore appealed only in matters concerning either civil servants' employment contracts or public services organization and provision.

These aspects will be discussed in a more detailed way below, in section 6 of the report.

5.6 Open access and open science strategies in the national science system

Open Access and Open Data initiatives are absent in national policies, as interviewees lament (NM#1, 23:00-25:20). For higher education institutions, a sort of systemic role in OpenAccess is played by the Cineca Consortium. Cineca (Consorzio Interuniversitario del Nord-Est per il Calcolo Automatico – Northeastern Inter-university Consortium for Automated Calculation – www.cineca.it) is a non-profit Consortium, gathering 77 Italian higher education institutions. Today it is the largest Italian computing centre and one of the most important worldwide. It provides services and knowledge transfer through high performance scientific computing, web-based services, and data management.

Cineca has provided services to universities and research bodies aimed at the design, creation, implementation and management of open institutional archives and through the creation of an infrastructure for the publication of open access academic and scientific journals. Through Cineca, Italian universities are partner of the OpenAIRE Consortium. The OpenAIRE project was initially funded by FP7 to support the implementation of the European Commission (EC) and of the European Research Council (ERC) Open Access policies. Its successors have accompanied the development of OpenAccess in the European Union, making Open access to scientific peer reviewed publications evolve from an FP7 project to an

underlying principle in the Horizon 2020 funding scheme and a cornerstone of FP9. OpenAIRE has created and maintains the OpenAIRE portal, which makes available European funded research outputs.

Moreover, Cineca has created the platform PLEIADI (Portal for Italian Electronic Literature Archives and Institutional Deposits, <http://find.openarchives.it/>), indexing and making available over 800,000 scientific contents produced in about 40 Italian universities and research centres.

5.7 Science education as integrated in research

As we have discussed in the section on societal engagement, science education, science communication, and public engagement activities properly understood are included in the same “basket” under the “Third Mission” label. Therefore, we refer to our discussion in section 5.4 for illustrating the main features of the ANVUR Third Mission framework and its effects on universities’ activities in the domain of public engagement and science education.

5.8 Incorporation of AIRR dimensions into science policy discussions

5.8.1 Diversity and inclusion

5.8.2 Anticipation and reflexivity

5.8.3 Openness and transparency

5.8.4 Responsiveness and adaptation

It is difficult to identify explicit references to AIRR dimensions in the public debate on science and innovation, as these dimensions do not enter the debate *as such*.

This absence does not mean that specific aspects of the public debate are irrelevant in terms of the AIRR dimensions. For instance, inclusion and responsiveness can be considered as implicit elements in the public discussions on vaccination and Industry 4.0. As our brief description explained, the controversy over mandatory vaccination was characterized by the mutual delegitimation of the social and political actors involved. The supporters of the law forcefully asserted expert authority as the legitimation source of their action; the critics of the law attacked the good faith of the legislators and of those who defended the law, on the grounds of a perceived conflict of interest. The public debate on Industry 4.0 is more ambivalent, as it combines an emphasis on automation and digitization in industrial production as a tool for Italian economic competitiveness, with the acknowledgement of the unwanted social effects of this transformation. Therefore, in this case, the idea of preventing and remedying the inequalities potentially created by the digitalization of productive processes has made room in the political discussion.

Furthermore, when we look at the regulatory and policy framework as described above, we can see that it provides opportunities for the incorporation of AIRR dimensions in decision-making about science and innovation. Although implementation is everything and the risk of bureaucratization is high, the way in which the “Third mission” of universities is defined opens a space for reflection and responsiveness, as it questions universities’ understanding of the “public goods” produced by higher education. Similarly, higher education planning processes as structured by the Triennial Performance Plan instil elements of anticipation

in universities' action.

The private sector initiative we described such as the responsible innovation certification and the Lombardy Region's policy framework are much less focused on the keys, and much more centred on science in society and on the governance of innovation. From this viewpoint, they design valuable mechanisms to anticipate and reflect upon the consequences of innovation. Moreover, they create mechanisms for inclusion of stakeholders and, potentially, of citizens in policy making (in the case of the Lombard Regional Law).

In this way, these initiatives rely on what one of the respondents called the "plasticity" of RRI, i.e. the capacity of this concept to transfer its main features in different conceptual frameworks, such as the new EU "Open Science, Open Innovation, Open to the world" framework²² (NM#3, 31:20) or the CSR principles and instruments in industry.

5.9 The integrated or fragmented nature of different responsibility related aspects

These brief considerations illustrate the fragmented nature of responsibility in general and, specifically, of the dimensions related to RRI. As we have seen, the national landscape is characterized by some important and advanced initiatives, from regional governments, chambers of commerce, industrial companies, and non-profit actors. Moreover, single aspects of RRI are covered, at least partly, by existing legislation and policies, such as public engagement and gender equality. Eventually, organizational processes such as performance planning and assessment provide important openings for anticipation, reflexivity and responsiveness, and establish the mechanisms to integrate these dimension in organizations' decision-making processes. The case studies will elaborate on this point.

However, these advancements and opportunities are largely disconnected and lack of a national reference framework. In academia, "responsibility is very much fashionable". Despite this fact, concrete improvements on a systemic level are slow, because there is no strong political mandate by the Ministry of University and Research (NM#2, 10:30-12:00), as the ambiguous commitment to RRI in the National Research Program shows.

The future of RRI in Italy is, therefore, uncertain. Yet, there are national and global trends which work towards a strengthening of the focus on responsibility in science, technology and innovation. These enabling conditions include international policy frameworks such as the UN Sustainable Development Goals and the current evolutions of EU science policy (Open Innovation, Open Science, Open to the world), and national policy commitments such as the Third Mission of higher education institutions (NM#2 13:20). Social practices such as Corporate Socially Responsible innovations have a place in their own right, accompanying the growing awareness in companies of the reputational benefits of responsible practices, and supporting the extension to this area of the traditional efforts to understand the needs and expectations of customers. In other words, market forces can foster companies' commitment to RRI. (NM#3, 52:00-57:20)

From a more political perspective, ongoing debates on the digitalization of industrial and productive processes (Industry 4.0) and vaccines confirm the willingness and interest of a heterogenous set of social actors to engage, also confrontationally, with the discussion of the consequences of innovation. These debates and their often adversarial nature questions the abstract potential and practical limits of the agency

²² European Commission (2016) Open innovation, open science, open to the world: a vision for Europe. Publications Office of the European Union, Luxembourg.

which social actors and citizens have in individual and collective decisions on economic development and public health.

Yet, a set of obstacles are identified to the more systematic and integrated take up of responsibility in science, technology and innovation. First, bureaucratization is seen as a possible risk. Responsibility is an inherently political act (NM#3, 42:20-43:50); converting responsibility in a bureaucratic checklist helps its organizational translation, but hampers its transformative potential (NM#1, 29:50-31:00; NM#3, 42:20-43:50). Second, research and innovation actors do not coalesce to influence policy. This is a weakness, as joining forces, for instance in the case of large universities, is seen as a condition to influence policies, regionally and nationally (NM#3, 25:50-27:00). Third, the temporal distribution of costs and benefits of RRI is likely to be skewed. This means that costs are likely born in the short term, and benefits play out in the longer term. This distribution is problematic for firms, especially SMEs. Small companies have limited resources and, therefore, they can be shy in investing in RRI, as long as they have to bear certain, additional costs, in exchange of future, uncertain benefits. (NM#2, 46:45-51:00). A further obstacle which specifically regards the firms of an export-oriented country, such as Italy, is the uneven commitment to RRI of competing companies on a global level. Indeed, there are countries in which RRI is not diffused, and this means that firms in that country do not have to bear the costs related to RRI implementation (NM#2, 43:00-46:45).

6. Organizational reviews and outlooks: Research conducting organisation

6.1 Mapping of the organization

Established in 1222, the University of Padova is the second oldest university in Italy. It has 32 Departments, ranging from Engineering to Veterinary Sciences, with more than 4,500 teaching staff in 2017 and more than 57,000 students in the academic year 2016-2017²³. In 2015, the University of Padova had a turnover of 598 Million euros in 2017 (<https://www.unipd.it/trasparenza/bilancio-preventivo-consuntivo>).

The University has been ranked first in the recent National research assessments conducted by the National Agency for Evaluation of the University System and of Research (ANVUR). As early as January 2017, the University has been awarded 81 H2020 projects for a total 32 million euros granted (cf. https://issuu.com/universitypadova/docs/webelong_web).

The University has gradually yet consistently moved to develop and implement actions in the various policy and practical domains described by the RRI keys. Increasingly, these actions are framed as part of the social responsibility of the university. The following sections illustrate how these improvements were sought and how this social responsibility is translated into policies and practices. However, we will show how this discussion has developed largely unaware of the ongoing debate on RRI in the European Union, despite the many overlapping aspects and points of contacts.

²³ Data from the Statistics Office of the Ministry of Education, University and Research (<http://dati.ustat.miur.it/dataset/2016-17-iscritti-e-immatricolati>).

6.2 Aspects of responsibility in organisational policy and practice

6.2.1 The conceptualisations of responsibility in the organisation

The vision of the university sets the goal to “strengthen its identity and reputation of large and high-quality university, developing a multi- and inter-disciplinary vision of research and teaching”. This vision assigns to the academic community “the responsibility to provide value and knowledge to the region [where the University is located]” (cf. <http://www.unipd.it/download/file/fid/17658>, p. 4).

This framing characterises the “social responsibility” of the University, which is listed among the values orienting its action and which the University actively promotes (cf. <http://www.unipd.it/download/file/fid/17658>, p. 4).

Similarly, the University's strategic plan sets as its first general objective:

[the goal] to deliver a decisive contribution to the sustainable economic, social and cultural development of the region [where the University is located] by disseminating knowledge, training opportunities and human capital and by transferring scientific and cultural outcomes (cf. <http://www.unipd.it/download/file/fid/17658>, p. 10).

One of the ways in which the University sees this role in fostering socially sustainable development in terms of facilitating innovation through the development of joint knowledge transfer projects with other societal actors, especially the public administration and firms. This is the essential aspect of its “Third Mission”, i.e. all the activities that university starts to respond to societal needs and market demands of their socio-economic context (cf. <http://www.unipd.it/download/file/fid/17658>, p. 19-22).

This general approach of the University seems to be confirmed in the interviews we have collected, where the autonomous knowledge production activity of the university forcefully emerged. For instance, the current leadership of the University considers the University Hospital as one of the main ways in which (medical) research is translated into benefits for all.²⁴

The unsurprising primacy assigned to the production of scientific knowledge tends either to incorporate the dimension of responsibility (being responsible means to produce quality research) or to emerge as a competing dimension. In the latter case, aspects of the research and innovation processes which are valued in RRI, such as societal engagement, are often seen as unwanted and unproductive distractions from pursuing the goal of excellent research. This is true both at the structural and cultural level.

This attitude is cast against a situation where the knowledge of Responsible Research and Innovation (RRI) is confined to the structures and persons who have tighter relations or more experience of EU programs, while the notion is most often ignored in all other cases.

The respondents, researchers and administrative officials alike, agreed that researchers often dismiss aspects of responsibility, and more specifically RRI keys, as “non-science” (R#10, 11:20-16:49). Moreover, the increasing demand of productivity is perceived as detrimental to the participation of researchers to other activities, such as public engagement. This conflict is made worse by the fact that this kind of activities does not positively impact career development. (R#8, 14:01-18:30) This situation has negative effects also on the University performance in EU R&D funding. As competition is increased in H2020, horizontal aspects such as public engagement are becoming more and more important to make projects succeed. (R#10, 11:20-16:49)

²⁴ This aspect emerged in a conversation with Professor Marcella Bonchio, Vice Rector for Research.

In general, it is indeed the participation in EU funding programs that is the single most important factor causing researcher to meet with RRI.

You get to know RRI when you prepare your project proposals (R#8, 27:59)

Interestingly, also when individual keys are considered and discussed, the reference to the broader RRI notion is not used, either because these aspects have been already institutionalized e.g. in national law, as in the case of gender equality, or because they are purely discussed in technical terms.

I must admit that when we had the chance to speak [about Open Access] either with the teaching staff [...] or with the Library Service, we never framed it as one of the five RRI macro-areas. We always discussed the topic from the technical point of view, [looking at] actions to be implemented, without focusing on the general ideas on which RRI relies upon. (R#11, 24:50)

The centrality of EU Programs makes the EU Office of the University a crucial spot for streamlining RRI into research practice, both in terms of individual advice to scientists preparing their bids for funding, and in terms of training events on EU programs where notions about RRI can be integrated, from the perspective of project evaluation. (R#10, 33:46-38:30) This state of affairs is not limited to the University of Padova. Nationally, the Italian Conference of University Director Generals (CODAU) has created a group on RRI, as a subgroup of the EU Programs working group. (R#10, 38:30-44:59). Other than that:

there's not so much about this, nationally. (R#10, 45:10)

Respondents offered also some general comments about the factors fostering scientists interest in RRI and its dimensions. As these comments are a general take, we report them here instead of in the keys sections that follow. According to the respondents, there are three major horizontal drivers for scientists' engagement with aspects of responsibility (and RRI):

- Firstly, the law or a funder mandate to consider one or more specific aspects in scientific work and projects. Ethics is likely to be the clearest example, as researchers are demanded to deal with a set of very formalized and specific procedures, and they know "they have to do paperwork" (R#11, 28:51-35:00).
- Secondly, the aspects are close to the scientists' research interests and activities or disciplinary traditions. This is the case of ethics and open access, or gender issues when social scientists are concerned. Also, when the topic is closed to the subject of the project that is either conducted or drafted. (R#10, 22:00-27:50)

Otherwise, the "idea of responsibility" is very much individualized (R#8, 14:01-18:30).

6.2.2 Ethics

Description of the practice and its development and an assessment of how well it currently works

Ethics is probably the aspect of responsibility which is most structured and subject to highly formalized procedures. The ethical aspects of research are assessed by three different ethics committees:

- The Animal-Welfare Body (formerly, Ethics Committee on Animal Research);
- The Ethics Committee for Clinical Trials;
- The Ethics Committee for Psychology Research.

There is no Ethics committee for social sciences or for other research domains different from the above.

The Ethics Committee for Clinical Trials is a committee appointed by the Padova Local Health Authority and does not serve exclusively the University (cf. <https://www.nihcollaboratory.org/sites/CbyC/Lists/ETHICS%20COMMITTEE%20INFORMATION/DispForm.aspx?ID=24> for a short overview of Ethics committees in Italy). The functions and powers of the Committee are established by the law and are defined by the Veneto Regional Government, which is responsible for managing healthcare in the region. It accepts and revises applications from researchers in the University, in the National Health System (Hospitals) of the Padova Province, and from Companies located in the area. There is no separate track for applications from the University (R#9, 4:00-5:59).

Before landing the Committee's desk, the financial (e.g. no additional costs for the National Health System) and organizational (e.g. number of patient, human resources and equipment available) feasibility of the study is assessed by a Research Unit (Nucleo per la ricerca), which is an office of the Padova Health Authority. (R#9, 6:00-16:30) In Padova, it is reported that the Research Unit is currently heavily understaffed and, therefore, studies arrive directly to the Committee's desk. Opinions are therefore conditional on the feasibility assessment of the Research Unit. (R#9, 30:15-34:30)

When they submit their studies for evaluation, companies pay a fee into a Fund which is used to pay the running costs of the Ethics Committee and to support non-profit research (e.g. by paying additional insurance coverage, when needed). (R#9, 6:00-16:30)

Overall, the Committee meets twice a month and reviews about 30-40 studies a month. (R#9, 6:00-16:30) Each submission is presented by a rapporteur and then discussed in the Committee. The Committee includes medical specialists, but also bioethicists, biostatisticians and a medical examiner. (R#9, 21:10-24:29) In addition to expert members, the Committee includes also representatives of professions (paediatricians, nurses, general practitioners) and of charities and other non-profit organizations. (R#9, 48:50-55) The Committee can approve the study as it is, request minor changes ("conditionally approved") or major modifications ("pending"), or reject the study. (R#9, 24:30-26:30)

When ethics assessments concern pharmaceutical trials, the study needs a second level of approval. On the national level, the National Medicines Agency (AIFA) is responsible for issuing the final approval for the study. (R#9, 26:31-30:14) AIFA can issue its opinion either before, in parallel or after the Ethics committee. If AIFA approves a study before the Ethics committee, the Committee has to examine the study in the first available meeting. Approximately, it takes one month to issue an opinion (R#9, 30:15-34:30)

The regime of ethics assessment is changing due to a new EU Clinical Trials Regulation (Regulation n.

536/2014) and the coordinated national legal framework²⁵. The new regulation establishes a harmonized and coordinated mechanisms for clinical trials authorization. Sponsor organizations will have to make only one submission for all the EU Member States (MS). They are required to propose a Reporting MS, which is in charge of the coordinated assessment of the research protocol for all MS (the so-called Part I of the assessment). Once they receive this single assessment, other MS have the possibility to disagree with Part I conclusions only if patients receive in trial an inferior treatment than normal practice in that MS; if the trial infringes the national law; if there are concerns about subject safety, or data reliability and robustness. MS have instead the responsibility to undertake the Part II of the assessment, which concerns issues such as informed consent, subject recruitment, data protection, reward/compensation of investigators/subjects, suitability of investigators and of trial sites, damage compensation, or aspects related to the collection/storage/use of biological samples. Each MS is responsible to decide how to involve the national competent authorities and the ethics committee in Part I and Part II of the assessment. However, if the national assessment of part I, part II, or both is negative, the trial is refused authorization for that MS. The Regulation requires MS to adopt a procedure to reach a single decision on each authorization request and to define the role of ethics committees in the decision-making process, according to national law (Art. 4 of the regulation). Such "single decision" is valid for that MS. In taking their decisions, MS should ensure the involvement of laypersons, in particular patients or patients' organisations, in the relevant decision-making body, e.g. in ethics committees.²⁶

The Animal-Welfare Body (OBA – Organismo per il Benessere Animale) has been created following Directive 2010/63/EU on the protection of animals used for scientific purposes.

The OBA is the successor of the Ethics Committee on Animal Research, which was established on the initiative of the University through an internal regulation. Before the Directive, there was no legal requirement to have such a body, while they were widespread due to the fact that an opinion by the Ethics Committee on Animal Research was generally a requirement for publication.

The OBA mandate is to ensure the welfare of animals used for scientific purposes in research projects conducted by the researchers in the University. Indeed, OBA differs from the Ethics Committee for clinical trials in being a body of the University of Padova.

OBA's actions follow the so-called 3R guidelines: Reduction, Refinement, Replacement, which are meant to balance considerations about animal welfare and the expected benefits from the research under consideration. The 3R recommend:

- the reduction of the number of animals required for conducting a research project;
- the refinement of research techniques in order to protect and promote animal welfare as much as possible;
- the replacement of more advanced species with less advanced ones. (R#12, 05:35-14:19)

With a few exceptions, the Italian Law transposing the Directive on animal welfare into the Italian legal system established also a second level of assessment, which is conducted by the National Health

²⁵ Since May 29, 2016, a three-year period started for a gradual transition to this new regulatory framework. Further information are available at: https://ec.europa.eu/health/human-use/clinical-trials/information_en.

²⁶ See Pioppo L., "Clinical Trials Regulation (EC) No. 536/2014", Presentation at the European Medicines Agency SME workshop (London, March 20, 2017). Available at http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2017/03/WC500224668.pdf (Accessed July 20, 2018). See also: Casabona CMR., "Clinical trial regulation and ethical committees", Presentation at the 23rd Congress of the EAHP (Gothenburg, 21-23 March 2018). Available at www.eahp.eu/sites/default/files/c._m._romeo_casabona.pdf (Accessed July 20, 2018).

Institute (ISS – Istituto Superiore di Sanità) upon request of the Ministry of Health. The final approval/rejection of the study is issued by the Ministry of Health based on the opinion of the ISS. (R#12, 05:35-14:19) This two-tier evaluation system is stricter than the one implemented for the research involving human beings. (R#12, 14:40-23:00)

Despite the significance of the national dimension in the activities of the OBA, such importance seems limited to the role of the National Government and its technical bodies. On the contrary, there is a perceived lack of coordination among the Animal Welfare Bodies, which are seen to seek dialogue only on specific questions and not in general terms. (R#12, 39:31-43:40)

Main barriers

A primary source of concern about the proper functioning of these tools for ethics assessment is related to **structural factors**, such as regulatory frameworks and resources.

Respondents lament the understaffing of the auxiliary offices to the Ethics Committee for Clinical Trials (the Research Unit) (R#9, 30:15-34:30), or legal changes that often revise the status and activities of Ethics Committees (R#9) or mandates changes without establishing transition periods (R#12, 05:35-14:19), thus affecting the good functioning of the bodies.

If interpreted in terms of research integrity, research ethics is negatively affected by an excessive emphasis on productivity. As pressure is mounting, so does increase the risk of domestication or even falsification of research data. (R#8, 42:40-48:20)

From the **cultural point of view**, researchers are seen as suspicious of a third party “certification” of the ethical consistency of their research. (R#9, 42:31-48:50) This attitude is perceived to be linked to a limited understanding of the ethical implications of their research activities.

They do not understand the moral and scientific importance [of ethics assessment] and without ethics, there is no science (senza eticità non c'è scientificità) (R#9, 37:20)

Also, there is a widespread perception of ethics assessment as a bureaucratic exercise.

Researchers absolutely feel vexed. They consider informed consent as mere bureaucracy [...], they do not have an understanding of research costs [...]: it is not fair that research is paid either by the NHS or by patients if you need [clinicians and nurses to work extra hours] for your research (R#9, 36:30)

Similar considerations are made for animal research. Respondents lament that the members of the OBA are committed and knowledgeable, but they experience the fatigue to explain to researchers the logic of the (bureaucratic) procedures and the necessity to work through administrative steps that sometimes seem useless (R#12, 5:35-14:19). Members of the OBA themselves do concord with their colleagues, at times. (R#12, 29:46-39:30)

Professional identity is at work also in shaping the relations between university researchers and the veterinary service members involved in animal welfare assessment. The University largely relies on external veterinary professionals to take responsibility for the management of animal welfare. Their perceived status of “outsiders” affects negatively their ability to communicate with and to forge effective working relationships with researchers and to convincingly perform their role in assessing and ensuring the respect of animal welfare guidelines. Respondents notice that there is no such difficulty when senior academics (rarely) take this role. (R#12, 29:46-39:30)

In terms of **interchange**, politics surfaces as a relevant dimension. On the one hand, activists of animal rights movements are seen as a force behind the Italian regulation on animal welfare. In particular, they are seen as the reason why the Italian regulation is stricter than the EU Directive it transposed into the national law. (R#12, 5:35-14:19) Similarly, the strict attitude of the Ministry to reduce as much as possible the number of animals used in studies is seen as a reaction to a public opinion hostile to animal experimentation. (R#12, 14:20-23:00) On the other hand, it is acknowledged a limited degree of integration between the Ethics Committee on Clinical Trials and the University. This lack of integration is believed to be caused by the will of the regulator (the Veneto Regional Government) to maintain the work of the Committee, and the University Hospital where it is located, squarely in the context of the NHS. (R#9, 55:0-57:00)

Main drivers

Law and regulations are the main drivers of ethics assessments, which are a largely regulated and formalized activity. Conversely, as we have seen above, cultural factors push generally into the opposite direction.

Best practices

Similarly to what has been noticed about Barriers and Drivers, it is probably not entirely appropriate to speak about “best practices”, as procedures are largely pre-determined by the regulatory framework.

One initiative that merits to be mentioned as a best practice is the digitalization of the process flow of Ethics Assessment for clinical trials. The workflow of the Committee's activity is recorded and tracked through a dedicated website that ensures the traceability of all the aspects of trials and their approval, recording aspects such as the length and outcome of approval processes, amendments requested during the implementation, results and conclusions. The website hosts also all the documentation concerning the study, such as a summary presentation, the research protocols, the costs and their covering, the draft contract between the trial site and the promoter of the study (e.g. a company), informed consent, a statement of conflict of interests, cv of the lead scientist. (R#9, 16:31-21:09)

Current indicators

There is no indicator system in place to monitor and evaluate the work of the Ethics Committees.

6.2.3 Societal engagement strategies in organisation

Description of the practice and its development and an assessment of how well it currently works

In defining the scope of societal engagement, we take a deliberately broad perspective, including under this label also science communication and knowledge transfer activities. This choice is not arbitrary, but reflects the perimeter of the University's “Third Mission”, as it is defined by the Italian National Agency for the Evaluation of the University and Research Systems (ANVUR). As we explained in Section 5.4, the definition of the Third Mission includes a broad array of activities (ranging from technological transfer to science communication). These activities do not coincide with the definition of “societal engagement” in RRI, which is more focussed on the involvement of public in defining research goals and in discussing the social significance and the cultural acceptance of research results. Nonetheless, the ANVUR guidelines an indicators constitute the official framework Universities must adhered to. It seems, therefore, an

appropriate classification to delimit the contents of this section.

On the university level, the University has a press office and has a weekly newsletter (“Il Bo”, The Ox, from the name of the historical building of the University, Palazzo del Bo – The Ox Building). The newsletter informs about the initiatives of the University of Padova and includes articles and commentaries about news and events. A web radio run by students (RadioBue, The Ox Radio) completes the picture. Very recently these communication activities have been grouped and reorganized into a new web-platform called “Il Bo live” (<http://ilbolive.unipd.it/>).

University’s engagement activities differ according to their target.

For the general public, the University collaborates in and directly promotes dissemination events about research and innovation activities and themes aimed at the general public. In 2016, the UNIVERSA initiative was introduced to define a yearly schedule of cultural and communication events (<http://www.unipd.it/universa>), which are dedicated to sharing with the public the research conducted in the University and to discuss with scholars from Padova and from other Universities topics of general interest. Universa is coordinated by the Deputy Rector for cultural, social and gender relations and implemented by the Communication Office of the University. Examples of events organised in the context of Universa are:

- *BoCulture*, a series of conferences whose protagonists are scholars from the University of Padova or guests who have a conversation with scholars from the University. Among the topics covered by BoCulture so far, there are: international migrations, literature, innovation and research policy, microelectronics, cultural heritage;
- *Equality Talks*, a series of events on themes such as human rights, social inclusion, equality and differences discussed with an intersectional approach, i.e. looking at the interplay of factors affecting (in)equality, such as gender, race, class, ethnic group, religion, disability.

In general, Universa combines three characteristics. Firstly, it adopts a multidisciplinary perspective: Universa aims at sharing the knowledge produced in the University from all disciplinary corners, including social sciences and the humanities. Secondly, Universa engages with contemporary ethical, social and political issues, showing what scientific knowledge can say and do for tackling these societal challenges. (R#14, Communication to the Authors)

Other events of the Universa series are instead targeted to specific publics. This is the case of Kids University, a one-week festival targeted to schools and families of 8-13 year-old kids. Kidsuniversity features more than 100 lessons, laboratories and other engagement activities organized by the University’s departments and research centres.

The Kidsuniversity initiative sees the participation of the University’s network of science museums, too. The presence of museums is an important dimension of the University’s public outreach activities in areas such as medicine, science and technology, botany, etc.. These structures offer their collections not only to the local community, but to a potentially much more extended public, in a town (Padova) which has 210,000 residents and hosted 1.5 million tourists in 2016 (cf. <http://www.padovanet.it/sites/default/files/attachment/Turismo%20a%20Padova%202016.pdf>).

For companies and economic actors, the University is actively promoting a path of engagement, which has the aim of promoting co-funded research projects on themes such as urbanization, demographic change, digital manufacturing, mobility, etc. (“UNImpresa” program). This emphasis on the link of

innovation and entrepreneurship is confirmed also by the creation of SCENT, the Padova School of Entrepreneurship, helping doctoral students to create new, high-tech firms, and by the kick-off of Unismart, a wholly-owned subsidiary of the University of Padova in charge of managing all the technology transfer and innovation consulting activities directed to companies, industrial associations, professionals, investors, banks, and other public and private bodies (cf. www.unismart.it).

Unismart is not the only technology transfer venture the University is part of. The Galileo Science and Technology Park is an older technology transfer organization, of which the University of Padova is a shareholder. Originally the technology transfer service of the Padova Chamber of Commerce, today the Park is today owned by a group of local public and private bodies, including the University, the Chamber of Commerce, the local Bank Foundation, the local Association of Industrialists (cf. www.galileovisionarydistrict.it).

Galileo has two domains of activities: innovative materials, and design. The innovative materials sector was created in collaboration with the University. The School of Design is unrelated to the University and the respondent says it is the University that relies on the skills of the students and faculty of the School. (R#13, 10:41-15:20) These two streams of activities are combined to accompany firms, mostly of them SMEs, to develop new engineering solutions, new products and new business models.

Galileo does not participate in the University's R&D activities, as it is more focused on applied research and short-term industrial needs. Coordination is now sought with the more recent Unismart, whose mission is more closely related to create direct links between companies and research groups and departments. Galileo, which hosts Unismart, aims at facilitating the creation of these networks. (R#13, 05:41-10:40)

In terms of organizational structures, the University has recently made organizational changes to ensure a coherent planning and implementation of public engagement activities. In 2018, the University created a "Public engagement office" under its Communication division. The Office has the task to coordinate and promote sustainability, inclusion and social innovation actions in the University and in the surrounding region. Moreover, it realizes actions for the promotion of sport, well-being, equal opportunities and gender equality, among others. Finally, the Rector has appointed a Commission for the Quality of Third Mission activities (Commissione per il Presidio di Qualità della Terza Missione). The Commission's members are academics and, as part of the broader quality assurance processes, they are tasked to define monitoring and training instruments for the Third Mission actions planned and implemented by the University.

Main barriers

Public outreach initiatives such as Kidsuniversity or the Researchers' Night see a broad and enthusiastic participation of scientists from the University (#R14, Communication to the Authors). Yet, the opinion that researchers are interested in public engagement and willing to organize this type of activities is not shared by all the respondents. Most of them lament that the many researchers do not commit enough to public engagement activities. Respondents, both researchers and administrative officials, agreed that many researchers dismiss aspects of responsibility, and more specifically RRI keys, as "non-science". (R#10, 11:20-16:49) Public engagement is no exception. As one respondent says: "there is still the prejudice that [public engagement] has nothing to do with science". (R#10, 57:20)

The reasons behind this attitude of researchers are various. For example, the increasing demand of productivity is detrimental to the participation of researchers to other activities, such as public engagement. This conflict is made worse from the fact that this kind of activities does not positively impact career development. (R#8, 14:01-18:30; R#10, 51:00-1:01:00) On the individual level, University's evaluation

policies and indicators only recently and just partially started to recognize this misalignment.

However, one respondent notices how this attitude of researchers actually misunderstands how scientific careers work nowadays and, in particular, it is seen as a self-defeating position in terms of grant seeking possibilities. As competition is increased in H2020, horizontal aspects such as public engagement are becoming more and more important to make a project succeed. (R#10, 11:20-16:49) PhD and Graduate students could benefit the most from training on these topics, as they could develop horizontal competences, which could be spent in grant preparation (R#10, 51:00-1:01:00) and on the job market.

The last barrier is structural, and it is linked to the nature of indicators that are now used to monitor and assess engagement activities. More precisely, indicators (cf. the corresponding section below) limit the scope of what types of activities are considered significant in the societal engagement domain, mainly to technology transfer and commercialization activities, on the one hand, and to science communication, on the other hand).

Main drivers

Individually, respondents suggest that upstream societal engagement can be effective in orienting research in a way that better responds to the needs of individuals and groups. One of the respondents exemplifies this role of engagement noting that, for example, interactions with patients' association and clinical professionals has helped reorient a research project on brain stimulation from therapy to rehabilitation. (R#8, 37:40-42:40)

In biomedical research, this place for professionals and civil society organizations is formally granted also in the composition of the Ethics Committee for Clinical Trials. However, respondents notice that these organizations are not patients' association, but the many volunteer associations serving in hospitals to improve the clinical conditions of hospitalized persons. Their contribution is mostly limited to commenting the fact sheets of trials, informed consent templates, and, in general, is concerned with the wellbeing of patients during their hospitalization. (R#9, 48:50-55:00)

Lastly, commenting the ongoing effort of the University researchers to organize the Researchers Night (a well-known pan-European dissemination event), one respondent observes that those researchers, who are more closely in contact with the EU dimension of research, appear more committed to societal engagement and dissemination activities. (R#10, 51:00-1:01:00)

On the systemic level, however, the most important incentive is probably a **structural** one, as the "third mission" of universities has been formally acknowledged as one of the "institutional missions" of the university and the Ministry of University and Research monitors the performance of all higher education institutions against this dimension. While this performance does not influence the annual allocation of funds to universities (Fondo di Finanziamento Ordinario - Operating Fund), "third mission" activities will likely enter the set of indicators used to distribute a part of these funds.

Best practices

The notes above explained that economic actors are an important target of the University's outreach activities. The Galileo Park is part of this effort, but some of its streams of activities suggest how it is possible to incorporate responsibility in this context.

Respondents from the Galileo Park noticed that both materials innovation and design were key in pushing ecological sustainability as a feature of the Park's clients industrial activities. Moreover, the Park experimented inclusive design, as a process for involving a social cooperative for the promotion of disabled persons in the design of industrial products (lighting design) (R#13, 20:11-23:20)

Drawing on these experiments, Galileo is setting up a new stream of activities labelled as "For social",

a set of services for supporting industrial companies and cooperative firms to develop socially and environmentally sustainable business models. These services include:

- Advising on Corporate Social Responsibility and Business Model Development;
- Offering services for sustainable design;
- Organising training and dissemination events.

Current indicators

The main driver for universities to foster their public engagement activities (their inclusion in the Ministry's assessment criteria) has nonetheless limited also the scope of what valuable societal engagement is, so far. Indeed, the Ministry has produced a short list of indicators that have to be reported and that clearly promotes a specific idea of what engagement should be (the criteria are listed in Annex E of the Ministerial Decree No. 47/2013, cf.

http://attiministeriali.miur.it/media/209830/dm_47_30_gennaio_2013_con_allegati.pdf).

The list includes:

- Average number of patents per researchers over the last 10 years;
- Income from contract research and project grants per researcher over the last 10 years;
- Number of spin-offs of the last 10 years;
- Number of extra mural activities linked to the University research activities, such as cultural and training events, museums, conferences.

As one can see, the list largely frames societal engagement in terms of knowledge transfer activities and of the economic impact of such actions.

On the organizational level, we can find more specific indications about the ways in which social engagement is conceived by examining the Triennial Performance Plan (2018-2020) of the University (cfr. <http://www.unipd.it/sites/unipd.it/files/2018/Piano%20Integrato%20della%20Performance%202018-2020.pdf>). The Plan is mandated by Law 33/2013 (so called “Transparency decree”), is applied to all public organizations in the country, and defines a set of objectives and indicators, which are the reference for the evaluation and self-evaluation of all the offices and structures of the university. In the Plan, the University has defined a cluster of actions and indicators with the labels of “public commitment” and “promotion of research activities”. However, a closer look at these indicators shows that they are related primarily to the *communication* of the university's activities²⁷, as the following examples suggests:

- registered participants to UNIVERSA events (Objective ACOM_7);
- visitors of the website (Objective ACOM_2);
- subscribers of the “Il Bo” Newsletter (Objective ACOM_2);
- subscribers to the Facebook page (Objective ACOM_2);
- results of a customer satisfaction survey (Objective ACOM_2).

At the same time, the Plan requires that a full program of events and activities is presented by

²⁷ A second line of activity under this heading refers to promoting the cultural and historical heritage of the University, including historical building and naturalistic facilities (Botanical Garden). We do not comment on these aspects, as they do not represent social engagement activities *per se*, no matter how broadly defined. Nonetheless, these historical facilities are often the location of the initiatives we are discussing in this report and, as such, they have an indirect importance for the engagement activities realized by the University..

December 2018. The events in the program will be subject also to a qualitative assessment (Objective ACOM_4).

6.2.4 Gender equality and diversity strategies in the organisation

Description of the practice and its development and an assessment of how well it currently works

This RRI Key refers to a broad range of issues and policies, from gender equality and gendered innovation, to the integration of cultural and ethnic differences, to access to work for people with disabilities. All of these issues are considered to deal with diversity and diversity management in organizations. This broad definition gathers under the same label policies whose target and premises are heterogeneous and which refer to different structures and normative frameworks in the University. Nonetheless, this section has to reflect this definition of the key and, therefore, it includes both a discussion of gender equality and an examination of inclusion policies targeted to people with disabilities, whose institutionalization is significant and long-established.

The University's commitment to gender equality and to equal opportunities in general, stems from a consistent legislative action on the National and European level.

The institutionalization of gender equality protection and promotion is implemented through a group of University bodies, with monitoring, advisory and enforcing tasks. The bodies are:

- The Deputy Rector for cultural, social and gender relations, whose task is to coordinate the equal opportunities initiatives of the University;
- The Central Committee for the promotion of equal opportunities, workers' welfare and non-discrimination (Comitato Unico di Garanzia - CUG), which is a mandatory body according to the National Law 183/2010 and which has advisory and monitoring tasks in matters of equal opportunities concerning the administrative staff of the University;
- The Commission for the promotion of equal opportunities and gender equality, which has the same tasks of the CUG, but whose mandate is limited to tenured and untenured academic staff;
- The Confidential Counsellor for mobbing and sexual harassment cases, who is established according to the University's Code of ethics (art. 12) and whom can be addressed, in order to obtain further information, counselling, support and intervention by all University students and staff.
- The Ombudsman (Difensore civico), which is not a University body but an independent office appointed by all Regional Parliaments, according to Law 142/90. The Ombudsman action is limited to ensuring the transparency, fairness and timeliness of public administration. The Ombudsman can be therefore appealed only in matters concerning either civil servants' employment contracts or public services organization and provision.

Eventually, the University has created an Equal Opportunities Observatory, working with the CUG and the Commission for the promotion of equal opportunities to gather, organize and analyse information and data about the presence and role of women in academic life.

An Interdisciplinary Forum for Gender Studies and Education promotes research and training activities on gender related issues in the university and in the region where the university is located.

As part of a broader reorganization of this area of activity which is being promoted²⁸, all the

²⁸ The structure of the Committees will be streamlined in 2018 and the CUG will be competent for both the teaching and the administrative staff.

structures and groups working on gender-related issues will be gathered in a single Research and Training Centre on Gender (#R14, 36:45-38:20).

In terms of results, the participation of women to academic life remains low. The limited impact which the bodies listed above had on this situation is likely due to their quasi-disciplinary responsibilities. They can start and conduct disciplinary procedures in response to individual complaints, but they have only advisory tasks in the planning processes and in corporate decisions. Therefore, the design and implementation of broader, systemic gender equality policies depends on the agenda of the university leadership and on their consequential action. Nonetheless, the situation is significantly improving with the current leadership, and more women are represented among the Deputy rectors and the Rector's delegates (about 49%), auditors (40%), quality assessment unit (50%), and across the administrative roles (on average, slightly more than 60% of employees are women). Much lower is women representation in the Academic Senate (22%), Board of director (22%) and among the Department directors (22%). Overall, women count for 35% of research and teaching staff, but only 1/5 of full professors are women (2016 data, from the report Gender Report 2016, <http://www.unipd.it/bilancio-genero>).

As part of the effort to increase gender equality and, in general, equal opportunities, the University has launched a set of “affirmative actions”, temporary initiatives aimed at removing the obstacles to real equality. For the 2015-2017 period (cf. http://www.unipd.it/sites/unipd.it/files/2017/Piano%20di%20Azioni%20Positive%202015-17_slides.pdf). The actions were meant to achieve:

- the elaboration of a Gender Report;
- the improvement of workplace wellbeing;
- the adoption of measures to educate to gender sensitive and non-discriminatory language;
- the adoption of measures to improve work-life balance.

This increasing centrality of gender equality is confirmed by the University's 2017-2019 strategic plan, which includes the goal of “promoting gender equality”. The related actions are:

- the improvement of gender equality in all academic ranks;
- the improvement of gender equality in oversight bodies;
- the number of implementation and monitoring activities of the University's Affirmative Actions.

Accordingly, the triennial 2019-2021 budget will assign more resources to the Departments to favour career progressions and new hires which increase the number of women scientists in their Faculty, across all academic ranks (Gender Report 2016, pp. 114-115).

Besides gender equality, all the academic policies for equality and inclusion have been grouped under the “Università Inclusiva” (Inclusive University) initiative in 2015, with a senior academic coordinator delegated by the Rector.

In addition to the services which the University has made available to promote the inclusion and participation in the academic community of students and employees with disabilities, a course on “Human rights and inclusion” has been opened to the participation of all the students starting from a.y. 2016-2017. The course aims at contributing to a culture of inclusiveness in the academic community (cf.

<http://www.unipd.it/inclusione/general-course>). The course is open to all the employees and it is officially recognized as professional training.

Main barriers

While official documents provide detailed information about policies, they are short of specifics about the barriers to their implementation. More information about barriers and the actual reach of gender equality policies are provided by respondents' comments.

One senior researcher we interviewed informed us that neither the Department nor the research group had specific policies for gender equality, nor was aware of the University's policies. While their research unit achieved a balanced gender representation, that was more the result of individual initiative rather than of official academic policy. Once more, the guidelines of calls for proposals are a powerful incentive to consider aspects such as gender representation. (R#8, 21:06-25:10)

The same respondent forcefully affirms that the most important barrier to achieve gender equality in research is the difficult recruitment of early career researchers in Italy. On the one hand, students seeking research careers move abroad earlier and earlier. On the other hand, Italian universities do not attract foreign students (R#8, 27:00-32:20). Therefore:

It is a question of possibility. If you have a system, a machinery that needs a good team to advance in a very difficult situation for recruitment, then gender becomes a secondary factor. (R#8, 32:00)

Eventually, one respondent observes the general lack of awareness about the gendered dimension of research. While the notion of gender balance has gained some traction in the scientists' approach to building teams and projects thanks to the criteria of EU call for proposals, they are considered less aware of how differences in gender and sex affect research results, including experiments in life sciences. (R#11, 28:51-35:00)

Main drivers

The refusal of any type of discrimination is part of the values of the University, both as described in the University's Bylaws and Codes of Ethics.

Moreover, equal opportunities in the workplace are an issue which is heavily regulated and institutionalized. Therefore, **structural incentives** are certainly at work as drivers of university policies.

Nonetheless, it is likely to be correct that the new leadership of the University (since 2013) has given impulse to the actual implementation and development of gender-related policies. This is shown both by the appointments of a Deputy rector, who is delegated to gender policies, and by both the implementation of a triennial affirmative action program and by the preparation of the Gender Report (Bilancio di Genere 2016), which was completed in October 2017.

Best practices

From the organizational point of view, the new leadership of the University has appointed a Vice Rector responsible for gender equality and inclusion. Moreover, 7 out of 12 Vice Rectors are women. This is important because, as one respondent says (R#14), having women in leadership positions is a requisite for organizational and cultural change.

In 2017, the University has completed a gender reporting exercise, aimed to identify existing gender gaps across roles and structures of the university. The exercise was explicitly aimed to improve the knowledge base of decisions for the programming period 2018-2020. In addition, Guidelines for non-discriminatory language have been issued in the same period.

Current indicators

In 2017, the University completed the development of a comprehensive set of gender-related indicators, as part of the creation of a Gender Report. The Gender Report provides an overview of the current status of all the university activities and structures from the point of view of Gender (equality). This initiative was promoted by the current university leadership and was aimed at creating the knowledge base for planning and implementing gender-related policies in the future.

The Gender Report dramatically expanded the range of indicators previously available, which were included in the Comprehensive Report on the University (Relazione Unica Ateneo), an annual report prepared as part of the Performance Assessment procedure.

Indeed, the work on the Gender Report provided a complete picture of the gender distribution in each of the academic groups and ranks, both administrative and academic, including students. The analysis covers also career progressions and the different choices of the staff related to entitlements and working-related options (e.g. telework, parental leave, etc.).

6.2.5 Open access and open science strategies in the organisation

Description of the practice and its development and an assessment of how well it currently works

The University of Padova has not yet fully developed Open Access and Open Data policies.

The significance and urgency of adopting an Open Access Policy is linked to the new status of Open Access in H2020. Developing from the pilot-based approach of FP7, the Commission requires all projects receiving Horizon 2020 funding to make sure that any peer-reviewed journal article they publish is openly accessible, free of charge (article 29.2. Model Grant Agreement) (cf. <http://ec.europa.eu/research/openscience/index.cfm?pg=openaccess>; see also R#10, 7:30-9:39).

Also for coping with this policy shift, the University of Padova has designed and implemented an institutional repository complying with the guidelines for Open Access as defined by the European Commission is available from July 2017 (cf. <https://www.research.unipd.it/>). The repository adopts the Guidelines developed by the OpenAIRE consortium, an EU-wide consortium of higher education institutions, funded by the EU and aiming at fostering Open Access policy in and collaboration on this matter between HE and research organizations across the continent.

Among other activities, Open AIRE has created Zenodo, an open source publications and data repository, maintained by CERN, which is an Open AIRE member (www.zenodo.org). (R#10, 9:40-11:19) However, building an own repository was considered more effective in increasing the visibility of university research. Moreover, this solution is considered more satisfactory in terms of accountability and transparency with respect to the EC (the funding contract is signed by the University itself) and National Evaluation bodies (R#10, 27:51-33:45)

Internally, the University Library Services and the International Research Office have partnered to design both the open access instruments and to start a dialogue on Open Data. The International Research Office performs also an advisory function about Open Access for researchers preparing an H2020 proposal or conducting an H2020 project.

For Open Data, this partnership is elaborating a standard template and guidelines to help researchers define Open Data policies compliant with the requests of H2020 Open data pilot, including an overview of the elements to be included in the project proposal, the software used for data analysis and whether the software is available and can be inspected, how data is saved and stored, etc. The same working group has started a survey to see whether there is expertise available in the Departments to support researchers with

Open Data. (R#11, 04:06-11:00) This activity was initiated by the International Research Office, as part of an effort for indexing key topics of interest for university researchers in order to diffuse more targeted information about funding opportunities. (R#11, 11:01-13:00)

Main barriers

On a systemic level (**interchange**), respondents consider publishers' policy the main barrier to the diffusion of Open Access. (R#10, 27:51-33:45) The combination of processing subscription fees and library subscriptions is seen as an excessive financial burden that limits the diffusion of open access publications.

In an organizational context in which Open Access was not prioritized (R#10, 27:51-33:45), researchers themselves are considered mostly unaware of Open Data and Open Data policies. Once more, respondents identify as exceptions those researchers who are most closely involved in EU Programs through their participation in calls for proposals (R#11, 13:01-20:21).

Nonetheless, part of researchers is seen as resisting the involvement of administrative officers in supporting project proposals preparation. Respondents consider this attitude is a major misunderstanding of the nature of EU Programs. Especially H2020, projects are successful not only for their science, but also for effectively dealing with horizontal matters such as Open Access. (R#10, 14:40-18:20)

This attitude reveals a misunderstanding about the Commission policy and, thus, of the operating environment of researchers' institutions (**interchange**). Open Access is key to the European Commission insofar it allows to reach the efficiency goal of allocating funds to projects which have similar or almost identical outcomes, and also to create the conditions for experiments replication and to uphold research integrity. (R#10, 14:40-18:20)

Main drivers

The growing importance of Open Access and Data in the University policies and researchers' activities is another example of the traction EU policies and programs have to influence local action (**interchange**).

The progressive adoption of Open Science policies is the result of the interaction of the University with international consortia (Open AIRE).

On the individual level, the increasing presence of Open Access as one of the dimension of Framework Programs' calls, requires scientists to carefully consider this aspect in their work and in their project proposals.

Finally, respondents emphasize the ethical case for Open data and Open access. From this point of view, sharing data is seen as a constitutive part of the professional identity and deontology. Once intellectual property rights are protected, data sharing is a powerful tool to protect science and the public from pseudoscientific activities and communication. (R#11, 18:21-20:20)

Best practices

Open Access policy is still in development. The recent roll out of the University research repository aligns the University of Padova with the existing European guidelines on Open Access.

In this preliminary phase, it is worth emphasizing the bottom up approach taken to survey the needs, resources, and expertise of Departments in order to design organizational solutions that can support researchers in gaining awareness about and complying with Open Data and Open Access policy.

Current indicators

As the policy implementation is at a nascent stage, there is no indicator system in place, yet. However, while it was not aimed at creating an indicator system, the data collection initiatives that have started will

provide also an indication about what indicators can be defined.

6.2.6 Science education as integrated in research

Description of the practice and its development and an assessment of how well it currently works

Like public engagement, science education activities are decentralized to a significant degree. It is therefore difficult to provide a comprehensive overview. This brief description will therefore focus primarily on the events organized centrally by the University administration and, as the reader will see, it will partly overlap with the section on social engagement. This partial conjunction is due to the primary focus on communication which engagement initiatives have, so that one can classify them also as examples of informal education activities. As we have said, the broad category of “Third Mission” includes both.

The educational activities of the University include the organizations of cultural and training events, as well as on the permanent and temporary exhibitions in the University's museums and Botanical Garden, which is a University Research and Service Centre.

While academics are part of their governing boards and provide the necessary scientific support, external companies may be hired to manage them.

Under the UNIVERSA label, which was described in the public engagement section, the University organizes a yearly schedule of cultural and communication events (<http://www.unipd.it/universa>). Part of the events are dedicated to specific target groups (e.g., Kidsuniversity, for children and their families). Others are specifically devoted to themes related to RRI, such as EqualityTalks.

In terms of training programs, two types of courses can be identified: (1) online MOOC modules; (2) life-long learning courses (Corsi di perfezionamento). Regarding the former, only two courses in mathematics are available (Pre-calculus, Advanced Pre-calculus) in Italian and English on two different web platforms (EduOpen and FutureLearn, respectively). Regarding the latter, among the many courses active in the current academic year, two of them address RRI-related topics: Animal welfare ethics, Bioethics.

While it does not entirely fit with the label of science education, it is interesting to mention a last initiative of the University for its relevance in terms of connecting teaching practice and social responsibility. The University of Padua has joined the UN Agenda 2030 Project, aimed at advancing the Global Agenda for Sustainable Development and its 17 Sustainable Development Goals (SDGs), which were approved by the Assembly UN General Assembly on 25 September 2015. Starting in 2018, the University of Padova has made mandatory for the academic staff to explain in their syllabi what is the contribution of the courses they teach to the achievement of SDGs. This initiative is important for increasing the reflexivity of the academic staff and, if extended to research activities, might prove effective to gradually orient scientific research and knowledge transfer to reach “societally desirable” goals.

Main barriers

Respondents do not identify any specific barrier to science education activities. However, it seems reasonable to compare science education initiatives with science communication/public engagement projects.

Accordingly, career incentives focused only on research performance limit the interest of scientists in knowledge dissemination through engagement and (informal) education activities.

From this point of view, it is interesting to notice a tension between the national evaluation of individuals researchers, in which dissemination does not feature prominently, and assessment of research

structures (departments), to which the Ministry dedicates an increasing attention, under the “Third mission” label.

Main drivers

When targeted to groups other than researchers and academics, science education is part of the University’s “Third mission”. This aspect of University’s activities is monitored by the National Agency for Evaluation of the University System and of Research (ANVUR) and it is therefore of increasing importance for the University, as we have explained in sections 5.4 and 6.2.4.

Best practices

While it does not properly constitute a “Best practice”, it is worth noticing the coordination efforts undertaken with regard to the dissemination/education initiatives. In particular, the centralized initiatives under the UNIVERSA label are accompanied by an attempt to segment the audience in order to improve the reach and quality of activity themselves.

Also, it is worth noticing the effort of introducing the reference to SDGs in teaching courses. While this experience has just started in 2018 and there is a real risk that it will resolve into a mere “box-ticking” activity, it has the merit to place the education activities of the University in a clear framework of social responsibility.

Current indicators

Education activities are currently monitored through quantitative indicators about the number of events organized.

As part of the graduate education offer of the University, the life-long learning courses are monitored by the University Assessment Commission (Nucleo di valutazione) and are organized under the responsibility of the Vice Rector for Graduate education. An annual evaluation identifies critical issues that have to be addressed before resubmitting the course proposal for the following year.

Relevant indicators are included also in the Triennial Performance Plan (2017-2019), which were discussed in the social engagement subsection.

6.2.7 Incorporation of AIRR dimensions into policies

Anticipation and reflexivity

One of the respondents is a senior researcher and research group leader. Unsolicited, this respondent closed the interview by affirming the importance of the collaboration between scientists and regulators in orienting research and innovation activities. Such collaboration is seen as necessary insofar new advances in science are fostering the rapid blurring of humans and technologies. While the integration of humans and machines opens up great possibilities in medicine, for example, it risks creating an unbearable dependency of humans from machines. It is important to anticipate and govern these issues before they are on a path that cannot be changed. (R#8, 49:00-57:39)

This individual emphasis on anticipation and reflection on the goals and consequences of research is more an individual attitude than an organizational capability. Planning exercises are conducted every three

years, but they concern mainly management and administrative matters, rather than prioritization in research activities. This is not unusual (cf. the report on Italian universities and RRI by RRI Trends, <http://rritrends.res-agera.eu/reports/second/>), but there are universities (e.g. the University of Venice “Ca’ Foscari” or the Turin University of Technology) that explored how their research and innovation activities can help tackle specific societal challenges.

Openness and transparency

The University approach to transparency is twofold.

Firstly, there are legal and administrative requirements which have to be complied with and they concern the generality of university's activities. Secondly, there are more specific transparency initiatives related to Open access and Open Data.

In their nascent stage, the latter are set to become a primary tool for the visibility of research results, but also, according to the logic of Open Data, as an instrument for ensuring the integrity of the research process. On this aspect, we refer to the section about Open Access.

The former are mandated by the Legislative Decree 33/2013 and later modifications about the “Reorganization of the regulation regarding citizens' right to access to information and public administration's obligation to ensure information's public availability, transparency and diffusion”.

The Law requires public bodies, including universities, to make available information about a whole set of domains and activities online and with other means of communication. The domains concerned by the law include:

- Staff and external consultants;
- Tenders and competitions for posts;
- Performance of the organization;
- Public works;
- Administrative workflow;
- Companies owned by the University;
- Financial aid to students and staff;
- Services delivered.

While many of these aspects are not directly related to research and knowledge transfer activities, data regarding dimensions such as staff and performance are significantly linked to research, and are informative about how research activities are planned, organized and implemented.

As we have said respectively in the sections about Gender Equality and Societal Engagement, the University has completed a Gender Report and preliminary work is under way to identify indicators for a Corporate Social Responsibility Report.

Responsiveness and adaptation

Italian universities have experienced a profound transformation since the creation of the Italian National Agency for the Evaluation of the University and Research Systems (Law 286/2006) and since the so-called “Gelmini Reform” of the University (from the Minister who steered the law through parliamentary

approval) was approved (Law No. 240/2010).

Throughout these changes, responsiveness has been mainly in terms of accountability as a part of a hierarchical relationships between universities, the Ministry of University, and its agencies. Furthermore, and often in conflict with the Ministry's policies, universities have been influenced by their internal stakeholders, such as researchers, administrative staff and students. For instance, these groups have been the target of several customer satisfaction surveys monitoring the wellbeing in the organization over the years (cf. <http://www.unipd.it/trasparenza/benessere-organizzativo>).

It is much more unclear, though, how much universities have started a bi-directional dialogue with their societal stakeholders. The analysis of the University of Padova suggests that economic actors and public administration bodies have a sort of privileged status in this conversation. This status is ensured primarily by the presence of stakeholders' representatives in Committees, Commissions and Boards. Civil Society Organizations (CSOs) are granted formal access to the University's Advisory Bodies only in specific cases and, as a rule, these bodies and committees have a sectoral mandate. Ethics committees best represent this situation, while CSOs' representation in governing bodies, such as the Board of Governors, is inexistent. We were able to find only one exception to this rule: a representative of the most important cultural bodies in the Veneto Region sits with industry, school authorities, professional associations, and regional authorities in one advisory committee gathering regional stakeholders (Consulta del territorio).

A broader involvement of societal actors seems instead absent.

Diverse & inclusive

Diversity is described mainly in terms of gender equality. Inclusion is framed in terms of access to work and study of persons with physical or mental disabilities and, in a broader sense, of the measures the university undertakes to ensure the right to study that is protected by Art. 34 of the Italian Constitution.

One missing dimension is cultural and ethnic diversity. While non-discrimination on the basis of culture and religion is part of the University Statutes and Code of Ethics, there is no body tasked with designing, monitoring and enforcing inclusive policies addressing specifically this aspect.

This omission is probably due to the homogeneity of both Faculty members and student population. Overall, the number of foreign students enrolled is low. Nationally, Italian universities registered only 76.351 foreign or stateless students in the 2016/2017 academic year (4.5% of the total number of enrollees). In Padova, foreign nationals are 4,1% of the total number of students in undergraduate and graduate courses. The number is higher in PhD courses, where foreign students count for the 13,9% of doctoral students in 2015 (cf. <http://www.unipd.it/download/file/fid/42638>). The composition of Faculty follows a similar pattern. Nationally, only 3,350 faculty members are foreign nationals (3.5% of the total) in 2017. In Padova, the number of foreign faculty is slightly higher, reaching 4.5% of the total academics employed by the University (4,529 in 2017).²⁹

6.2.8 Other concepts used to characterise responsibility in the organisation

There is no overarching definition of responsibility that can be considered as alternative or competitive

²⁹ These observations are based on the data provided by the Statistics Office of the Ministry of Education, University and Research (<http://dati.ustat.miur.it>).

with RRI.

The University's Bylaws and Ethics Codes respectively mention the “social responsibility” (Art. 1.5) and “social function” (Preamble) of the University. According to the Bylaws, the social responsibility of the University is exercised through its research and teaching activities, and the action dedicated to ensuring the right to education, pursuant art. 34 of the Italian Constitution.

In 2016, the Rector appointed a Commission to select and analyse a set of indicators to be used for elaborating a Social Responsibility Report, pursuing Art. 1.5 of the Bylaws. The Commission is set to end its work in October 2018. The work of the Commission and the eventual, possible adoption of a Social Responsibility Report can give a significant impulse to the establishment of CSR as an important reference framework for responsibility in the University,

Also the Ethics Code refers to the Constitution to define the “social function” of education. What is detailed in the document are, however, the mutual responsibilities of the member of the academic community and their responsibility with respect to third parties in matters such as discrimination, harassment, plagiarism, teaching liberty, reputation, impartiality.

Overall, also when considering third mission activities, knowledge transfer *from* the University to society seems the way through which responsibility is exercised, while less emphasis seems to be put on the mechanisms to determine with stakeholders what knowledge transfer is for.

On a lower level, interviews suggested only one more comprehensive perspective on responsibility, which is the 3R models adopted in animal research: reduce, replace and refine. The 3R define the responsibility of researchers using test animals and recommend:

- the reduction of the number of animals required for conduction a research project;
- the refinement of research techniques in order to protect and promote animal welfare as much as possible;
- the replacement of more advanced species with less advanced ones. (R#12, 05:35-14:19)

Commenting the limited diffusion of the RRI concept among the University researchers, one respondent interestingly noticed that the continuous shift in concepts promoted in policy, such as precaution, the “integrated, safe and responsible” approach to research in nanotechnology, and now RRI leaves researchers bewildered. Selecting a concept and focusing on the same notion over time is important to incorporate it into research and research management culture. (R#12, 48:01-50:40)

6.3 Reflection on Review findings, Outlooks developed and ways forward³⁰

The RRI Review of the University of Padova tried to illustrate the actions that the University has undertaken to advance along the RRI keys and which are relevant to the AIRR dimensions. These various activities define a coherent view of university’s responsibility which increasingly distances itself from the traditional view of responsibility limited to knowledge production. Also, we have seen how this discussion has developed largely unaware of the ongoing debate on RRI in the European Union, despite the many overlapping aspects and points of contacts.

This section describes the RRI Outlook for the University. As such, it identifies the key action points

³⁰ This section develops the contents of two subsections which were distinct in the deliverable template, and namely: ‘all points of improvements’ (point E) and ‘agreed points of improvement’ (point G).

resulting from the analysis and the engagement process with key informants and actors both in the individual interviews and in the focus group. The action points represent policy measures that are now at the attention of the competent authorities in the University in order to be translated into governance activities.

6.3.1 The integrated or fragmented nature of different responsibility related dimensions

RRI is not present as such in the university debate on responsibility in science and innovation, as well as in the discussion on the individual RRI keys. This “fragmented nature” of responsibility is clearly described by a participant to the focus group, who affirmed:

*There is a report on gender issues, a CSR report. Do you want to make another report on RRI?
(FG#11)*

This absence corresponds to a situation where Responsible Research and Innovation (RRI) is ignored, except by those who have tighter relations with or more experience of EU programs. This situation is coherent with the fact that participation in EU funding programs is seen as the single most important reason for researchers to work on RRI, as long as it mandates to consider one or more RRI-related aspects in research activities and projects. Responsible practices and conceptions are, otherwise, very much individualized (R#8, 14:01-18:30), and researchers’ interest for, as well as their perception of and ideas about responsibility are closely related to their scientific interests, disciplinary traditions, or the projects they are working in.

The way the University “officially” defines its “social responsibility” does not help to build an overarching framework for RRI. As we explained in the opening sections of this report, the production of scientific knowledge has a central role in defining responsibility (being responsible means to produce quality research), thus restricting the scope of topics and issues covered by this concept.

6.3.2 Common barriers or drivers

Resources availability is commonly considered a significant barrier to implementing RRI-related policies. For instance, the understaffing of the auxiliary offices to the Ethics Committee for Clinical Trials (the Research Unit) is lamented as an obstacle to the Committee’s efficiency.

Barriers and drivers are also determined by the **regulatory and policy environment**. For instance, law and regulations are the main drivers of ethics assessments: compliance originates from obligation, not conviction. Attention to Open Access is a result of the traction of EU policies. Equal opportunities in the workplace are an issue which is heavily regulated and institutionalized. Therefore, structural incentives are certainly at work as drivers of university policies in gender equality. However, environmental factors can constitute a barrier to implementation, too. For instance, frequent changes in the structure and mandate of Ethics Committees (R#9) affect negatively the functioning of the bodies and the lack of integration between the Ethics Committee on Clinical Trials and the University is considered as depending on the political will of the regulator (the Veneto Regional Government) to maintain the work of the Committee, and the University

Hospital where it is located, squarely in the context of the NHS. (R#9, 55:0-57:00)

Respondents share a certain degree of disillusionment on researchers' interest in RRI-related activities. **Cultural resistance** to ethics assessment is an example mentioned by the respondents. Public engagement follows this pattern. As one respondent says: "there is still the prejudice that [public engagement] has nothing to do with science". (R#10, 57:20) Similarly, disregard and inattention to Open Access is blamed on the lack of knowledge and awareness researchers have of Open Access policies and of the significance of these policies in the broader context of EU science policy framework. On the contrary, the new leadership of the University has given a strong impulse to build a culture of gender equality and to the actual implementation and development of gender-related policies. The appointments directly made by the Rectorate, the implementation of a triennial affirmative action program, and the compilation of the Gender Report are achievements that confirm this commitment.

Structural incentives are often ineffective or counterproductive in encouraging cultural change. For instance, an excessive pressure for productivity is detrimental to research integrity, as it increases the risk of domestication or even falsification of research data. (R#8, 42:40-48:20) On the individual level, evaluation policies and indicators disregard participation in public engagement activities as a valuable aspect for career progression. On the organizational level, the most important incentive is probably a structural one to promote societal engagement activities, as part of the "Third Mission" of universities. As we have seen, these indicators are significantly skewed towards commercialization and knowledge transfer. The Third Mission is one of the activities which is presently monitored by the Ministry of University to evaluate higher education institutions' performance and this assessment is likely going to affect the distribution of funds from the Ministry.

6.3.3 Final reflections and plan for follow-up

This section reports the final outcome of the organizational study. As part of the organization's Outlook and drawing on the individual interviews and the focus group, a list of "action points" was drafted. For each of the keys, action points describe concrete steps (and related indicators) that translate the directions of improvements which were identified in the research. The list will provide the University leadership with options and guidelines for RRI implementation, in the context of the organization's decision-making procedures and multi-annual planning.

Before reviewing each of the RRI keys, it is important to briefly present one of the focus group's results on RRI implementation. The Triennial Performance Plan was identified as the most important entry point to RRI integration into the University's decision-making. The Performance Plan defines strategic organizational objectives and the related progress indicators to be monitored. As a legally mandated framework and as a part of the overall planning structure of the University, the Performance Plan has limited flexibility in adjusting its format and contents. Unanimously, the participants in the focus group were sceptical of the possibility and relevance of including an explicit reference to RRI in the Performance Plan. It would be certainly more feasible to include specific indicators related to individual RRI keys, also because parts of those areas are already covered by the planning.

This strategy has upsides and downsides. The upside is the certainty that the inclusion of an action in the Performance Plan maximises its impact. The downside is that the elaboration of the Performance Plan is a centralized process, with a fixed schedule. The current plan refers to the 2018-2020 period; this fact means that any discussion started by RRI-Practice will be focused on including one or more indicators in the

2019-2021 Triennial Plan. Moreover, it means that any discussion should include the Central administration of the University and the Rectorate.

6.3.3.1 Ethics: directions of improvement and action points

On the regional and national level, respondents suggest that standardization of fact sheets (*note informative*) and informed consent templates should be a goal to pursue, as today every local health authority has a different template for clinical trials. (R#9, 34:31–39:00)

On the same level, it is noticed that the digital monitoring system now in place does not allow the Committee for Clinical Trials to make queries and export data about the studies. Only single case browsing is allowed. Only the manager of the platform can perform data extraction operations. However, this function could help the Committee itself to monitor both research activities and its own performance. (R#9, 57:00-59:00) This latter aspect could feed positively the creation of an indicator system.

Training for researchers is also seen as an important activity. The current absence of training initiatives is blamed on the string of emergencies that have affected the work of both the Committees in the recent past, which were most due to the rapidly changing regulatory environment. For the Ethics Committee for Clinical Trials, it is stressed that training should be targeted to researchers from both the University and the NHS, also as an instrument to overcome the existing divisions between the Health Authorities and the University. Regulatory stability itself is seen as an important factor to help the Committee work and an enabling condition to develop longer terms activities, such as training. (R#9, 55:01-57:00) Despite this hope, there are projects for an overhaul of the Ethics Committees system with the creation of only one Committee in each Italian regions – now, the law mandates one Committee per one million of inhabitants. This solution is seen as problematic because of very different size of regions, which would imply an excessive burden on many of these newly created ethics committees. Such a burden would be impossible to manage for a semi-voluntary body such as the Ethics Committee. (R#9, 39:01-42:30)

The focus group picked up this emphasis on training and complemented it with a focus on what ‘ethics’ means in the context of research and innovation. More precisely, it was noticed that relevant ethical issues are much broader than those adjudicated in ethics committees. The following action points and related indicators reflect this discussion in the focus group:

Ref.	Action point	Indicator
ETH1	Training for researchers is seen as a key measure to improve the knowledge, interest and attitude of researchers towards ethics committees and their procedures, but also to the changing regulatory environment.	No. of researchers participating in ethics training initiatives
ETH2	Mapping researchers' perception of ethical issues is an action preliminary to designing and starting training activities. While the focus group did not discuss how the mapping should be implemented, the practical translation of this action point would require the organization of survey activities, such as questionnaires, focus groups or workshops.	Researchers' perception of the importance of ethics issues
ETH3	Request of identifying ethical aspects in research projects. Acknowledging that ethical issues cover a much broader area than what is considered by ethics committees, it is advised that proponents of research projects explicitly explore the broader ethical and social implications of their research when writing and	Research projects raising ethical issues (percent of all research projects)

	submitting their research proposals.	
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6.3.3.2 Societal engagement: directions of improvement and action points

Training actions are suggested to overcome the individual reticence to invest in engagement activities, with the specific intent to show that societal engagement is an important component of career development. (R#10, 51:00-1:01:00)

In the context of technology transfer to the business sector, the integration of responsibility and entrepreneurship is seen in the framework of the Open Innovation paradigm. Multidisciplinary collaborations should be encouraged early on in higher education, involving undergraduate students and using their dissertation as opportunities to develop, cooperatively, business plans. This activity requires that professors from different departments collaborate and coordinate their teaching activities. However, respondents said that this exchange and circulation of ideas is the essence of Open Innovation. This collaboration should find space for humanities scholars and social scientists, who can help explore dimensions which are often neglected (e.g. the legal one) and incorporate social and ethical aspects in product and business development. (R#13, 37:31-45:00)

The priorities identified in the focus group centred on the 'enabling conditions' of public engagement activities. On the one hand, changes to the University budget structure are proposed in order to precisely assess the efforts in public engagement (PE) activities. On the other hand, individual incentives are advocated in order to align ministerial/organizational priorities and individual ones, so that researchers can take a more active role in public engagement.

Ref.	Action point	Indicator
SOC1	In the current budget of the University, PE activities are not registered under a separate heading. A separate budget could be important to enable a more accurate monitoring and assessment of the PE effort and of its effectiveness. A working group is currently discussing the introduction of a Social Accounting system and this suggestion may be included in the Working Group's proposal.	Inclusion of a specific heading on PE in the organization's budget structure (preliminary to define quantitative indicators measuring increases in staff and budget to perform engagement activities)
SOC2	Creating an incentive system for researchers who work on public engagement issues. Currently, there is a contradiction between the request that researchers should work on public engagement and the lack of incentives to perform these activities. Nationally, the National Agency for University Evaluation is introducing an assessment framework, which applies, however, to Departments, not to individuals. Initiatives to create local incentives on the individual level may therefore contribute to reduce this misalignment.	Existence of an incentive system for researchers working on public engagement activities (Yes / No)

6.3.3.3 Gender equality: directions of improvement and action points

Gender equality is a priority of the current academic leadership and, therefore, gender policies are subject

to a significant development and expansion. As for the other keys, the most important action points selected in the focus group covered two directions: (1) gaining better knowledge of the processes related to each RRI component; (2) generating changes in organizational structures. The following tables specified the priorities identified in the focus group:

Ref.	Action point	Indicator
GE1	Understanding what is the differential performance of female and male scientists in leading scientific projects is seen as an important metric to legitimize policies for gender equality in research. The proposed indicator focuses on the social and economic impact of research.	Return on investment from projects led by male and female Principal Investigators (metrics depending on the dimension of impact which is measured)
GE2	Despite improvements, the baseline indicators of gender balance in the university confirms a disparity between men and women in academic progressions. To further balance the composition of the university research staff, it is proposed to introduce an incentive system for academic scientific structure hiring women scientists. These incentives can amount to an increased share of budget for hirings for those structures who commit to select women candidates in the context of (temporary) affirmative action policies. This proposal is aligned with the current indications for the 2019-2021 budget planning.	Incentive system for hiring female scientists (Yes/No)

6.3.3.4 Open access: directions of improvement and action points

Given the small number of researchers aware of Open Access policies and requirements, training is seen as a key activity to diffuse the awareness about Open access in the academic community (R#11, 13:01-20:21).

From the organizational point of view, the current exploratory phase is aimed at surveying the expertise available in the Departments in the view of suggesting the creation of a network of experts (ideally, one for each disciplinary area) who could support researchers to design and build datasets compliant with open data guidelines. (R#11, 04:06-11:00) Strengthening the role of the International Research Office is seen a condition to make the Office, which now has a key role in diffusing the topic, an effective hub for policy coordination on this matter. (R#11, 13:01-20:21)

This step is seen as preliminary to establish a University-wide policy on the matter, by involving the research commissions of the Departments and the University leadership. (R#11, 20:21-23:05) Policy coordination across the University is seen also as an asset for the external communication of the University. (R#11, 04:06-11:00)

When asked about priorities in the focus group, participants took a stance which is similar to what we have seen for ethics and public engagement. In examining and proposing action points for Open Access, the actual alignment of incentives on different levels (national, organizational, and individual) was identified as a priority. Considering Open Access publications as a plus for the national Scientific Qualification exercises (the procedures that grant academics the qualification to compete for associate and full professorships) was mentioned as an important instrument to foster researchers' commitment to and compliance with Open Access rules. However, this aspect is far from the reach of the University (the Ministry is competent). Therefore, the following table includes only a second strategy that was mentioned to achieve this objective,

and which referred to the organizational (University) level. Accordingly, below is the action point and the related indicator which was identified in the focus group:

Ref.	Action point	Indicator
OA1	Incentives should be introduced to foster knowledge and awareness about Open Access, as well as to promote researchers' interest in choosing this option for publishing research outcomes and data. The discussion illustrated various options the University leadership have for building these incentives: (1) hiring budget for the scientific structures of the University (departments); (2) additional research funds for researchers publishing open access. Another option referred to using Open Access funds as an incentive: an ad hoc budget could be distributed to leading researchers in the University as a reward and as a tool for ensuring a broader impact for their research.	Incentive system for publishing Open Access publications and data (Yes/No)

6.3.3.5 Science education: directions of improvement and action points

Despite the University having science education activities (see above), the focus group neglected this aspect of RRI. A possible explanation is that many of these activities, such as all the initiatives that could be labelled as "informal education" (seminars, workshops, etc.), are formally defined as public engagement and they are part of the University's "Third Mission".

As an exception to what we have done for the other keys, the table that follows does not include the priorities identified in the focus group, but a suggestion by the Padova RRI-Practice team who has coordinated the Review and Outlook. In suggesting an action point, we start from noticing that only once the University organized a training event on RRI as such in the past.³¹ A simple, yet important action point could regard the implementation of new RRI education events. The following table describes this point and the related indicators:

Ref.	Action point	Indicator
SE1	Training events on RRI should be organized, targeting researchers of different seniority. Raising awareness and improving knowledge of RRI are important measures not only for fostering the commitment of researchers either to this approach or to its different keys. It is also useful to diffuse a comprehensive attitude to responsible innovation, in an organizational context where keys and dimensions will be treated separately, in terms of planning and implementation.	No. of dedicated educational projects (annual evolution) No. of students, teachers and other personnel reached

7. Organizational reviews and outlooks: Research funder

³¹ The workshop on "Responsible Research and Innovation, ethical aspects and gender", organized by the International Research Office in May 2016.

7.1 Mapping of the organization

Fondazione Telethon (in short: Telethon) is a non-profit organization founded in 1990. Telethon's mission is to foster research that leads to cures for rare genetic diseases. Therefore, research represents its core activity. To achieve this goal, Telethon performs research activities on rare genetic diseases, but also funds extramural research project on the same subject. Because of this hybrid status, the Foundation was included in the project as a research funding organization.

Telethon's bylaws set the following aims for the Foundation: (1) support and perform research on neuromuscular and genetic diseases; (2) disseminate knowledge about the research on genetic diseases supported by the Foundation and its results, as well as on the social implications of these pathologies; (3) foster and promote the development of technologies to support the autonomy of persons affected by neuromuscular and genetic diseases (art. 2).

Since 1990, the Foundation reports that more than 450 million euros have been assigned as funding for more than 2,500 scientific research projects (cf. <http://www.telethon.it/en/about-us/official-positions/faq>). In 2016, Telethon has invested in research 41 million euros, as per their 2016 Annual Report. As part of the research performing activities, Telethon runs three research institutes: Tigem – Telethon Institute of Genetics and Medicine, SR-Tiget – San Raffaele Telethon Institute for Gene Therapy³², DTI – Dulbecco Telethon Institute (DTI).

While Tigem and SR-Tiget are research institutions, DTI is a programme whose aim is to provide support and guidance for young researchers embarking on an independent career to study genetic diseases in Italian research laboratories.

In the first period of activities (1991-1995), 87% of funds were channelled to basic research. In 2011-2016, 43% of funds targeted basic research, while 29% and 28% were channelled respectively to pre-clinical and clinical studies. In Telethon's latest annual budget (2015-2016, budgets run from July to June), the Foundation invested more than 41.5 Million Euros in intra- and extra-mural research activities (cf. <http://www.sfogliami.it/sfogliabili/143903/Bilancio%20di%20missione%202016.pdf>).

Telethon is run by a Board of Directors, which appoints a General Manager. Operationally, Telethon is structured into five different divisions (Human Resources, Budget and Administration, Fundraising, Clinical Development, Research and Development).

Telethon's research programs are assessed and steered by two expert advisory bodies: the Scientific Committee (Commissione Medico-Scientifica), and the Scientific Advisory Board (Consiglio di Indirizzo Scientifico). The former has the responsibility of evaluating the project proposals to be funded and of assessing the research activities of the Telethon Institutes. The latter supports the Board of Directors in defining the research strategy of the Foundation. The Chair of the Commission is a member of the Advisory Board too.

The Scientific Committee, made by international experts, assesses project applications based on two key criteria: research excellence and impact on patients. While research excellence concerns the scientific quality of proposals, impact refers to the proximity of the project to clinical development. Fundamental research gets a lower impact score; preclinical research based, for instance, on in-vitro modelling, has an intermediate score; clinical research has the highest score. The evaluation score of a project proposal is 90% about research excellence, 10% about impact. International external referees, selected by the Telethon research program managers, may also support the evaluations of the Scientific Committee with specific external reviews. This applies to both intramural and external projects obtaining Telethon's funds.

³² The San Raffaele Hospital is a research hospital based in the Italian city of Milan.

The peer review process and the scientific management of research initiatives is performed by a team of research program managers, who also take care of monitoring research outputs and performance of grantees. A Scientific Convention, convening all Telethon investigators, is held biennially. Telethon also performs direct fund management for both intramural and external research, through dedicated administrative staff.

For clinical development, Telethon has started partnerships with hospitals and pharmaceutical companies. Examples of these partnerships are the development and production of Strimvelis with GSK and the collaboration agreement with Editas Medicine to research and develop genome edited haematopoietic stem cell (HSC) and T cell therapies. Professional staff is dedicated to technology transfer, intellectual property protection, business development, partnership negotiation and management.

In addition to industry partnerships, Telethon has a number of collaborations and is part of numerous research networks. We emphasise here three collaborations which can be singled out:

- The creation of the “Associazioni Amiche di Telethon”, an informal network of “Friends of Telethon Patient Organizations, gathering patient associations dealing with one or more rare genetic diseases. Updated figures from one of the respondents point at about 190 partner associations. Telethon's website reports more than 100 associations in the Network (cf. <http://www.telethon.it/cosa-facciamo/per-i-pazienti/associazioni-amiche-telethon/elenco>). A conference of the associations runs parallel to and shares joint sessions with the biennial Telethon Scientific Convention.
- The participation in a consortium of Italian biomedical research organizations called Research4Life. The most visible result of Research4Life is a web information portal for scientific communication (www.research4life.it). However, one of the respondents characterises Research4Life in much broader terms, as a pressure group aimed at influencing the policy environment and public opinion to protect and develop scientific and medical research:

[Research4Life] is a communication initiative, it is a sort of pressure group to influence the government – for instance – to cope with animal-rights movements that protest against us and thus to defend research from the boycott of animal-rights [activists'] communication and from the fact that there are also members of the parliament that support their arguments (R1#, 28:45).

- The participation in Europe PubMed Central (<https://europepmc.org/>), a database of open access biomedical research publications (Telethon is the one Italian organization to participate in the portal by contributing Telethon-supported open access papers; the service entails payment of an annual fee, which is proportional to the research budget of the Portal's partner).

Telethon and its research institutes have 496 employees. 152 are men. 340 work in research, as researchers, technicians, project managers, or clinical staff. The Foundation has two main offices in Rome and Milan.

While a minor part of the funding of specific research projects comes from institutional donors, Telethon's main fundraising activity is to solicit contributions from companies, civil society organizations and, especially, individual citizens. Fundraising is conducted by a team of professionals, who engage volunteers in fundraising and awareness raising activities all over the country, with 58 provincial coordinators and dedicated Regional Managers for Campania, Latium and Lombardy, three of the most

populated Italian regions of the country and the areas from which most of donations are collected.

An Oversight Committee (Comitato di Vigilanza) is tasked to monitor administrators' and employees' conduct according to the Foundation's Code of Ethics and regulations.

7.2 Aspects of responsibility in organisational policy and practice

7.2.1 The conceptualisations of responsibility in the organisation

Overview

All respondents but one converged in acknowledging the absence of overt references to Responsible Research and Innovation in Telethon's activities and in their personal professional experience. This is confirmed by the lack of direct reference to RRI in the documentation available on the Foundation website.

Nonetheless, respondents were quick in linking RRI to their professional experience in the organization. As it happened in the National Workshop, RRI keys were apt entry points, as they were seen as already part of the organization's policies, activities, and culture. For instance, societal engagement is key for a funding organization that collects the bulk of money from Italian citizens to finance its research initiatives and operations, and relies on volunteers for a significant portion of these operations and ultimately on the commitment of donors to Telethon's goals. Similarly, engagement of younger people via social media is considered of particular importance, as this age group is not reached by the traditional mass media strategy of the Foundation (via the television fundraising "marathon") (R#6, 38:30-41:10). Open access to research publications is seen as a strategy to foster the public awareness about scientific research and to stimulate the growth of scientific culture in the Italian public (R#7, 1.07:40-1.11.00), and, more specifically, it is seen as an effective instrument to address specific targets, such as the scientific community itself, and to transparently provide information about the outcomes of Telethon funding and research activities.

Overall, the social responsibility of the Foundation is defined by its mission of doing and funding excellent research to cure rare genetic diseases. Excellence and impact are the chief criteria Telethon has set to deliver its mission and, therefore, to be responsive to the community and to its stakeholders, such as donors, individuals affected by genetic diseases, and their families. In this context, responsible research is research that keeps excellent standards, in terms of scientific quality and in terms of compliance with existing regulatory frameworks, such as Good Clinical Practices and Good Laboratory Practices guidelines, which ultimately safeguard patient safety and rights (R#4, 42:40-52:50). These can be seen as requirements to translate this research into clinical practice and, ultimately, as the condition to deliver impact on patients. As one respondent affirms:

Perhaps, I am still a bit close-minded... I have a fundamental bias: I believe that responsible research is tied to data quality, to research quality, to the respect of patient rights, to [regulatory] compliance. This is what I call "responsible research". (R#4, 49:40)

When asked about RRI, responses received see it mainly as a vehicle for communicating the "social utility" of Telethon's work (R#1, 41:01-44:20). In another case, one respondent interestingly links the personal responsibility of employees and their behaviour in the workplace, citing the current development

of a new “code of conduct” for Telethon's staff and presents an internal communication project to foster sustainable behaviour in the organization (R#6, 33:41–38:30).

Diverging from other interviewees, one respondent notices instead that RRI is making its way in the internal debate within Fondazione Telethon, though no formal incorporation of RRI notion and principles is made in the Foundation's activities and policies. The same respondent noticed that EURORDIS, the European umbrella organisation of non-profit and rare disease patient organisations, considered RRI in its activities and prepared recommendations for its members. (R#2, 57:41-1:01:10)³³

Competing concepts

Respondents' views seem to closely reflect Telethon's vision of ethical conduct as it is described in the Foundation's Code of ethics (cf. <http://www.telethon.it/chi-siamo/organizzazione/codice-modello-etico>).

This document defines Telethon's vision as “making available to patients the results of excellent research [which the Foundation] selects and supports over time” (p. 5). Ethical research is subsequently defined as “work aiming at bettering the quality of life of today's and tomorrow's recipients of Telethon's research results, along with ensuring the respect of all the subjects involved in our work”. Alongside ethics, Telethon's Code of ethics lists three other values: transparency, continuing improvement and quality. To ensure quality of research, Telethon is committed “to promote competitive and rigorous selection modalities and criteria, in order to award and value talent and competence” (p. 6). This emphasis on scientific excellence and quality is reflected, for instance, in the criteria for ex-post, research impact assessment, which include, to date, aggregated bibliometric citation assessments. Similarly, intellectual property protection and technology transfer activities are assessed according to quantitative criteria, such as the number of patents developed, the number of industrial collaborations started, the number of products on the market or in the pipeline (R#3, 20:40-21:10).

Excellence is the main criterion used for selecting external projects funded by the Foundation. In a situation of limited resources, measuring proposals against this yardstick allows to fund only a portion of all the valid proposals, despite they may focus on issues of interest for the Foundation and despite they are follow-up of previously funded projects.³⁴

It is a difficult choice because, you know, if there were a [national] funding program for research on rare genetic diseases with an annual budget of 10 million, then we could afford to use [different criteria] for selection, because the basic seed money is guaranteed.

(R#3, 44:50)

In other words, this rigorous method of selection is also a response to a national context where institutional (public) funding is seen lacking and in which Telethon assumes the onus of funding most of basic and pre-clinical research on rare genetic diseases.

As explained above, impact on patients is the second component of Telethon translation of social responsibility. This is translated in an additional score (with a relative weight of 10%), in addition to the scientific merit score (which weighs 90%), reflecting an attention to the potential applicability of the proposed research and to the effective delivery of benefits for patients.

³³ We are not able to locate the reference to RRI in the Eurordis portal.

³⁴ General calls are open to any applications, irrespective of prior applicant or application status, mainly because running separate tracks for different types of applicants (e.g. past applicants, young investigators, renewal applications, revised applications) would require economic and human resources, which Telethon considers beyond its reach. The downside of this approach is that it reduces the possibility to capitalize on previously funded projects through new follow-up projects.

7.2.2 Ethics

Description of the practice and its development and an assessment of how well it currently works

The issues covered by this key include: research integrity and deontology of researchers' conduct, and ethical aspects of research projects. We interpret this second dimension in broader terms to include regulatory compliance, which is an important element in the management and practice of research activities in regulated fields such as biomedical and, specifically, genetic research. Moreover, regulatory compliance encompasses issues of ethics clearance and ethics evaluation, and it can be considered, in a broad sense, an indicator of ethical responsibility. However, we will discuss also an additional, important dimension of ethics in Telethon, which relates to the more general code of conduct of the Foundation's staff.

Regarding regulatory compliance and in order to ensure adherence to regulations and quality standards of clinical trials, which are meant to guarantee patients' safety, Telethon has appointed a Clinical Development Manager since 2015 to advise and guide researchers on these issues. The manager coordinates the set-up of clinical research in the two SR/Tiget and Tigem Telethon institutes and supports extra mural research grantees upon request.

Besides regulatory compliance, the ethical conduct of the scientific work is defined in the broader terms of research integrity. Integrity is seen as one key condition "to maintaining public trust in [the] research enterprise" and, therefore, must be safeguarded. While a publicly diffused policy is in preparation and Telethon Institutes have their own integrity policy, the Foundation relies on the procedures and oversight bodies of host institutions to enforce research integrity policies for extra mural research. Requirements are set in the calls for proposals, which state that "the highest standards of research integrity" must be adhered to (cf. http://www.telethon.it/sites/default/files/Call%20for%20Grant%20Application%202017_0.pdf). According to the text of the calls, research integrity includes:

the use of honest and verifiable methods in proposing, performing, and reporting research projects and results according to rules and regulations that are in force within the international scientific community the commonly accepted professional codes or norms.

In case of misconduct in extra mural research, Fondazione Telethon issues a formal notification to the Principal Investigator's Host Institution, which should then respond according to its own policy for handling this type of allegations. In case of misconduct in a Telethon Institute, the notification is issued to the Director of the Institute, who has then the responsibility to handle the allegations. A comprehensive policy is now being developed and will be made publicly accessible.

In 2008, Telethon embarked in applying ISO 9001 certification to the research review process. This initiative, which is an independent decision of the Foundation, is aimed at ensure transparency and fairness, by subjecting the project proposals review and monitoring processes to the quality standards defined by the ISO norm. The standard applies to both the initial evaluation and selection of project proposals, to their final evaluation, but also to the scientific and administrative monitoring during the project cycle. The ISO 9001 norm are both extra-mural and intra-mural research.

The last dimension of ethics this section introduces regards the more general conduct of staffers and managers. Telethon has developed a Code of ethics which applies to all the employees (for instance, all the

new employees receive a specific and detailed training on the ethics code) and regulates the relations between colleagues, and of Telethon's staff with stakeholders, suppliers, and public institutions.

Besides the Code, Telethon has implemented the so-called "Model 231" – Model of Organization, management and control pursuant the Legislative decree 231/2001 (Regulation of administrative responsibility in legal persons, corporations and associations, including associations without legal personality). The Model 231 (cf. <http://www.telethon.it/en/about-us/code-ethics-model-231>) describes in a detailed way all the actions bearing a potential for administrative criminal responsibilities for managers and employees of corporations and other legal bodies (e.g. conflicts of interest, corruption, money laundering, etc.). According to the Legislative decree, organizations may be held responsible, and subjected to penalties, for such activities. The adoption and effective implementation of an organisational model complying with the Legislative decree discharges the body from this responsibility, insofar it proves to be a model of management and control of the organisation capable of preventing criminal offences.

Main barriers

Remembering that here we understood ethics in a broader sense which includes also regulatory compliance, the main barrier is here a **cultural** one. In this context, lack of awareness and knowledge of the regulatory requirements to set up clinical and pre-clinical research projects is seen as a major weakness in the full implementation of regulatory requirements in research. On the more general theme of research integrity, training of young researchers is deemed crucial.

Main drivers

Interchange is the central driver to enforce research integrity principles and to consider and implement regulatory compliance, again taken as an indirect indicator of ethical responsibility. Medical research in general is heavily regulated and national and international norms shape the regulatory environment of researchers and research managers. Regulatory agencies such as the European and Italian Medicines Agencies and industrialist associations promote initiatives for sharing and coordination.

Environmental factors are crucial in a second sense. Ensuring high quality research is essential to move successfully the research, either performed or funded by Telethon, to clinical and, ultimately, product development in collaboration with the pharmaceutical industry. Commenting the collaboration between Telethon and GSK leading to the production and commercialization of Strimvelis, the first genetic therapy addressing ADA-SCID³⁵, one of the respondents noticed how thinking proactively to the expectations and requirements of industrial partners and regulatory authorities was an essential element to start this collaboration and to successfully develop and commercialize Strimvelis.

[W]e realized that data were promising and we wanted to have a broader horizon than a simple clinical research in one hospital, in order make the outcome reach the market. In that moment, Telethon was acutely aware of the need to further develop that research, that clinical study. It had to be structured so that it could be acceptable to GSK, which became involved at a later stage, and to the regulator. [This was needed], as I said before, for them to accept those data and, based on their acceptance, to make the drug available [on the market]. (R#4, 24:35)

Cultural factors account for drivers too. The reorganization of the clinical research area was driven by

³⁵ ADA-SCID is a specific form of SCID, accounting for the 10-20% of the cases. SCID (Severe Combined Immunodeficiency) describes a group of rare congenital disorders characterized by severe impairment of immunity and absence of T lymphocytes. ADA-SCID is a type of SCID caused by a deficiency of the enzyme adenosine deaminase (ADA).

the injection in the organization of staff coming from the pharmaceutical industry. While this is not exclusive of this area, it was a strategic choice to involve staff from the private sector in order to introduce standards and practices that can facilitate the interaction with potential industrial partners. Cultural issues are seen as important drivers for research integrity too. The call for proposals explicitly mention the goal of “maintaining public trust in [the] research enterprise” as the chief reason to ask grantees to “strictly adhere to the highest standards of research integrity” and to enforce a research integrity policy, with the involvement of host institutions.

Best practices

Telethon's response to the complexity of ensuring ethical and regulatory standards in clinical and pre-clinical research was based on two actions. A research program manager is dedicated to dealing with issues related to research integrity. Structurally, Telethon created a new position in the organization tasked with the coordination of the set-up of trials and the regulatory design and assessment of clinical research project. This Clinical Development Manager coordinates two teams in the Telethon Institutes (Tigem and SR-Tiget). Culturally, the Foundation organizes training sessions on this topic, including during the biennial scientific conference for intra- and extra-mural researchers.

Current indicators

The reliance of recruitment on the business sector was mentioned above. This tight link with organizations and practices of the corporate world is not limited to clinical development and concerns most of top managers, including the director general of the Foundation.

Therefore, it is not surprising that, when assessing the existing assessment criteria and indicators for ethics and regulatory compliance in research, the respondents notice that “performance evaluation mechanisms are similar to those I was used to in [Name of the Company]” (R#4, 32:00), though less quantified. As we will see for the other keys, this approach is consistent across the functional areas of the Foundation. Yearly objectives are set with the line manager and two evaluations are performed after 6 and 12 months.

Interestingly, the objectives set for the Clinical Development Area do not explicitly concern the (assurance of) quality in clinical studies and they refer rather to the creation and development of clinical research units in partner hospitals and other medical research structures, as well as the finalization of related cooperation agreements (R#4, 32:00 – 39:00).

An interesting perspective from the focus group, concerns the “ethical use” of financial resources. The definition of strict policies to ensure the efficient and careful use of resources is seen as a moral commitment due to the patients and their families (FG#1).

7.2.3 Societal engagement strategies in organisation

Description of the practice and its development and an assessment of how well it currently works

Public engagement is key to the whole set of Telethon's activities: (1) fundraising; (2) scientific research and clinical development. On the one hand, public engagement is seen as a two-way process of learning, of the public about biomedical research, and of scientists, who can know better what the expectations of patients and their families can be. On the other hand, engagement is an instrument which contributes to the public's (volunteers and citizens) commitment to the Foundation's goals and to their mobilization to help Telethon

achieve its objectives. More generally, public engagement, alongside communication activities and education initiatives, is part of an effort to create a positive environment for the activities of the Foundation.

With regard to fundraising, engagement is important for recruiting volunteers that can join campaigns. Social media and a call centre are the primary tools used by Telethon's central offices to recruit fundraising volunteers. Ad hoc training is provided to volunteers joining Telethon's campaigns. Most of volunteers are "volunteers for a day", i.e. they join a single campaign for a short time. However, a smaller number is selected for an ongoing commitment and collaboration with the Foundation. (R#1, 19:00-22:00)

An additional initiative to recruit volunteers has been implemented as part of the activities targeted at schools. By signing an agreement with the Regional Government of Lombardy and in the context of the national work-experience training schemes (all Italian students are expected to spend part of their school time working in a company or in another type of organization), Telethon has presented a project for secondary school students aimed at introducing the topic of rare genetic diseases, and the mission and activities of the Foundation, including fundraising. After this short training period, students participating in the project spend the time of their work experience joining Telethon's fundraising campaigns.

Regarding scientific research and clinical development, engagement is sought for patients who are benefitting or may benefit from therapies and research developed either by or with the support of the Foundation. To this end, Telethon has promoted the creation of an informal network of "Friends of Telethon" Patient Organizations. The Foundation actively interacts and collaborates with these associations, which are reference organizations for patients and their families and which represent their concerns with other stakeholders in the medical research system. Moreover, Telethon works with patient organizations and individual patients to build and maintain biobanks for research on rare genetic diseases research, in order to make high-quality biological samples available to the scientific community (see also below).

One of the goals of patient engagement activities is aimed at the creation of what respondents called "the expert patient". This label does not mean that the Foundation aims at transforming the patient in either a medical doctor or a scientist, but it expects to empower patients by making them knowledgeable on issues such as the mechanisms of research selection and management (e.g. peer review, funding) and patients' rights, including the meaning and form of informed consent.

Who knows enough about research and healthcare can take informed decisions: for themselves, if they are a patients; for their children, if they are parents; for their own association, if they work in a [patient] association. (R#2, 38:26)

The most important examples of this kind of activities are two meetings targeted to patient organizations, which take place in alternate years: the biennial "Spring meeting" and the biennial "Friends of Telethon" patient associations meeting taking place within the Telethon Scientific Convention. These patient engagement initiatives are aimed at improving the knowledge which patients and their families have about rare genetic diseases and their understanding of scientific research. Through this greater knowledge, Telethon seeks to empower them in their relationships with researchers and regulators. During the Spring meetings, the Associations are invited to present good practices of participate in the research on rare genetic diseases. During the conference, Telethon researchers inform patient organizations about aspects of scientific research, such as clinical trials, biobanks, disease registries, and research projects selection and funding. By way of these initiatives, Telethon has the goal to move "towards a participatory, innovative, and responsible scientific research" (<http://www.telethon.it/cosa-facciamo/per-i-pazienti/associazioni-amiche-telethon/eventi-informativi>).

Besides these institutional activities, patient engagement is performed also as part of specific collaborative projects. For example, Telethon joined the training project “Determinazione Rara” (Rare Resolve), organized by UNIAMO – Rare Diseases Italy in 2013-2014. Determinazione Rara involved patients associations to inform, discuss and learn about biobanks in order to improve associations’ participation in the collection of biological samples that can be used in research. Telethon participated in this engagement effort as part of the Foundation's commitment to build and maintain a biobank network for rare genetic diseases research, the Telethon Network of Genetic Biobanks (TNGB). This initiative was aimed at making high-quality biological samples from rare diseases patients accessible to the scientific community, establishing governance and standardization of operations, and fostering collaborations with patient organisations. The biobanks in the TNGB are peer-reviewed by a Biobank Committee made up of international experts (cf. <http://www.telethon.it/en/research/for-researchers/biobanks>). The TNGB contains more than 95 000 biospecimens representing approximately 850 distinct rare genetic diseases. Request for sample usage is open for all researchers worldwide (cf. http://europebiobankweek.eu/wp-content/themes/offreWP_ebw/images/chiaraBaldo.pdf). Reporting on this activity, Telethon researchers have pointed at the mutual learning aspect of this participatory process, both for lay people, who increased their understanding of biomedical research, and for professionals, who gained awareness of the needs and expectations of the people involved. More than a dozen agreements have been established between patient organizations and biobanks of the Telethon network, whereby patient organizations deposit biological samples in the biobanks according to shared and agreed principles. Moreover, a representative of patient organizations (specifically, from the Italian UNIAMO umbrella patient organization) is a member of the network's advisory board.³⁶

Besides biobanks, Telethon has collaborated with a group of patients associations suffering from genetic neuromuscular diseases to create an Italian patient registry (cf. <https://reg.registronmd.it/>). While Telethon has been frequently involved in the development of registries (in fact, funding to other neuromuscular diseases registries has been part of specific grants within a dedicated initiative for clinical studies on neuromuscular diseases), respondents noticed that it is beyond the Foundation's resources to provide assistance and funding for all the associations interested in developing this type of infrastructures. (R#2, 38:20-41:10)

Besides research, research infrastructures, and fundraising, societal engagement with the general public is considered important to ensure a positive environment for the Foundation's activities. From this point of view, societal engagement is close to science communication and it is aimed to increase the public awareness on rare genetic diseases and Telethon's activities to cure them. (R#2, 12:00-14:20)

Finally, Telethon has created a helpline information service named “Info-rare” to provide tailored assistance and information to individual patients, their families, and the general population. The service offers from medical geneticists, who answer written queries on genetic diseases, which can be sent via an online form.

In terms of organizational structures, a patient representative sits in the Scientific Advisory Board with the mandate is to specifically address the relevance and impact of research investment, to the benefit of patients. In other cases, the contact with patients and the attempt to respond to their needs prompted the creation of new organizational units. For instance, Telethon created a new office called Patient Care Unit, to coordinate all the activities and services supporting patient and their families participating in gene therapy clinical trials and undergoing therapies. The creation of the unit responded to a deliberate strategy

³⁶ Baldo C., Casareto L., Renieri A., Merla G., Garavaglia B., Goldwurm S., Pegoraro E., Moggio M., Mora M., Politano L., Sangiorgi L., Mazzotti R., Viotti V., Meloni I., Pellico M.T., Barzaghi C., Wang C.M., Monaco L., Filocamo M. (2016), The alliance between genetic biobanks and patient organisations: the experience of the telethon network of genetic biobanks. *Orphanet J Rare Dis.* 11(1):142.

to better support the persons affected by rare genetic diseases throughout the experience of their disease, with counselling and advising, logistic support to participate in trial and therapies. The creation of the unit was an autonomous initiative of the Foundation (R#2, 23:30-31:10) to try and answer to patient needs as directly experienced by the clinical team dealing with them. As such, it is an attempt to take responsibility for necessities which are often felt, yet unspoken or unsatisfied by individual patients and by patient organizations.

Main barriers

Structural factors influence Telethon's capability for public engagement. This point was raised about the efficacy of fundraising Regional Managers to engage volunteers and stakeholders in the effort of streamlining and coordinating fundraising activities in in the Milan/Rome/Naples areas. In general, a more effective and integrated collaboration with the central offices of the Foundation and its national initiatives is recommended ("now we are a little bit kind of freelance", R#1). More specifically, the Milan area is said to require an ad hoc development plan to counter the absence of a strong group of volunteers that can guarantee a sufficient public outreach and engagement. (R#1, 34:55-41:00)

When asked about the actual inclusion of patients and patient groups in the decision-making of the Foundation, one respondent suggested that the organizational culture privileges the autonomy of the Foundation over the acceptance that "*choices [in funding and research priorities] are decisively steered by our reference [patient] organizations too*" (R#2, 55:10). The concept of mediation probably better describes this relation between Telethon and patient organizations than notions such as autonomy or independence. Patients and patient organizations' priorities are included in Telethon policies and initiatives, but they are mediated through the scientific planning and through the work of the scientific bodies of the Foundation. This work serves the purpose of balancing the needs of Telethon target groups and the characteristics of the research field of rare genetic diseases, Telethon's mission and objectives, the principles upon which research evaluation is based (scientific merit and impacts), and the limited resources available to fund research proposals.

Dealing with 7,000+ genetic diseases, direct involvement of and consultation with disease-specific patient organizations is hardly possible if not at the level of specific funding initiatives. An example on how Telethon attempts to achieve this balance is the mechanism of "exploratory projects", which the Foundation run in the 2012-2015 period. Through the Call for "Telethon Exploratory Project Proposals", Telethon solicited research on neglected genetic diseases, i.e. those which international research has not substantially addressed so far. These projects were low budget, short (1 year) projects and they did not require the collaboration of more research groups. Exploratory projects aimed at collecting initial evidence on neglected diseases, thus collecting data which were preliminary to bigger investments at a later stage. Each year, Telethon reserved the right to focus the Exploratory Project call on specific research topics. Associations were involved in the definition of these priorities.

Main drivers

As illustrated in the section above, what drives Telethon to engage with stakeholders and the public is manifold. First of all, it engages with the scientific community, inside and outside the boundaries of the Foundation. It supports researchers to produce knowledge about the therapies for rare genetic diseases, and it creates collaborations with scientists and experts to perform research evaluation. Secondly, patients and patient associations are engaged for increasing their awareness and their understanding of scientific and medical research, thus training "expert patients" that can take informed decisions for themselves and

be willing to join collaborative initiatives, such as the contribution of personal clinical data or biological material to research infrastructures (e.g. disease registries and biobanks). Thirdly, the selection of volunteers is crucial for Telethon to implement its fundraising strategies and activities. Fourthly, public engagement activities, together with communication campaigns and educational projects, are tools to create a positive environment for the activities of the Foundations.

Best practices

Besides fundraising activities, whose assessment can be done especially in terms of efficacy and efficiency, we would like to emphasize as best practices the engagement of patients associations in the construction of biobanks. In this collaborative framework, patients associations are asked to deposit biological samples, while Telethon biobanks store, catalogue and standardize the specimens. Similar considerations can be done for the construction of patient registries.

Eventually, it is worth emphasizing again the notion of “expert patient”. While the relevant actions, such as training courses and conferences, are not unusual, their finalization to patient empowerment is a remarkable aspect in Telethon's engagement activities.

Current indicators

Like other activity areas, societal engagement is assessed according to a quantitative approach borrowed from the business sector.

We are organized pretty much as a for profit company. Therefore, we have fundraising targets, individual goals, division goals, general objectives, group objectives. (R#1, 31:30)

The introduction of structured indicator and assessment system was brought by the new management, who had long experience in the business sector before joining Telethon.

The same quantitative approach is applied also to the management of the volunteers who participate in the fundraising activities, for instance setting a target numbers for individuals and groups to be recruited. (R#1, 30:31-35:54)

The number of participants to information meetings and training events, the number of association having “Friends of Telethon”, the number of advisory opinions requested by patient organizations, the time elapsed before getting with a reply from the Telethon helpline “Info_rare”, are all indicators that are used to assess the engagement of patients and patients associations. (R#2, 46:00–57:40)

Currently, there is the attempt to broaden the assessment approach to include a qualitative perspective. Accordingly, a qualitative feedback form is being prepared for assessing the Info-rare service; a similarly qualitative form is in preparation for distribution during the information meetings organized with patient association. This discussion is part of a broader revision of the engagement and evaluation strategies which involves both the research and fundraising directorates, in dialogue with patients associations themselves.

7.2.4 Gender equality and diversity strategies in the organisation

Description of the practice and its development and an assessment of how well it currently works

7 in 10 Telethon's employees are women and 3/4 of directors, area managers and coordinators are women. (R#6, 16:20-19:40) The gender composition of Telethon's workforce has been stable over the years since its foundation.

Staff management is a responsibility of a specific directorate in the Foundation (Human Resources Management) that centralized competences and roles previously dispersed between the Administration Directorate and external consultants. This radical change in personnel management has been implemented since the arrival of the new top management in early 2000s, who has brought to Telethon experience, practices and tools from industrial companies (R#6, 8:00-13:15)

As part of this reorganization, Telethon introduced a formal system of job descriptions and a systematic mapping of technical and soft/behavioural skills. The result of this mapping exercise is collected in a "dictionary of skills", which groups positions in the organization by professional activity, seniority, and skill type (cognitive, relational, operational) (R#6, 13:15-16:20).

Telethon has implemented a significant array of work-life balance initiatives that are designed to promote recruitment and retention of women workers, such as flexible working hours and teleworking.

Main barriers

Respondents pointed at the absence of specific gender balance policies, which are considered unnecessary, given the performance of Telethon in terms of women participation in the workforce and in women taking leadership posts. No perceived barrier was reported to women inclusion in every group of professional roles in the organization, where women are dominant with the exception of IT systems management. (R#6, 24:21-28:35)

However, in terms of participation in the workforce, gender balance (or women predominance, in fact) is limited to administrative and management roles in the Foundation staff and it is largely reversed in research roles. For instance, during the focus group, one of the participants mentions that Principal Investigator positions are held, predominantly, by male researchers (FG#3).

Main drivers

In absence of formal policies and mechanisms targeting gender balance, two main drivers can be recognized.

Firstly, the inclusion of women in the work force is a principle that is deep seated in the **culture of the organization** since Telethon's start in 1990 and it is the shared experience of the organization's employees, including those sitting in the offices tasked with human resources management and recruitment.

This [situation] makes the organization clearly attentive to the recruitment of these candidates [women], especially in the selection stage. (R#6, 17:30)

Secondly, Telethon partakes a shared characteristic of the non-profit job market: women are the majority of candidates for jobs in the non-profit sector, including in those organization working on medical research. The consequence of this **interchange** between Telethon and its operational environment is that the pool of candidates applying for jobs or project at Telethon is skewed towards women. However, this pattern of staff composition regards only administrative and management posts (see the section on 'Barriers' above). (R#6, 24:21-28:35)

Best practices

As far as gender balance is not perceived as a problem, no formal policy has been implemented to ensure a

fair composition of the workforce. Nonetheless, a number of policies for work life balance are in place and they are seen as a key reason for staff retention, such as flexible entrance time and working schedule. (R#6, 19:40-24:20)

Teleworking is seen as a further element of flexibility that can facilitate work life balance for the workforce, especially the female workforce, which is overwhelmingly responsible of home care. (R#6, 41:11-46:30)

These policies are periodically reviewed. Organizational climate is periodically assessed to inform managerial decisions and to anticipate the consequences of organizational change. (R#6, 28:36-31:00)

Current indicators

Job applications, new hires and, in general, the workforce is monitored according to gender and age. A similar analysis is performed for funding decisions and research outputs (grants obtained, and scientific articles authored by female researchers). Nonetheless, there is no quantitative target in terms of recruitment and retention of women employees and “scientific excellence” is reportedly the one criterion used to allocate grants and select projects. As one of the participants of the focus group put it (FG#6), these policies are “gender neutral”.

Another notable absence is related to anti-harassment measures. To the best of our knowledge, no formal policy is in place for awareness raising, reporting of incidents in a safe and confidential setting (e.g. setting up an institutional hotline), or ad hoc training.

The Human Resources directorate regularly implements surveys on the organizational climate to inform managerial decisions and anticipate the consequences of organizational change. (R#6, 28:36-31:00)

7.2.5 Open access and open science strategies in the organisation

Description of the practice and its development and an assessment of how well it currently works

Telethon's open access policy for scientific publications was defined early in 2010, when the debate on open access in Italy was in its infancy. The policy established a dedicated budget to fund open access options for all the original research papers written by Telethon researchers, be they intra-mural researchers or grantees (extra-mural). To be eligible, researchers have to be first, last, or corresponding authors. (R#7, 13:21-25:30). It is important to notice that the budget was not incorporated in researchers' grants but set aside and managed centrally. Nonetheless, the choice of the journal was entirely delegated to researchers, with no use of evaluation criteria such as impact factor to select priority journals for publication.

This policy was revised in September 2017 and now it is envisaged that researchers include a budget for open access publications in their grant submissions. Participants in the focus group emphasised the importance of the previous program based on a centralized budget as a tool to raise researchers' awareness on open access, and to change their view of open access from a “burden” to an “opportunity”. (FG#9) The opinion is that, now, this goal has been achieved and that a less costly funding scheme can be adopted, counting also on the broader diffusion of open access policies in funding and research organizations. Such a more diffused support of open access creates more funding opportunities for Telethon researchers who are involved in collaborative projects (fees can be share with other partner organizations, or payed by them)

To effectively promote open access, the Foundation has created an ad hoc office providing support to researchers on free and paid options for publishing with an open access licence, advising on issues such as the use of repositories, embargo periods, pre- and post-print versions, and contacts with publishers.

To ensure the visibility and availability of Telethon's publications, the Foundation joined Europe PubMed Central (PMC), an open access repository providing access to life sciences articles, books, patents and clinical guidelines. Europe PMC provides links to relevant records in databases such as Uniprot, European Nucleotide Archive (ENA), Protein Data Bank Europe (PDBE) and BioStudies. Europe PMC is the sister site of PMC and is part of the PMC International Network of repositories. Telethon is the one Italian organization which has joined, and still supports, Europe PMC and its development, providing Telethon grantees with their own accounts within Europe PMC, where they can self-archive their publications.

Despite the early involvement with open access publications, Telethon currently does not have an open data policy. Although Telethon grantees are required to deposit genomic and other data as clearly specified in Telethon's calls for proposals, no mandatory indication of specific repositories is provided, as it is felt that several options are available to serve this purpose. On this aspect, the Foundation is willing to adapt to the guidelines which will be issued for the whole sector by regulatory or by (public) funding institutions (respondents cite the European Commission and open data policies in H2020 as an example, cf. R#7, 39:00-42:30).

Main barriers

Telethon prides itself for being best-in-class for open access among the Italian organizations working in biomedical research and for being the sole organization with such a comprehensive policy and strategy, including the availability of an advisory office.

Like in other contexts, **interchange** with other Italian organizations was not a factor in developing and pursuing this policy. In fact, a comprehensive participation of Italian public institutions, especially the Ministry of Research, has been missing in formulating and promoting policy coordination among the research actors in the field (R#7, 1.11.00-1.15.30).

The decision of being recipients of sectoral guidelines issued by regulators and public funders is linked to the peculiar nature of data in biomedical research and their accompanying regulatory framework. This nature has strong implications in terms of privacy and protection, as well as in terms of their property and commercial use. In turn, these implications raise important regulatory and ethical issues, whose complexity make them difficult to master for a single organization (R#7, 42:31-51:10).

Culture is seen to play a role in determining the interest of researchers in open access and their capacity to comply with the policy. More specifically, non-compliance is blamed on a cultural attitude that gives preference to other aspects of the job over the not-negligible work that is needed to understand how open access options function and to carry out the work required by the various editorial policies and funders' mandates in order to publish with an open access licence. (R#7, 51:10-59:50)

Main drivers

Interchange played also a stimulating influence on the development of open access policies. The recognition and adaptation of best practices developed in the international context was the main driver behind the development of Telethon's open access policy. Once more, the example of and the dialogue with other prominent funding institutions abroad, for instance the Wellcome Trust, has been key in developing the policy and in joining specific initiatives, such as the Europe PMC repository, which was initially launched by the Wellcome Trust as UK PubMed Central. (R#7, 25:31-29:59)

On a similar note, participation in international initiatives, such as IRDiRC (the International Rare Diseases Research Consortium – <http://www.irdirc.org/>), of which Telethon is a member organization, provides valuable opportunities to align with and contribute to international guidelines and policies, including on open access and open science.

Best practices

The allocation of a specific budget for open access, either from operating funds or from individual researchers' grants, the creation of an ad hoc office supporting open access in the organization, and the participation in international OA repositories such as Europe PMC are all considered by the organization as best practices and they are regarded as unique actions in the Italian context.

Current indicators

Indicators for assessing this policy are the degree of compliance of researchers and the budget effectively spent. In 2013-2015, about 90% of Telethon's publications have an open access licence. It is important to notice that there are neither sanctions for the researchers who do not comply with the policy nor rewards for those who adhere to the policy. Two reasons are illustrated to justify this choice. Firstly, the management opted for not being too forceful in pushing the policy. Secondly, respondents acknowledge that implementing an incentive/disincentive system to enforce the policy would prove too much consuming in terms of time and resources invested. The availability of an ad hoc budget was seen as a sufficient incentive (R#7, 51:10-59:50).

7.2.6 Science education as integrated in research

Description of the practice and its development and an assessment of how well it currently works

Telethon organizes various training and education activities that can be included in this category, for both internal and external target groups.

The Telethon Academy provides training on the scientific aspects of Telethon initiatives to all the Foundations employees. The logic of this educational action is to raise the level of scientific culture in the organization, in order to expose the staff, independently from the role they have in the organization, to the research activities of the Fondazione. The Telethon Academy has begun its activity in 2018.

Though it overlaps with the considerations we did about societal engagement, it is worth mentioning that also the Telethon Scientific Convention provides a training opportunity for volunteers and patient organizations' too. In the convention, these groups can meet researchers and improve their knowledge about rare genetic diseases and about Telethon research.

Furthermore, a specific stream of Telethon's outreach activities is targeted to schools, as we have noticed in the social engagement section. This collaboration with the Italian school system started in 2005. More recently, the Foundation has entered an agreement with the Ministry of Education to ensure the diffusion of its educational offer across the system.

In the social engagement section, we briefly presented the work experience program Telethon is implementing in Lombardy region as an example of school training activity aimed at secondary school students in the Foundation's (fundraising) operations (R#1, 11:41:19:00).

More in general, Telethon's educational activities focus on two dimensions we already highlighted in the societal engagement section. Firstly, they aim at creating awareness in society about rare genetic diseases and about the life of persons affected by such diseases.

To this end, Telethon created an educational kit for the Primary School titled "Together we are more special". The goal of the kit was to communicate values such as the acknowledgement and inclusion of diversity, providing both teaching aids to stimulate children's capacity to elaborate these values in their

everyday life and materials for parents so that a meaningful link can be created between school and the family. (R#5, 7:46-15:30)

The goal is to create a more favourable environment for the integration of children affected by genetic diseases, via teachers' training and students learning. Respondents reported that the Ministry has deemed this training program as a particularly valuable activity for small cities, where teachers have less professional training opportunities. (R#5, 15:21-18:50)

Secondary School materials currently focus on scientific information about genetic diseases rather than on values. Students in secondary school are informed about the diffusion of genetic diseases in society by way of examples from popular culture's (real or fictive) characters; they are also given basic scientific information about genetic diseases and about Telethon's activities. (R#5, 7:46-15:30)

Since the interview was released, evaluations have been made on whether to formalize the project and extend it at the national level, but given the additional requirement that training on safety issues should be also provided to students, it was decided not to proceed. The road that the Telethon Foundation has chosen to follow is to promote the involvement of students in voluntary activities, thus also providing training credits for interested students.

Main barriers

Safety regulation and training has jeopardized Telethon's plans for laboratory training targeted to secondary school students. Other barriers related to organizational matters are mentioned in relation to a pilot program for STEM promotion and university counselling for high school students now suspended (see improvement section).

Main drivers

Education is seen as one of the ways to fulfil Telethon's goals, which include the dissemination of knowledge about existing research on genetic diseases and its results, as well as on the social implications of these pathologies (cf. <https://www.telethon.it/sites/default/files/atoms/files/statuto-fondazione-telethon.pdf>). Education is one of the tools to achieve this broad goal: “[e]ducating students and the continuous professional training of school teachers at every education grade, by way of organizing courses, seminars, conferences and by producing information materials and teaching aids” (Art. 2 of the Bylaws). There are therefore both **structural** (the mission set formally in the organization's bylaws) and **cultural factors** at work in making school education and outreach an important activity for the organization.

One note about *what is not a driver* for science education allows to reflect about the influence of the operational environment on organizational decisions. While certainly the Ministry of Education is a key enabling actor of Telethon's education activities, respondents notice that there is no structured exchange about education initiatives among non-profit organizations involved in medical research. This happens despite the fact that most of these organizations have school outreach initiatives, produce classroom materials, organize meetings with researchers, use similar assessment indicators (respondents mention AIRC – Italian Association for Cancer Research, as an example). (R#5, 33:31-35:20)

Best practices

Currently, there is no educational activity aimed at promoting the STEM curriculum and research careers. It was reported that a pilot program existed in Rome and Milan until 2016. Researchers met students in schools and a small group of the most interested students could spend one day in Telethon's laboratories with the researchers they met. The program has been suspended because of difficulties in managing researchers' and teaching schedule, as well as the administrative difficulties for organizing students' visits to

the laboratory. (R#5, 18:51-22:35)

At the time of the interview, a revision of the Secondary School kit was under way, also to tackle this problem (R#5, 18:51-22:35). Now, the kit is available for all secondary schools that request it. The “Geni in Gioco” (Genes Game) kit is an entirely digital science course, created in collaboration with one of the leading publishers in school education. The kit is an interactive game in which students take on the role of the researcher in one of the research institutes of the Telethon Foundation. Inside a virtual genetic laboratory, the students will face an interactive path, from the diagnosis to the therapy of a patient suffering from a rare genetic disease. The kit allows you to acquire skills in basic biology, genetics and anatomy through questions to be solved and multimedia learning objects.

Current indicators

Like in all the other fields of Telethon's activities, educational initiatives are meticulously monitored and assessed, using quantitative outcome indicators, such as the number of schools involved, the number of educational kits which are distributed, the number of students involved (as the average of kit distributed in each school), as well as process-related ones, such as the number of invitations sent, the number of confirmations received, the number of recalls necessary to get a confirmation from a school, how many teachers who were involved in previous editions responded to new requests. Monitoring actions run each semester. (R#5, 31:30-33:30)

7.2.7 Incorporation of AIRR dimensions into policies

A preliminary consideration is needed before discussing the incorporation of RRI principles into organizational structures, policies and practices. It is important to consider the specific characteristics of Telethon as an organization. Firstly, the Foundation funds and directly performs research activities. Secondly, Telethon has not a general mandate, but works exclusively in the field of rare genetic diseases. Therefore, the ways in and the degree to which principles are incorporated in policy should be assessed against these boundaries.

Anticipation and reflexivity

Institutional reflexivity is well present in Telethon's activities. Our brief comments about keys above have shown, for instance, the horizontal diffusion and continuous refinement of monitoring and assessing indicators. Also, the Codes of ethics, internal training materials and meetings, other voluntary monitoring and certification models, such as respectively the Model 231 and ISO 9001, internal surveys, show the degree of deliberate self-reflection of this organization.

The sources and motivations of this reflective approach are various and diverse, including national law in the case of the Model 231, international soft regulatory standards in the cases of the ISO 9001, or of the Good Clinical and Laboratory practices, and the “traditional” deontological code of scientists, in the case of research integrity rules and procedures.

Openness and transparency

Telethon invests heavily in communication to stakeholders. Open access policy is considered one of the chief instruments for achieving transparency and openness.

[The researchers funded by Telethon] must do everything they can to make these results freely visible and reusable to all our stakeholders. First of all, researchers themselves all over the world [can take advantage of that], because new research builds upon existing research and we want, in general, to make research advance as much as we can; but also, and clearly, patients, who are our final target, and, in general, society. [Society] for us means donors because we should remember that our funding derives from donations, let's say, from society and, therefore, anybody who wants to see how we spend money, what are the results of the research we fund also through their donations, can rightly see it. (R#7, 15:30)

While Open Access specifically concerns research results and it is reasonable to expect it will represent an effective communication tool mainly for certain groups of stakeholders, transparency has a more general scope and regards all the organizational processes of the Foundation, including aspects such as research selection, grants allocation, and, more generally, the use of collected funds.

Moreover, the way in which Telethon operates in this field is influenced by accounting and social accounting practices in the business world. The Foundation issues an Annual Report detailing what has been done and the allocation of the collected resources (cf. <http://www.telethon.it/chi-siamo/il-bilancio/bilancio-sfogliabile>):

The annual report is prepared to verify that all the activities are in line with the goals defined by the bylaws and to allow the readers to assess the work done by Telethon (Annual Report 2016, p. 2)

Similarly, Telethon borrows from the business world's widespread practices and corporate oversight. In addition to the internal Group of auditors mandated by the law, Telethon annual budget is certified by an external auditing company. Also, the Foundation established a "Vigilance body" to ensure the application of the Model 231 guidelines. The application of ISO 9001 to the research review processes may be seen as another initiatives taken with the objective to ensure the transparency of the Foundation activities.

Responsiveness and adaptation

'Accountability' describes better than 'responsiveness' the relation between Telethon and its donors. The Foundation has a strong commitment to transparency in communicating the use of funds, but there is no mention in the interview of changes in Telethon's operations or structure following donors' feedback or requests. One plausible reason for this is (also) the fact that donations are collected mainly from individuals. This fact reduces the presence (and influence) of large donors to whom Telethon could be directly responsive.

When exploring responsiveness, three groups are worth considering, in addition to donors: the scientific community itself, patients and peers, i.e. other non-profit organizations working in medical research.

Regarding the latter, respondents converged to a large extent in downplaying the existent interchange between Telethon and its national peers. Contacts exist, but they are mostly informal and limited to specific areas and activities (for instance, no cooperation is reported in defining evaluation criteria for research

impact and for science education program). The lack of a top-down push from policy makers (the Ministry of Research) is blamed for this state of affairs. (R#3, 31:55-34:10) A notable exception is the Research4Life platform, a consortium of Italian biomedical research organizations which was created to act as a pressure group and whose goal is to influence the policy environment and the public opinion to protect and develop scientific and medical research.

Peers in Europe and the world have had a much larger role in influencing Telethon's operations and the Foundation's efforts to respond to the perceived best-in-class research and funding standards, adapting consequently their own operations and structure. This was evident in the discussion about open access, but has a more general validity, for instance in shaping research evaluation.

[Research evaluation] originates from an exploration [benchmarking exercise, Authors' Note] of Wellcome Trust, NIH, etc., regarding the strategic plans of large foundations, [...] where are they going, what they are doing, how they assess themselves (R#3, 31:10)

With regard to the scientific community, responsiveness is translated into organizational configurations (e.g. offices, committees), which involve representatives of research institutions. This aspect is principally ensured through the work of two Telethon's committees: the Scientific Committee and the Scientific Advisory Board. As we illustrated above, these two expert groups are incorporated in Telethon's structure and are tasked to provide an expert evaluation of research projects to be funded against the criteria of scientific excellence and research quality (the Scientific committee, via peer review) and to advise on research investment strategies (the Scientific Advisory Board).

Finally, responsiveness towards persons affected by rare genetic diseases is well exemplified by the creation of the Patient Care Unit to assist comprehensively patients and their family participating in clinical trials or undergoing therapy. This newly created office tells us about the concept of “mediation” we described above. As it was said by one of the respondents and reported above, the creation of the Patient Care Unit was kicked-off for responding to internal pressures rather than following external recommendations and requests. However, this action had the goal to answer what was perceived as a manifest need, and yet unspoken through formal and ad hoc consultation channels. The creation of the Info-rare information service, or the organization of regular meetings with patient organizations respond to this logic, too.

The broadness of the research field and the perceived role of Telethon as the “funder of last resort” of research on genetic diseases in Italy (absent a public funding program) is one remarkable source of tension between the possibility to manage research priorities through direct, one-to-one relationships with patient organizations, and the operational necessity to convey resources on scientifically valid projects. This is particularly true for neglected diseases, on which little or no research activity has been performed. The absence of available data and of previous research affects negatively the competitiveness of projects tackling these diseases in the review process. The tentative solution given to this problem reflects again the logic of mediation we have mentioned: exploratory projects were funded to fill this knowledge gap.

A last point concerns the criteria used for project evaluation. The introduction of “impact on patient” as a dimension of evaluation (the closer to clinical trials, the higher the score) reflects the same attempt to balance scientific excellence and responsiveness to patient needs, in a context where funded and performed research is the primary activity of the organization.

7.2.8 Other concepts used to characterise responsibility in the organisation

In absence of references to the European Commission RRI notion, the conceptualization of responsibility oscillates between an emphasis on single RRI-related policies (the “keys”) and the assertion of the social benefits at large brought about by biomedical research Telethon performs and funds.

The previous sections described analytically the former perspective on responsibility and explained how the social responsibility of Telethon is framed in terms of excellent research and impact on patients.

Assessment of research impact has been largely consistent with this twofold characterization. On the one hand, publications impact has been evaluated via bibliometric measurements based on citations. In other words, impact is defined as impact on the scientific community, through the measurements which have been refined through the years, from an agreement with Thomson Reuters to a collaboration with the NIH in Bethesda and the use of their refined citation ratio. The NIH Relative Citation Ratio (RCR) allows to measure citations in the narrower specialist research field of the specific publication. This index is normalized for comparisons using NIH publication as a term of reference. NIH has used Telethon as a case study to test RCR. (R#3, 27:45-31:55)

Other indicators are routinely applied to measure the application and applicability of research outcomes, thus providing an estimate of the progression towards therapies and, of the “impact on patients”. Relevant indicators include: the number of projects; the amount of money invested in the different stages of research (from fundamental, to preclinical, to clinical); the number of patients treated in clinical trials; the ensuing partnerships with pharmaceutical companies.

An interesting development sees research impacts from a broader perspective, including impacts on the scientific community itself. In fact, to be designed and implemented, there is awareness that impacts are not only on scientific knowledge itself, but on those who are part of the scientific communities.

[You can measure] the social impact on the research world. Over the years, how many postdoc contracts have we funded? How many Principal Investigators working abroad have come back to Italy? It would be wonderful to know [also] how many of them we convinced to stay [in the country], but it is impossible to assess this latter one [...]. Thus, [you should measure the] social impact on scientific workers. [...] Then, you can conduct assessments on patients and their families. (R#3, 22:30-23:20)

This route to broader assessment mechanisms and criteria has been taken separately with the introduction of quality of life surveys of patients and their families. While research impact is a responsibility of the Telethon Research Impact and Strategic Analysis Unit, patients' surveys were implemented in the context of the newly formed (2014) Patient Care Unit.

Telethon set up a participatory research exercise to explore five “matrixes” of quality of life (cf. the Memole Project – <https://drive.google.com/open?id=0B2WYrIKngISrbW03WWITSktxTjg>): three thematic matrixes (inclusion and valuation of capacities, autonomy, self-awareness) and two horizontal ones (information, enabling environment). Understanding these matrixes is Telethon's responsibility in order to fulfil its social mission: quality research for effective therapies for rare genetic diseases.

7.3 Reflection on Review findings, Outlooks developed and ways forward³⁷

7.3.1 The integrated or fragmented nature of different responsibility related dimensions

Formal references to RRI in the organization were inexistent at the time of data collection. Nonetheless, Telethon's activities covered all the five RRI keys and respondents were able to link RRI to their professional experience and roles in the organization.

As it happened in the National Workshop, RRI keys were apt entry points, as they were seen as already part of the organization's policies, activities, and culture. For instance, societal engagement is key for a funding organization that collects the bulk of money from Italian citizens to finance its operations and (internal and external) research projects. Volunteer fundraisers are an important part of these operations, albeit they grant only a minor part of the donations which are collected. Their significance is, indeed, not only financial, but their involvement lends also legitimacy to the Foundation's action. Moreover, engagement of younger people via social media is considered of particular importance, as this age group is not reached by the traditional mass media strategy of the Foundation (television fundraising "marathons") (R#6, 38:30-41:10). Open access is seen as a relevant strategy to foster the public awareness about scientific research and to stimulate the growth of scientific culture in the Italian public (R#7, 1.07:40-1.11.00).

Similarly, responsibility is interpreted differently by different respondents, as complying with existing regulatory frameworks, performing "excellent research", adopting responsible behaviours in the organization, or using efficiently financial resources, according to individual professional roles and experiences. Overall, Telethon's Code of ethics defines the perimeter of the Foundation's idea of responsibility.

As we explained above, Telethon's vision is defined in terms of "making available to patients the results of excellent research [which the Foundation] selects and supports over time" (p. 5). Ethical research is subsequently defined as "work aiming at bettering the quality of life of today's and tomorrow's recipients of Telethon's research, along with ensuring the respect of all the subjects involved in our work". In other words, excellence in research is seen as a way through which impact on patients is delivered and through which social responsibility is exercised.

From the organizational point of view, potential tensions with other selection criteria are acknowledged. For instance, the lack of sufficient resources and the breadth and complexity of the field impede to create separate funding tracks for different applicants, e.g. past grantees, resubmissions, follow-up projects. One of the possible downside of this situation is that, in the case of follow-up projects, the funding may not capitalize on previously funded researches.

Impact assessment of Telethon's intra and extra-mural research follows this pattern (see section 7.2.8 for further details).

7.3.2 Common barriers or drivers

Cultural barriers are lamented as an obstacle to RRI diffusion and implementation. Researchers are said to lack detailed knowledge of norms regulating research and clinical practices (see the Ethics Key), as well as open access requirements and procedures (see the Open Access Key).

³⁷ This section develops the contents of two subsections which were distinct in the deliverable template, and namely: 'all points of improvements' (point E) and 'agreed points of improvement' (point G).

Coherently with the organization's mission, Telethon clearly prioritizes (performed or funded) research over other activities, which are seen as instrumental to sustain the former. While this is not to be understood as a 'barrier' in itself, it may partly explain the sometimes difficult attempts to involve researchers in education activities on a regular basis (science education).

Structural and interchange factors affect negatively societal engagement and open access policies. For instance, the former is said to be negatively affected by a relative lack of coordination between Telethon's central administration and regional coordinators of fundraising activities. Open access suffers from the lack of a national open access policy and of the related commitment of the Ministry of Research.

Interchange is the central driver to consider and implement research ethics, in a heavily regulated national and international regulatory environment. Also, the demands of industry requirements are a second driver for considering ethics and regulatory issues, as the possibility to move research from pre-clinical research, to clinical trials and to the market, depends on the interoperability of Telethon's and industry's standards. International peers played a key role in shaping Open Access policies, too.

7.3.3 Final reflections and plan for follow-up

This section reports the final outcome of the organizational study. As part of the organization's outlook and drawing on individual interviews and on the outcomes of the organizational focus group, a list of "action points" was drafted. For each of the keys, action points describe concrete steps (and related indicators) that translate the directions of improvements identified in the research.

The resulting list will provide the Telethon Board of Directors with options and guidelines for RRI implementation, in the context of the organization's decision-making procedures and multi-annual planning.

The organization of the list according to the keys reflects a common trait of the discussion and of the development of this organizational research in both Telethon and the University of Padova, i.e. the prompter and easier engagement with the individual keys rather than with the RRI concept in itself. Nonetheless, Telethon's participation in RRI-Practice has created opportunities for a broader engagement with RRI per se. On this, it is interesting to notice the participation of Telethon to the activities of the project "NewHorRizon - Excellence in Science and Innovation for Europe" (SwafS-09-2016, <https://newhorizon.eu/>). The fact that this new opportunity to work with RRI comes from EU programs, confirms their centrality in the diffusion of Responsible Research and Innovation, as well as their influence across different governance levels.

7.3.3.1 Ethics: directions of improvement and action points

Regarding ethics, improvement is sought along two directions: (1) fostering researchers' awareness and knowledge of ethics in research, so that they can effectively detect issues when they emerge; (2) creating a supporting infrastructure in the organization for advising researchers on these topics.

Drawing from the priorities identified in the focus group, the following action points and related indicators can be specified:

Ref.	Action point	Indicator
ETH1	Creating an ad hoc office to advise and support researchers on ethics and regulatory issues, especially in pre-clinical research and clinical trials. Given the hybrid nature of Telethon's research activities (external, based on grants or collaboration agreements; internal, in Telethon's institutes; hybrid, in joint facilities with external partners), this support infrastructure may assume the form of a network of offices located in and affiliated to different organizations.	Whether staff knows where to turn for ethical advice (perception indicator, to be collected through organizational surveys)
ETH2	Preliminary to all, it is important that researchers are able to identify (potential) ethics issue when they design research projects or trials, so that they can be effectively and thoroughly examined. However, this capacity needs to be fostered by way of ad-hoc training initiatives. The point is not to transform medical researchers into ethics experts, but to make them able to interact effectively with dedicated structures (to be built) in the organization (see Action Point ETH1).	No. of ethics training projects funded/realised
ETH3	The Foundation is developing public guidelines to manage conflict of interests and cases of research misconducts. The publication of these guidelines is seen as an important step in terms of transparency and openness to the Foundation's stakeholders.	Publication of integrity/conflict of interest guidelines developed by the organization (Yes/No)

7.3.3.2 Societal engagement: directions of improvement and action points

From this point of view, patient engagement emerged as a promising direction of improvement. For instance, the following interview's excerpt emphasizes the mission-oriented nature of Telethon activities.

When I first arrived in Telethon [...], sometimes I felt like the mission [of the Foundation] was research funding. No, it is not. Research should be considered as an instrument. The mission is to make cures available to persons affected by genetic diseases or, when there is no cure, to improve their quality of life. (R#2, 53:00).

However, the way in which engagement is operationalised is deeply influenced by the research mission Telethon has. This entails a constant mediation and a delicate balance between the recognition and uptake of patients and patient organizations' priorities and expectations, and the characteristics of the research field of rare genetic diseases, the principles upon which research evaluation is based (scientific merit and impacts), and the limited resources available to fund research proposals.

In this context, many actions are already implemented: organizing empowerment workshops with associations and groups before the start of clinical trials – this measure has been implemented in one case, but could be generalized –; implementing training activities based on suggestions and priorities of the associations; facilitating the creation of new associations by reaching out to affected persons via web communication; awareness raising activities organised with patients associations; showcasing associations events through the internet.

However, the focus group concentrated on a limited set of priority indicators and actions, centred on the skills and mandates of Telethon's researchers and on the financial resources dedicated to this type of activities. The following action points and related indicators describe these priorities:

Ref.	Action point	Indicator
SOC1	Training of researchers in science communication and public engagement is seen as a condition to overcome what the limited interest many researchers have in engaging the public and stakeholders. The development of communication/engagement tools (e.g., information packages) is considered as a part of this effort.	No. of participants to training initiatives on PE / total No. of people working in the organization (changes over time) No. of communication/engagement packages distributed to target social groups
SOC2	The explicit inclusion of public engagement activities as a formal task in researchers' job description is seen as an important step in creating researchers' commitment in these activities.	No. of employment contracts awarded to researchers that formally include PE as a job task
SOC3	In the current budget of the Foundation, PE activities are not registered under a separate heading and they are included under the budget for communication activities. A separate budget could be important to enable a more accurate monitoring and assessment of the PE effort and of its effectiveness.	Inclusion of a specific heading on PE in the organization's budget structure (preliminary to define quantitative indicators measuring increases in staff and budget to perform engagement activities)

7.3.3.3 Gender equality: directions of improvement and action points

As described in the Organizational Review, gender equality has always been perceived as a strength of Telethon, which prides itself to have an excellent performance in gender equality and diversity. The performance on this matter is indisputable. At the same time, the role of informal rules, attitudes, and, in general, of organizational culture and leadership clearly emerged as a key driver for this performance. The discussion in the focus group was instrumental in reflecting on what actions/indicators could complement the current activities and tools with a more formalized framework for monitoring, assessment, and decision making.

The following action points and related indicators describe the priorities identified in the focus group:

Ref.	Action point	Indicator
GEN1	Today, gender is monitored only in grant applications (applicants and associate researchers) and in scientific articles (authorship). However, there is no monitoring activity of research staff throughout the project life cycle and students are not included in the assessment. Similarly, the different roles of authors are not tracked. Adding indicators covering these aspects is seen as useful to improve the knowledge base of gender related policies.	% of men/women in projects throughout the whole life cycle (annual evaluation, in full-time equivalent) % of men/women that are first (corresponding) authors on research papers/publications (annual evaluation).
GEN2	Considering the stark difference between the administrative and research roles in terms of gender equality, it is suggested that Telethon's staff participates in common training initiatives on gender issues.	No. of participants to training initiatives on gender issues / total No. of people working in the organization (changes over time)

7.3.3.4 Open access: directions of improvement and action points

Improvement is seen here more as a consequence of systemic change rather than a question of policies issued by a single organization. The current so-called “Gold” Open access mechanism institutionalizes a double source of funding for publishers: via article processing fees and via journal subscriptions. While it is acknowledged that this change cannot be achieved by a single organization, Telethon supports the international collective effort to change the current publishers' policies on open access. As part of this effort, Telethon, with the Italian Rectors Conference, was among the signatories of the “Expression of Interest in the Large-scale Implementation of Open Access to Scholarly Journals”, the final document of the 2015 Berlin 12 Conference on Open Access, and now part of international Open Access 2020 initiative (cf. <https://oa2020.org/mission/>). The main recommendation of the “Expression of interest” is the conversion of the resources currently spent on journal subscriptions into funds to support Open Access publications. (R#7, 59:51-1.07:39)

Apart from this, two Action points were raised during the focus group. The first one refers to the usefulness of assessing the effectiveness of different open access solutions (e.g. institutional repositories vs. sector-specific repositories). The second one regards open data and it is related to the adoption of institutional guidelines for internal and external researchers. These action points (and the related indicators) are described in the following table:

Ref.	Action point	Indicator
OP1	Telethon invests in the Europe PMC repository to showcase the outputs of intra- and extra-mural research. However, the Foundation has no data about the degree of effectiveness, in terms of increased visibility, of sectoral repositories when compared with institutional repositories of single organizations. Such an assessment would be useful to determine the course of open access policies for Telethon, and beyond. At the same time, it would require research and assessment beyond this individual organization. Therefore, it seems more a matter of collaborative assessment/research project, than an organizational initiative.	No. of downloads of scientific papers in sectoral repositories / No. of downloads of scientific papers in institutional repositories
OP2	Absent an Open Data policy, the development of official guidelines would be an important progress in the institutionalization of open science in Telethon's activities.	Official Open Data guidelines (Yes/No)

7.3.3.5 Science education: directions of improvement and action points

Improvements are sought in the monitoring process, which, by now, provides only quantitative feedback on the “mechanics” of the process, but which does not provide any subjective assessment of users' experience. The definition and implementation of standardized tools and procedures, for collecting qualitative feedbacks from school teachers on the learning kits and on their overall experience with this Telethon initiative is seen as a valuable potential improvement. Also, the ongoing digitalization of the educational product is seen as a must to effectively frame the initiative within the broader push of the Ministry of Education towards digitalization. (R#6, 35:21-39:20)

However, the focus group prioritized one specific action point, which is related to the expansion of Telethon's science education activities in higher education institutions. The following table describes such

point and the related indicators:

Ref.	Action point	Indicator
SC1	While Telethon is interacting with secondary schools and school regional and national authorities, there is no program targeting higher education. Developing training packages and formats for university students is important to increase their awareness and to contact a potential pool of volunteers for Telethon's activities. Moreover, these initiatives can play a role in the vocational guidance in STEM disciplines.	No. of collaborations with universities and higher education establishments No. of training packages distributed No. of training events organized

8. Summary of findings on each responsibility dimension

8.1 The concept of responsibility

Nationally, the governance of technology-induced social transformation has gained traction in the political discourse and public debates, primarily thanks to the growing awareness of the disruptive effects of digitalization and automation of productive processes, and to prominent public controversies, such as the recent one on compulsory children's vaccination. Yet, this interest is infrequently transformed into policy initiatives and organizational practices. The most advanced examples are likely the Lombardy Regional Law on research and innovation, enshrining "responsible research and innovation" into law, the reference practice on responsible innovation by UNI, AIRI and CISE, and the inclusion of RRI in the funding programs of Fondazione Cariplo. Finally, the Third Mission of Universities, as formally determined by ANVUR and by the Ministry of University and Research, represents a developing framework for defining the meaning of social responsibility for higher education institution.

The University of Padova primarily sees its social responsibility as the mission to facilitate innovation and to foster socially sustainable development in terms of facilitating innovation through the development of joint knowledge transfer projects with other societal actors, especially the public administration and firms. The view of the University Hospital a strategic endeavour transforming knowledge into benefits for the community, exemplifies well this point. Such a centrality of the production of scientific knowledge tends either to incorporate the dimension of responsibility (being responsible means to produce quality research) or to emerge as a competing dimension (activities such as public engagement should not interfere with research work).

In Fondazione Telethon, responsible research is, first and foremost, "excellent research", both in the sense of its quality and impact, as well as in terms of its full compliance with professional ethics and existing regulatory frameworks, especially when clinical trials are concerned. Research is the tool the Foundation has to be responsive to the community and stakeholders, including donors, individuals affected by genetic diseases and their families. As we have said in Section 7, research is seen as a way through which social responsibility is exercised.

8.2 The notion of 'RRI'

While responsibility has made inroads in the public debate, RRI per se is almost absent. In Section 8.1 we made three examples which explicitly refer to RRI: the Lombardy Regional Law on research and innovation, the reference practice on responsible innovation by UNI, AIRI and CISE, and the call for projects of Fondazione Cariplo. We can add the reference to RRI in the 2015-2020 National Research Program, though the actual commitment to this policy goal looks unsure. In the context of higher education, CODAU created a Working Group on RRI as a subgroup of the EU Programs initiative. While these initiatives attempt to translate RRI into the Italian context – sometimes in a sophisticated and ambitious way –, they remain isolated activities and a systemic framework or national initiatives lack are still lacking.

A similar situation can be seen in the case study organizations: RRI is largely unknown, but by those who are closer to EU R&D funding programs. On the contrary, when keys are considered and discussed, these aspects have been already institutionalized e.g. in national law, as in gender equality, without the reference to the broader RRI notion. Respondents suggest that scientists' interest in RRI is low, too. In the University of Padova, respondents, both researchers and administrative officials, agreed that researchers often dismiss aspects of responsibility, and more specifically RRI keys, often because they are perceived as an unproductive activity in terms of career development. In general, researchers' engagement with RRI-related aspects happens only either when it is mandated, by the law or by a funding agency, or when these aspects are close to the scientists' research interests and projects or to their disciplinary traditions. This is the case of ethics and open access, or gender issues when social scientists are concerned.

The situation is similar in Fondazione Telethon, in which, for instance, societal engagement, open access and gender equality policies and practices are well established, independently from any reference to RRI, which has been instead seen by some of the respondents as a chance to communicate in a new way the “social utility” of Telethon's work.

8.3 Ethics

On the national level, consultative bodies such as the Italian National Ethics Committee (Comitato Nazionale di Bioetica – CNB) and the National Committee on Biosecurity, Biotechnologies and Life Sciences independently conduct studies on the ethical, social and legal aspects of scientific research and technological development, issue opinions on this matter, and reply to specific requests from the Government or other social actor.

On the local level, Ethics Committees are involved in the authorization procedures of clinical trials. Local Ethics Committees are established by the administration of the public health local authorities in which clinical trials are conducted. The Regional Governments are responsible for the accreditation of the Ethics Committees working within their regions and for the transmission of the list of them to the Italian Medicines Agency. For the University of Padova, this legal framework means that the Ethics Committee for Clinical Trials is appointed by the Padova Local Health Authority and does not serve exclusively the University. Following the approval of the EU clinical trials regulation (Regulation EU 536/2014), the national legal framework of ethics committees is being amended.

In general, ethics is probably the aspect of responsibility which is most structured and subject to highly formalized procedures. Moreover, local institutions and procedures are highly dependent on broader regulatory frameworks, as happens for both clinical trials and animal welfare.

Researchers are believed to lack awareness and sufficient knowledge of the ethical implications of their research activities. They are also viewed as suspicious of a third-party assessment of the ethical consistency of their research, which is often believed to amount to a mere bureaucratic exercise and, therefore, is frequently considered as an unproductive and unnecessary burden.

Locally, ethics committees focus on research ethics and the ethical clearance for specific projects, while no forum is formally delegated to reflect on the broader ethical and social implications of technological development and scientific research.

A variation of this theme can be found in Fondazione Telethon. As we said above in Section 7 commenting the framing of responsibility in Telethon, responsibility and ethics in research are equated to regulatory compliance. In this context, lack of awareness and knowledge of the regulatory requirements to set up clinical and pre-clinical research projects is seen as a major weakness in the full implementation of ethical and regulatory requirements in research.

8.4 Societal engagement

In systemic terms, the most important policy framework for societal engagement in research is represented by the “Third Mission” definition and evaluation performed by the Italian National Evaluation Agency of University and the Research System. An important aspect of this definition is the explicit acknowledgement that research contributes to the production of public goods of social, cultural and educational nature. This dimension is complementary with a second one, stressing the objective to extract economic and financial value from research. However, assessment indicators are still significantly skewed towards this second dimension and, therefore, the practice of evaluation largely translates societal engagement in terms of knowledge transfer activities and of the economic impact of such actions.

The commitment to public engagement by Fondazione Telethon is much wider and more sophisticated. Firstly, insofar Telethon raises its funds from the public, so engaging citizens is key to the financial sustainability of the Foundation. Secondly, Telethon has close collaborations with associations of persons affected by rare genetic diseases and their families. This informal yet continuous dialogue has created opportunities for reorienting the work of the Foundation, both with regard to the allocation of research grants and, in our view more importantly, in terms of broadening the Foundation’s operational perspective from curing patients to improving the quality of life of persons affected by rare genetic diseases. This expanded perspective helped change research priorities and expand the range of services for patients and their families.

8.5 Gender equality and diversity strategies

In terms of gender equality policies and strategies, the University of Padova and Fondazione Telethon are almost on two opposite sides. The former is a public body, in which specific policies and organizational bodies are often mandated by law. The latter has a remarkable performance in terms of gender balance and gender policies, but this achievement is almost entirely the consequence of the organizational culture.

Nonetheless, a few similar traits can be identified. Firstly, organizational leadership has played a key role in advancing gender equality policies, either as it established this dimension as a priority since the organization was formed (Telethon) or it renewed a push towards this direction in more recent years (Padova). Secondly, women in leadership positions are seen as a condition to maintain this effort over time.

Thirdly, diversity policies focus essentially on gender and abilities, while other aspects such as ethnic background, religion, or sexual orientation are not the subject of specific attention. In the University of Padova, this implicit neglect of the religious, cultural and ethnic background is likely to be motivated by the overwhelming ethnic and cultural homogeneity of the Italian faculty and student population (see Section 6.2.7). Moreover, issues of sexual orientation and gender identity have only recently become prominent in the public debate, and this newly discovered visibility is the likely reason of the limited recognition they still have in University policies. On these aspects, there was no indication of specific policies in Fondazione Telethon, either. Fourth, gender balance is more effectively achieved in administrative role, than in research role, where it is infrequent to see women in leadership positions as, for instance, full professors, research group leaders or department directors.

8.6 Open access and open science strategies

Like for gender equality, Telethon and Padova's positions with regard to Open access seem to be almost opposite. On the one hand, Fondazione Telethon developed an established policy to support researchers in open access publishing through a dedicated budget (this program was terminated, however) and through its membership of Europe PubMed Central, an open access database on biomedical research (Telethon is the only Italian member of the portal). The University of Padova is building now an integrated Open access policy and opted for a different type of repository, by creating its own platform in 2017. It is interesting to notice that neither Telethon nor the University have data supporting the choice between these two models – whether thematic repositories increase the visibility of research products more than institutional repositories, and vice versa.

On the contrary, the two organizations share a similar situation with regard to Open data, as both lack an Open data policy. On this, the University's central administration (the Library services and the International Research Office) has started a consultation with the University Departments to raise awareness and to cooperatively elaborate common policies on the matter. Fondazione Telethon has decided to uptake and adapt the guidelines which will be issued by European policy makers.

The lack of uniform response reflects the absence of a national policy or national guidelines on this subject. Absent such clear directives, the international dimension of interchange was crucial for both organizations to find the motivation to engage with Open access and Open data and to learn from good practices, abroad. This is true for Fondazione Telethon, which became involved in Open access as a consequence of its participation in European philanthropic networks. This is true for the University of Padova, too. Padova has started to consider this aspect as a result of EU policies on this subject, especially in the context of the Framework Programs. Finally, both organizations report a limited commitment of researchers to Open access, which is blamed on the absence of rewards for the researchers who choose this type of publication. Often, Open journals are not the top journals in a discipline and this fact deters submissions.

8.7 The inclusion of science education into research

For the University of Padova, defining a clear-cut distinction between social engagement and science education activities proved elusive. First, educational activities are often one-off events, such as seminars. These events are perhaps more aptly labelled as science communication events, than as science education

activities. Second, both types of initiatives formally belong to the same group, i.e. “Third mission activities”, whose classification is based on the target (social groups different from students, communities, etc.) and not on the type of activity. The ANVUR Third Mission policy Guidelines are likely the most important systemic/national framework to assess these initiatives of higher education institution.

For different reasons, education and engagement initiatives overlap in Telethon, too. Science education is here considered mainly as a tool for raising awareness about genetic diseases, creating an inclusive attitude towards the persons affected by them, fostering a positive social environment for Telethon’s activities. When targeted to high school or higher education, education activities are seen as important tools for increasing the number of future volunteers, too.

8.8 Incorporation of AIRR dimensions

8.8.1 Diversity and inclusion

For both organizations, diversity seems to be understood primarily in terms of gender equality, while cultural and ethnic diversity does not have the same prominence. Inclusion is mostly intended in terms of access to work and study of persons with physical or mental disabilities.

Non-discrimination as a guiding principle is included in the Codes of ethics of both Padova University and Fondazione Telethon. Moreover, the attention to inclusion is part of the University’s institutional efforts to ensure the right to study, as protected by Art. 34 of the Italian Constitution.

8.8.2. Anticipation and reflexivity

The national policies we discussed in Section 5 are ambitious in designing organizational mechanisms and entities to reflect on research and innovation activities, and their governance. On different levels, the responsible innovation certification and the Lombardy Region’s policy framework provide such a context for anticipation and reflection.

In our two case studies, reflexivity is institutionalized through numerous instruments, such as Codes of ethics, internal training materials, other voluntary monitoring and certification models, monitoring and assessment systems. It is important to say that this reflexive function is performed on a much more general level than research and innovation themselves. Reflexivity regards organizations per se, their missions, and their functioning, rather than, specifically, scientific research and their consequences.

Discussing this dimension in the University of Padova, we commented an excerpt of an interview with a senior researcher and research group leader. Unsolicited, this respondent closed the interview by affirming the importance of anticipating and governing these issues before they are on a path that cannot be changed. However, this individual emphasis on anticipation and reflection on the goals and consequences of research is more an individual attitude than an organizational capability.

8.8.3 Openness and transparency

Telethon and the University of Padova have a sophisticated and detailed reporting system, which in part is mandated by law (Padova) and in part borrows from corporate practices, including Corporate Social Responsibility. However, just like for reflexivity and anticipation, transparency is understood and systematized as a requirement of organizational processes in general, rather than a specificity of research and innovation activities.

While the objects of transparency requirements are often unrelated to research and knowledge transfer activities, aspects such as staff are significantly linked to research. Therefore, these general transparency obligations are nonetheless informative about how research activities are planned, organized and implemented.

Open access policy is considered as an important instrument for achieving transparency and openness, too. On this aspect, we refer to the section about Open access and open science strategies.

8.8.4 Responsiveness and adaptation

In our two case studies, responsiveness follows accountability. Moreover, accountabilities are multiple.

The Ministry's evaluation schemes for research, teaching and Third Mission activities defines the essential evaluation framework for universities. This role of the Ministry largely shapes how universities' understand their activities and mission in operational terms. This vertical line of accountability is complemented by horizontal ones, such as towards other research conducting organizations, students and of social stakeholders, especially the local ones.

Examining Telethon's accountabilities, four groups are worth considering: donors, the scientific community, patients (and their families), and peers, i.e. other non-profit organizations working in medical research. Peers in Europe and the world have significantly influenced Telethon's operations, and one might say that the development of the Foundation's activities is, at least in part, an effort to adapt its structure and operational processes to what the organization perceived to be best-in-class research and funding standards. When donors are concerned, responsiveness is linked to transparency, too: a strong commitment to transparency in communicating the use of is seen as an essential and basic activity of the Foundation.

Finally, responsiveness towards persons affected by rare genetic diseases is probably best represented by initiatives, such as the dialogue Telethon constantly has with the "Friends of Telethon" Patient Associations network, the creation of the Patient Care Unit to assist comprehensively patients and their family participating in clinical trials, or the provision of an information service on rare genetic diseases for affected persons and their families.

Responsiveness is translated into organizational processes and structures by creating *ad hoc* offices and committees, such as the Patient Care Unit in Telethon and the Local Stakeholder Committee in the University of Padova. Representation is the principle according to which stakeholder groups are incorporated in organizations' structure, strategy, and practices (see e.g. the Telethon's Scientific Committee or Padova's Regional Stakeholder Advisory Committee).

8.9 The integrated or fragmented nature of different responsibility related dimensions

In describing each organization and in comparing their familiarity with the notion of RRI, we already noticed

that a comprehensive perspective or policy was lacking. Individual policies are present and, to a certain extent, their integration with organizational processes and the organization's mission is ensured by the existing coordination and planning frameworks.

However, each policy is treated as an isolated item and there isn't a unified viewpoint on the policy domains described by RRI Keys.

9. Discussion of findings

As the preceding sections showed, individual initiatives on the level of organizations, interest groups, and territories are developed in absence of a clear national framework on RRI or, more generally, on responsibility in science and technology. Individual keys or dimensions of RRI are dealt with, but that happens mostly because of sectoral legislation and policies, rather than as the consequence of an explicit endorsement of RRI.

In this fragmented situation, the international context is certainly one of the driving factors to make RRI a policy priority. The importance of the international dimension is not limited to the EU endorsement of the RRI notion, and it has instead a more general validity. For instance, interactions with European peers and US leading research and research funding organizations were crucial in developing Telethon's policies on Open access and impact assessment. Moreover, EU regulation is fundamental in shaping the form, role and mandate of Ethics Committees. Ethics and quality standards such as Good Clinical Practices (GCP) have an international validity and they are an essential reference for Italy, too. Global industry requirements for drug development are equally forceful in shaping organizational practices.

On the national level, regulatory frameworks and policy initiatives create opportunities for reflecting on the social responsibility of research organizations. Bureaucratization notwithstanding, the Ministry's evaluation of higher academic institutions has definitely had an impact on how universities define and measure their social responsibility, in terms of research, teaching, and public engagement activities.

However, such incitements to enter this responsibility domain, is counterbalanced by an opposite push inside organizations, which appears to be driven by cultural factors. Researchers' lack of awareness and limited knowledge of ethics and regulations, open access requirements and procedures, public engagement techniques and opportunities, are often lamented as barriers to RRI implementation. Moreover, scientists are believed to clearly prioritize research activities over other aspects of their work, such as engagement and education initiatives. This deeply rooted, cultural aspect of scientific work is in contrast with the emerging, more general trends towards the strengthening of the focus on responsibility in science, technology and innovation, such as the reference to the UN Sustainable Development Goals, the current evolutions of EU science policy (Open Innovation, Open Science, Open to the World), or the growing diffusion of Corporate Social Responsible instruments and approaches.

If this analysis is correct, the way forward requires the design and implementation of organizational solutions aligning individual interests and preferences with systemic orientations towards responsibility.

Redefining structural incentives for researchers is crucial in this respect. Introducing assessment indicators which include, for instance, social engagement activities in academics' evaluation would be an important move in this direction. The same logic could be applied to other keys, for instance linking ad hoc funds for Gold Open access publications to scientists' performance in research assessments. Similarly, Open access journals could feature more prominently among the journals which are considered researchers' evaluation.

10. Conclusions

The last section of the report draws on the summary and discussion of findings to identify a limited number of recommendations for policy implementation on the organizational, national and EU level. While the organizational analysis resulted in a set of Action points mostly focused on RRI keys, the following recommendations concentrate on how *RRI as such* (or, in broader terms, responsibility) can be diffused and strengthened in policies and organizational practices.

10.1 Policy recommendations to national policy makers

On the national level, the analysis identified significant levers to influence Universities' commitment to RRI, while it is less clear what space there is for national policy makers to impact private, independent organizations such as Fondazione Telethon.

For universities, the Ministry of Education, University and Research has a crucial instrument in the Italian National Agency for the Evaluation of the University and Research Systems (ANVUR). ANVUR defines the indicators according to which universities are evaluated. Third Mission indicators should be broadened and a more fine grained distinction between technology transfer, science communication, and public engagement should be introduced. Such a modification could foster higher education institutions' commitment to RRI, expanding and refining their current understanding of public engagement. Moreover, asking universities to make explicit what is the contribution of their research to solve societal challenges, as defined in the EU, or to achieve UN Sustainable Development Goals, may be instrumental to the systemic adoption of RRI in the higher education system.

10.2 Policy recommendations to European policy makers

The analyses of research conducting and research funding organizations were consistent in showing that involvement in or proximity to EU programs was a potent factor in raising awareness of and in fostering individual commitments to RRI.

Maintaining RRI as a horizontal element in FP9 and extending this approach to other funding programs beyond R&D is essential to further diffuse and consolidate RRI as an object of policy and practice. Smart Specialization Strategies and, in general, regional policy seem the best candidate for enabling this consolidation, for their systemic character (they address territories, not organizations) and their importance in funding applied research and technology development in a variety of domains, such as healthcare, social policies, economic development, energy production and consumption, and environmental protection.

10.3 Recommendations to research conducting and funding organisations

Training and awareness raising activities are recurrent action points for both the University of Padova and

Fondazione Telethon. Knowledge about RRI and individual keys are seen as important as structural configurations to foster policy effectiveness and increase compliance with regulations.

Therefore, organizing or funding training opportunities on RRI and its keys is an important tool to ensure the diffusion, strengthening and institutionalization of RRI in the research community. From this viewpoint, training opportunities addressed to graduate students and early-career researchers (PhD students) seem particularly important, as they can make RRI a constitutive part of the professional background of young and would-be scientists.

10.4 Best practices scalable to European or national level

We would like to emphasise two best practices, one for each type of organizations:

- *Research Conducting Organizations: making explicit the link between teaching/research activities and their contribution to solve societal challenges.* Using UN Sustainable Development Goals (UNSDGs) as a reference, the University of Padova has made mandatory for the academic staff to explain what the contribution of the courses they teach is to the achievement of UNSDGs. This initiative is important for increasing the reflexivity of the academic staff and, if extended to research activities, might prove effective to gradually orient scientific research and knowledge transfer to reach “societally desirable” goals.
- *Research Funding Organizations: integrating issue-based civil society organizations into organizations’ decision-making.* Telethon has supported the creation of an informal network of “Friends of Telethon” Patient Organizations. The network gathers patient associations dealing with one or more rare genetic diseases and has had a role in influencing funding priorities of the organizations. Nonetheless, and perhaps more importantly, the dialogue between Telethon and the Associations contributed to strengthen the Foundation operational perspective, which is characterized by a focus on improving the quality of life of persons affected by rare genetic diseases and not only on curing patients. In doing so, it helped shape research priorities and expand the range of services for patients and their families, for instance when they participate in clinical trials. Creating similar mechanisms to integrate issue-based civil society organizations into organizations' decisions might prove instrumental to build structures, make funding choices and, subsequently, research activities closer to societal expectations and needs.

Annex 1

Summary matrixes for each RRI key, University of Padova

Ethics

	Structural issues	Cultural issues	Interchange related
Aspects of organisations	<p>The University has three ethics Committees: the Committee for Animal Welfare, the Committee for Psychological Research, the Committee for clinical research (as part of the local Health Authority).</p> <p>A digital workflow and management system for the Committee for clinical research has been created.</p>		<p>Organizations and procedures are largely determined by the European, national and regional regulatory framework (e.g., Health Authority, Regional Government, European Commission).</p> <p>Sometimes, procedures refer to both local and national levels of decision (AIFA, National Health Institute).</p> <p>The new Clinical Trials Regulation establishes a European coordinated assessment (mechanism of Reporting Member States).</p>
Potential drivers	Internal regulations with mandatory character.		<p>For animal research: importance of animal-rights movements in the public opinion.</p> <p>Hard regulatory framework.</p>
Potential barriers	<p>Lack of human resources and low retention of trained staff.</p> <p>The body responsible for the preliminary evaluation of projects to be submitted to the Clinical Research Committee was disbanded when the interview was released.</p>	<p>Researchers' distrust in the "third-party certification" of research ethics.</p> <p>Emphasis on productivity negatively affects integrity.</p> <p>Perceived bureaucratization of ethics committees' procedures.</p>	<p>Limited integration between the Clinical Research Committee and the University.</p> <p>Ongoing modification to the operating procedures and legal context of the Clinical Research Committee.</p> <p>Frequent changes affect the stabilization of procedures.</p>
Most important potential organisational actions	Standardization of information sheets and informed consent forms in clinical research.	Training about the Committees' procedures and their importance.	
Indicators for success	No indicator is used to monitor the activity of the Committee.		

	Structural issues	Cultural issues	Interchange related
New indicators for improvement³⁸	<p><i>Researchers' perception of the importance of ethics issues.</i></p> <p><i>No. of researchers participating in ethics training initiatives (percentage of all research projects).</i></p> <p><i>No. of research projects raising ethical issues (percentage of all research projects).</i></p>		

Societal engagement

	Structural issues	Cultural issues	Interchange related
Aspects of organisations	<p>The University organises a broad set of outreach initiatives targeted to the general public and to specific groups (e.g. UNIVERSA, Kiduniversity, Il Bo Live).</p> <p>Recently, a central Office for Public Engagement and a Central Commission for the Quality of Third Mission activities have been created.</p> <p>The University owns important historical buildings and naturalistic facilities, which host museums and parks (Botanical Garden). External companies may be hired to manage</p> <p>The University has created (Unismart) and participates in (Parco Galileo) technology transfer organizations and structures.</p> <p>Through these organizations (Parco Galileo), the University participates in CSR and sustainability training and awareness raising programs for industrial and service companies.</p>		<p>Integration of stakeholders in the University bodies and structures, such as the Board of Directors, the Local Advisory Committee, or the Ethics Committees for Clinical Trials.</p>
Potential drivers	<p>Inclusion of stakeholders in the decision-making bodies of the University.</p>	<p>Outreach to firms fostered by an emphasis on technology transfer and enterprise creation (entrepreneurial "culture").</p>	<p>The "Third mission" is included in the national assessments procedures of Universities.</p>

³⁸ Indicators of improvements are analysed and discussed in section 6.3.

	Structural issues	Cultural issues	Interchange related
Potential drivers (follows)		On the international/EU level, public engagement (PE) is increasingly part of researchers' professional profile.	The closer to EU programs/project, the more individual researchers are interested in public engagement.
Potential barriers	Organisational priorities and individual career incentives are misaligned and discourages researchers' commitment to PE.		The "Third Mission" evaluation indicators are skewed towards the extraction of economic value from research and towards science communication.
Most important potential organisational actions	Creation of multi-disciplinary models for technology transfer, according to the logic of Open innovation (including SSH).	Training of researchers on public engagement tools and their importance.	Increased scope of Third Mission evaluation indicators to include PE as properly understood.
Indicators for success	The annual performance assessment includes quantitative indicators on the events organized by the University and its structures.		The Ministry mandates the monitoring of the following indicators: patents, external grants and contract research, spin-off, dissemination activities.
New indicators for improvement	<p><i>Existence of an incentive system for researchers working in PE activities (Yes / No).</i></p> <p><i>Inclusion of a specific heading on PE in the organization's budget structure (preliminary to define quantitative indicators measuring increases in staff and budget to perform engagement activities).</i></p>		

Gender equality

	Structural issues	Cultural issues	Interchange related
Aspects of organisations	The University has various offices monitoring and supporting students, teaching staff and administrators (e.g. Central Committee for the promotion of equal opportunities, workers' welfare and non-discrimination, Confidential Counsellor, Interdisciplinary Forum for Gender Studies and Education).	<p>The University organizes a course on "Human rights and inclusion" since 2016. The course is open to all the employees and it is officially recognized as professional training.</p> <p>Compilation of a Gender Report and adoption of guidelines for non-discriminatory use of language (2017).</p>	Discrimination issues are regulated on the national (creation of the Central Committee for the promotion of equal opportunities, workers' welfare and non-discrimination - Comitato Unico di Garanzia) and the regional level (appointment of the regional Ombudsman).

	Structural issues	Cultural issues	Interchange related
Aspects of organisations (follows)	In the 2015-2017 period, the University started a program of affirmative actions, aimed at removing obstacles to actual equality.		
Potential drivers	The University leadership has pushed forward an agenda about gender equality and inclusion. The creation of a Vice Rector responsible for gender and inclusion policies is part of this strategy.		The National regulation establishes mandatory offices/bodies and procedures.
Potential barriers		Lack of awareness and actions on gender equality and inclusion in research roles on the departmental level. General lack of awareness of the gender dimension in research (gendered research and innovation).	The achievement of a balanced composition of research groups in terms of gender, is jeopardized by the limited pool of job applicants.
Most important potential organisational actions	Targeted actions to improve women's participation in research roles. Women scientists in leadership positions.		
Indicators for success	Increase of gender equality in career progression for all academic ranks. Increase of gender equality in the governing bodies of the University and its structures.		
New indicators for improvement	<i>Incentive system for hiring female scientists (Yes/No).</i> <i>Return on investment from projects led by male and female Principal Investigators (metrics depending on the dimension of impact which is measured).</i>		

Open Access

	Structural issues	Cultural issues	Interchange related
Aspects of organisations	There is no comprehensive Open Access and Open Data policy.		

	Structural issues	Cultural issues	Interchange related
Aspects of organisations (follows)	<p>The Library Management Service and the International Research Office are currently drafting such policy.</p> <p>A survey of Open access competences and resources in the Departments was launched in the second half of 2017.</p>		<p>As a member of the CINECA consortium, the University participates in the OpenAIRE network to promote Open Access.</p> <p>In 2017, the University has created a research repository complying with the OpenAIRE guidelines.</p>
Potential drivers	Bottom-up initiative to identify and locate resources and elaborate guidelines.		<p>EU policies (Open access/data in Framework Programs).</p> <p>Interaction with international consortia (OpenAIRE).</p>
Potential barriers		Researchers' lack of awareness of Open access and Open data policies.	Publishers' policies (Gold Open Access).
Most important potential organisational actions	<p>Adoption of an official policy.</p> <p>Strengthening of the advising role of administrative offices.</p> <p>Creation of an expert network on the departmental level, possibly with one expert for each scientific area.</p>	Training of researchers about the importance of Open access and about its rules.	
Indicators for success	No indicator is in place to assess University's performance.		
New indicators for improvement	<i>Incentive system for publishing Open Access publications and data (Yes/No).</i>		

Science education

	Structural issues	Cultural issues	Interchange related
Aspects of organisations	Since 2016, the University has a coordinated offer of cultural events, including festivals, permanent exhibitions, conferences (UNIVERSA).		

	Structural issues	Cultural issues	Interchange related
Aspects of organisations (follows)	<p>The University has programs targeted to specific audiences (e.g., Kidsuniversity).</p> <p>The University organizes several life-long learning courses, including training in: Animal welfare ethics, Bioethics.</p> <p>There are only two MOOC courses, in mathematics.</p> <p>The University has an important heritage made of museums and parks (Botanical Garden). External companies may be hired to manage these assets.</p>		
Potential drivers			The “Third mission” is included in the national assessment procedures of Universities.
Potential barriers	Organisational priorities and individual career incentives are misaligned and discourages researchers' commitment to PE.		
Most important potential organisational actions	Expansion of the MOOC portfolio and of the life-long learning courses to cover topics related to responsible research and innovation.		
Indicators for success	<p>Participation to cultural events organized by the University (UNIVERSA)</p> <p>No. of collaborations with schools, research organizations, and local authorities.</p> <p>No. of exhibition, events and festivals.</p>		
New indicators for improvement	<p><i>No. of dedicated educational projects (annual evolution).</i></p> <p><i>No. of students, teachers and other personnel reached.</i></p>		

Annex 2

Summary matrixes for each RRI key, Fondazione Telethon

Ethics

	Structural issues	Cultural issues	Interchange related
Aspects of organisations	<p><i>Regulatory compliance:</i> Appointment of a Clinical Development Manager to coordinate regulatory aspects of clinical trials.</p> <p><i>Research integrity:</i> - Adoption of ad hoc rules in funding calls.</p> <p>- Existing policies in Telethon Institutes.</p> <p>- Ad hoc research manager appointed to deal with issues related to research integrity.</p> <p><i>Other relevant dimensions:</i> - Telethon has an ethics code and adopted the Model 231 on administrative responsibility.</p> <p>- Research evaluation and the associated administrative procedures comply with the rules of ISO 9001 standard.</p>		<p><i>Regulatory compliance:</i> international and national regulatory environment (EMA, AIFA, Good Clinical e Good Laboratory Practices, ISO 9001).</p>
Potential drivers	<p><i>Other relevant dimensions:</i> adoption of the Modal 231, an organizational model, waiving the organization of legal responsibility for misconducts in its operations.</p>	<p><i>Research ethics and integrity:</i> - Researchers' deontological rules.</p> <p>- Belief that integrity is essential in preserving public trust in science .</p>	<p><i>Regulatory compliance:</i> - National and international regulations.</p> <p>- Embrace of standards accepted by industry to ease the development and marketisation of drugs.</p>

	Structural issues	Cultural issues	Interchange related
Potential drivers (follows)		<i>Other relevant dimensions:</i> organizational culture supporting inclusive and sustainable behaviours (e.g. the project called “The rules of Telethon’s house”, in development).	
Potential barriers		<i>Research ethics:</i> researchers have a limited knowledge of the regulatory framework.	
Most important potential organisational actions	Official research integrity policy in development.	<i>Research ethics:</i> training for researchers about existing regulations. <i>Research integrity:</i> training for young researchers.	
Indicators for success			No. of research units in created in collaborating hospitals. No. of collaboration agreements signed.
New indicators for improvement³⁹	<i>Whether staff knows where to turn for ethical advice (perception indicator, to be collected through organizational surveys).</i>		

Societal engagement

	Structural issues	Cultural issues	Interchange related
Aspects of organisations	Crucial dimension for fundraising activities (volunteers, donors). Public engagement (PE) sought through (social) media, call centre, regional and local coordination offices, schools (work experiences).	Emphasis on patient engagement e empowerment (“expert patient”).	Creation of a network of “Friends of Telethon” Patient Organizations and organisation of periodical dialogues. Interaction with patients/their families as main beneficiaries/stakeholders of Telethon; creation of direct channels of communication/consultation.

³⁹ Indicators of improvements are analysed and discussed in section 7.3.

	Structural issues	Cultural issues	Interchange related
Aspects of organisations (follows)	Creation of ad hoc structures (Patient Care Unit) aimed at engaging with patients and their families to answer their needs for participation in therapies and clinical trials.		Collaboration to build research infrastructures (biobanks) and communication/engagement projects under “umbrella organizations” such as UNIAMO.
Potential drivers	Scientific planning and bodies mediates the priorities of patient groups.	Emphasis on patient engagement and empowerment (“expert patient”).	Goal to build/maintain a positive climate for the Foundation mission and activities.
Potential barriers	The complexity of the research field limits the possibility to satisfy the priorities of all patient groups. Scientific planning and bodies mediates priorities of patient groups.	Individual career incentives (research output) discourages researchers’ commitment to PE.	Partial disconnection between local/regional initiatives and national campaigns/activities. Uneven distribution of volunteers all over the country.
Most important potential organisational actions		Profiling of target groups and public based on social media analytics.	Collaboration with patient associations to generalize pre-trial information workshops.
Indicators for success (current)	Quantitative targets for fundraising and the recruitment of volunteers.		No. of “Friends of Telethon” associations. No. of participants attending training/ communication events. No. of expert advices requested. Waiting time before a request of information is answered by Telethon’s Info-rare service. Qualitative indicators to evaluate the Info-rare services and the training/communication events targeted to patients associations.
New indicators for improvement	<p><i>No. of participants to training initiatives on PE / total No. of people working in the organization (changes over time).</i></p> <p><i>No. of communication/engagement packages distributed to target social groups.</i></p> <p><i>No. of employment contracts awarded to researchers that formally include PE as a job task.</i></p>		

	Structural issues	Cultural issues	Interchange related
New indicators for improvement (follows)	<i>Inclusion of a specific heading on PE in the organization's budget structure (preliminary to define quantitative indicators measuring increases in staff and budget to perform engagement activities).</i>		

Gender equality

	Structural issues	Cultural issues	Interchange related
Aspects of organisations	Though no gender equality policy is formally adopted in recruiting and in the composition of teams, women are a majority of the workforce and of managers.		
Potential drivers	Work-life balance policies are implemented (e.g., flexible office hours and entry time, teleworking).	Inclusive organizational culture.	In administration and management roles, Telethon shares its labour market of reference with third sector organizations, rather than research institutes and academia. In this market, job applicants are predominantly women.
Potential barriers		Uneven gender representation when the research staff is compared to the administrative and management staff.	
Most important potential organisational actions			
Indicators for success (current)	No. of persons using work-life balance services and opportunities.	Positive results of periodical evaluation of organizational climate.	
New indicators for improvement	<p><i>% of men/women in projects throughout the whole life cycle (annual evaluation, in full-time equivalent).</i></p> <p><i>% of men/women that are first (corresponding) authors on research papers/publications (annual evaluation).</i></p> <p><i>No. of participants to training initiatives on gender issues / total No. of people working in the organization (changes over time).</i></p>		

Open Access

	Structural issues	Cultural issues	Interchange related
Aspects of organisations	Existence of an open access policy. Creation of an ad hoc office to advise research on open access.		Participation in the creation and maintenance of international open access repository (PMC). Participation in the Open Access 2020 Initiative.
Potential drivers	Until 2017, ad hoc budget for open access publications. From 2017: possibility to pay for OA expenses from the grant budget.		International benchmarks to compare and assess Telethon's performance (e.g., Wellcome Trust). Participation in the Open Access 2020 Initiative.
Potential barriers	Lack of a national collaboration policy framework on open access and open data.	Researchers have a limited interest in open access and a limited knowledge of open access technicalities.	Absence of an official Open Data Policy, pending the elaboration of the EU guidelines for the FP9. New EU privacy regulation as a potential obstacle for data openness.
Most important potential organisational actions			Revision of Gold Open Access mechanisms according to the proposal of Open Access 2020 Initiative (the amount now used for subscription fees should be used to fund open access).
Indicators for success (current)	Degree of compliance with open access policy (No. products with open access / total No. of products). Ratio between available financial resources and amount actually spent.		
New indicators for improvement	<i>No. of downloads of scientific papers in sectoral repositories / No. of downloads of scientific papers in institutional repositories.</i> <i>Official Open Data guidelines (Yes/No).</i>		

Science education

	Structural issues	Cultural issues	Interchange related
Aspects of organisations	<p>Programs and activities aimed at raising the public awareness of genetic diseases and the life conditions of patients.</p> <p>Programs targeted to employees to promote scientific culture and knowledge.</p>		<p>Agreement with the Ministry of Education and with the Lombardy Regional Government to implement training and work experience programs.</p>
Potential drivers	<p>Education is part of Telethon's mission as stated in the Foundation's bylaws (art. 2).</p> <p>Collaborations with the national and regional public bodies in charge of education and training (besides individual schools).</p>	<p>Perceived need to diffuse scientific culture among the employees in order to make them better understand the mission and activities of their employer.</p>	
Potential barriers		<p>Individual career incentives (research output) discourages researchers' commitment to science education.</p>	<p>Regulation negatively affects the feasibility of a STEM education program involving study visits in laboratory (the program was postponed indefinitely).</p> <p>Lack of exchanges/interaction with other third sector organizations that are active in medical research.</p>
Most important potential organisational actions			<p>Creation of a digital learning package on genetic research and genetic diseases for secondary school.</p>
Indicators for success (current)	<p>Quantitative indicators about:</p> <ul style="list-style-type: none"> - Schools and students involved; - Packages distributed; - Ratio of invitations to actual participation; - Continuity of participation over time. 	<p>Qualitative survey of teachers' satisfaction about the digital learning packages (in development).</p>	
New indicators for improvement	<p><i>No. of collaborations with universities and higher education establishments.</i></p> <p><i>No. of training packages distributed in Universities.</i></p> <p><i>No. of training events organized in Universities.</i></p>		

Annex 3

Participants in individual interviews and in focus groups

- Nicoletta Ariani, Administrative Officer, Individual Grants Team, International Research Office, University of Padova
- Andrea Arrigo, Head, Business Planning and Management, Fondazione Telethon
- Danila Baldessari, Research Program Manager, Fondazione Telethon
- Luca Battocchio, Area Manager Lombardy Region, Fondazione Telethon
- Ambra Corti, Clinical study manager, San Raffaele Telethon Institute for Gene Therapy (SR-Tiget)
- Alessia Daturi, Patient Advocacy, Fondazione Telethon
- Anna Chiara Frigo, President, Ethics committee for clinical research, Padova Hospital; Associate professor of Medical statistics, University of Padova
- Francesca Gambarotto, President, Galileo Technology Park; Associate professor of applied economics, University of Padova
- Martina Gianecchini, Member, Working Group on the University Gender Report; Associate professor of organization studies, University of Padova
- Leopoldo Laricchia-Robbio, formerly Head, Research Analysis & External Grants, Fondazione Telethon
- Barbara Mantelli, Research Manager, Life Sciences Cluster, International Research Office, University of Padova
- Elvio Mantovani, Scientific Director, AIRI/Nanotec.it, Rome
- Michela Marcotulli, Coordinator, Marketing projects, Fondazione Telethon
- Lucia Monaco, Head, Research Impact and Strategic Analysis, Fondazione Telethon
- Rosa Nardelli, Head, Public Engagement Office, University of Padova
- Annalisa Oboe, Vice Rector for cultural, social and gender relations; Professor of English literature, University of Padova
- Mariassunta Piccini, Member, Ethics committee for clinical research of the Padova Hospital; Member, Animal Welfare Body of Padova University; Assistant professor of private law, University of Padova
- Silvia Pozzi, Research Program Manager, Fondazione Telethon
- Andrea Riccio, Head, Research Observatory, Sapienza University of Rome
- Francesco Samorè, Director, Fondazione Giannino Bassetti, Milan
- Monica Saraceni, Human Resources Officer, Fondazione Telethon
- Arjuna Tuzzi, Member, University Assessment Commission; Associate professor of social statistics, University of Padova
- Stefano Vassanelli, Group Leader, Vassanelli Neurochip Lab; Associate professor of physiology, University of Padova
- Anna Maria Zaccheddu, Content manager, Fondazione Telethon
- Stefano Zancan, Clinical trial office Coordinator, San Raffaele Telethon Institute for Gene Therapy (SR-Tiget)