

EnTIRE: Mapping Normative Frameworks for EThics and Integrity of REsearch

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Abstract

Background: The areas of Research Ethics and Research Integrity (RE+RI) are rapidly evolving. In the EU and internationally, new legislation, codes of conduct and good practices are constantly being developed. New technologies (e.g. gene editing), complex statistical methods (e.g. biostatistics), pressure to publish and obtain grants, and growing emphasis on stakeholder driven science (e.g. public-private partnerships) increase the complexity of conducting science. In this complex and dynamic environment, researchers cannot easily identify the correct rules and best tools for responsible conduct of research. This also increasingly constitutes a challenge for RE+RI experts.

Aim: Our aim is to create a platform that makes the normative framework governing RE+RI easily accessible, supports application in research and evaluation, and involves all stakeholders in a participatory way, thus achieving sustainability. The platform will foster uptake of ethical standards and responsible conduct of research, and ultimately support research excellence and strengthen society's confidence in research and its findings.

Vision: Our vision is that in order to make the normative framework governing RE+RI accessible, a dynamic online Wiki-platform, owned by the community of RE+RI

stakeholders, is needed. The value of this platform will lie in the availability of practical information on how to comply with EU, national and discipline-specific RE+RI standards and legislation, including information on rules and procedures, educational materials, and illustrative cases and scenarios. Adopting open science (open source and open data) approaches, the platform will be easy to use, by applying novel techniques for data collection and comparison, enabling users to navigate quickly and intuitively to appropriate content. In order to keep the platform up-to-date and sustainable, it will be based upon active involvement of the RE+RI community, and will contribute to further development of this community by providing a podium for reflection and dialogue on RE+RI norms and practices.

Objectives: EnTIRE's work packages (WP) will: undertake an in-depth stakeholder consultation across EU countries exploring RE+RI experiences and practices in order to define the boundaries of data to be collected, and developing a mapping structure adapted to user needs (WP 2); assemble the relevant normative elements, including RE+RI rules and procedures, educational materials, and illustrative casuistry, and identify relevant institutions across EU countries (WP 3-5); develop a user-friendly Wiki-platform and online resources to foster and facilitate responsible research practices and to promote compliance amongst European researchers with RE+RI standards and pertinent legislation and regulations (WP 6); and foster further development of the RE+RI community, that will support the platform and be supported by it, will keep the information up-to-date, disseminate the project's findings and develop innovative strategies for maintaining the platform and building relationships to relevant organisations for further dissemination, including sustainable funding (WP 7).

Relevance to the work programme: The proposed project responds directly to the core requirement of call SwafS-16-2016 to 'provide a dynamic mapping of the RE+RI normative framework which applies to scientific research conducted in the EU and beyond'. Our proposal does this by using a participatory approach, stimulating knowledge transfer regarding codes and regulations, resources and institutions, and cases, by applying innovative ICT solutions and open science approaches, and by further developing a community of active users, to enable sustainability after the end of the project.

Keywords

Research ethics, Research Integrity, Responsible Conduct of Research, Research Policy

List of participants

Consortium partners are listed in Table 1.

Table 1.

List of Participants.

Participant no.	Part. short name	Participant organisation name	Country
1 (Coordinator)	VUmc	Stichting VUmc	The Netherlands (NL)
2	GI	gesinn.it	Germany (DE)
3	KUL	Katholieke Universiteit Leuven	Belgium (BE)
4	MEFST	Sveuciliste U Splitu, Medicinski Fakultet	Croatia (HR)
5	DCU	Dublin City University	Ireland (IE)
6	UEM	Universidad Europea De Madrid SI	Spain (ES)
7	UNIDEB	Debreceni Egyetem	Hungary (HU)
8	UiO	Universitetet I Oslo	Norway (NO)
9	UNIMAN	The University Of Manchester	United Kingdom (UK)
10	EUREC	European Network of Research Ethics Committees	Germany (DE)

Excellence

1.1 Objectives

1.1.1 Challenge

Responsible research conduct seems under increasing pressure: recent cases of scientists falsifying (Godlee et al. 2011) and fabricating (Crocker and Cooper 2011) data got tremendous public attention and the Science article by Nosek et al. (2015) on the reproducibility of psychological science led many to openly question the integrity of the scientific community as a whole. Although research integrity assessments indicate that only few researchers commit such serious violations, it is clear that the changing scientific environment puts researchers under more and more pressure: publication pressure, reducing research funds, public pressure to justify spending public research budgets and promotion of public-private partnerships. Together these external factors can ultimately lead to a research environment where ethical norms may lose out to other norms and so called questionable research practices arise. In response to these changing research environments, the areas of Research Ethics and Research Integrity (RE+RI) are rapidly evolving. In many European countries, regions and institutions guidelines, standards, laws have been drafted (Godecharle et al. 2014, Godecharle et al. 2013). However, the effect can be the opposite: because of the resulting diversity and continuously changing norms, researchers lack up-to-date and easily accessible information on relevant rules and regulations as well as on how to apply them. The same is true for RE+RI evaluation committees who are hindered by the absence of easy access to cases and practices elsewhere. RE+RI leaders and followers lack a platform that provides easy access to RE+RI norms, and serves as a basis for deliberation, fostering improvement and practical

relevance of these norms. There is currently no platform that allows for efficient navigation and interpretation of relevant RE+RI rules and regulation.

This project will develop a platform that makes the normative framework governing RE+RI easily in Europe accessible. Before describing how this will be achieved, it is important to define what is meant by RE+RI and the associated normative framework.

Defining research ethics and research integrity (RE+RI), and their mutual relationship

In describing the study of research behaviour, Steneck (2006) proposes definitions of 'research ethics' and 'research integrity': research ethics is described as the 'critical study of the moral problems associated with or that arise in the course of pursuing research', whereas research integrity is said to entail 'possessing and steadfastly adhering to professional standards, as outlined by professional organizations, research institutions and, when relevant, the government and public'. (Steneck 2006) From these definitions it follows that research ethics deals with moral challenges (for example, how to weigh burdens and benefits of research and to ensure proper and informed consent of participants) and the norms and regulations that guide the response to those challenges. It also implies that research integrity will focus on the professional standards (values) of scientific research, (for example, transparency and replicability). Yet, research ethics also involves overarching values (such as respect for persons), and research integrity entails clear norms which should be obeyed (for example the rules concerning scientific misconduct). Thus, any effort at mapping the RE+RI normative framework must cover not just the regulations that promote RE+RI, but also the values and norms developed in practice and through processes of deliberation regarding responsible conduct of research. RE and RI have a different focus. RE review committees, for instance, emphasize the protection of research subjects (ethics ad scientiam), whereas RI review committees investigate scientific misconduct (ethics in scientia). Yet, there is also a clear overlap. RE review committees are interested in responsible research, as research that is not scientifically valid is *a priori* unethical. RI review committees will also investigate whether data are acquired in an ethically justified way. The normative framework that we envisage will focus on general values, norms and regulations in both RE and RI, as well as their mutual interdependence. RE review committees work on a structural basis, evaluating all relevant research proposals, whereas RI review committees are convened ad hoc, judging serious cases of (potential) misconduct. Moreover, the field of RE review is much more developed than that of RI review. Mutual communication and exchange, aimed for in e.g. the EC funded ENERI project, will highly benefit from our platform.

Normative framework governing RE+RI

The normative framework governing RE+RI consists of explicit rules, formulated in laws, regulations, codes, and guidelines, and implicit rules, which structure local RE+RI practice, and influence the application of explicitly formulated rules. Mapping the normative framework requires making accessible explicit rules (assembling them, and comparing them through normative analysis) and showing how they can be applied in local practice

(which is an object of, for instance, teaching and training programmes, fostering practical insight and experience, and which is supported by assembling cases, analysing them and building scenarios). Thus, the mapping of the normative framework should pay attention to both explicit elements (laws, regulations, codes, guidelines) and implicit elements (addressed in teaching programmes, cases and scenarios).

1.1.2 Overall aim and objectives

The overall aim of the project is to create a platform that makes the normative framework governing RE+RI easily accessible, supports application in research and evaluation, and involves all stakeholders in a participatory way, thus achieving sustainability. The platform will foster uptake of ethical standards and responsible conduct of research, and ultimately support research excellence and strengthen society's confidence in research and its findings.

To achieve this aim, the EnTIRE project will address the following objectives:

- **Objective 1:** To undertake an in-depth stakeholder consultation across EU countries exploring RE+RI experiences and practices, defining the boundaries of data to be collected, and developing a mapping structure adapted to user needs (WP 2)
- **Objective 2:** To assemble the relevant normative elements, including RE+RI rules and procedures, educational materials, illustrative cases, and relevant institutions across EU countries (WP 3-5)
- **Objective 3:** To develop a user-friendly platform, including a website and online resources, to facilitate access to RE+RI knowledge and experience, and support application in research and evaluation, thus fostering uptake of ethical standards and responsible conduct of research (WP 6)
- **Objective 4:** To foster the further development of the RE+RI community, that will support the platform and be supported by it, disseminate the project's findings, apply innovative strategies for maintaining the platform through stakeholder participation, and relate the platform to relevant organisations for further dissemination fostering sustainability (WP 7).

1.1.3 Approach

Developing such a platform comes with a specific set of challenges, including:

- How can the platform cope with the diversity of data that is difficult to find and to compare?
- How can the platform be easy to use and meaningful for all stakeholders and researchers from different sectors and research fields?
- How can the platform be designed such that it will be sustainable?

To address these, EnTIRE will build upon the following principles:

- EnTIRE will foster stakeholder participation and community engagement;
- EnTIRE will focus on (diversity of) RE+RI practices (i.e. the translation of rules and regulation to research practice);
- EnTIRE will build an advanced IT infrastructure based on an interactive Wiki-platform that is easy to navigate, based upon open source and open data principles, and novel techniques for data search and comparison.

Our approach has three unique features

Feature 1: Stakeholder participation and community engagement

The key unique feature of this proposal is the iterative, ‘bottom up’ approach, making explicit normative experiences of local stakeholders and principles embedded in local rules and practices, and enabling the structuring of data in a way that fits in with research and evaluation practice, providing useful, accessible information for local users Fig. 1. The project will entail stakeholder consultation, designed according to a participatory approach that has been successfully developed and applied in the context of empirical ethics in healthcare (Widdershoven et al. 2009, Kim et al. 2009) and that fosters impact of results in practice. The stakeholder approach will make use of experiences and insights from practice (Borry et al. 2005, Borry et al. 2004, De Vries et al. 2016), and focus on implicit rules, practices, and cases, that, next to explicit rules and regulations, are crucial elements of the normative framework. The consultation will identify relevant stakeholder groups in each country, including researchers, journal editors, national and local ethics/integrity committees, policy makers, industry, including pharmaceutical companies, and research funding and process organisations. The stakeholder consultation will combine assembling information from all stakeholder categories through a questionnaire and focus groups enabling further exploration. It will consist of a pilot phase in three countries, representative of EU regions (Croatia, Spain, the Netherlands), with face-to-face focus groups, followed by a scale-up for all European countries, with online focus groups. The consultation will enable identification of the RE+RI issues of concern to the stakeholders, practical experience with regulations and guidelines and other professional, institutional and national norms, resources, and existing best practices. The consultation will also be used to generate, and to reflect and deliberate on instructive cases from local practice. The findings from the consultation will help define the boundaries of content to be collected and structure the information on the platform according to stakeholders’ concerns; enabling the collection, provision and presentation of data sensitive to stakeholder needs. The process will also foster an ongoing dialogue on the content, priorities, data structure, and acceptability and usability of the platform by the stakeholders.

This participatory approach will provide the basis for the dynamic mapping of the relevant norms, processes, resources and institutions, which will entail the collection of:

1. policies, guidelines, standards legislation, regulations and procedures;

2. resources, including training courses, e-learning modules, educational materials and contact details of committees; and
3. relevant cases and scenarios.

Stakeholders will also be involved in the evaluation and improvement of the ease of use of the platform. Like the stakeholder consultation, the mapping will be carried out in two phases: a pilot phase in three countries, followed by a scale up phase in all European countries. The lessons learnt during the pilot phase will enable a more rapid data collection during the second, scale-up phase.

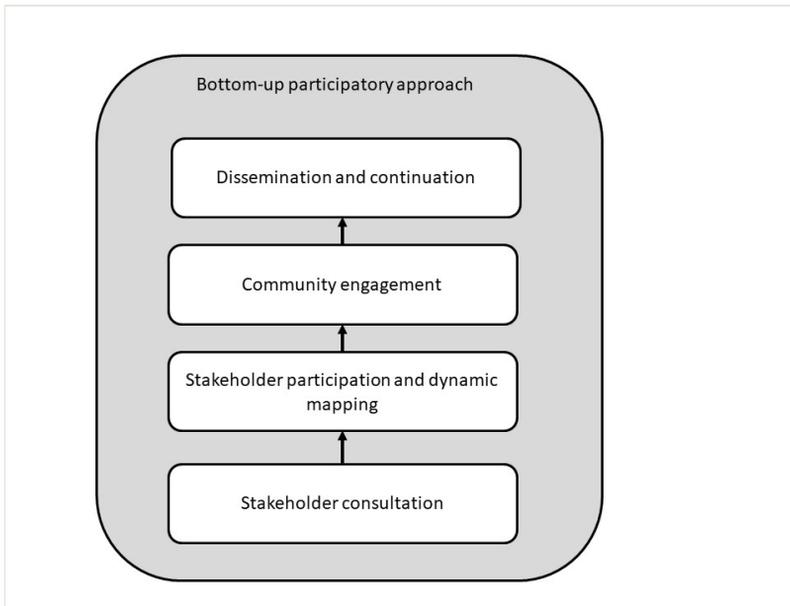


Figure 1. [doi](#)

Bottom-up participatory approach.

Stakeholder participation will provide the basis for community engagement, necessary to secure continuity of the platform and further development of the content. The platform will be owned by the RE+RI community, preventing a vendor lock-in by the ICT firm. All relevant parties will be involved in the process of developing the platform and in gathering its content. The community will perform periodic critical content review, in order to keep the platform up-to-date and involve (other) users actively in fostering awareness of and debate on RE + RI. The basis for the community will be the participants in the European Network of Research Ethics and Research Integrity (ENERI), and the participants in the online focus groups. In order to expand the community, we will perform a stepwise scaling-up procedure, inviting selected researchers in the different regions and other stakeholders to become reviewers and moderators/editors. We will invite RE+RI committees to curate their own page. Further cooperation with other established bodies, many of which include RE+RI working groups, will be explored e.g. the European University Association (EUA - www.eua.be/), the League to European Research Universities (LERU - www.leru.org/),

Science Europe - www.scienceeurope.org/, the European Network of Research Ethics Committees - www.eurecnet.org/ - or the European Network of Research Integrity Offices - www.enrio.eu/).

Community engagement will provide the basis for dissemination. Dissemination activities will be two-part: dissemination for awareness and understanding (amongst RE+RI followers, that is stakeholders interested in information on RE+RI issues) and dissemination for continuity (amongst RE+RI leaders, that is members of the RE+RI community who actively contribute to the development of RE+RI norms). Dissemination for continuity includes embedding RE+RI in teaching curricula and including adherence with standards and regulations in research funding and publication criteria. This will necessitate active involvement of learned societies (such as All European Academies (ALLEA - www.allea.org/) and LERU), organisations involved in research publication (such as the Committee on Publication Ethics (COPE - publicationethics.org/), European Association of Science Editors (EASE - www.ease.org.uk/), the World Association of Medical Editors (WAME - www.wame.org/), and the Council of Science Editors (CSE - www.councilscienceeditors.org/)) and research funding organisations (such as Science Europe). Indeed, Hiney (2015) highlights that there is still wide variation between different funding organisations in the importance placed on research integrity in their grant conditions and the robustness of integrity oversight. The EnTIRE consortium includes participants with expertise in the areas of stakeholder participation and community building through processes of engagement of stakeholder groups.

Feature II Focus on (diversity of) RE+RI practices

The second unique feature of our project is acknowledging the substantial and essential diversity of practices within and between countries and disciplines (Godecharle et al. 2014, Godecharle et al. 2013, Institute of Medicine and National Research Council 2002, Broga et al. 2013), because ethical frameworks, professional values and norms, and pertinent legislation, regulations and procedures are strongly influenced by socio-cultural, political, economic and institutional contextual factors (Institute of Medicine and National Research Council 2002). Normative analysis of explicit rules and case analysis, elucidating implicit rules, will make (diversity of) RE+RI practices accessible on the platform. Diversity is even more prominent if we recognize that RE+RI is much more than just a collection of rules and regulations, but rather encompasses the normative views and experiences of stakeholders and learning processes during the application of rules and regulations in research and evaluation practices. This implies an interaction between key players in research organizations, RE+RI committees, government regulation, journal policies and practices, policies and practices of scientific societies, funding bodies, and professionals with specific levels of education and training (human resources) (Institute of Medicine and National Research Council 2002). By using a stakeholder approach, the project will provide insight in how rules and regulations governing RE+RI work in practice. Moreover, data from various countries and regions will be checked by local experts, both consortium partners and the existing network of contact persons for each EU member state, used in previous research (Godecharle et al. 2014, Godecharle et al. 2013) This network will be updated for the current project. Normative documents will be analyzed so that the retrieved information

will be easily available for researchers. This will include making abstracts, key words, summaries of relevant parts of the documents, providing electronic links, etc. Through normative analysis, differences will be made explicit and open for comparison and deliberation. Cases will be tagged and categorized. Moreover, a selection of prominent RE+RI cases will be analysed with different case analysis methods, and scenarios will be developed. This will result in a structuring of data, based on their relevance for actual use by researchers. The project will use relevant insights and data from previous projects such as EC funded ENERI, SATORI, PRINTEGER and HEIRRI and the international research integrity 'Report Cards' project (Kleinert and Marusic 2016). Whilst these projects also collect much data (e.g. on relevant training courses and expertise), they tend to focus on the harmonization of values and standards within EU. That is not the primary focus of our proposal. Recognizing the variation that exists across the EU, we aim to produce a dynamic reflection of the actual RE+RI normative framework, including differences between countries. This may lead to deliberation on differences and thus foster development of RE+RI knowledge, which in the end will also benefit the (EU) activities dedicated to harmonization. Rather than providing a set of harmonized rules and regulations across Europe straight away, we anticipate to capitalize on Europe's diversity as the best starting point for mapping the RE+RI normative framework, acknowledging that mapping differences forms a necessary prerequisite for any harmonization that wants to be feasible in practice. The EnTIRE consortium unites research groups that have experience in assembling data entailing a large variety of rules, regulations and practices, making explicit and engendering reflection and deliberation on differences between practices.

Feature III Interactive self-sustainable Wiki-platform

The third unique feature consist of the techniques we propose to develop the EnTIRE platform which will be hosted on www.embassy.science (ownership obtained). The main ICT challenge lies not in performing the mapping as such, but performing it in such a way that it creates an online platform that is dynamic, customer-tailored, up-to-date and self-sustainable. Through a commitment to open source and open data approaches we aim to develop an online platform that is sustainable, user-friendly, low cost, and designed by and for the target RE+RI community. For this purpose, a Wiki-platform is the most suitable basis. The online platform will support the user with unique content analysis features. This entails, amongst other things, 'Birds Eye View Dashboards' which use semantic and data mining approaches to allow quick comparisons and easy extraction of information by researchers, policy makers and governmental bodies to find overlaps and differences between countries and topics in legislations and policies, find related case reports etc. Combining novel data mining approaches with conventional hierarchical approaches will allow researchers to perform analyses more easily – greatly enhancing the ability to perform cross-country comparative research with low effort and cost. We will adopt an open source approach to address the challenges of maintaining the relevance of platform data and minimizing recurrent costs. The Wiki-platform is open access and will be adapted to the specific needs of the project. Commitment to an open science and Wiki-approach, involving stakeholder expertise, makes the platform dynamic, user-friendly, up-to-date and self-sustainable.

The platform will incorporate several novel ICT techniques (e.g. full content search, data mining, semantic analysis) to ensure that users can find relevant, reliable and up-to-date information efficiently. Recent innovations in ICT, which, for example, drove the commercial success of companies such as Spotify and Netflix, will enable the user to navigate the content on the platform dependent on the profile and previous searches of the user. The use of such techniques in itself implies ethical issues, that will explicitly be addressed on the platform. The dynamic and efficient nature of our website will allow and promote the development and improvement of RE+RI practices across the EU, ultimately strengthening the regulatory process and researchers', regulators' and society's confidence in scientific research and its findings. Through an open and interactive platform, the project will improve the effectiveness and efficiency of both institutional and national RE+RI committees and RE+RI activities of other stakeholders, like scientific journals, funding agencies and professional associations. Effectiveness will be enhanced by providing region and domain specific standards, legislation, regulations and procedures and by providing access to best practices which may serve as examples. Furthermore, the platform will include a continuous improvement cycle; an interface will allow users to provide feedback on areas of RE+RI that are not clearly covered – providing institutional and national committees and other stakeholders with the impetus to clarify 'grey areas' and develop inclusive, anticipatory RE+RI governance. Efficiency will be enhanced as greater transparency will enable institutional and national committees and other stakeholders to identify similarities and differences in approaches - thus stimulating shared learning and communication. Efficiency will also be improved indirectly because better informed and trained researchers will produce more appropriate research proposals – saving RE+RI committees time and resources.

The EnTIRE consortium has the necessary expertise to develop an interactive platform. The partner gesinn-it holds the specific expertise of knowledge management and is a specialist in Wiki-software development. The three unique features described above are clearly linked to the project's objectives and Work Packages (WP). The bottom-up stakeholder and community approach is the basis for meeting Objective 1 and 4, and are exemplary for the activities in in WP 2 and 7. The focus on diversity is related to Objective 2, and crucial for the gathering of data in WP 3-5. The interactive Wiki-platform, to be created in WP 6, will enable reaching Objective 3. (See Fig. 2).

Successful knowledge management – the Wiki approach for the EnTIRE platform

Wikimedia Foundation, Inc. (WMF) is a non-profit organization founded in 2003 by Jimmy Wales. It hosts sites such as Wikipedia [[https://en.wikipedia.org/wiki/Wikimedia Foundation](https://en.wikipedia.org/wiki/Wikimedia_Foundation)]. Wikipedia is an international online project which attempts to create free encyclopedias in multiple languages. Within three years, the world's largest open content project has achieved more than 1.500.000 articles, outnumbering all other encyclopaedias. Voss 2005 The operation of Wikimedia depends on MediaWiki, a free and open-source wiki software platform. Bergman 2008 Semantic MediaWiki (SMW) is a free, open-source extension to MediaWiki. Semantic MediaWiki can turn a wiki into a powerful and flexible knowledge management system. All data created within SMW can easily be published via the Semantic Web, allowing other systems to use this data seamlessly

[https://www.semantic-mediawiki.org/wiki/Semantic_MediaWiki]. Adapting the Semantic MediaWiki platform using expertise of the stakeholders will result in a dynamic platform which will contain numerous resources for the RE+RI community. The ability of linking related articles together will allow the novice to quickly find key information with minimal effort – including information which he might not have been aware of to be of relevance in the first place. Indeed, this has been mentioned before. “What makes the Wikipedia so compelling—and this article so hard to finish—is the way everything is so massively linked. You read one entry, and before you know it, you’re reading up on Anne Boleyn or Italian greyhounds.” Ben Hammersley, “Common Knowledge”, Guardian (Jan. 30, 2003). For the RE+RI expert, the platform will support research on its content using novel types of analysis such as textual data mining (a form of automatic analysis in the class of ‘machine learning’) and semantic analysis (from the SMW extension). These techniques will transcend current text search abilities and will be made available on the platform using a dashboard which effectively removes the necessity of having the technical ‘know-how’. This way, the EnTIRE platform supports generating its own content, compelling the RE+RI community to engage in its movement on www.embassy.science.

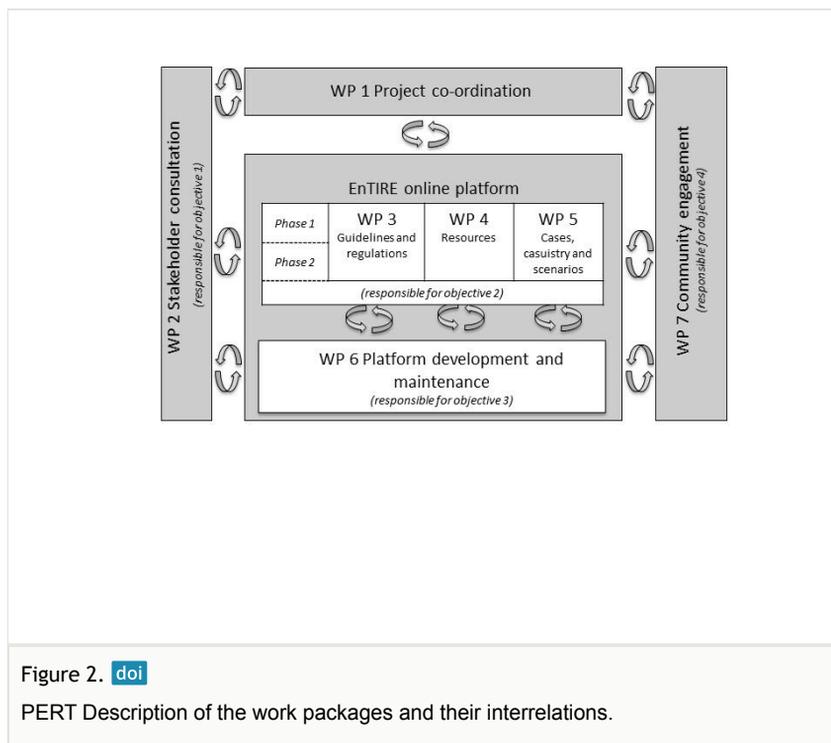


Figure 2. [doi](#)

PERT Description of the work packages and their interrelations.

1.2 Relation to the work programme

1.2.1. Relation to the general objectives of Horizon 2020 and to the Work Programme 2016-2017 Horizon 2020 has general objectives of supporting excellent science and addressing the great societal challenges of our age. The ‘Science with and for Society’

(SwafS) programme specifically aims to build effective cooperation between science and society, to recruit new talent for science and to pair scientific excellence with social awareness and responsibility. In order to meet the general aims and objectives of Horizon 2020 and the SwafS programme our proposal contains all the necessary elements. It enables further awareness of the relationship between science and societal responsibility, both among researchers and the general public, and is innovative by making use of novel ICT techniques. Specifically EnTIRE's vision, aims and approach:

- Demonstrates a commitment to open debate and incorporates the experiences and priorities of all stakeholders in a 'bottom up', participatory approach;
- Promotes the development and continuous improvement of an ethics and integrity (RE+RI) framework for research and innovation across the EU;
- Includes a commitment to an open science (open source and open data) approach for the online platform;
- Promotes the development of a community of dedicated researchers and other stakeholders, which is actively involved in making information about RE+RI accessible and fosters further development of the field;
- Fosters easy access to data, thus enabling better research on RE+RI issues, ultimately leading to better quality and integrity of research;
- Promotes RE+RI compliance and strengthens the regulatory process and researchers', regulators' and society's confidence in research and contributing to responsible research and innovation (RRI), ensuring adherence to the highest ethical standards and supporting scientific excellence;
- Raises awareness of and promotes policy initiatives in relation to RRI;
- Creates a platform for dialogue between researchers, academy, industry (including SMEs) and policymakers;
- Encourages inclusive, anticipatory and dynamic governance for research and innovation by allowing online platform users to provide feedback on areas of RE+RI that are not clearly covered;
- Promotes awareness, know-how, expertise and competence of RRI for curricula and trainings;
- Encourages change in research performing organizations (RPO) and research funding organizations (RFO) by involving them, and fostering inclusions of adherence with RE+RI standards and regulations in publication and funding criteria.

1.2.2. Relation to the specific topic: SwafS-16-2016: Mapping the Ethics and Research Integrity Normative Framework

One of the eight activity lines of the 'Science with and for Society' programme 2016-2017' is 'developing inclusive, anticipatory governance for research and innovation' which includes the current topic 'Mapping the Ethics and Research Integrity Normative Framework'. The topic's aim is directly reflected in EnTIRE's overall aim. In Table 2 below we outline EnTIRE's strategic approach in relation to the scope of the specific SwafS-16-2016 call.

Table 2.

EnTIRE Objectives and Approach in Relationship to the Scope of the Topic:

Scope of SwafS-16-2016	EnTIRE strategic approach
<p>The action aims at providing a dynamic mapping of the ethics/integrity normative framework which applies to scientific research conducted by European research teams, in the EU and beyond.</p>	<p>The RE+RI normative framework is understood to encompass more than just the rules and regulations, but also the normative experiences of stakeholders and learning processes during the application of rules and regulations. Experiences, values, norms and priorities will be explored during the stakeholder consultation (WP 2). The findings from the consultation will help define the focus and the boundaries of content to be collected in the mapping exercise (WP 3-5) and structure the information on the website according to stakeholders' concerns; enabling the collection, provision and presentation of data sensitive to stakeholder needs. The mapping is considered 'dynamic' as the open source/open data approach for the online platform will enable the RE+RI community to keep the content and platform up-to-date (WP 6 and 7).</p>
<p>The work undertaken shall primarily aim at supporting the work of researchers and ethics/integrity review committees.</p>	<p>The participatory approach ensures that the online platform will be sensitive to the priorities and preference of various types of users. We distinguish RE+RI leaders (who are highly committed to RE+RI norms and contribute to their development), and RE+RI followers (who are eager to comply, but require easy access). RE+RI leaders will be supported by the platform by continuously staying up-to-date and having possibilities for dialogue and deliberation. RE+RI followers will be enabled to disentangle complexities in rules and regulations and in applying them to daily practice.</p>
<p>The action shall design the most appropriate mapping methodology, the processes and institutions to be mapped and produce appropriate process maps, indicating the criteria/dimensions (geographic scope, thematic coverage, stakeholder involvement, etc.) and enable comparative analysis.</p>	<p>A bottom-up, participatory approach is the most appropriate to capture the diversity of explicit and implicit RE+RI rules across the EU (WP 2). Data collection (WPs 3-5) encompasses the following processes, resources and institutions: WP 3 - EU, country and domain specific policies, guidelines, standards and legislation and legislative bodies; WP 4 - RE+RI resources, including training courses for researchers and RE+RI review committees, contact details of RE+RI review committees and RE+RI experts for advices; WP 5 - Cases, derived from literature, published by RE+RI committees, and presented and discussed during focus group meetings. WPs 2-5 will start with a pilot phase, followed by a process of scaling up to all EU countries, and will include normative analysis and case analysis. Data mining features, which allow for searchability, will be combined with more conventional, hierarchical data organization approaches (e.g. by geography or discipline), allowing researchers to perform analyses more easily – greatly enhancing their ability to perform cross-country comparative research with low effort and cost.</p>

Scope of SwafS-16-2016	EnTIRE strategic approach
<p>The outcome of the mapping action shall stimulate knowledge transfer and ultimately promote the uptake of the highest ethical standards. In order to facilitate this role, English summary/abstract of the normative elements (e.g. legislation, code, etc.) focusing on the main practical requirements/recommendations should be made available.</p>	<p>Knowledge transfer will be stimulated through widespread dissemination. EnTIRE includes a WP dedicated to dissemination in recognition of the importance of knowledge transfer to the project's success (WP 7). The stakeholder and community approach provide an excellent basis for dissemination. Activities will be two-part: 1) dissemination for awareness and understanding, involving RE+RI followers, by offering easily accessible information; and 2) dissemination for continuity, engaging RE+RI leaders, offering up-to-date information and the possibility for contributing to platform development. This will be based on extensive cooperation with ENERI and other relevant EU projects/organisations. It also requires commitment and action to change current practices amongst journal editors and research funding and publishing associations. English summaries of the main normative elements of research ethics and integrity will, of course, be easily accessible via the online platform.</p>
<p>Researchers shall also be helped to distinguish between the legislation that must be applied (highlighting the practical obligations) and the soft laws and best practices that must be taken into account (illustrating them with concrete examples) in the research design and implementation to guarantee the compatibility with the highest ethical standards.</p>	<p>The innovative, user-friendly open access and open source WIKI-platform developed by WP 6 will allow RE+RI followers to become aware of the legislation and regulations that must be applied, and of cases and scenarios embodying best practices; RE+RI leaders will be involved in developing and deliberating upon norms guiding responsible research conduct, thus creating preconditions for scientific excellence.</p>
<p>The resulting mapping shall be made available online and include beyond the constitutive elements of the normative framework information on the available trainings and education activities as well as on where to find appropriate ethics/integrity expertise</p>	<p>In collaboration with partner gesinn-it, an innovative online Wiki- platform will be developed (WP 6). Novel elements include: the participatory mapping of data sensitive to stakeholders priorities and preference; the data mining features which will support the discovery of actionable insights; and community engagement to ensure the platform's long term sustainability. As mentioned previously, the online platform will identify relevant training courses, resources and where to find appropriate expertise.</p>
<p>Practical information on how to comply with the legislation and standards should be provided</p>	<p>Practical information and best practice examples will be collated by WPs 3-5.</p>

Scope of SwafS-16-2016	EnTIRE strategic approach
<p>In addition, the work must rely on a real case and scenario building approach based on existing literature, court cases etc.</p>	<p>There is a dedicated WP to the collection of cases (WP5). Cases come from existing sources (literature, websites, court cases) and stakeholder focus groups. Also, methods of analysis will be assembled and applied, resulting in illuminating scenarios. This process will extend beyond the duration of the project, based upon community engagement in the Wiki-platform.</p>
<p>The mapping shall also include contact details of the ethics and research integrity committees/ bodies and other relevant authorities (e.g. for personal data protection) which shall deliver the necessary approvals/authorisations.</p>	<p>The contact details of the ethics and research integrity committees/bodies and other relevant authorities that deliver the necessary approvals/ authorisations are included in the initial processes, resources and institutions to be mapped, they will be available through the online platform and, in the future, updated by users via the open editing feature. RE+RI committees are invited to participate in the platform and create and maintain their own pages.</p>
<p>The construction and update of this online database must be done in close cooperation with the "European Ethics and Research Integrity Network" which is supported by Horizon 2020</p>	<p>ENERI will serve as an important source in the processes of stakeholder consultation and community building. Close cooperation already exists between partner members and ENERI, and will be further developed during the project. ENERI has offered to participate substantially in the analytic part of EnTIRE and to provide network, expertise, website and communication channels for dissemination of EnTIRE's activities. The EnTIRE platform will benefit from expertise gathered in ENERI and provide a tool for ENERI to foster further cooperation in the RE+RI community.</p>
<p>This cooperation shall notably ensure positive synergies and guarantee the long term continuity/sustainability of the resulting output</p>	<p>The unique combination of EnTIRE's innovative, sustainable vision for the online Wiki-platform and the active involvement of the RE+RI community, many of whom are involved in ENERI, will result in long term continuity. Since sustainability forms such an important aspect of this project, one workpackage (WP 7) is specifically dedicated to dissemination and continuity. Sustainability is based upon the stakeholder and community approach, the Wiki-platform and the ICT innovations fostering searchability and user friendliness. Moreover, additional steps to ensure the project's long-term continuation include: 1. Developing an adequate infrastructure for teaching and higher education organisations (such as ALLEA, LERU and EUA) to embed RE+RI in teaching curricula. 2. Providing support to national and European research funding organisations to include adherence with RE+RI standards and regulations in research funding criteria, such as the requirement of adherence to data management standards in Horizon2020 projects. 3. Providing support to journal editors and publishing associations (such as COPE, EASE, WAME and CSE) to include, promote and emphasize adherence with RE+RI standards and regulations in publication criteria. 4. Building links with local, national and EU wide RE+RI websites to enable coupling to maintain the website content with the website with the help of ICT partner gesinn-it (WP6) 5. Developing a long-term continuity plan – in collaboration with the private ICT partner gesinn.it (WP 7)</p>

Scope of SwafS-16-2016	EnTIRE strategic approach
In addition to the above cited network and in order to avoid duplication of work already undertaken, it is essential to ensure that the publicly available results from relevant EU funded research projects (from FP7 and Horizon 2020) are taken into account.	Publicly available results from relevant EU funded research projects (ENERI, SATORI, PRINTEGER, RRI Tools and HEIRRI) will be included in the mapping process. The partners in these projects are important RE+RI leaders who will be addressed in the community approach, ensuring that output of these projects will immediately be visible on the EnTIRE platform.
International cooperation is encouraged	Although the project focuses on mapping the RE+RI framework in Europe, it is clearly international. The kick-off will be during the World Congress on Research Integrity, organized by the Dutch lead partner in Amsterdam 2017. The Advisory Board includes international RE+RI expert Ray de Vries. This will ensure that the approach used in the project meets international standards. International contacts of EnTIRE partners will provide the basis for scaling up to other regions of the world (after the end of the project).
The Commission considers that proposals requesting a contribution from the EU of the order of EUR 3.8 million would allow this specific challenge to be addressed	The project stays within the budget. See section 3.4. for a specification of the allocation of the resources.

1.3 Concept and methodology, quality of the coordination and support measures and approach

1.3.1. Overall concept

The current situation: researcher behavior

Confidence in research is severely undermined by evidence of violations, misbehaviours and poor judgement (National Academy of Sciences NA 2009). In recent years, high profile cases of scientists falsifying (Godlee et al. 2011) and fabricating (Crocker and Cooper 2011) data have put a spotlight on researcher behaviour and damaged public confidence in research findings. Thankfully, serious violations – such as falsification, fabrication and plagiarism (FFP) - are relatively rare, with an estimated 1 to 2% of scientists engaged in such practices (Martinson et al. 2005, Fanelli 2009, Swazey et al. 1993, Steneck and Zinn 2007). Less serious issues, generally known as questionable research practices (QRPs) - such as inappropriate authorship (Marušić et al. 2011) or research design and analysis - however, are more prevalent (undertaken by approximately a third of scientists) (De Vries et al. 2016, Martinson et al. 2005, Fanelli 2009) and arguably have a greater impact on the research process. In daily research practice, however, much of the focus is on preventing

serious research violations - FFP. Researchers are often unaware about which laws, policies and best practices to deal with the less serious but more prevalent issues; it is up to the researcher to take the initiative to locate information and advice which is scattered across various guidelines, protocols and quality handbooks, an initiative that time poor researchers often neglect. Moreover, RE+RI regulatory structures and procedures are experienced as remote from the day-to-day lived experiences of conducting research and can be reduced to 'box-ticking' exercises (Guillemin and Gillam 2016). More influential to researchers' behaviour are often the example of supervisors and peers and the pressure to publish and obtain funding (De Vries et al. 2016, Ware and Munafò 2014). There is, therefore, a pressing need to make the regulatory structures and procedures less remote and abstract, and foster community engagement of stakeholders, supported by an interactive platform. This will enable RE+RI followers to find accessible and relevant information, and RE+RI leaders to foster reflection and dialogue on RE+RI issues, resulting in improvement of the RE+RI normative framework.

The current situation: online ethics databases

A number of US based projects have started with similar goals in the past, but all have considerable limitations, which are outlined below:

1. The Office for Research Integrity (ORI), has an online repository of misconduct case summaries and learning resources (<https://ori.hhs.gov/>). The case summary 'naming and shaming' approach, whilst making interesting reading, does not engender a discussion on RE+RI nor support a community of interest, whereas the negative content can repel rather than attract stakeholders. Furthermore, the learning materials, many of which are now out of date, advocate a top-down, paternalistic approach to RE+RI learning.
2. The National Ethics Center's 'collaborative online resource environment', EthicsCORE (<https://nationalethicscenter.org/>), appears, superficially, to encompass a broader range of perspectives as it aims to collect and create resources for undergraduate/graduate students, postdoctoral scholars, instructors, administrators, and practicing scientists and researchers. Users are able to share teaching resources, but are unable to modify existing content. It has, therefore, developed into a large repository of unchangeable teaching resources and its search function also retrieves resources of questionable relevance.
3. The National Academy of Engineering's 'Online Ethics Center' (www.onlineethics.org) describes itself as a 'repository of resources on the ethics of science, engineering, and research' to 'understand and address ethically significant topics and problems that arise in the practice and results of science and engineering'. The website contains a good filter function, however this links mostly to external sites; the site is not therefore a 'one stop' resource. The search feature also currently retrieves few results for simple RE+RI search terms. The site appears, therefore to have high face validity but low content validity at this time (it looks good, but functions sub-optimally). Another issue is that research 'integrity' has been classified as a branch of ethics (micro-ethics), a classification which perhaps limits the conversation regarding practical issues that researchers encounter in their day-

to-day work. Some content is also clearly out of date and there is no option of review by users. Furthermore, the site was recently awarded \$5million to update and expand. This funding however highlights the site's lack of self-sustainability and suggests that subsequent updates will also require future funding sources.

The current situation of researchers needing accessible information whereas websites are too static and limited to serve researchers' needs can only be solved by creating an interactive platform, enabling users to navigate quickly and intuitively to appropriate content, developed and kept up-to-date by a community of active users. EnTIRE will create an online platform that is neither a repository nor a database, but rather a platform that supports the development of a RE+RI community where the content can both stimulate and follow the development of the field. The platform will harbour all relevant content (laws, regulations, procedures, policies, views, opinions, casuistry) for RE+RI in a structural way that enhances the ability to find what the user seeks in an efficient manner. As there are several types of users (RE+RI leaders and RE+RI followers), different levels of information will be used. Information content will be organised in a way that it will guide the user through applicable resources, but will also allow the expert to find the content which is relevant to him or her. The platform will also account for the relevance and importance of the information content. For example; a law which is highly relevant will be prioritized over a case report when searching the full content of the platform. External search engines will be given full access to ensure that the platform becomes widely known to the target audience. EnTIRE is inspired by a project which has already succeeded in addressing the main failings of past projects (keeping content up-to-date, searchable and appropriate content, building a community): Wikipedia. Wikipedia's framework is completely free to use because it is open source. It provides open source applications that can be tailored to specific projects and which allow for content editing from users and speedy and efficient data retrieval and processing. Furthermore, we will additionally develop an extension for the most appropriate information analysis for the site (data mining). The goal of EnTIRE is not to replace either current available search engines or Wikipedia itself. Both initiatives serve a general audience. EnTIRE will harbor specialty content and contains information which is not of relevance to the general audience. The future user of the EnTIRE platform (www.embassy.science) will only frequent the platform if the information is visibly reliable and up-to-date. Therefore, in contrast to the conventional Wikipedia approach, review and moderation/editing of pages or information content which is essential to RE+RI will be performed by researchers, monitored by RE+RI leaders. All the information content is publicly available ('open data approach') allowing researchers across Europe and beyond, to study RE+RI issues and find relevant information. This will be further enhanced by a data mining approach. An extension to the platform will be developed which allows the users in a 'birds eye view' dashboard to compare relevant information content between countries (e.g. compare legislation between countries and easily find gaps and overlaps). From a risk perspective, one of the strongest arguments for this approach is that the Wiki approach has been very successful in the past in achieving distributed, international and accurate knowledge management. An investment of the EU in this project prevents that a new platform is developed, decreases the (recurring) maintenance costs, allows future EU projects to benefit from the investment in this platform and thus ensures that the funds

have a maximum impact. Combining the Wiki approach with new assets, such as datamining, may result in new and economically viable technologies. This is an incentive for partner gesinn-it to contribute to developing ICT products which are not directly profitable because of the open source formula.

1.3.2. Relations with other research and innovation activities

In addition to the US based projects discussed above, a number of EC funded projects and networks are of particular relevance. These include ENERI, PRINTEGER, SATORI, HEIRRI, FOSTER, RRI-TOOLS and EnRRICH. They often have higher level aims focusing on the harmonization of values and standards within EU. These aims are positively supported by the more practical, applied ambitions of the EnTIRE project. Furthermore, many have involved the collection of data such as training courses and ethics experts contact details which are publically available and will be fed directly into the EnTIRE project. Finally, these projects and networks embody the RE+RI community, which EnTIRE aims to engage and support. The relations between EnTIRE and other research and innovation activities are listed below:

- **ENERI** is the GARRI 10 funded European Network of Research Ethics and Research Integrity. Its central goals of sharing experiences, improving competence, ensuring awareness and enhancing interaction in regard to RE+RI are closely aligned with the vision of the EnTIRE project. Indeed, the current call stipulates that the successful consortium work closely with the network. Positive synergies from co-operation with ENERI will stem from the unique combination of EnTIRE's innovative, sustainable vision for the online platform and the community approach which will actively involve ENERI members. ENERI has provided the project with a letter confirming that they will collaborate with EnTIRE. ENERI will participate substantially in the analytic part of EnTIRE and will provide network, expertise, website and communication channels for dissemination EnTIRE's activities. ENERI coordinator Prof. Dirk Lanzerath will act as a member of EnTIRE's Advisory Board. In addition, Prof Lex Bouter (EnTIRE participant) is a member of the Expert Advisory Boards of ENERI. This will secure strategic alliances between the two projects.
- **PRINTEGER** aims to improve governance of integrity and responsible research by improving the fit of governance to practice, improve integrity policies of national and international research organisations, and provide tools and resources for research leaders and managers. These aims fit the goals of the EnTIRE platform, Thus, PRINTEGER output will be an important element of the platform, which in turn can support PRINTEGER in influencing policy and providing educational tools. Prof. Lex Bouter, participant in EnTIRE, is a member of the Advisory Board of PRINTEGER. Thus, close cooperation between these two projects is guaranteed.
- **SATORI** is a platform for the 'consolidation and advancement of ethical assessment in research and innovation' which aims to develop a common framework of ethical principles and practical approaches. The mapping of the normative framework in

EnTIRE, will provide relevant information for SATORI, and SATORI will be invited to contribute to the platform as part of the RE+RI community.

- **HEIRRI**, (Higher Education Institutions & Responsible Research and Innovation) is working to develop training programmes and teaching material tailored to Higher Education Institutions but useful also for other relevant stakeholder groups. The aim of HEIRRI project is to 'start the integration of Responsible Research and Innovation (RRI) within the formal and informal education of future scientists, engineers and other professionals involved in the research, design and innovation process'. The publically available training and education resources available from HEIRRI will be an important source to be used in WP 4 of the EnTIRE project. Prof Ana Marusic, leader of WP4, is an active member of HEIRRI.
- **The FOSTER portal** is an e-learning platform that brings together the best training resources for those who need to know more about Open Science, or who need to develop strategies and skills for implementing Open Science practices in their daily workflows. It includes a growing collection of training materials to meet the needs of many different users, from early-career researchers, to data managers, librarians, funders, and graduate schools. The training materials of the FOSTER portal will also be used in WP 4 of the EnTIRE project.
- **RRI TOOLS** is developing the RRI-TOOLKIT, an online tool designed for all stakeholders of the research and innovation system - researchers, policy-makers, business and industry, educators, and civil society organizations - and for individuals as well as institutions. The RRI Toolkit contains over 350 resources to help design and bring projects to life, and to train on RRI. These resources include: inspiring practices; manuals, guidelines, how-tos, catalogues and online databases of resources; background documents including presentations, reports, cross-analysis and Pan-European surveys; other European projects that developed RRI resources; and, a self-reflection tool to assess professional practices. Results of RRI TOOLS will provide content to the EnTIRE platform, which will in turn help disseminating them.
- The Enhancing Responsible Research and Innovation through Curricula in Higher Education (**EnRRICH**) project will identify, develop, pilot and disseminate good practice and relevant resources to embed the 5 RRI policy agendas 'Public Engagement', 'Science Education', 'Open Access', 'Ethics' and 'Gender' (and optionally also the additional policy agendas 'Governance', 'Sustainability' and 'Social Justice') in academic curricula across Europe. The aims of EnRRICH partly overlap with those of EnTIRE, which provides a basis for cooperation regarding the content of the EnTIRE platform and the expansion of the community which will support it. EnRRICH and EnTIRE both adhere to principles of open access. Open access is also an important issue on the agenda of COPE (Committee on Publication Ethics).
- **COPE** is a platform for publishers and journal editors, who are important stakeholders in EnTIRE. The platform also contains valuable expertise in the area of RE+RI, as COPE advises editors on all aspects of publication ethics and, specifically, on how to deal with cases of research and publication misconduct. Dr.

Elisabeth Moylan is Council member for COPE and a member of the Advisory Board of EnTIRE. This ensures close cooperation between EnTIRE and COPE.

1.3.3. Overall approach and co-ordination

The aim of EnTIRE is to map the normative framework governing RE+RI, paying attention to both explicit and implicit elements. To get insight into implicit elements of the normative framework, focus groups with stakeholders will be organized, aimed to elucidate experiences and cases from practice (WP 2). Next, explicit elements of the normative framework, including laws, regulations, codes and guidelines will be assembled and analysed (WP 3). Also, practical resources, especially teaching programmes, focusing on implicit elements will be collected (WP 4). Furthermore, we will collect and analyse cases and build scenarios, again embodying implicit elements of the normative framework (WP 5). The results of WP 3-5 will be used as content for the platform (WP 6). In order to make the platform sustainable, the RE+RI community will be engaged (WP 7), in line with the stakeholder approach (WP 2). For WP 2-5, we will use a pilot phase, to get data from a limited number of EU countries, followed by a scale-up phase, extending the data collection to all EU countries. See, for more information on the timing and planning, the GANTT chart in section 3.1.

1.3.4. Consideration of gender aspects

EnTIRE adheres to the underlying H2020 gender equality objectives:

1. fostering gender balance in research teams;
2. ensuring gender balance in decision-making; and
3. integrating the gender dimension in research and innovation content Directorate-General for Research & Innovation 2016.

Firstly, the EnTIRE project strives for gender equality at all levels (researchers, advisory board, management team, stakeholder consultation participants, and managing of the Wiki-platform). WP 1 will be responsible for monitoring the gender distribution of the project participants and taking any necessary remedial actions. EnTIRE includes women who are early, mid, and late career researchers. Women are WPs leads or have a managing role in three of the seven WPs: WP 1 Laura Hartman (partner 1. VUmc, management), WP 2 Natalie Evans (partner 1.VUmc), WP 5 Ana Marusic (partner 4.MEFST). Secondly, EnTIRE takes gender into account in the RE+RI mapping process itself. As EnTIRE acknowledges the importance of implicit rules and contextual factors, it will address the gendered aspects, as well as the socio-cultural, political, economic and institutional factors implicit in the RE+RI normative framework. Examples include the effects of women being less likely to be promoted to top positions, low proportion in decision-making roles and gender pay-gap. By making such implicit elements explicit and allowing for reflection and dialogue, EnTIRE will contribute to making research practice more gender equal, as well as more equal concerning socio-economic factors.

Impact

It is the ultimate aim of the EnTIRE consortium to promote responsible research conduct by stimulating awareness of, and reflection and deliberation on, formal and informal RE+RI rules and practices. We will do this by developing an interactive platform sensitive to user needs, that makes the RE+RI normative framework, containing explicit elements (laws, regulations, codes, guidelines) and implicit elements (practical experience addressed in teaching programmes and embodied in cases), easily accessible. We consider our efforts (within and beyond this project) successful when:

- All European researchers are aware of and sensitive towards relevant formal rules, informal cultural aspects and key ethical challenges in their scientific field and understand their influence on responsible conduct of research, across all levels of seniority. Within this project we will make rules, resources and cases accessible to researchers and foster an awareness of diversity and the possibility to learn through reflection and dialogue an integral part of the EnTIRE platform. The platform will cater to three types of researchers:
 1. RE+RI leaders, there are researchers who are eager to comply with RE+RI norms and actively contribute to their development. The EnTIRE platform will help them to better support their peers, continuously stay up-to-date on latest developments, and actively contribute to the EnTIRE platform with new ideas, reflections and practice examples;
 2. RE+RI followers, these are researchers who are eager to comply but struggle to identify how to cope with complex regulations and regional diversity. The EnTIRE platform will help them to disentangle this complexity and translate them into their day-to-day practice; and
 3. RE+RI non-compliers, there are researchers who are not interested in or deliberately disobey RE+RI rules and regulations. Although this project will not be able to change their moral principles it will become much more difficult for these types of researchers to blame or hide behind complex regulations.
- Both the scientific system and the organizational culture is structured in such a way that all European researchers, from scientific organisations and industries, are stimulated to comply with national and international rules and guidelines for conducting responsible research. Relevant tools, the right infrastructure and support are available and accessible for all European researchers. Within this project, a dynamic platform, combined with innovative techniques for data searching, will establish an important first step in this direction by enabling access to existing rules and their interpretation and application in the real world, teaching resources, and illustrative cases and methods of analysis.
- European policy makers and relevant bodies such as RE+RI evaluation committees, journal editors and funding organisations are equipped to develop better rules, guidelines and codes, and know how to translate these into effective policies and review mechanisms that match research workflows and challenges

(fostering the development of a scientific system that makes it in the best interest of researchers to comply with RE+RI rules). Within this project, rules, resources and cases will be made available, thereby fostering reflection, research, analysis and deliberation, contributing to the improvement of explicit and implicit rules regarding responsible research conduct. The platform is sustained by the RE+RI community, ensuring that RE+RI rules are further developed through interaction and dialogue between stakeholders (participatory approach).

- We have contributed to restoring public confidence in the scientific community when it comes to research integrity by:
 1. Educating the public on how research works and what the community considers ethically sound; and
 2. Making research itself more transparent and reliable. Within this project we will inform the public of systemic aspects of research, best practices, the importance of rules and resources concerning RE+RI, and the relevance of an interactive platform.

2.1 Expected impacts

Table 3 below further outlines the project's impact across sectors and timelines.

Table 3. Impact across Sectors and Timelines.			
	Short-term impact (during project)	Mid-term impact	Long-term impact
		(< 5 years after project)	(> 5 years after project)
Scientific community	The interactive platform, providing open access to rules and regulations, resources and cases, will support 1.6 million European researchers by making RE+RI information available. Increased awareness of and sensitivity towards formal and informal rules governing RE+RI. Case-based learning through instructive cases and methods of analysis.	Novel tools, based on the EnTIRE platform, help researchers to understand and apply formal and informal rules governing RE+RI in day-to-day research. Novel insights and ideas to improve research culture for the benefit of RE+RI, for example concerning open access, research funding, workload and responsibilities and responsible publication practice will be available.	Provide confidence amongst European researchers (and beyond) that they comply with formal and informal RE+RI rules, which are normatively adequate and serve to guarantee scientific quality and foster excellence. Compliance will be fostered by harmonisation of rules and guidelines.

	Short-term impact (during project)	Mid-term impact	Long-term impact
		(< 5 years after project)	(> 5 years after project)
Policy makers	Mapping of rules and regulations, elucidating regional differences and detecting 'white spots'.	More effective RE+RI review mechanisms. Increased consensus between policy makers and researchers, leading to more effective policies.	Harmonisation of policies across scientific fields and countries and regions. The EnTIRE platform will also be the appropriate medium to publish harmonized rules in the future, since it will be well known in the research community.
Researchers in ethics	Improved accessibility to data for comparative studies and increased contacts with engaged members of the platform community for more than 1000 researchers in ethics. Its open access nature will contribute to a level playing field in ethics research.	Boosting European ethics research excellence through increased innovation capacity from the EnTIRE platform, evidenced by novel policies with significant input from ethics expertise.	Joint endeavour between ethics researchers and other stakeholders to ensure improvement of RE+RI rules and practices that stimulate compliance of researchers .
Industry	Better access to guidelines on how to do responsible research and how to cooperate with scientific research organisations, including sponsorship, in a responsible way.	Novel tools, based on the EnTIRE platform, helping to understand and apply formal and informal rules governing RE+RI in day-to-day research.	With laying the foundations for a harmonization of and improvement of the rules and guidelines regulating the conduct of responsible science, there will be less need to invest in bureaucratic efforts to map and comply with different regulations per organisation, per region and per European country. (also contributing to a level playing field among research bodies in Europe and a favourable research climate).
Society	Growing awareness of the importance of RE+RI issues and policies and a better understanding of research conduct and output.	Growing interest in and engagement with further development of rules and resources of responsible research practice.	Widely supported trust in scientific communities and results.

Expected impact according to the call: The proposed action will facilitate the work of researchers to comply with research integrity and ethics standards and legislation while improving the effectiveness and efficiency of committees and competent national bodies. Consequently, the excellence of public and private research in the European Research

Area will be promoted. As described in Section 1, this project will lay the foundations for these expected impacts through:

- Making RE+RI regulations, resources and cases accessible and responsive to stakeholder experiences and needs;
- Creating a dynamic platform with innovative searching techniques, easy and intuitive to use, making the relevant information accessible in a quick way for researchers as well for RE+RI review committees and other regulatory bodies promoting RE+RI;
- Engaging the RE+RI community in sustaining the platform, and keeping it up-to-date and responsive to user needs, and stimulating debate, analysis and research into differences, similarities and innovation in rules, resources and cases.

Table 4 below describes external barriers that need to be addressed to reach the abovementioned impact.

2.2 Measures to maximise impact

2.2.1. Dissemination of results

Dissemination strategy The consortium recognises the importance of awareness regarding the EnTIRE project and its outcomes across sectors to reach the goals listed above. Therefore, the partners are dedicated to reaching all stakeholders involved before, during and after the project. The main goal of the dissemination strategy is to:

1. Ensure that EnTIRE will achieve the expected impact of the call,
2. Contribute to the long-term impacts as listed above,
3. Foster collaboration between involved stakeholders, and
4. Ensure sustainability of the EnTIRE platform.

Table 4. External Barriers to be Addressed.	
External barrier	Mitigation
Lack of priority amongst researchers	We will foster debate between leading researchers on relevance of RE+RI issues for the quality of research (through platform design and community action) and will explicitly target the “peace of mind” that can be established through proactive discussion of RE+RI and its challenges.
Lack of political interest in improvement and harmonisation of policies on EU scale	We will integrate policy makers as stakeholders in the process of stakeholder consultation and community engagement, making them experience the value of exchange of practices and deliberation on RE+RI issues.

External barrier	Mitigation
Abundance of issues other than RE+RI asking attention of researchers in ethics	We will put RE+RI issues on the agenda of relevant societies for ethical researchers in Europe and highlight the EnTIRE platform as an attractive source of information for research and communication. (See 2.2.3 for the participation in relevant societies of our consortium members.)
Lack of interest in industry in RE+RI issues and improvement of rules	We will foster debate on relevance of RE+RI issues for responsible cooperation between science and industry (through platform design, community action and presentations at conferences such as EuroScience Open Forum (ESOF).
Doubts in society about normative attitude of scientists and results of research	We will leverage the active involvement of researchers in the platform to show the surplus value of a community of stakeholders assembling and editing information (compare confidence of the public in Wikipedia)
Delays and lack of interest in the political arena to changes of policies that contribute to an improvement of RE+RI rules	Through the involvement of policy makers and regulatory bodies in EnTIRE, we have laid a foundation for a supportive network and support to change policies and keeping RE+RI high on the political agenda.

In addition, dissemination promotes transfer of knowledge and expertise between consortium partners and other stakeholders. The dissemination strategy will be developed, monitored, evaluated and continuously improved in WP7 by all partners under coordination of partner VUmc and in close collaboration with ENERI, which has offered to participate substantially in the analytic part of EnTIRE and to provide network, expertise, website and communication channels for dissemination of EnTIRE's activities. The EnTIRE platform will benefit from expertise gathered in ENERI and provide a tool for ENERI to foster further cooperation in the RE+RI community. The people involved in WP7 will also be responsible for developing a dissemination policy that has to be signed by all consortium participants and which will be included in the consortium agreement.

Dissemination policy principles Dissemination activities are conducted by all partners but directed by the WP7 team. However, prior to distributing information there must be final approval from the whole consortium in order to be sure that every partner is aware when dissemination of results takes place and that it does not have sensitive information which is important for the partner. Finally, the final approval will be provided by the Project Coordinator to prevent any leak of sensitive information.

Stakeholder Analysis Our dissemination strategy builds upon targeted communication to, and involvement of, all groups in society with a vested interest in EnTIRE's results and groups that are affected by the results of the project (stakeholders). EnTIRE is based in stakeholder participation from the very start. Understanding the interests and motivations of all stakeholders will allow the consortium not only to make the platform meet user needs, but also to effectively reach and inform them in the most optimal way about the outcomes of EnTIRE. Table 5 shows how all stakeholders will be informed including intended effects, message and specific channel for each stakeholder. The target groups we want to reach are:

Table 5.

Stakeholder Overview, Envisioned Effect, Specific Message and Dissemination Channel.

Stakeholder	Intended effects	Message	Targeted dissemination methods
Scientific community	Awareness of and compliance with rules governing RE+RI.	"We have a simple, accessible system that allows for searching relevant information, learning, and discussion."	<ul style="list-style-type: none"> • Alerts when content relevant for researchers (further specified in research disciplines) is added to the EnTIRE platform, invitation to add and edit information. • Making the platform visible in common search engines, such as Google (using pushing strategies such as adwords). • Making animation videos of key learning points on the website for easy transfer.
Policy makers	Improved policy making, based on relevant information and stakeholder participation.	"Our platform, through advanced searching techniques, enables easy comparison of regulations, and provides a basis for better policy making."	<ul style="list-style-type: none"> • Relevant journals. • Alerts when content relevant for policymakers is added to the EnTIRE platform, invitation to add and edit information. • Relevant conferences, e.g. WCRI 2017 Amsterdam.
Ethics researchers	Active use of platform, involvement in editing, participating in the community.	"Our platform provides accessible data for comparative research and normative analysis and serves as a basis for active involvement in furthering normative deliberation and improving policies."	<ul style="list-style-type: none"> • Relevant journals. • Alerts when content relevant for ethics researchers is added to the EnTIRE platform, invitation to add and edit information. • Conferences of societies of ethics researchers.
Industry	Awareness of and compliance with rules governing RE+RI.	"We have a simple, accessible system that allows for searching relevant information, learning, and discussion concerning (multinational) research."	<ul style="list-style-type: none"> • Alerts when content relevant for industry is added to the EnTIRE platform, invitation to add and edit information. • Making the platform visible in search engines, such as Google (using pushing strategies).
General public	Awareness of importance of RE+RI issues and policies.	"Responsible research requires addressing RE+RI issues, we foster this by proving support for researchers and policy makers, thus contributing to trustworthy research."	<ul style="list-style-type: none"> • Mass media news items. • Alerts when content relevant for the general public is added to the EnTIRE platform, invitation to add and edit information. • Social media. • Flyers/brochures. • Participation in public debates. • Develop animation video's to capture the main points of the scientific system to educate the public.

1. Researchers in all fields of research and across all seniorities (scientific community);
2. Policy makers at universities, research institutes, governmental bodies and funding agencies;
3. Ethics researchers;
4. Private sector companies (industry and investors);
5. General public.

Stakeholder Involvement A unique feature of EnTIRE is stakeholder consultation and community engagement. We will involve all stakeholder groups in two face-to-face focus groups in three countries (Croatia, Spain, the Netherlands) and in a cross-country focus group. In the scale-up phase, online focus groups will be organized in all European countries. Results will be used to define the boundaries of the data to be collected and to adapt the platform to stakeholder needs. Stakeholders will also be involved in evaluating the platform. Community engagement will entail approaching all relevant stakeholders in the RE+RI community to actively participate to the EnTIRE platform with new ideas, reflections and practice examples.

2.2.2. Exploitation of results

This project will support research and innovation in a number of ways and can lead to a number of commercial and non-commercial spin-offs.

- The modifications which are made to the Wiki-platform will be published open source in line with the the MediaWiki license. This will support many SME's across Europe whose primary business it is to employ, rather than develop, similar platforms. Future EU funded projects might benefit from the availability of such a modified platform as well.
- Additionally, there will be a focus on novel types of textual analysis on this platform. The open source availability of an implementation that has succeeded in enabling its users to perform an analysis on the vast textual content will be very valuable to projects with a similar aim, inside as well as outside the scope of science. Initiatives for which knowledge management is important such as the open governance movement will benefit from a 'template data mining platform' to quickly gain insights in large volumes of texts.
- The data on the platform itself will create economical utility for many commercial (e.g. CRAs) and non-commercial organisations (e.g. universities) in educational activities (training programmes, lectures, textbooks etc.). The partners in the project have experience in this, and will initiate and support such activities (after the end of the project).
- The data and the RE+RI community also hold an economic value in improving research efficiency on several levels (more effective Ethic Review Committee applications, risk management for industry, editor assessments of submitted manuscripts etc.).

- Possible business/earning models will be investigated as part of WP7. Amongst others, we will explore the role of specific stakeholders in sustaining the platform, for example by creating fee-based patronships for CRAs, pharmaceutical associations and non-profit organisations.

2.2.3 Communication activities

As this is a CSA project, communication is a corner stone of the project. EnTIRE will communicate to stakeholders via several communication channels at major milestones of the project. The following dissemination resources will be used:

- Conferences: Conferences provide an excellent opportunity to exchange experience and ideas about the latest advances established by EnTIRE. In addition, they are a perfect platform for stakeholder involvement and consensus making. Representatives of the consortium will actively participate in outside conferences and events relevant to the consortium activities. The start of the project will be announced during WCRI 2017 in Amsterdam, Lex Bouter (partner 1. VUmc) is a member of the program committee and organizing committee. We will also present the results of EnTIRE at other conferences such as EuroScience Open Forum (the biennial, pan-European, general science conference dedicated to scientific research and innovation). At the end of the EnTIRE project, a final conference will be organized with all relevant stakeholders, to inform them about the results. In addition, during these conferences we will have specific open and closed sessions to discuss project results and strategies with the consortium partners and selected stakeholder. Conference and events where the project will be disseminated are presented in Table 6.
- Scientific publications: Results originating from the research will be published in high impact scientific journals, such as Science, Nature and PNAS or more specialized journals such as BMC Research Integrity and Peer Review, Accountability in Research, Journal of Empirical Research on Human Research Ethics, Science and Engineering Ethics, Research Policy.
- External collaborations: Exchanges and collaboration with other researchers and groups outside the consortium which are active in RE+RI will be setup. ENERI has declared that they support EnTIRE and will cooperate. ENERI coordinator Dirk Lanzerath will act as a member of EnTIRE's Advisory Board. Lex Bouter (partner 1. VUmc) is a member of the advisory board of ENERI and PRINTIGER. Ana Marusic (partner 4) is involved in HIERRI. Finally, Elisabeth Moylan is Council member for COPE and member of the Advisory Board of EnTIRE. The platform will provide new ways for communication and dialogue for the RE+RI community, active in these projects.
- Press releases: At key milestones in the project, press releases will be developed and distributed through all relevant national and international networks with help of the communication departments of partners involved.

- **Dissemination material:** To inform policy makers, the general audience, relevant patient groups and industry that have vested interest in the project findings will be informed using brochures, newsletters and media campaigns.
- **Branding:** For communication activities, a corporate style, such as logos and standard templates, will be developed. This corporate style will maintain a consistent and recognisable image of the project and will be implemented for all communication materials.
- **Animation videos:** We will capture the key learning points in 10 short animation videos to make them easily transferrable (published on the EnTIRE platform and social media).

Table 6.
Events and Conferences for the Dissemination of EnTIRE.

Events and conferences	
Event	Timing
Kick-off during 5th World Congress of Research Integrity in Amsterdam	May 2017
EuroScience Open Forum (ESOF)	July 2018
7th World Congress of Research Integrity	May 2019
International Center for Academic Integrity (ICAI)	February 2020
National data integrity conference	June 2020
EuroScience Open Forum (ESOF)	July 2020
End conference EnTIRE	2021 (to be decided)

Outreach

Public confidence in the scientific community has been challenged by research integrity scandals, including the Stapel case, the Poldermans case, and the Penkowa case. This makes public outreach more important than ever. Therefore, we have implemented several special outreach measures, including:

- Animation videos that explain the challenges of RE+RI in layman terms, distributed through social media.
- Participation in inspirational events such as TED talks.
- Specific sections on the EnTIRE platform will be dedicated to and accessible for the general public.
- Involvement via mass and social media, including active participation in Facebook, LinkedIn and Twitter channels and responses to opinion articles in national newspapers.
- Contributing to the national public debate on research ethics and research integrity, by publishing in national newspapers and magazines.

Project year and month		Year 1				Year 2				Year 3				Year 4			
		3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48
T6.2	Content structure organisation of the platform					x	x	x	x	x	x	x	x	x	x	x	x
T6.3	Publish open source software modification on online repositories					x	x	x	x	x	x	x	x	x	x	x	x
T6.4	Platform adaptation to the feedback from stakeholders										x	x					
T6.5	Develop and employ a tool to search in and compare relevant topics across countries on the platform										x	x	x	x	x	x	x
T6.6	Evaluation of efficiency of information retrieval on the platform													x	x	x	x
T6.7	Steady-state maintenance of the platform													x	x	x	x
T7.1	Structuring community development	x	x	x	x												
T7.2	Fostering community awareness of the platform	x	x	x	x	x	x	x	x	x	x						
T7.3	Creating platform endorsement									x	x	x					
T7.4	Extended platform development and community engagement													x	x	x	x
T7.5	Fostering long term sustainability														x	x	x
		3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48

All consortium members have an extensive track-record in their respective fields and have collaborated successfully in many national and international research projects before. Members of the team have extensive knowledge in the fields of RE+RI and a large experience with collecting and analyzing relevant data. The consortium has access to the technology needed to develop the EnTIRE platform, including WikiMedia and datamining; the consortium has a sound methodological background and experience with participatory approaches and community engagement. Therefore, the consortium is well-equipped to complete the project successfully and on time. See Fig. 2 of section 1 for a schematic overview of the inter-relations of the work packages and their components.

3.1.2. Detailed work description

Work package 1: Project Co-ordination

Start date M1, end date M48

Lead beneficiary: VUmc

Participants: VUmc (25.8 PM); GI (1 PM); KUL (1 PM); MEFST (1 PM); DCU (1 PM); UEM (1 PM); UNIDEB (1 PM); UiO (1 PM); UNIMAN (1 PM); EUREC (1 PM).

Objectives

The main aim of WP 1 is to ensure the day-to-day project co-ordination activities and to provide scientific, administrative, and financial direction to the EnTIRE consortium and all WPs.

This aim will be achieved by pursuing the following objectives, to:

1. Bring together the strategic objectives of each WP to achieve the project's overall aim and objectives.
2. Provide daily coordination, management and support for all WPs.
3. Take responsibility for collation and integration of all outputs, in partnership with WP6 (Platform development and fair data management).
4. Ensure financial regularity.
5. Ensure ethics and fair data management compliance.
6. Service the General Assembly (GA), Executive Board (EB) and Advisory Board (AB) and Work Package Leads.
7. Report to the European Commission.

Description of work

The project coordination structure will contain a General Assembly, Executive Board and Advisory Board. This is further described in section 3.2. The EnTIRE project will be coordinated by VUmc, who will coordinate the project's day-to-day activities and chair the Executive Board. As designated by the EC, the coordinator (VUmc) will be responsible for legal, ethical and gender issues, contractual management (Grant Agreement, amendments and Consortium Agreement, incl. handling of IPR issues), processing EC audits and reviews and management of EC payments.

The project coordination WP will achieve the above objectives by conducting the following tasks:

Task 1.1. Scientific coordination (M 1-48, VUmc)

1. Providing scientific coordination and direction to ensure the integration of WP outputs, particularly the integration of results from the stakeholder consultation into all WPs.
2. Identifying synergies and sharing good practice in data across WPs.
3. Supporting WP6 to collate and integrate all outputs in order to construct the online platform.
4. Providing scientific oversight to integrate the findings of previous EC funded projects such as ENERI, SATORI, PRINTEGER, HEIRRI and RRI Tools.
5. Liaising with the Executive Board to monitor ethics and data protection compliance.

Task 1.2. Administrative coordination (M 1-48, VUmc)

1. Developing project coordination and quality assurance plans.
2. Handling of the project correspondence and the day-to-day requests from partners and external bodies.
3. Implementing and maintaining internal reporting and monitoring procedures (including gender distribution in line with gender mainstreaming).
4. Reporting on the progress and findings from all WPs and making any necessary changes to the work plan as a result of those findings, according to project milestones and indicators.
5. Managing timelines for WP deliverables and milestones and ensuring their delivery.
6. Providing daily liaison between the Project Office and WP Leads to assist in delivery and ensure timely actions.
7. Timetabling and reporting of General Assembly, Executive Board and Advisory Board meetings and following up on actions.
8. Providing logistical support for communication and meetings.
9. Maintaining the project archive.
10. Writing reports for the EC.

Task 1.3 Financial coordination (M 1-48, VUmc)

1. Liaising with finance departments to monitor contracts.
2. Establishing and maintaining financial records,
3. Co-ordinating financial statements submission by all project partners,
4. Calculating partner shares according to rules agreed in the Consortium Agreement.

Work package 2: Stakeholder Consultation

Start date M1, end date M48

Lead beneficiary: VUmc

Participants: VUmc (32 PM); GI (2 PM); KUL (2 PM); MEFST (4 PM); DCU (1 PM); UEM (3.5 PM); UNIDEB (3 PM); UiO (1 PM); EUREC (1 PM).

Objectives

This work package is responsible for meeting overall objective 1: to undertake an in-depth stakeholder consultation across EU countries exploring RE+RI experiences and practices, define the boundaries of data to be collected, and developing a mapping structure adapted to user needs (WP2).

WP sub-objectives include to:

1. Identify, include and engage a diversity of stakeholders. First, in face-to-face focus groups in three countries (Croatia, Spain and the Netherlands) and, subsequently, in online-focus groups across Europe.

2. Explore stakeholders' experiences and perspectives regarding RE+RI, including implicit rules and practices.
3. Define the boundaries of the data to be collected (i.e. to provide guidance to WP 3-5 on how to delineate the information to be collated), ensuring that all stakeholders perspectives are represented.
4. Iteratively assess the acceptability and usability of the platform developed in WP 6 with stakeholders using the feature to provide feedback on articles on the EnTIRE platform.

Background

A central element of the EnTIRE project is the inclusion of stakeholders' priorities and perspectives both in relation to the boundaries of the data to be collected and in the design and development of the online platform. Indeed, buy-in and intensive participation of a diversity of stakeholders from across Europe is key to the project's success; a sense of ownership amongst stakeholders and their associated networks will result in an online community that will make the platform self-sustainable.

The stakeholder consultation will be conducted through a questionnaire, followed by a focus group methodology (Kim et al. 2009, De Vries et al. 2016). The focus groups will be performed in two stages: face-to-face focus groups in three countries (Netherlands, Spain and Croatia) and online focus groups with participants from all EU countries (Stewart and Williams 2016).

The focus groups will investigate experiences of participants, clarifying how rules and regulations function in practice and identifying information needs. Also, cases from practice will be solicited and discussed. The focus groups will be analysed, taking into account the literature on RE+RI, in order to optimize interaction between practice and theory (Widdershoven et al. 2009).

Description of work

Task 2.1. Preparation of the stakeholder consultation (M1-3, VUmc, UEM, MEFST, UM)

1. Identify representatives of all stakeholder groups (researchers (4), journal editors (1), national and RE+RI committees (4), policy makers (2), industry, including pharmaceutical companies (2), and research funding and process organisations (2)) in the Netherlands, Spain and Croatia, and invite them to provide information on RE+RI practice through answering a questionnaire and participation in two consecutive mixed focus group meetings in their country.
2. Prepare the questionnaire and scripts for the first focus group meetings in order to solicit the ways rules and regulations function in the everyday practice of research, the information needs of participants regarding the interactive platform (WP 6), and cases that best illustrate key issues in RI+RE (WP 5).

Task 2.2. Pilot: face-to-face focus groups with takeholders (M4-8, VUmc, UEM, MEFST, UM)

1. Conduct a first round of focus groups in each country.
2. Analyse focus group data and adjust the scripts for second focus group meeting, allowing further in-depth discussion of the topics identified from the analysis.
3. Conduct the second round of focus groups in each country.
4. Analyse focus group data and create the script for the multi-country focus group.
5. Organize multi-country focus groups involving stakeholders from all three pilot countries (representatives from stakeholder groups in each country will take part) to discuss similarities and differences between countries.

Task 2.3. Defining the boundaries of the data to be collected (M8-12, VUmc, UEM, MEFST, UM)

1. Use the outcome of the face-to-face focus groups to assess the relevant elements of elements of the normative framework and define the boundaries of the data to be collected.
2. Discuss the assessment of the relevant elements of the normative framework and the boundaries of the data to be collected in a meeting of the Advisory Board
3. Deliver input for WP 3-5, and for the platform to be developed in WP 6.

Task 2.4. Scale -up: Online focus groups with stakeholders (M9-18, VUmc, all partners)

1. Identify representatives from stakeholder groups in each EU country.
2. Conduct synchronous online focus groups amongst stakeholders in each EU country.
3. For each country, specify the relevant elements of the normative framework and the boundaries of data to be collected as input for WP 3-5.

Task 2.5. Assessing the acceptability of the online platform (M18-48, VUmc)

Iteratively assess the acceptability and usability of the platform developed in WP 6 with stakeholders using the online community developed through the platform.

Work package 3: Guidelines and regulations on RE & RI in the European Union

Start date M1, end date M48

Lead beneficiary: KUL

Participants: VUmc (2 PM); GI (2 PM); KUL (48.9 PM); MEFST (2 PM); DCU (2 PM); UEM (2 PM); UNIDEB (5 PM); UiO (2 PM); EUREC (1 PM).

Objectives

This WP will be responsible for the collection of data on the diversity of guidelines, codes, legislations, and standards that have been created in the EU.

WP sub-objectives include:

1. To assemble normative documents on RE+RI in all European countries.
2. To integrate the normative documents in a meaningful and useful way in the Wiki-platform that will be developed in WP6.
3. To analyse these different kinds of documents.
4. To iteratively assess the acceptability and usability of the platform developed in WP 6 with stakeholders using the online community forum.

Background

The work package will offer a detailed mapping and analysis of the normative documents on research ethics and research integrity that are available within the European Union. Our previously published overview of guidelines, standards, laws, and codes in European countries, regions and institutions (Godecharle et al. 2014, Godecharle et al. 2013) will be updated and extended, regarding the nature of the documents to be included (research integrity, research ethics), regarding the level (national, regional, local, institutional), regarding the status (hard law, grey literature, etc). The collection of data will be double checked by researchers and fellows in each EU country: the bodies that have drafted the normative documents as well as a network of national legal and scientific experts will be asked to check our findings. Also practical information on the interpretation and coordinates of the bodies that have drafted the normative frameworks will be gathered in coordination with WP4. Further on we will analyse and prepare the normative documents for integration in the wiki-platform of the project (eg distinction between legislation that must be applied and the soft laws and best practices that must be taken into account).

Description of work

Task 3.1. Preparation of data-collection on normative documents (M1-6, KUL)

1. Prepare the search strategy and protocol for data collection, based on our previously published work, and a search in the scientific literature and the internet.
2. Update and extend the existing network of contact persons for each EU member state.

Task 3.2. Pilot collection of data on normative documents(M6-12, KUL, UEM, MEFST)

1. Conduct pilot searches in Belgium, Spain and Croatia to see whether the initially chosen search methodologies are adequate and feasible.
2. Adjust the search strategy based on results of the pilot searches and the normative framework defined in the focus groups (WP2).

Task 3.3. Scale up: Collecting normative documents in all EU countries (M12-36, KUL, all partners)

1. Collect data from European countries.

2. Deliver input for the EnTIRE platform. This task will include among others to make abstracts, key words, summaries of relevant parts of the documents, providing electronic links, etc.

Task 3.4 Analysis of the normative documents (M11-32, KUL)

1. Content analysis of the collected guidelines, standards, laws, and codes. This will allow us to see parallels, distinctions, contradictions in the available documents. This analysis will contribute to the knowledge and promotion of the highest ethical standards for researchers.

Task 3.5. Testing, updating and optimizing online platform (M18-48, KUL and GI)

1. Iteratively assess the usability, interactivity and sustainability of the platform developed in WP 6 with regard to the normative documents.

Work package 4: Resources for RE & RI

Start date M1, end date M48

Lead beneficiary: MEFST

Participants: VUmc (2 PM); GI (2 PM); KUL (2 PM); MEFST (30 PM); DCU (5 PM); UEM (2 PM); UNIDEB (2 PM); UiO (2 PM); UNIMAN (2 PM); EUREC (1 PM).

Objectives

This work package is responsible for collecting and synthesizing the information about:

- RE+RI committees in different European countries and for different research domains;
- RE+RI training courses for researchers on; and
- RE+RI experts' advice and contact details.

WP sub-objectives include:

1. Constructing the information framework for RE+RI resources (committees, training opportunities and experts).
2. Create an inventory database of RE+RI committees in EU countries and for different research domains, as well as training opportunities and experts, making use of the definition of the normative framework (WP 2) and building on systematic harvesting of the results from other EU projects on RE+RI.
3. Iteratively assess the acceptability and usability of the platform developed in WP 6 with stakeholders using the online community forum.

Background

WP4 will focus on systematic and comprehensive inventory of RE+RI committees, currently available training resources, and experts across Europe. This is crucial for

creating a functional platform, as there is little information or harmonization of RE+RI structures in Europe (Godecharle et al. 2014). Furthermore, there is a gap in RE+RI policies in different European countries, particularly in the Central and South-East Europe (Famenka 2015), as well as RE committees training (Cairolì et al. 2011) and graduate education (Mijaljić 2013).

Based on the information from other EU projects, such as RRI Tools and HEIRRI, and available literature on RE+RI (Marusic et al. 2016), as well as initial input from WP2, we will first construct the information framework for resources and contact point for RE+RI, following the initial discussions about structures, processes and outcomes for research integrity from the 2015 World Conference on Research Integrity (Kleinert and Marusic 2016). The information framework will be first pilot tested in three countries (Netherlands, Spain and Croatia), modified and then systematically used to collect information for the whole Europe. The methodological approach to the data collection will include systematic overview of publicly available data for individual countries (including scientific and grey literature) and consultations and participation of experts and stakeholders to collect country information, and locally available training resources (including individual interviews, online contacts using surveys, online webinar- or workshop-type small strategic groups).

In parallel with data collection, we will work on the best model for sharing the information on the OA platform developed by WP6, to ensure participation of stakeholders and commitment to full sustainability of the platform beyond the project.

Description of work

Tasks

Task 4.1 Preparation of data collection on resources(M1-6, MEFST and DCU, UNIMAN)

1. Prepare the search strategy and protocol for data collection, including the interaction with RE+RI bodies in countries.
2. Identify the elements of the information framework for RE+RI committees, trainings and experts in consultation with all consortium members and Advisory Board.

Task 4.2 Pilot collection of data on resources(M6-12, MEFST, VUmc, UEM)

1. Collect data for three countries (Netherlands, Spain and Croatia).
2. Collect data from literature (scientific and grey).
3. Discuss the method and content in regard to the first results from WP2 and revise the collection protocol.

Task 4.3 Scale-up: Inventory database on resources for European countries (M12-39, MEFST, and all members)

1. Collect data from European countries.
2. Synthesize and update data from literature
3. Deliver input for the project OA platform.

Task 4.4 9. Testing, updating and optimizing the online platform (M18-48,MEFTS and GI)

Iteratively assess the usability, interactives and sustainability of the platform developed in WP 6 with the regard to collected data on RE+RI committees, training opportunities and experts.

Work package 5: Cases, casuistry and scenarios

Start date M1, end date M48

Lead beneficiary: DCU

Participants: VUmc (2 PM); GI (2 PM); KUL (2 PM); MEFST (5 PM); DCU (27 PM); UEM (2 PM); UNIDEB (19 PM); UiO (2 PM); UNIMAN (2.5 PM), EUREC (2 PM).

Objectives

This work package is responsible for gathering and make available cases, methods of case analysis, and to present actual case analyses as well as a set of scenarios.

WP5 sub-objectives include:

1. To collect RE+RI cases across the whole spectrum of RE+RI issues / research areas.
2. To tag and categorise these cases so as to enhance the indexing and retrievability of cases in the EnTIRE database.
3. To aggregate and apply case analysis methods suitable for the ethical analysis of RE+RI cases
4. To build a comprehensive set of RE+RI scenarios.
5. Iteratively assess the acceptability and usability of the platform developed in WP 6 with stakeholders using the online community forum.

Background

Work package 5 “Cases, casuistry and scenarios” contains all tasks that provide for a comprehensive selection of RE+RI cases and case analysis methods as well as the presentation of actual case analyses. Moreover, a selection of prominent RE+RI cases will be analysed with different case analysis methods. Finally, a set of scenarios will be developed. The purpose of making the cases, case analysis methods, actual cases analyses and scenarios available is to foster structured analysis and thorough debate about RE+RI cases, which in its turn might serve as the bedrock for responsible future RE+RI regulation and practice.

The RE+RI cases to be uploaded onto the EnTIRE platform will result from searches in different potential sources, e.g. academic literature, reports of RE+RI committees, professional regulators, grey literature, media outlets and the blogosphere. In addition, the focus groups sessions, both the face-to-face and the online focusgroups, in WP2 will be used to generate, as well as to reflect and deliberate on, cases from local practice. The

cases resulting from the searches within these different sources will be tagged and categorized, with the purpose of enhancing the indexing of cases in the EnTIRE platform. Both traditional methods of categorisation – e.g. using well-known concepts such as misconduct, falsification, fabrication, plagiarism - as well as more innovative ways of categorisation, such as using the ethical principles within the RE+RI normative framework, will be applied and a thesaurus developed. In addition, case analysis methods suitable to the analysis of RE+RI cases will be identified through a systematic literature review and made available on the online platform. Moreover, a selection of prominent RE+RI cases will be analysed thereby showcasing relevant case analysis methods. Finally, a set of scenarios will be built for educational purposes and in order to stimulate strategic thinking about RE+RI.

Description of work

Task 5.1. Preparation of data collection on cases (M1-6, DCU, UNIDEB, Manchester)

1. Identify potential sources of RE+RI cases, for example, a) academic literature; b) reports by RE+RI committees and regulatory bodies; c) grey literature such as government documents, white papers, theses and dissertations, conference proceedings and policy statements; d) media outlets such as newspapers and magazines; and e) the blogosphere.
2. Develop appropriate systematic methods to conduct searches within these sources so as to gather RE+RI cases, e.g. through a systematic literature review.
3. Develop a system of categories, a 'thesaurus', for tagging cases that enhances retrievability and orientation within the EnTIRE database. Tagging methods will involve traditional approaches, e.g. tagging according to issues such as misconduct, falsification, fabrication, plagiarism, fake peer-review, data management, as well as innovative methods, for example tagging according to the main ethical principles from the RE+RI normative framework that have been violated.

Task 5.2. Pilot collection of data on cases (M6-12, DCU, UNIDEB, Manchester)

1. Conduct pilot searches in IE, HU and UK within each of the potential pools of RE+RI cases to see whether the initially chosen search methodologies are adequate and feasible. Make adjustments, if necessary.
2. Conduct structuring, posting and testing activities on the web platform.
3. Adjust the system of tagging based on the results of the pilot searches and the normative framework defined in the focus groups (WP2).

Task 5.3. Scale up: Collecting and categorizing RE+RI cases (M12-36, DCU, UNIDEB, VUmc)

1. Conduct full-scale systematic searches for RE+RI cases.
2. Add the RE+RI cases that have resulted from the face to face and the online focus groups sessions
3. Work through the RE+RI cases and tag them

Task 5.4. Identifying and applying appropriate case analysis methods and building RE+RI scenarios (M12-48, DCU, UNIDEB)

1. Conduct a systematic literature review to identify case analysis methods suitable for the analysis of RE+RI cases.
2. Analyse a set of particularly prominent and/or topical RE+RI cases showcasing relevant case analysis methods.
3. Develop a set of RE+RI scenarios for educational purposes and in order to stimulate strategic thinking about RE+RI.

Task 5.5. Testing, updating and optimizing the online platform (M18-48, DCU and GI)

1. Iteratively assess the usability, interactivity and sustainability of the platform developed in WP 6 with regard to collected cases and scenarios.

Work package 6: Platform development and maintenance

Start date M1, end date M48

Lead beneficiary: GI

Participants: VUmc (4 PM); GI (46 PM); KUL (1 PM); MEFST (1 PM); DCU (1 PM); UEM (1 PM); UNIDEB (1 PM); EUREC (1 PM).

Objectives

This work package is responsible for meeting overall objective 3: to develop a user-friendly platform, including a website and online resources, to facilitate access to RE+RI knowledge and experience and support application in research and evaluation, thus fostering uptake of ethical standards and responsible conduct of research. WP sub-objectives include to:

1. Develop and employ the platform.
2. Evaluate and adapt the platform together with stakeholders.
3. Develop the tools for performing data mining and semantic analysis on the full information content.

Background

The main aim of this WP is to develop the EnTIRE platform (www.embassy.science) and allow the EnTIRE consortium to deliver, structure, review, edit and analyse content on the platform. The platform should have a high level of user-friendliness (intuitiveness) that allows any user to start working on it immediately without further instructions. The platform will use publically funded, open source, freely available software: (Semantic) MediaWiki (Krotzsch et al. 2011). This open source software has proven to be useful for large scale, international knowledge management, which greatly reduces replication of work and costs. Using mature open source software ensures that no investments in the foundation of the platform are necessary. Instead, investments can be directed to optimizing the platform for

meeting objective 3. Also novelties such as (external) research on the content should be enabled ('open data approach'), by using new techniques such as automatic text data mining and semantic analysis. This approach will facilitate access to RE+RI knowledge, thus fostering uptake of ethical standards and responsible research. It also promotes compliance amongst European researchers with RE+RI standards and pertinent legislation, regulations and best practices.

Description of work

Task 6.1. Development of the platform (M1-12, GI)

1. Initiate a non-profit organisation and register the applicable domain name (www.embassy.science) in its name.
2. Host and deploy the adapted Wiki-platform once the project starts.
3. Provide documentation of the hosting, deployment and software development to ensure transferability.
4. Develop a custom graphical user interface aimed at maximizing ease of use.
5. Adapt the platform to allow for online focus groups on the platform.

Task 6.2. Content structure and organisation of the platform (M12-48, All partners, GI)

1. Support the consultation of stakeholders in achieving the appropriate information content structure (e.g. database and data models) for the website.
2. Design the platform structure in line with the normative framework developed as developed in WP 2.
3. Make the platform the primary place to create, edit and review the content on the platform.
4. Establish a system where different types of users gain appropriate types of permissions (to create, to edit, to review and to curate information content) on the platform.

Task 6.3. Publish open source software modification on online repositories (M12-48, GI)

1. Publish and make freely available all adaptations and developments made to the platform freely available, in an open source repository, for future (e.g. EU funded) projects to benefit from. Push back all relevant modifications to the platform to (Semantic) MediaWiki.

Task 6.4. Platform adaptation to the feedback from stakeholders (M30-36, GI)

1. Adapt the custom graphical user interface to maximize ease of use based upon the evaluation from stakeholders.

Task 6.5. Develop and employ a tool to search in and compare relevant topics across countries on the platform (M30-48, VUmc, GI)

1. Develop an extension to the platform to search through all content available on the platform.

2. Develop an extension to the platform to perform data mining and/or semantic analysis on the content of the platform.
3. Develop a 'bird's-eye view' styled dashboard where relevant RE+RI topics can be compared across Europe and where content can easily be extracted by users live on the platform. This ensures open access to data.

Task 6.6. Evaluation of efficiency of information retrieval on the platform (M36-42, VUmc, GI)

1. Evaluate the retrieval of relevant information by users (e.g. time spend searching, quality of information organisation) on the platform.
2. If bottlenecks are identified, the platform will be adapted to improve performance.

Task 6.7. Steady-state maintenance of the platform (M36-48, GI)

1. Continuously implement all software patches from the Wikipedia project (security, performance, ease of use). New functionalities will be monitored closely.

Work package 7: Community engagement, communication and dissemination

Start date M1, end date M48

Lead beneficiary: VUmc

Participants: VUmc (30 PM); GI (5 PM); KUL (2 PM); MEFST (1 PM); DCU (2 PM); UEM (2 PM); UNIDEB (2 PM); UiO (2 PM); UNIMAN (2 PM), EUREC (1 PM).

Objectives

This work package is responsible for meeting overall objective 4: to foster the further development of the RE+RI community, that will support the platform and be supported by it, disseminate the project's findings, apply innovative strategies for maintaining the platform through stakeholder participation, and relate the platform to relevant organisations for further dissemination fostering sustainability.

WP sub-objectives include to:

1. Engage the RE+RI community to create and maintain content on the EnTIRE platform (www.embassy.science).
2. Create platform awareness in the RE+RI community for successful dissemination.
3. Gain platform endorsement by RE+RI organisations.
4. Develop, evaluate and adapt the incentives in order to foster willingness for participating on the platform.
5. Develop a plan to promote the maintenance of the platform and results.

Background

The main objective of WP 7 is to engage the RE+RI community, that will disseminate the project's findings, apply innovative strategies for maintaining the platform (WP 6) through

stakeholder participation, and relate the platform to relevant organisations for further dissemination fostering sustainability (Waldrop 2008). For this purpose, an EnTIRE community taskforce will be installed, which will structure the further development of the RE+RI community. The primary role of this taskforce is to engage the community of RE+RI researchers, RE+RI committee members, researchers and other stakeholders such as representatives from pharmaceutical companies and medical device companies in creating, reviewing, editing and moderating information on the platform. The vastness of the relevant information content, which is further complicated by the different languages of the content across Europe, makes it impossible for any sized consortium to ensure that information content is correct and always up-to-date without engaging the community. Over time, the content creation, review, editing and curatorship will be gradually migrated from the consortium to the target community of stakeholders. This ensures that the content meets the stakeholders expectations, remains up-to-date and achieve a maximum impact. This approach should ensure the long-term sustainability as well. At the end of the project, a new consortium will be established to meet the new requirements of the platform in that stage of its maturation. (Fig. 3).

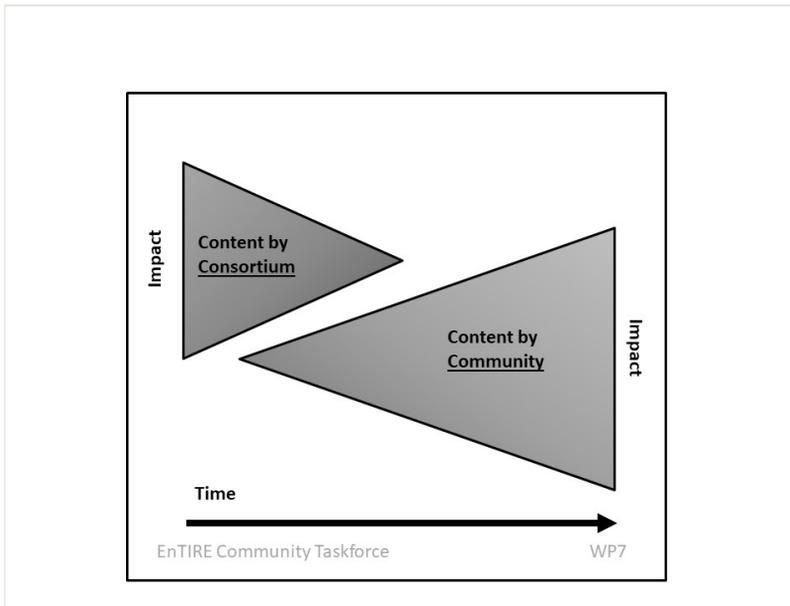


Figure 3. [doi](#)

Content for and by the community.

Description of work

Task 7.1. Structuring community development (M1-18, VUmc)

1. Establish the EnTIRE community taskforce which will be responsible for community development and maintenance. The taskforce will be led by a coordinator who will act in close collaboration with the coordinator of the platform (WP6). The taskforce

- will include one representative from every consortium member group to ensure that international cultural differences are taken into account. A representative from ENERI will also be part of the taskforce.
2. The EnTIRE community taskforce will develop a procedure for moderation and identify suitable moderators and editors and accredit them to manage the content on the platform.

Task 7.2. Fostering community awareness of the platform(M4-36, VUmc, all partners, ENERI)

1. Invite stakeholders to participate in and create and review content on the platform. These stakeholders will include local, national and EU wide RE+RI organisations.
2. Make an inventory of and invite them all European RE+RI committees, SMEs and research funding and publishing organisations to create and moderate their own page on the platform.
3. Employ the platform (WP 6) and give common search engines full access to the information content.
4. Structure information content to enable search engine optimisation to optimize the ability of users to find the platform and its content.
5. Increase the user base of the platform by allowing current users and stakeholders to invite other users in their social network on a referral base.
6. Distribute 'explanations' promoting the platform on social media amongst researchers. These animations will cover key topics to illustrate the added value of the platform in finding relevant information and best practices.

Task 7.3. Creating platform endorsement (M24-32, VUmc)

1. Identify incentives for participation by stakeholders in the project (e.g. increase of public visibility by external linking to the organisation's website, a decrease of bureaucracy).
2. Identify and lobby related, formal stake holding RE+RI organisations. Stakeholders such as learned societies (such as All European Academies (ALLEA)), research funding (such as Science Europe) and research publication organisations (such as the Committee on Publication Ethics (COPE), European Association of Science Editors (EASE), the World Association of Medical Editors (WAME), and the Council of Science Editors (CSE)) will be actively lobbied to participate and endorse the platform.

Task 7.4. Extended platform development and community engagement (M32-48, VUmc, GI)

1. Engage the previously uninvited stakeholders to ensure a large target RE+RI public in the end stage of the project. These stakeholders for example include all types of researchers across Europe.
2. Make the content on the platform available to individual researchers outside the project (open data approach) to enable analysis and evaluation.

3. Evaluate the efficacy of the platform in engaging and sustaining the community.
4. Adapt and extend the platform based on the evaluation of task 10.
5. Issue a press release which includes the endorsements by external RE+RI organisation of the platform, the amount of active users and the incentives for participation.
6. Distribute 'explanations' promoting the platform on social media for the general public. These animations will illustrate how the EU funded platform promotes good and trustworthy research and provides a reliable resource for background information.

Task 7.5. Fostering long term sustainability (M40-48, VUmc, Aall partners, ENERI)

1. Make an inventory of options for sustaining the platform on the long term, including endorsement by relevant organisations and applicable grants, and develop a long-term continuity plan.
2. Identify the lead and participants of the future consortium to sustain the platform.

A descriptive overview of the work packages is provided in Table 8, work package deliverables are listed in Table 9, and work package milestones are listed in Table 10.

Table 8.

List of Work Packages.

Work package No	Work Package Title	Lead Participant No	Lead Participant Short Name	Person-Months	Start Month	End month
1	Project Coordination	1	VUmc	34.8	1	48
2	Stakeholder consultation	1	VUmc	49.5	1	48
3	Guidelines and regulations on RE & RI in the European Union	3	KUL	66.9	1	48
4	Resources for RE+RI	4	MEFST	53.5	1	48
5	Cases, casuistry and scenarios	5	DCU	65.5	1	48
6	Platform development and maintenance	2	GI	56	1	48
7	Community engagement, communication and dissemination	1	VUmc	50	1	48
				Total months		
				376.2		

Table 9.

List of Deliverables.

Deliverable (number)	Deliverable name	Work package number	Short name of lead participant	Type	Dissemination level	Delivery date
D.1.1	Project management and quality assurance plans	WP1	VUmc	R	CO	(Month 2)
D.1.2	Document providing the logo and templates for a uniform corporate look	WP1	VUmc	DEC	PU	(Month 3)
D.1.3	Data management plan	WP1	VUmc	OTHER	PU	Month 6
D.1.3	Partner-specific templates for collecting input for internal reporting and monitoring and required EU documents	WP1	VUmc	OTHER	PU	(Month 12)
D. 1.4	Reports for the EnTIRE consortium	WP1	VUmc	R	CO	(after General Assembly, Executive Board and Advisory Board meetings and when required)
D.1.5	Reports for the EC	WP1	VUmc	R	PU	EC according to funding requirements)
D.2.1	Protocol for the phased multi-country stakeholder consultation	WP2	VUmc	OTHER	PU	M3
D2.2	Definition of the boundaries of data to be collected for the mapping exercise (WPs 3-5):	WP2	VUmc	OTHER	PU	M12
D2.3	Report of results from the stakeholder consultation	WP2	VUmc	R	PU	M33
D.2.4	Work package report: project end	WP2	VUmc	R	PU	M48
D.3.1.	Template for the collection of guidelines, codes, laws:	WP3	KUL	OTHER	PU	M7

Deliverable (number)	Deliverable name	Work package number	Short name of lead participant	Type	Dissemination level	Delivery date
D.3.2	First online content for OA web platform	WP3	KUL	OTHER	PU	M15
D.3.3	A report containing the most significant similarities and contradictions (at level of content and approach) within the different guidelines in the member states	WP3	KUL	R	PU	M38
D.3.4	Report on functionality of OA resource	WP3	KUL	R	PU	M40
D.3.5	A report containing all the documents ranked per member state, enforceability, level ((intra)national, PU regional, institutional), web links, etc	WP3	KUL	R	PU	M48
D.3.6	Final WP report	WP3	KUL	R	PU	M48
D.4.1	Content framework for data collection	WP4	MEFST	OTHER	PU	M6
D.4.2	Protocol for literature and country resources search and data collection	WP4	MEFST	OTHER	PU	M9
D.4.3	Online content for OA web platform	WP4	MEFST	OTHER	PU	M15
D.4.4	Report on functionality of OA resource	WP4	MEFST	R	PU	M40
D.4.5	Final WP report	WP4	MEFST	R	PU	M48
D.5.1	Protocol for systematic searches and tagging of RE+RI cases:	WP5	DCU	OTHER	PU	M7
	Delivery of the first tagged RE+RI cases as input for the platform	WP5	DCU	OTHER	PU	M18

Deliverable (number)	Deliverable name	Work package number	Short name of lead participant	Type	Dissemination level	Delivery date
D.5.3	Delivery of the entire set of case deliberation methods and case analyses as input for the platform	WP5	DCU	OTHER	PU	M24
D.5.4	Delivery of the first RE+RI scenario as input for the platform	WP5	DCU	OTHER	PU	M30
D.5.5.	Report on functionality of OA resource	WP5	DCU	R	PU	M40
D.5.6.	Work package report	WP5	DCU	R	PU	M48
D.6.1	EnTIRE platform	WP6	GI	DEC	PU	M12
D.6.2	Publication of the adapted platform software in a public open source software repository	WP6	GI	DEC	PU	M12
D.6.3	Report of the evaluation and graphical user interface of the platform	WP6	GI	R	PU	M23
D.6.4	Publication of the extensions to the platform in a public open source software repository	WP6	GI	OTHER	PU	M40
D.6.5	Report of the efficiency evaluation of the platform	WP6	GI	R	PU	M42
D.6.6	Report for future plans of the platform	WP6	GI	R	PU	M48
D.7.1	Communication and dissemination plan	WP7	VUmc	DEC	PU	M6
D.7.2	Platform community management plan	WP7	VUmc	DEC	PU	M12
D.7.3	Report of platform endorsements, usage statistics and an analysis	WP7	VUmc	R	PU	M36

Deliverable (number)	Deliverable name	Work package number	Short name of lead participant	Type	Dissemination level	Delivery date
D.7.4	Final and future Community management, Communication and Dissemination Plan:	WP7	VUmc	DEC	PU	M46
D.7.5	Plans of the newly formed consortium to sustain the platform beyond the end of this grant	WP7	VUmc	OTHER	PU	M48

Table 10.
List of Milestones.

Milestone number	Milestone name	Related work package(s)	Estimated date	Means of verification
M1.1.	Kick-off meeting	WP1	M4	Conference website
M2.1	Elements of the normative framework defined:	WP2	M 12	Table
M2.2	Stakeholders' experiences, priorities and preferences established:	WP2	M32	Report
M3.1	Format for collecting normative documents constructed	WP3	M7	Format
M3.2	First input for EnTIRE platform created	WP3	M16	Screenshot
M3.3	Content analysis available on the website	WP3	M40	Screenshot
M4.1	Content framework constructed	WP4	M9	Table
M4.2	Data from pilot data collection finalized and discussed with consortium members and Advisory Board	WP4	M13	Report
M4.3.	First input for OA platform created	WP4	M16	Screenshot
M5.1	First tagged RE+RI cases available on the platform	WP5	M18	Screenshot
M5.2	Case deliberation methods available on the platform	WP5	M24	Screenshot
M5.3	First RE+RI case analyses available on the platform	WP5	M24	Screenshot
M5.4	First RE+RI scenario available on the platform	WP5	M30	Screenshot
M6.1	The EnTIRE platform (www.embassy.science) is brought online for stakeholders	WP6	M12	Website

Milestone number	Milestone name	Related work package(s)	Estimated date	Means of verification
M6.2	The EnTIRE platform (www.embassy.science) is brought online for the general public	WP6	M24	Website
M7.1	EnTIRE community taskforce initiated	WP7	M3	Report
M7.2	New consortium composed to sustain the EnTIRE platform beyond the end of this grant	WP7	M48	Report

3.2. Management structure and procedures

The success of the EnTIRE project and its anticipated achievements will to a large extent be dependent on the management of the project and the structure and procedures to enable this. Prof. Dr. Guy Widdershoven (Project leader of WP1) has extensive experience in managing large collaborative projects, for instance a Dutch national project concerning reduction of seclusion in psychiatry and a large project funded by the Dutch funder NWO on empirical ethics. As former scientific director of the Care and Public Health Research Institute of Maastricht University (400 fte) and as current head of the department of the medical humanities (30fte) of the coordinating beneficiary, the VUmc, he has been successful in scientific supervision and financial management. He will be supported by Laura Hartman MA, who was a project leader on several large research projects at this department. The VU medical centre (VUmc) is highly experienced at hosting the coordination and management of large collaborative research projects. From this experience, an extensive set of structures and procedures have been put in place to ensure the successful management and delivery of the project, the scientific quality of the research, and make sure that dissemination and stakeholder engagement deliver the expected impacts.

The management structure and procedures in EnTIRE are designed to:

- Manage and support the full consortium team scientifically i.e. in terms of relevance of the work, its scientific quality and its coherence;
- Manage and support the full consortium team financially and administratively i.e. in terms of keeping to timescale; effective use and suitable reporting of budget resources;
- Liaise effectively with the Commission on all matters of strategy, relevance, scientific quality, timescale, administration, reporting, and budget.

A schematic overview of the intended management structure of EnTIRE is presented in Fig. 4. Due to the size of the consortium and the complexity of the project we will facilitate an accountable and efficient way to manage EnTIRE through efficient decision-making and through setting up a financially and scientifically transparent management structure. The management activities of EnTIRE will largely be grouped in work package 1 (WP1). WP1 will closely monitor the interrelations between the scientific work packages and its participants, notably between the activities concerning day-to-day project co-ordination

activities and providing scientific, administrative, and financial direction to the EnTIRE consortium and all work packages. See above section 1 for a description of the objectives of WP1.

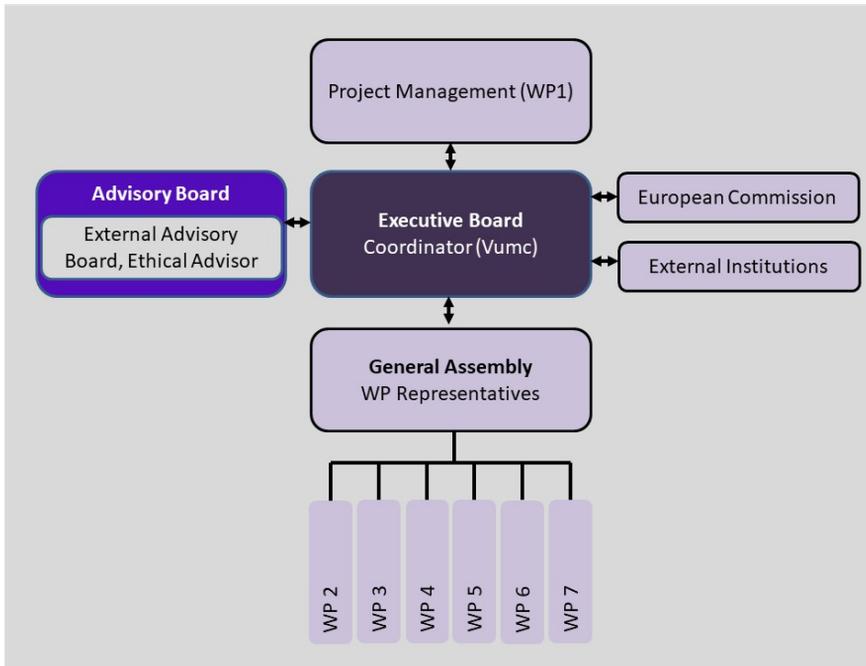


Figure 4. [doi](#)

Management structure of EnTIRE

As will be further detailed in the CA, three levels of management are distinguished. Each of these levels has different authorities and responsibilities as described in the following sections.

3.2.1. General Assembly

The General Assembly's (GA) main responsibility is to advise and review the project results in accordance with the GA and the CA. It consists of one representative of each project partner. The GA will meet face-to-face, preceding and preparing the contractual reporting obligations to the European Commission (EC). These meetings will be used to review the progress of EnTIRE discuss problems and formulate advice on future directions. As such, the GA is the appropriate internal advisory body in the following issues:

- Disputes: in case of disputes between two or more partners the GA will advise on any resolving measures by majority voting.
- IPR: management of IPR strategy, queries and exploitation.
- Dissemination: perform regular review and approval of dissemination plans.

In addition, the GA has specific decision-making responsibilities in the following issues:

- Taking decisions on alterations in work package-related activities and associated budgets.
- Budget-related matters and allocation of financial resources.
- Reporting to the European Commission: agreement on the completeness, timeliness and quality of all formal reports to the European Commission.
- Consortium composition: identification of and corrective measures to (including termination) defaulting, adding and replacement of partners and the change of the coordinator.
- Deciding on corrective measures in case of anticipated or unanticipated contingencies
- Changes in the CA: changes in the rights and obligations of the partners and/or decision-making procedures that necessitate amendments in the agreement.

The GA is chaired by the principle investigator Prof. Guy Widdershoven: PI of the coordinating beneficiary, the VUmc. Extraordinary meetings can be convened at any time, following a written request by (or via) the Executive Board. At other times, communication between the GA members and the consortium will take place via means of postal mail, e-mail and telephone. The CA will address further details of above mentioned issues including voting procedures, veto rights, representations and agreed procedures on distribution of meeting documents.

3.2.2. Executive Board

The Executive Board (EB) acts as the central management team of EnTIRE, and is responsible for overall monitoring of the scientific and financial progress of the project activities towards the main objectives of the project. The activities of the EB are based on agreed deliverables and associated milestones, within the budgetary limits. It consists of the work package leaders of WP3, 4 and 5 (Prof. Kris Dierickx, Prof. Anna Marušić, Prof. Bert Gordijn respectively and is chaired by Prof. Guy Widdershoven (PI). The EB is responsible for and has decision-making authority in the following issues:

- Agenda setting: definition of the scientific agenda and monitoring of the overall course of the project, including major deviations in the course, objectives and/or financial budgets of the activities that require consulting the European Commission and amendments to the contract with the European Commission.
- Preparation and organisation of management meetings, including those of the GA. This entails timely preparation and distribution of the agendas and any supporting documents necessary for the meeting.
- Monitoring the inter-work package alignment and progress of the work package deliverables towards the overall objectives of EnTIRE
- Monitoring the progress of the activities towards the specific deliverables and objectives of the work package, based on the defined milestones and means of verification.

- Drafting of the reports and associated documents and forms as required by the agreement with the European Commission.
- Informing and reporting to the GA of any major modifications in to the project related work and/or deliverables together with proposing appropriate measures.
- Advising the GA on corrective measures in case contingencies occur
- Liaising with external stakeholders, streamlining and coordinating activities of EnTIRE with other to the project relevant activities to ensure synergies and avoid redundancies and duplications.

The EB will meet at least twice a year; one of these meetings will be a telephone conference, whereas the other meeting precedes the annual GA meeting. Additional meetings can be convened at any time following a written request by any member of the EB to the chairman. All decisions in the EB will be taken by majority voting.

3.2.3. Advisory Board

By means of the external Advisory Board (AB), EnTIRE will seek regular external advice on relevant issues. The AB will provide expert advice on the quality of the deliverables, in order to oversee that the project will develop in accordance to the appropriate legal, ethical and social issues, general philosophy and direction of the project. It will also advise on corrective measures in the content of the work if necessary and the dissemination and exploitation of the projects results. The AB has no formal decision power within the project. The members of the AB are independent and therefore no budget is reserved for AB consultations. The members of the advisory board are be selected for:

- their experience in research and project management,
- their prominent role in their respective scientific communities,
- their prominent role in national and international policy making, and/or
- their link to relevant stakeholders.

Persons will be invited when necessary and in consultation with the EC representative. The following persons and/or organisations are committed take seat in the AB (Table 11).

Table 11. Advisory Board Members.		
Representative on AB	Organisation / affiliation	Expertise relevant to the project
Prof. Ray de Vries,	University of Michigan	Professor Emeritus in the Department of Learning Health Sciences and the Department of Obstetrics and Gynecology at the University of Michigan. Prof. de Vries has a long-term interested in the regulation of science and the production of scientific knowledge and has published extensively on research misbehaviours.

Representative on AB	Organisation / affiliation	Expertise relevant to the project
Dr. Maura Hiney	Health Research Board, Science Europe, ALLEA	Head of Post-Award Management and Evaluation at Health Research Board (HRB) and Chair of ALLEA Task group on research integrity and Chair of Science Europe Working Group
Dr. Nicole Foger	European Network of Research Integrity Offices & Austrian Agency for Research Integrity	Chair of European Network of Research Integrity Offices (ENRIO)
Dr. Elizabeth Moylan	BioMed Central, Committee on Publication Ethics (COPE)	Senior Editor for Research Integrity on the BMC open access-series journals, Council Member for COPE

3.2.4. Coordinator - Project Office

In compliance with the GA and consistent with the CA, the coordinating institute, or Coordinator (CO) VUmc, will be the intermediary for any communication with the Commission and any partner. As such, the CO will be responsible for:

- Acting as the primary spokesperson on behalf of the participants of EnTIRE for all formal written and verbal communication with the European Commission.
- Collecting, reviewing and submitting the obliged reports, technical input and associated documents and forms to the European Commission as required by the GA.
- Administering and distributing the financial contribution of the European Commission to the partners as agreed in the GA and CA.

The CO employs a dedicated Project Office (PO) that acts as central day-to-day management office. The PO is located at the premises of partner 1 and consists of the PI, a project manager, a financial controller/administrator and a project secretary. The main duties of the project office include the activities allocated to WP1: Project management. This includes the preparation of the EB meetings, preparation and timely distribution of the agendas as well as supporting documents and minutes of the meetings. If necessary, the Project Office can be expanded with a legal and/or financial and/or valorisation expert to support the PI. Under responsibility of the coordinating PI Prof. Guy Widdershoven, the project manager will execute all daily administrative, legal and financial issues concerning the whole project and will be in direct contact with the representatives of the European Commission. The financial controller will assist the project manager in monitoring the budget and financial reporting to the EC and is available to the consortium partners for financial or budgetary questions during the implementation of EnTIRE. Furthermore, the Project Office has dedicated support offices at its disposal to provide expert legal, administrative, financial and project management advice and support to the project management team. These services include a Technology Transfer Office, the Grants Desk VU/VUmc, and Project Control and Administration Office.

3.2.5. Work Package Teams

At the operational level, the task of Work Package Teams (WP Teams) is to ensure an effective and efficient implementation of the activities within their WP. WP Teams consist of the WP Leader and other key investigators that are participating in that specific WP.

WP leaders are responsible for developing detailed WP implementation plans on the basis of the current proposal, and for the efficient and effective implementation of these plans. More specifically, the Work Package leaders are responsible for:

- Input on their work package for the work plan.
- Informing the project Coordinator on a quarterly basis, or more frequently if so required, about the progress made to allow the coordinator to control the project and implement corrective actions if needed.
- Task assignment for individual members of the WPs.
- Progress monitoring of milestones and expected outcomes of the WPs (Table 10).
- Reviewing all deliverables, as part of the quality controls.
- Delivering input to the coordinator for the preparation of reports.
- Organisation of stakeholder/user workshops (if included in the WP).
- Organisation of work package meetings if necessary to ensure proper execution of their WP.
- Stimulation of interaction and proactive sharing of information with other work packages.

Extraordinary reporting to the Coordinator will be provided by the WP leader particularly in cases of a specific milestone or deliverable of the WP being in danger of being delayed or unattainable relative to the schedule. This shall include a suggestion for remedies or solutions regarding the apparent shortcoming to keep the project on schedule and to minimize unfavourable consequences for other WPs and the project as a whole. Related decisions to be taken will be brought to the attention of the EB and decision-making of the EB will be assured in a short time – either by a regular or – if appropriate – an extraordinary meeting or email.

Work Packages (WP) will be implemented by the WP partners, each of which will be led by a WP leader. Each WP has been divided into tasks with clearly defined activities and outputs. Tasks are led by a Task leader who will be responsible for management of the research within the task. This structure provides WP leaders with support in the execution of their WP duties however the final responsibility for implementation of all tasks remains with the WP leader. The Coordinator will support the WP leader in the implementation of all WPs stepping in to ensure the work plan is adhered to. The Coordinator will organize regular conference calls (at least once in two months as necessary more frequently) with WP leaders, and – as necessary - partners involved in each WP. Progress reporting by each WP leader will be made at General Assembly meetings.

3.2.6. Partners

Each participant appoints one formal contact (the Principle Investigator, PI) for the GA. This partner contact is the first spokesperson for his/her institute vis-à-vis the GA and the Project Office on issues (a.o.) related to:

- IPR and use and dissemination of foreground.
- Financial performance in relation to the partner budget input (e.g. Forms C or certificate of costs).
- Legal and/or ethical issues.
- Reporting.

3.2.7. Quality Procedures

The PO will implement standard quality procedures, to ensure smooth management and monitoring of the project progress and to ensure the quality of all outputs of the project in particular deliverables. The procedures include, amongst other things, the establishment of meeting and communication procedures, guide on reporting procedures, standard procedures for data collection and procedures on conflict mediation and corrective actions.

Before submission to the EC, the quality of all deliverables will be checked with a system of academic peer review and also quality control. Each deliverable will be subject to a peer review either by the external advisors or by two scientific experts from the across the project consortium. The overall quality and delivery against the Description of Work will then be checked at two at three levels by:

- the partner responsible for producing the deliverable
- by the WP leader and
- by the Coordinator.

Any issues with quality will be resolved before final approval and submission to the EC.

3.2.8. Communication

To be effective as a large collaborative consortium, sound internal communication is essential. To that end, EnTIRE will implement a communication strategy aimed at efficient and effective communication with all relevant stakeholders. The EnTIRE platform will be instrumental with this, maintained by our partner 2. GI. A collaborative working platform will be set up in order to provide the appropriate tools for distributing information internally in an effective and user friendly way. WP7 will be responsible for the public part of dissemination and will take the lead in drafting the communication strategy (as part of the dissemination plan).

3.2.9. Meetings

For all meetings, the chair (the Coordinator for the GA and EB and the WP Leaders for the WP Teams) is responsible for preparation, planning and if necessary a follow-up of the meetings. Table 12 gives an overview of the several meetings and their characteristics.

Table 12. Intended Meetings.			
Body	Frequency	Preparation	Method and scope
General Assembly	Every year	EB	Face to face - formal accord on progress reporting to EC, decisions affecting CA and/or EC contract, knowledge dissemination and exploitation, dispute resolution.
Executive Board	Every 6 months	EB	EB meetings are alternating between interim meetings that will be held through telephone conferencing, and face to face meetings that precede the annual GA; coordination, overall progress of the WPs to the project objectives, inter WP alignment, scientific discussions and associated decisions, financial reporting, reporting to the GA.
Advisory Board	Every 12 months	EB	Regular contact, Face to face & teleconference. For external advice on relevant issues.
WP Teams	Frequently	WP Leaders	Face to face & teleconference; WP progress, intra WP alignment of tasks, financial monitoring.
All members of the consortium	Every 12 months + 1 kick-off meeting	EB	Face to face - exchange of scientific data with a special focus on junior staff and bench workers with the aim to share information between WPs, and accelerate implementation of information.

3.2.10 Reporting

In addition to regular periodic reports, a final report will be submitted, within 60 days after the end of the project. This final report shall comprise:

- A final publishable summary report which includes: an executive summary, a summary description of project context and objectives, a description of the main S&T results, the potential impact (including the socio-economic impact of the project) and the main dissemination activities and exploitation of results/foregrounds
- A plan for the use and dissemination of foreground, to spread awareness on exploitation or the project results.
- A report covering the wider societal implications of the project, in the form of a questionnaire, including gender equality actions, ethical issues, efforts to involve other actors.

The final report, cost certificates (audit certificates) and other deliverables foreseen will be sent to the EC representative by the deadline given in the contract.

The CA will detail all other project specific reporting procedures. Each report will have a defined frequency, format and list of topics to be covered. All reports will be distributed within a set time-limit which as agreed upon in the GA or CA, before the respective meeting. The reports listed above cover the formal reporting obligations to the EC. Other scientific and/or technical documentation to be circulated amongst the various consortium partners as a result or part of scientific and/or technical activities within the project is not included. In addition, the lead investigators from each of the consortium partners will be held responsible for providing the Coordinator with relevant and necessary input (e.g. Forms C or certificate of costs) towards the obligatory formal EC reporting. Financial reporting will be done through the Participant Portal. Towards this end, each partner will appoint a Financial Statement Authorised Signatory (F-SIGN). An overview of reporting is provided in Table 13.

Table 13. Delivery of Periodic Reports.	
Report	Delivery date (month)
Periodic Report	M 18
Periodic Report	M 36
Final Report	M 48

3.2.11 Critical Risks

No project is without its risks. Critical risks identified by the consortium, and possible mitigation measures, are outlined in Table 14.

Table 14. Critical Risks.		
Description of risk	Work package(s) involved	Proposed risk-mitigation measures
Lack of communication, lack of respect for planning and deadlines, or partner underperformance	WP1	An adequate management structure has been designed, which will be carried out by management-skilled academics and experienced consultant companies. Frequent (teleconference) meetings will be held. Most partners already know each other in their respective fields.

Description of risk	Work package(s) involved	Proposed risk-mitigation measures
Organisational financial problems require reducing project budget	WP1	All partners will monitor audit certificates and financial problems and will report to the EB on a regular and planned basis.
Partner leaves the consortium	WP 1	Consortium partners have a large mutual drive to work together. In the unlikely event a partner leaves the consortium, all partners will be responsible for seeking a new partner that has similar capabilities and is able to finish the work. All participants have an extensive network to tap into. For other parts, the remaining partners will finalise the work.
Lack of integration of results of partners leading to underperformance	WP 1	An adequate management structure has been conceived. The consortium partners will organise dedicated site visits and exchange of personnel if needed.
A potential risk is the lack of willingness of stakeholders to participate in the face-to-face focus groups.	WP 2	The partners involved in the identification and invitation of stakeholders for each country know the field very well and are able to address relevant individuals and organisations personally if interest is low.
A potential risk is the large number of elements in the normative framework.	WP 2	The partners involved in analysing the focus groups have experience in clustering data and determining core concepts. By organizing two rounds of focus groups, the stakeholders will be included in this process. Results will also be discussed with the Advisory Board.
A potential risk is the lack of willingness of stakeholders to participate in the online focus groups.	WP 2	The partners in the project together know relevant colleagues in all European countries which will be asked for assistance in identifying and inviting participants.
Based on our experience with the collection of national guidelines and legislation in EFTA member states it is clear that most of these (at that time national) documents are not always easy to find, although one would expect otherwise. A possible risk is that the period of the project will not be sufficient to collect all the relevant documents in the EU member state.	WP 3	We expect that the expertise and experience of our consortium, and the existing network of national contact persons will be able to limit this risk.

Description of risk	Work package(s) involved	Proposed risk-mitigation measures
A potential risk is the lack of willingness of stakeholders to contribute to data collection.	WP 4	The partners involved in the identification and invitation of stakeholders for each country know the field very well and are able to address relevant individuals and organisations personally if interest is low.
A potential risk is the systematization of possibly very heterogeneous data from different countries.	WP 4	We will use the normative framework developed in the stakeholder consultation and experience from other organizations (such as World Health Organization country statistics, http://www.who.int/gho/countries/en/) to construct the information so that it includes general indices of RE+RI plus individual country specificities.
A potential risk is the language barriers, particularly for information from the South-East Europe.	WP 4	The lead partner for the WP (MEFST) has excellent contacts in the countries of the region and speaks similar language to many of the countries in the region.
A potential risk is the number of RE+RI cases that are found, which may be either too small or too large. If the number is too small, further search strategies will be applied, making use of expert knowledge of partners and other RE+RI leaders. If the number is too large, methods of limiting the number of cases will be deployed in the search strategies such as exclusively focusing on a recent time period.	WP 5	It has to be kept in mind that a community will be established, dedicated to the project's long-term continuity of the online forum. So the platform will be interactive and sustainable, meaning that additional cases can be gathered, added and analysed after the EnTIRE project has been completed. Hence, aiming to be exhaustive is not pivotal.
The project becomes dependent on the ICT supplier through the use of proprietary software.	WP6	This risk is fully mitigated as we will only work with open source software and will publish the entire platform online together with sufficient documentation. This ensures that any other ICT firm (and the open source community) can continue to work with the platform. The platform is created by and for the community and will become an entity (non-profit organisation) independent from the ICT partner and the consortium by using this approach.

Description of risk	Work package(s) involved	Proposed risk-mitigation measures
The platform will be attacked by computer hackers	WP6	We will ensure the latest versions of relevant software packages to mitigate this risk. Also adequate infrastructure to prevent common security attacks will be used. Moreover, a back-up of the platform will be created on a daily basis.
The vastness of (different types of) content on the platform inhibits efficiently finding what is relevant.	WP6	As mentioned in Section 1, several similar attempts in the US have succumbed to this risk. In this project it will be actively mitigated by using a software platform which was designed to handle large and different types of content (Wiki-software). The advisory board includes professor Ray de Vries from the University of Michigan in the US who, based on the prior experience in the US, will advise about what is relevant.
Lack of volume of users ('critical mass')	WP7	Approaches include but are not limited to giving stakeholders an active role, distributing the benefits of an open access platform, active lobbying of research organisations and tailoring the incentives (taking into account any cultural differences).
Not achieving an elaborate community and stable long-term committed user base.	WP7	The EnTIRE platform allows for effective community management by design. Moreover, the lead of WP 7 has experience in open source community management, the overall lead of the project has an elaborate network in RE+RI and has invited other WP leads with similarly sized RE+RI networks which mitigates this risk.
Lack of budgets and external investments for long-term sustainability.	WP7	The community approach will mitigate this risk, because financial needs will be comparatively limited and community members will include organisations which can act as lead and partners in the future consortium.

3.3. Consortium as a whole

The EnTIRE consortium consists of 10 partners from 9 different institutions, located in 9 different countries, within and beyond the EU. Each partner has been carefully chosen to reflect leading expertise in the tasks and WPs they will participate in. Consequently, there are many complementarities, for example. The scientific partners are all leading experts in

research ethics and research integrity. Partner 2 (GI) is a specialist in building an open access interactive Wiki-platform.

The lead partner 1 (VUmc) has a track record in addressing normative issues and providing normative support by fostering stakeholder participation through qualitative research, both nationally (in developing networks for clinical ethics support and for patient participation in healthcare, and internationally (for instance the European Clinical Ethics Network). Other partners, especially 6 (JEM), 9 (UNIMAN), and 10 (EUREC), are also experts in the field of stakeholder research. The participatory approach, focusing on stakeholder consultation and community engagement, is endorsed by all partners.

The partners who are responsible for the collection of data (WP3-5) have much experience in assembling and analyzing large data sets. Partner 3 (KUL) has made an inventory of European Laws, regulations, codes and guidelines, published in *The Lancet*. Partner 4 (MEFST) has a broad overview of resources, such as teaching materials and contact persons. Other partners, especially 9 (UNIMAN) and 7 (UNIDEB) will assist, bringing in their expertise. Partner 5 (DCU) has experience in collecting cases, and is an expert in case analysis and making scenarios. The other scientific partners are also experienced in gathering RE+RI normative documents, resources and cases, and will assist in collecting and analyzing data. The distribution of partners over various European regions ensures that the consortium will be able to reach all EU countries (see Section 3.3.3).

The platform will be built by partner 2 (GI), who has expertise in WikiMedia, and has experience in making a platform in interaction with key-users. In order to make the platform sustainable, the RE+RI community will be engaged. Partner 1 (VUmc) has large experience in fostering community engagement in large projects aimed at reforming healthcare practice (in primary healthcare and mental healthcare), using a stakeholder approach. All partners are active in several relevant networks and communities, including ENERI, PRINTIGER, HIERRI, FOSTER, RRI-TOOLS, EnRRICH, COPE, and others. Thus, the consortium is firmly rooted in the RE+RI community and will be able to engage this community in the process of making the platform sustainable.

Through a joint commitment to stakeholder participation and community engagement, a shared awareness of the importance of (differences in) RE+RI practices, and the conviction that making accessible RE+RI information requires an interactive and open access platform, the EnTIRE consortium members will effectively work together with a clear focus, contributing their expertise in a complementary way.

Lastly, the consortium posits an Advisory Board that consists of experts from different countries within and beyond the EU. These experts will consistently provide advice on the deliverables of the EnTIRE project (Table 9).

In all, the consortium is balanced over the objectives and is efficient, primarily aimed at achieving synergy and excluding any unnecessary overlap in expertise and resources. These complementarities are maximised by the inclusion of well in depth knowledge, expertise and experience with collaborating in large consortia.

3.3.1. Track record and achieved impact

Excellence is a prerequisite for achieving impact. The EnTIRE partners individually and in partnership have demonstrated their contribution to academic advances across and within relevant disciplines more than once. For example, partner 1 (VUmc), 3 (KUL), 5 (DCU), and 10 (EUREC) have provided significant advances in our understanding of the relation between empirical science and bioethics, developed innovative research methods such as interactive empirical ethics, and contributed to the development of the theory on empirical bioethics.

Besides this evidence of having academic impact, the partners individually were involved in the uptake and usage of their academic results by healthcare professionals and institutions. A compelling examples is the implementation of Clinical Ethics Support (especially Moral Case Deliberation) in Europe, with a leading role for partner 1 (VUmc) and 8 (UiO).

Another important prerequisite for achieving impact is to have excellent communication capacities. As various the track records of the involved partners show, this consortium is well equipped to engaging in societal debates, to communicate scientific results to a wider public and with that, to create support and engagement to ensure a sustainable impact.

3.3.2. Community wide network and access to stakeholders

All partners are highly active in their respective context and have access to and active participation in relevant networks and organisations. Some examples are: the central role of partners 1 (VUmc) , 3 (KUL), 4 (MEFST), 5 (EDC), 6 (UEM), 7 (UNIDEB) , 8 (UiO), 9 (UNIMAN) and 10 (EUREC) in national and international bioethics organisations, and the central role of partners 1 (VUmc), 3 (KUL), 4 (MEFST), 8 (UiO), 9 (UNIMAN), and 10 (EUREC) in RE+RI networks.

Measured by current and previous participation in national, European and global networks and their active relations with important stakeholders, EnTIRE ensures capitalisation on current networks and knowledge available throughout the EU.

3.3.3 A balanced geographical spreading

The EnTIRE consortium consists of 10 partners from 9 different EU Member States and 1 Associated Country (Fig. 5) illustrates the diversification and geographical spread ensuring the expected pan-European impact. While ensuring the benefits of a geographical diverse composition of the consortium, all partners included bring together the various specific competences in one or more technical aspects of the research plan, allowing the successful achievement of the objectives set in this call. The consortium as a whole is balanced over the objectives and is efficient, primarily aimed at achieving synergy and excluding any unnecessary overlap in expertise, geographical location and resources.



Figure 5. [doi](#)

Geographic spread of participants.

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