Roadmap towards adoption of a fully developed ethics assessment framework

Authors: Anna Leinonen (VTT), Raija Koivisto (VTT), Anu Tuominen (VTT,) David Douglas (UT), Agata Gurzawska (UT), Philip Jansen (UT), Alexandra Kapeller (UT), Stéphanie Gauttier (UT) Philip Brey (UT)

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Contact details for corresponding authors:
Anna Leinonen, VTT Technical Research Centre of Finland
anna.leinonen@vtt.fi
Dr. Raija Koivisto, VTT Technical Research Centre of Finland
raija.koivisto@vtt.fi

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LIST OF ABBREVIATIONS

CEN	European Committee for Standardization
CIOMS	Council for International Organizations of Medical Sciences
CSO	Civil Society Organisations
CSR	Corporate Social Responsibility
EA	Ethics Assessment
EIA	Ethical Impact Assessment
GMO	Genetically Modified Organisms
NEC	National ethics committees
NGO	Non-Governmental Organization
OECD	Organization for Economic Co-operation and Development
PO	Professional Organisations
R&I	Research and Innovation
REC	Research Ethics Committees
RFO	Research Funding Organisations
RRI	Responsible Research and Innovation
SA	Science Academies
SME	Small and Medium-sized Enterprises
TPB	Theory of Planned Behaviour
UN	United Nations
UNESCO	United Nations Educational, Social, and Cultural Organization
WHO	World Health Organization

SATORI

ABSTRACT

The aim of the SATORI roadmap process was to work out how the SATORI ethics assessment framework can be implemented in practice. The timespan of the roadmap was set at 10 years. To begin, a *vision* of a future in which the SATORI framework is implemented was formulated. Theories about the implementation of new social practices were subsequently studied, and a model for the implementation of the SATORI framework was constructed. This model was then used as the basis for identifying the *steps* (or *outcomes*) that need to be taken in order to realise the vision. Finally, these steps were fleshed out by listing *recommendations* and associated *actions* that need to be taken by various stakeholder groups that are involved in ethics assessment of research and innovation.

Our graphical presentation of the SATORI roadmap integrates the aforementioned steps towards the vision with key *institutional* and *procedural* actions that are necessary to realise these steps. The institutional and procedural actions were identified through (1) the use of previous work in SATORI (including 230 interviews with experts in ethics assessment[1], and various reports on the state of ethics assessment in various types of organisations[2,3,4,5,6,7,8]) and (2) the organisation of two SATORI roadmapping workshops[9]. Besides the SATORI roadmap graphic, this deliverable reports on the process of creating the roadmap and it includes a number of tables that list more detailed recommendations for reaching the roadmap vision, with corresponding actions, actors who should perform the actions, and timeframes in which to complete the actions.

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[1] Shelley-Egan, C., P. Brey, R. Rodrigues, D. Douglas, A. Gurzawska, L. Bitsch, D. Wright and K. Wadhwa, "Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries", SATORI D1.1 including 5 annexes, June 2015. (see http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/)

[2] Wolfslehner Doris, Wessel Reijers & Sudeep Rangi, "Standards, tools and best practices for policy-oriented assessment and guidance of new developments and practices in research and innovation", SATORI Task 4.2.1 report, February 2016, 20 p.

[3] Benčin Rok, Gregor Strle, Sudeep Rangi & Dubravka Vejnović, "Standards, tools and best practices for guiding, assessing and supporting ethical professional behaviour by scientists and innovators", SATORI Task 4.2.2 report, March 2016, 33 p.

[4] Jansen Philip & Agata Gurzawska, "Standards, tools and best practices for the ethics assessment of innovation and technology development plans", SATORI Task 4.2.3 report, April 2016, 8 p.

[5] Brey Philip, David Douglas, Alexandra Kapeller , Rok Benčin, Daniela Ovadia & Doris Wolfslehner, "Models for Ethics Assessment and Guidance in Higher Education", SATORI Task 4.2.4 report, March 2016, 26 p.

[6] Warso Zuzanna & Dalibor Petrović, "Models for ethics assessment and guidance at CSOs", SATORI Task 4.2.5 report, March 2016, 16 p.

[7] Gurzawska Agata, Andrea Porcari, "Models for ethics assessment and guidance in industry", SATORI Task 4.2.6 report, March 2016, 34 p.

[8] Doris Wolfslehner, "Standards, tools and best practices for policy-oriented assessment and guidance of new developments and practices in research and innovation - Models for ethics assessment at research funding organisations", SATORI Task 4.2.7 report, 2016, 13 p.

[9] SATORI partners' workshop in Copenhagen on the 31st of May, 2016, and the expert workshop in Vienna on the 20th of June, 2016.

1   INTRODUCTION

The SATORI project (Stakeholders Acting Together on the Ethical Impact Assessment of Research and Innovation) has as its aim the creation of an ethics assessment framework for research and innovation. This should be achieved by acting together with different stakeholders concerned. These stakeholders represent different disciplines, kinds of organisations, cultures, and countries: some of these already have highly developed ethics assessment practices in place, whereas others lack them entirely. The potential impacts of emerging technologies, globalisation, climate change, and other developments provide significant challenges to ethics assessment in research and innovation. Harmonized structures and practices in ethics assessment are therefore needed that are comprehensive, robust, and widely accepted.

Roadmapping is a tool to gather the needed constituents to form a vision and to present the result on a time frame in a visual form. The roadmapping process typically includes participatory processes where different kinds of stakeholders have say in the development of the roadmap. There are many ways to create a roadmap. The process may include literature studies, surveys, and workshops. The roadmapping expert is the one to select the optimal process for the situation depending on the calendar time and resources in use for the purpose.

The aim of the SATORI roadmap process is to work out how the SATORI ethics assessment framework can be implemented in practice. For that purpose, a special application of the roadmap process was designed which implements the idea of the social change. This was achieved by integrating various theoretical approaches, participatory elements and the extensive information collection done in the earlier phases of SATORI project.

Section 2 provides brief descriptions of the SATORI ethics assessment framework and the types of stakeholders involved in ethics assessment of research and innovation, thus offering context for the roadmapping work. Chapter 3 explains the roadmapping process used in this deliverable. Chapter 4 discusses the implementation of a new social practice. Chapter 5 presents the resulting SATORI vision and roadmap to the vision. Finally, chapter 6 presents recommendations based on the roadmap and previous work in the SATORI project.

2 CONTEXT: PERFORMING ETHICS ASSESSMENT

2.1 ETHICS ASSESSMENT FRAMEWORK

The SATORI framework[10,11,12] is concerned with *ethics assessment*: that is, an institutional form of applying (primarily) ethical principles and criteria to assess, review, appraise or evaluate research and innovation (R&I) activity. This activity may include basic research, applied research, or product development and testing. It is an institutionalised or formal method of assessment as it is performed within an institutional setting, with defined procedures, by an organisation or a particular unit within a larger organisation. Such assessment may be performed by research ethics committees (RECs), universities, industry, research funding organisations (RFOs), civil society organisations (CSOs), or other organisations with an interest in R&I activity Ethics assessment is also distinct from ethics *guidance*, which is to produce codes of conduct for ethical behaviour and to provide advice.

The central unit of ethics assessment is called an ethics committee in this report. This term is intended to include research ethics committees, Institutional Review Boards, ethics divisions, ethics officers and other organisational units that have as their mission to performs ethics assessment of R&I activity. Ethics committees can be found in universities, medical hospitals, research funding organisations, civil society organisations, and other organisations that assesses R&I activity for potential ethical concerns. While Ethics committees may also provide ethics guidance, it is their role in ethics assessment that the SATORI framework is intended to address.

The SATORI framework presents both a set of ethical principles and issues that can assist in identifying and resolving potential concerns, and a series of recommendations for how organisations should perform ethics assessment. An objective of the framework is to identify common ethical principles and issues that arise in the different fields where R&I activity occurs. It also aims to demonstrate the existing similarities in how ethics assessment is performed across different research fields, organisations, and countries. Highlighting and building upon these similarities allows for the creation of a common framework that may be adopted by any ethics committee, regardless of its size, the R&I activity it assesses, or whether it operates at the local (institutional), regional, or national level.

The set of ethical issues and principles proposed in the SATORI framework draws on the survey of the different fields where R&I activity occurs that was conducted at the start of the SATORI project. By drawing on both this survey and by consulting the academic literature on research and professional ethics, we distinguish between principles and issues that are common to all types of research, and principles and issues that are relevant to specific fields of research and innovation. The categories of common ethical principles and issues relevant to all fields of research and innovation are:

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[10] Callies Ingrid and Philip Brey (Editors), 2016. "Outline of an Ethics Assessment Framework". Part of the SATORI D4.1. 36 p.

[11] Jansen, P., W. Reijers, D. Douglas, A. Gurzawska, A. Kapeller, P. Brey, R. Benčin, and Z. Warso, 2016. "A reasoned proposal for shared approaches to ethics assessment in the European context". SATORI D4.1, December 7, 2016, 182 p.

[12] CWA SATORI-1:2016. "Ethics assessment for research and innovation — Part 1: Ethics assessment unit", A CEN draft, NEN 2016.

- Professional Principles
  - Research integrity and professional integrity;
  - Avoidance of and openness about potential conflicts of interest.
- Research Practice
  - Protection of human research participants;
  - Protection of animals used in research;
  - Protection and management of data and dissemination of research results;
  - Protection of researchers and the research environment.
- Impacts of research
  - Social responsibility

The six fields of research and innovation that have ethical principles and issues that specifically relate to their subject matter are:

- the natural sciences;
- the engineering sciences and technological innovation;
- the medical sciences;
- the life sciences;
- the computer and information sciences;
- the social sciences and the humanities

The framework of common ethical principles and issues serves as a toolkit to assist Ethics committees in identifying and evaluating ethical concerns in the R&I activity they assess. In addition to these recommendations, the framework also presents recommendations for best practices in the structure and operation of Ethics committees themselves. It distinguishes between several parameters that are relevant to the effectiveness of Ethics committees. These parameters are:

- The composition of the ethics committee's membership and the expertise of its members
- The appointment and training of ethics committee members
- Procedures prior to assessing R&I activity
- Procedures for assessing R&I activity
- Procedures that follow the assessment of R&I activity and the appropriate supervision of the ethics committee
- Quality assurance for the ethics committee's work
- Efficiency considerations for the ethics committee's work
- Cultural and organisational factors that may affect the ethics committee's work.

The framework presents a number of recommendations for best practice in each of these parameters. These recommendations are based on the review of existing ethics committee practices that were revealed during the project's survey of how ethics assessment is currently performed across Europe and in the US and China. The academic literature on research ethics and ethics assessment is also used as a source for recommendations.

ETHICAL IMPACT ASSESSMENT

Another important element of the SATORI framework is a proposal for an ethical impact assessment (EIA) methodology.[13,14] This proposal draws on existing methods of impact assessment and ethical impact assessment methods for specific fields (such as information technology) to develop a new methodology that is applicable to all forms of R&I activity.

The proposal for EIA begins with a *threshold analysis* that determines whether performing the EIA is necessary, and if so, what the scale of the assessment should be. If the threshold analysis confirms the need for EIA, further preparatory work is performed before the assessment begins in earnest. This preparatory work includes determining the available budget, establishing the terms of reference for the assessment, identifying the relevant stakeholders to be consulted during the assessment, and confirming that the planned assessment meets all of the necessary ethical and legal requirements.

Following the completion of this preparatory work, the *foresight analysis* begins. This stage collects information and develops plausible scenarios for the research or technology that is object of impact assessment, and the social and environmental consequences resulting from these developments. The foresight analysis relies on a balanced combination of expertise, interaction, creativity and evidence to produce these potential future scenarios.

The outcomes of the foresight analysis serve as the material for the actual ethical impact assessment itself. The assessment process has three stages: *identification, evaluation*, and *final steps*. The identification stage determines the ethical aspects of the R&I activity being assessed. Checklists of ethical issues, other forms of ethics assessment, literature reviews, and expert interviews are possible sources for the values and principles that are used in this stage.

Once the issues have been identified, the evaluation stage determines their significance and how they might be resolved. This involves considering the relative importance of the various values and principles that are relevant to the activity or technology being assessed, the urgency of the ethical issues raised by the activity, and the likelihood of the potential issues that have been identified.

Following the completion of the evaluation, the assessor presents recommendations for how the identified issues should be addressed. This is the final steps stage. The recommendations may then be applied to the R&I activity. The EIA process itself may be reviewed and audited for effectiveness. For on-going R&I activity, it may go through the EIA process several times during its duration, as EIA recommendations are implemented and tested to ensure that any unforeseen ethical issues that emerge during the course of the activity are identified and addressed.

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[13] Jansen, Philip, Wessel Reijers, David Douglas, Agata Gurzawska, Alexandra Kapeller, Philip Brey, Rok Benčin, Zuzanna Warso, "A Reasoned Proposal for Shared Approaches for Ethics Assessment in the European Context", SATORI Deliverable D4.1, December 2016. See Annex 1: "A Reasoned Proposal for Ethical Impact Assessment"

[14] CWA SATORI-2:2016, "Ethics assessment for research and innovation — Part 2: Ethical impact assessment framework". A CEN draft. NEN 2016. 37 p.

2.2 STAKEHOLDERS

In roadmapping exercises, it is important to identify the stakeholders for the activity in question. Different stakeholders have different roles in ethics assessment, and they can contribute in different ways to the change that is desired. Figure 1 shows the different roles of stakeholders in the context of ethics assessment of research and innovation. The middle column of the figure lists those organisations or organisational units that perform ethics assessment activity. These organisations include research ethics committees, national ethical committees, research funding organisations, civil society organisations, and other organisations that *assess* R&I activity for potential ethical concerns. The SATORI framework is aimed mainly at addressing the practices of these types of organisations. However, there are also other important kinds of organisations that have a stake in ethics assessment. The first column of Figure 1 lists types of organisations that have a role in regulation, guidance and policy setting in relation to the institutional and procedural context of ethics assessment of R&I. The third column, finally, lists types of organisations that play a role in dissemination and raising awareness on issues concerning ethics assessment or ethics assessment methods and procedures. The different stakeholders and their roles in ethics assessment of R&I are discussed in more detail in this section.
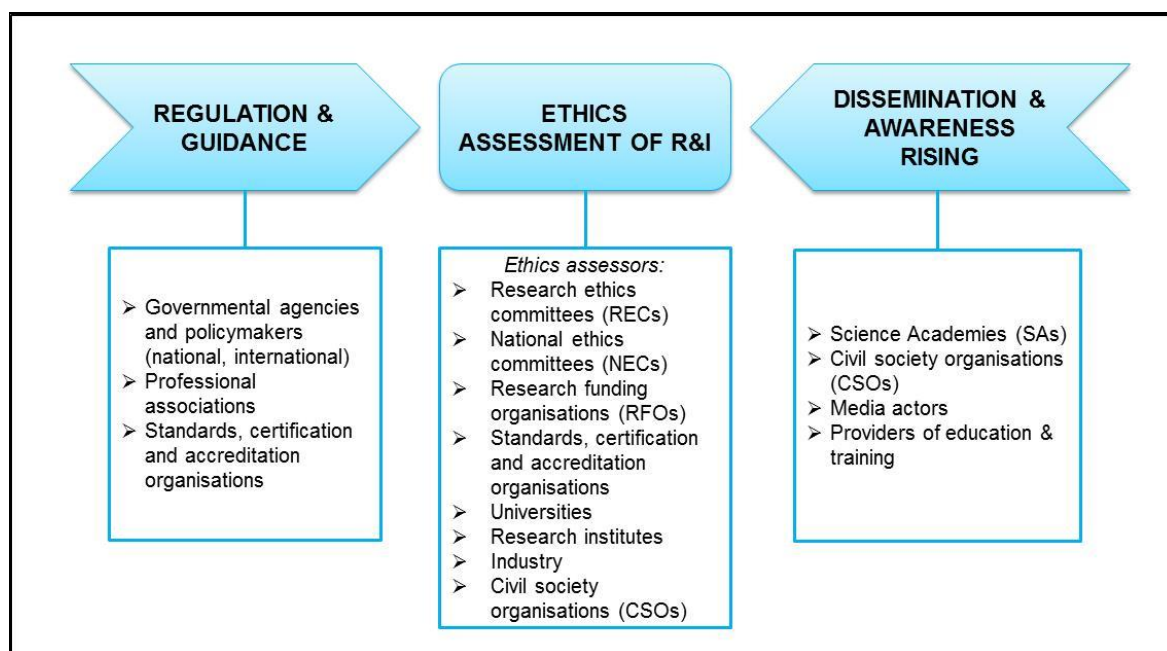
Figure 1. Relevant stakeholders and their roles.

Research ethics committees (RECs)

In the SATORI reports, RECs have been defined as 'multidisciplinary, independent groups of individuals appointed to consider ethical issues in research'.[15] RECs can operate on different

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[15] Díaz, Javier Arias, Mª Concepción Martín-Arribas, Laura Herrero Olivera, Leyre de Sola Perea, and Johanna Romare, "Ethics Assessment and Guidance in Different Types of Organisations: Research Ethics Committees", *SATORI D1.1*, June 2015, p.4. http://satoriproject.eu/media/3.a-Research-ethics-committees.pdf.

levels: local, regional and national.[16] Local RECs commonly belong to universities, hospitals or research centres. Regional and national RECs assess ethics in a certain geographical area. However, a REC is not necessarily limited to one level, since they can collaborate in networks and associations. As all RECs evaluate practices and products of research, RECs are ethics assessors.

National ethics committees (NECs)

The Universal Declaration on Bioethics and Human Rights advocated for the establishment of NECs.[17] Their set-up is characterized as pluralist, independent and multidisciplinary. NECs are commissioned to assess technological and scientific developments and to give recommendations.[18] In contrast to national RECs, which *assess* the ethics of actual research and innovation projects, NECs are committees that provide ethics guidance and policy advice.[19]

Research funding organisations (RFOs)

RFOs are, as their name suggests, not primarily assessing ethics, but supporting research with private or public funds. Accordingly, RFOs aim at improving the developments in science and innovation, as well as increasing the attractiveness for researchers in their location.[20] In the selection of which proposed researches to fund, ethics assessment plays an important part. As RFOs evaluate concrete products and procedures of research, they belong to the category of ethics assessors.

Science Academies (SAs) and Professional Organisations (POs)

Science academies are associations of distinguished researchers that promote standards of practice within their field and represent their field in society. They may provide policy advice to governments and present awards to recognise outstanding work in their field.[21] Part of their role is establishing the expected standards of ethical behaviour for researchers working in their field. Professional organisations perform a similar role for professionals who are not necessarily scientists but who also perform R&I activity, such as engineers.

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[16] Ibid, p. 5.

[17] Unesco, "Universal Declaration on Bioethics and Human Rights", http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

[18] Wolfslehner, Doris, "Ethics Assessment and Guidance in Different Types of Organisations: National Ethics Committees", *SATORI D1.1*, June 2015, p. 4. http://satoriproject.eu/media/3.b-National-ethics-committees.pdf.

[19] Díaz, Javier Arias, Mª Concepción Martín-Arribas, Laura Herrero Olivera, Leyre de Sola Perea, and Johanna Romare, "Ethics Assessment and Guidance in Different Types of Organisations: Research Ethics Committees", *SATORI D1.1*, June 2015, p.5. http://satoriproject.eu/media/3.a-Research-ethics-committees.pdf.

[20] Wolfslehner, Doris "Ethics assessment and guidance in different types of organisations. Research Funding Organisations." *SATORI D1.1*, June 2015, p. 6. http://satoriproject.eu/media/3.c-Research-ethics-committees.pdf.

[21] Strle, G., R. Benčin, J. Šumič-Riha, R. Riha, "Ethics Assessment and Guidance in Different Types of Organisations: National Science Academies and Academic & Professional Organisations." *SATORI D1.1*, June 2015, p. 4. http://satoriproject.eu/media/3.d-National-academies-of-science-and-POs.pdf.

Universities and research institutes

Universities are institutions that educate new generations of scientists and perform research. *Research institutes* specialise in research only. Ethics plays a role both in educational programmes and in relation to research. Universities often institute RECs to monitor their own research, and develop and implement ethical guidelines, assessment protocols and training programmes for staff and students. University RECs often have a guidance role and their advice is generally non-binding. Universities and research institutes have established *associations* at regional, national and international levels for the purposes of mutual cooperation. These associations often engage in ethical guidance, and may have their own ethical codes and guidelines as well as a research ethics or research integrity office.

Standards, certification and accreditation organisations

A *standards organisation* is an organisation whose primary activities are in developing standards, or specifications, to which products, services and systems should conform. To the extent that standards organisations provide standards that are based on ethical principles, they provide ethical guidance for organisations that follow the standard in question. Certification organisations are independent entities that provide an assurance that a product, service, system, person or organisation meets specific requirements. *Accreditation organisations* are organisations that ensure that organisations that offer certifications employ acceptable certification practices. In some case, accreditation and certification are explicitly focused on quality assurance in the realm of ethics (e.g., accreditation of organisations using animals in research, and standards for social responsibility). In other cases, meeting ethical criteria or paying attention to ethics may be one of the parameters that are assessed in accreditation or certification.

Industry[22]

Companies are legal entities engaged in commercial activities, usually with a for-profit motive. Companies vary depending on their size, from small and medium-sized enterprises (SMEs) to corporations including multinational and transnational corporations. Ethics assessment by industry is often related to the concept of CSR (Corporate Social Responsibility), which is well-established in the business world. In general, CSR refers to *responsibility*, hence duties and obligations or motivation and opportunities of the companies towards society. Companies, businesses and industry associations have various roles in the implementation of CSR. Firstly, they engage in the regulation and guidance through CSR policies intended to function as a self-regulating mechanism for business to ensure its compliance not just with laws, but also with the spirit of the law, with international norms and with ethical standards. Secondly, they engage in the ethics assessment of R&I (e.g. internal CSR officers or divisions and external CSR consultancy). Thirdly, they have a role to play in dissemination and awareness raising, particularly Business and Industry Associations and Chambers of commerce through facilitating networking and collaboration among companies.

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[22] Gurzawska, Agata, Rossella Cardone, Andrea Porcari and Elvio Mantovani, Philip Brey, "Ethics assessment and Guidance in Different Types of Organisations: Industry", SATORI D1.1 Annex 3.h, June 2015, 50 p. http://satoriproject.eu/media/3.h-Industry.pdf

Civil society organisations (CSOs)[23]

The concept of civil society encompasses a wide range of organizations, including all non-market and non-state organizations and structures in which people organize to pursue shared objectives and ideals. Examples are religious organisations, environmental organisations, civil liberties/human rights organisations, consumer (protection) associations, development (aid) organisations, animal rights organisations, disease charity and patient/disabled rights organisations, labour unions. Although activities carried out by CSOs are rarely termed as ethics assessment, many CSOs perform (informal) ethics assessment or guidance in the course of their activities, e.g. advocacy work. Assessment by CSOs is carried out at different stages of the R&I process and focuses on various elements. The objects of assessment/guidance range from the conduct of scientists, professionals, or companies, to the involvement of particular groups in research and innovation and the impacts of particular technologies. In order to influence policy making on a larger scale, CSOs offer guidance in the course of setting research agendas. CSOs that conduct research make sure that it adheres to ethical standards. Furthermore, CSOs have a role to play in dissemination and awareness raising in the public discussion.

Governmental organizations[24]

Governmental organizations include national governments and their specialized agencies, and intergovernmental and supranational organizations and their specialized agencies, which are an organization composed primarily of sovereign states or of other intergovernmental organizations. Some government organizations, such as the European Commission, are emphasizing ethics and responsible conduct of research and innovation in their policies. At the global level, the main intergovernmental and supranational organizations engaged in policy development for ethics in R&I include the United Nations (UN), The United Nations Educational, Social, and Cultural Organization (UNESCO), the Organization for Economic Co-operation and Development (OECD), the World Health Organization (WHO), the Council for International Organizations of Medical Sciences (CIOMS) and the Council of Europe. These organizations have been involved in the formulation of important principles, legislative instruments, policies, standards, and guidelines. Therefore, they engage in regulation and guidance but they are also ethics assessors. However, the role of government in ethics assessment and guidance are different, ranging from strong (China) to weak (US) regulation and intervention, with EU countries located at different points in between.

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[23] Warso Zuzanna and Marcin Sczaniecki , "Ethics assessment and guidance in different types of organisations: Civil Society Organisations (CSOs)", SATORI D1.1 Annex 3.g, June 2015, 100 p., http://satoriproject.eu/media/3.g-Civil-society-organisations__.pdf

[24] Ibsen-Jensen Jacob and Anne Kristine Lygum, "Ethics assessment and guidance in different types of organisations: Government and Government-Funded Organisations", SATORI D1.1 Annex 3.g, June 2015, 40 p., http://satoriproject.eu/media/3.f-Govt-and-govt-funded-orgs.pdf

3 TOOL: ROADMAPPING METHODOLOGY

Roadmapping is a methodology that has originated in industry to facilitate and communicate technology strategy and planning. Basically, roadmaps aim to provide an extended view on the future of a chosen field of inquiry.[25] They provide a structured and graphical means for exploring and communicating the relationships between various levels and elements over time. They can also help make inventories of different possibilities, communicate visions, stimulate investigations, and monitor progress. In other words, roadmaps are composed of the collective knowledge and the imagination drivers of change in a particular field.[26]

Roadmaps can take a variety of specific forms depending on the roadmap scope and time frame. For example, one may distinguish between often short term, detailed action plans and technology roadmaps, and longer term, societal strategic roadmaps and system transition roadmaps.[27] In the latter varieties, the scope is often broad, covering a number of complex conceptual and human interactions. In a multi-organisational context, the contribution of a roadmap may also be capturing the threats and opportunities within a technological or another application area.

Roadmapping process can be implemented in many ways, but the following general steps can be identified in the process: (1) defining the focus and time scale of the roadmap; (2) building the vision; and (3) creating roadmap content. Participatory methods are an integral part of roadmapping.

The SATORI roadmap graphic (Figure 2) distinguishes three analytical levels: the *institutional perspective* (top layer), the *procedural perspective* (bottom layer), and the *desired outcomes* (middle layer). The institutional perspective refers to the institutional settings of ethics assessment. The procedural perspective covers the development of procedures and methods of ethics assessment, but it is also a perspective of organisations or particular organisational units engaged to ethics assessment in practise. The temporal dimension of SATORI roadmap stretches from the present to the next 10 years, and is divided into three phases that reflect the urgency or feasibility of actions. The top and bottom levels list the institutional and procedural actions that are necessary in order to realise the desired outcomes for the desired state of ethics assessment practises presented by the middle-layer elements. The *vision* box on the right side of the graphic presents the desired future state, which can be achieved by the outcomes presented in the middle layer.

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[25] Kostoff, R.N. and R.R. Schaller "Science and technology roadmaps". *IEEE Transactions on Engineering Management* Vol. 48, Issue 2, 2001, pp.132-143

[26] Tuominen Anu and Toni Ahlqvist "Is the transport system becoming ubiquitous? Socio-technical roadmapping as a tool for integrating the development of transport policies and intelligent transport systems and services in Finland", *Technological Forecasting & Social Change*, Vol. 77, Issue 1, January 2010, pp. 120-134

[27] See for example: Auvinen H., S. Ruutu, A. Tuominen, T. Ahlqvist & J. Oksanen "Process supporting strategic decision-making in systemic transitions: A case study of emission-free transport in cities by 2050", *Technological Forecasting and Social Change*, Vol. 94, May 2015, pp. 97-114
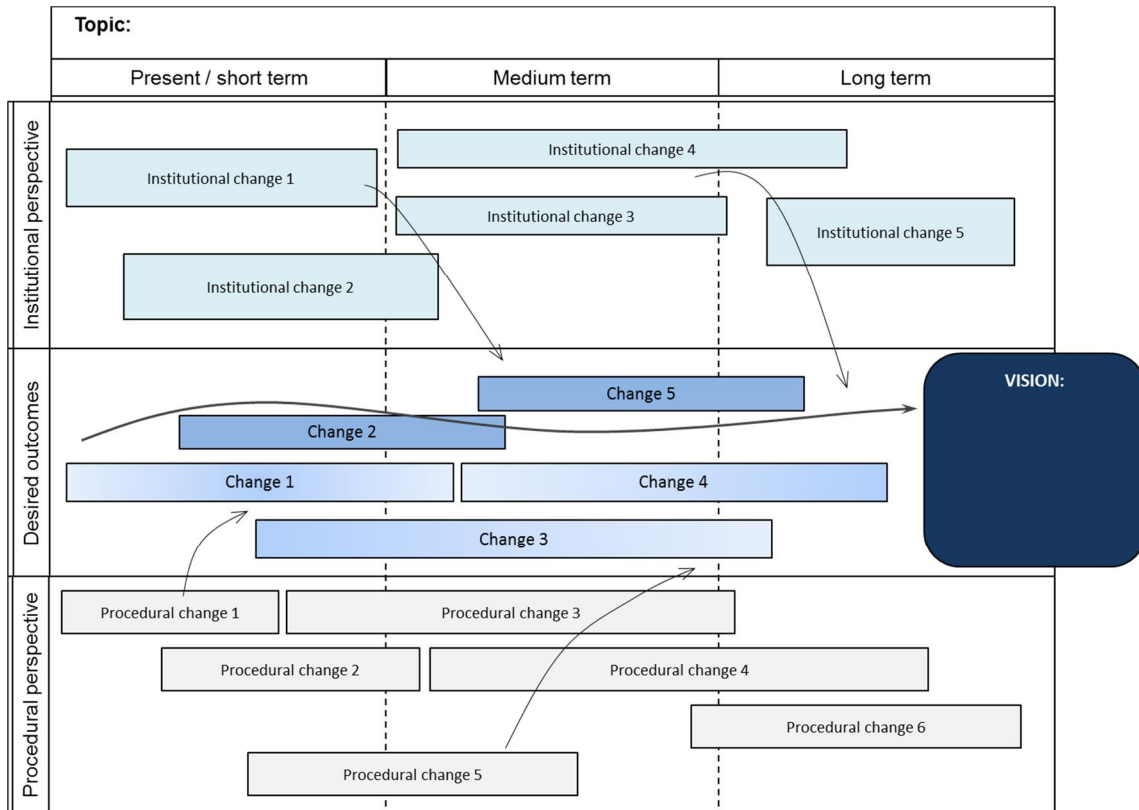
Figure 2. Roadmap template used in Satori project.

Participatory approaches have been applied in the SATORI roadmapping process. The participatory material and methods used in the process comprised documented interviews with the stakeholders in ethics assessment carried out in SATORI WP1,[28] the results of the SATORI consortium roadmap workshop in Copenhagen (May 2016), and the results of the SATORI stakeholder engagement workshop in Vienna (June 2016). The steps of the process and their contents are shown in Figure 3.
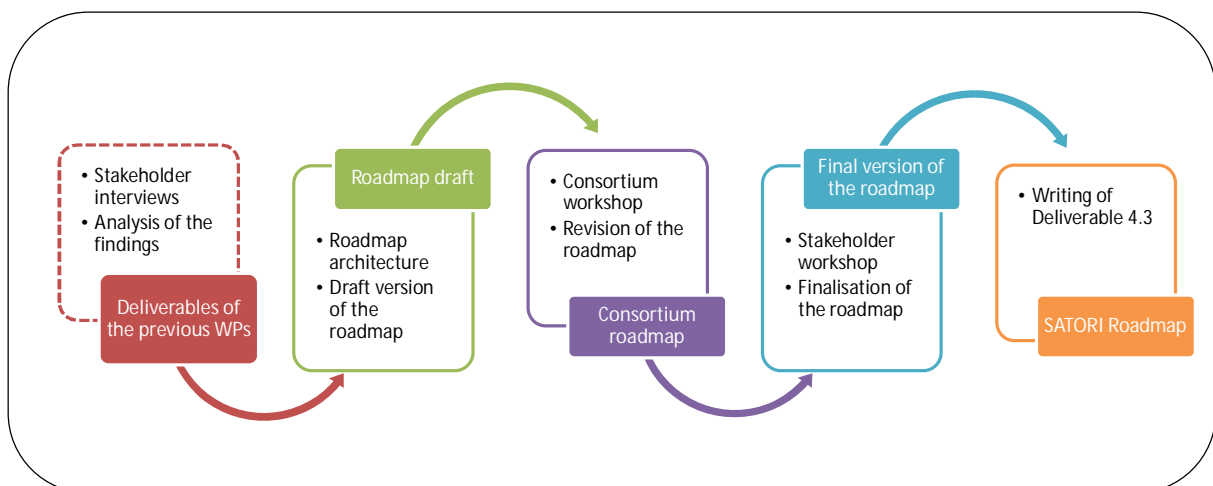
Figure 3. Roadmapping process in the SATORI project.

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[28] Shelley-Egan, C., Brey, P., Rodrigues, R., Douglas, D., Gurzawska, A. Bitsch, L., Wright, D., Wadhwa, K. 2015. Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries. SATORI D1.1 including 5 annexes, June 2015. (see http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/)

4 AIM: IMPLEMENTING NEW SOCIAL PRACTISE

When describing the topic of SATORI roadmap in general terms, one could say that it aims to depict a social change towards a new, improved practice. In other words, the European research and innovation community should adopt a well-developed practice of ethics assessment as a part of its operation. In determining the social change that is required, we can distinguish at least two dimensions:

a) The first dimension is *institutional change*. The research and innovation system as a whole should be able to implement ethics assessment practises. This means that there should be adequate incentives and appropriate institutions to carry out ethics assessment. This dimension refers to the institutional setting of ethics assessment, and the required social change would be to improve the research and innovation system's capacity to carry out ethics assessment.

b) Another dimension is *individual change*. Individuals should be able and willing to implement ethics assessment as a part of their professional roles in the research and innovation field. This may require a change in attitudes, better knowledge or improved skills or even changing one's professional identity in way that puts greater emphasis on professional ethics.

To analyse the above-mentioned systemic or institutional dimensions and individual dimensions in more detail, we must turn to the literature. Cooke (2005)[29] offers an interesting approach to the institutional dimension if developing 'ethics assessment capacity' is seen as analogous to research capacity building. Cooke argues that a framework measuring research capacity building should include both *process measures* and *outcome measures*. This stands in contrast to the traditional approach, which concentrates only on outcome measures, such as the number of publications, conference presentations or successful grant applications. To identify the process measures, Cooke presents a framework containing two dimensions: (1) the structural levels of development activity, and (2) the principles of capacity building. The structural levels include the *individual* level, the *team* level, the *organisational* level, and the *network or supra- organisational* support level (networks and support units). The six principles of capacity building are: (1) building skills and confidence, (2) developing linkages and partnerships, (3) ensuring the research is 'close to practice', (4) developing appropriate dissemination, investments in infrastructure, and (5) building elements of sustainability and continuity. The framework also acknowledges that research capacity building is conducted within a policy context, meaning that policy decisions may nurture or restrict the capacity building through supporting or limiting the realisation of the six principles of capacity building.

The structural levels of Cooke's framework, together with the policy context, are a useful starting point for developing the institutional dimension of the social change that we are approaching in SATORI roadmap. For our purposes, however, the team level is not necessary, although it can be included in the organisational level. The six principles of research capacity building can also be used as inspirational material for the roadmap development, even if the

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[29] Cooke Jo, "A framework to evaluate research capacity building in health care", *BMC Family Practice* Vol. 6, Issue 44, October 2005 Available from: http://www.biomedcentral.com/1471-2296/6/44

precise content of the measures describing these principles may differ from the needs of research capacity building.

Other research on capacity building that we can draw from has been conducted by Potter and Brough (2004).[30] These authors approach capacity building in the context of development programmes and health sector reforms. They argue that capacity building should be seen as developing a sustainable and robust system that enables programme execution independent of any changes taking place in the parts of the system, such as personalities, technologies or resources. They also outline a hierarchy of capacity building needs composed of four levels: (1) *structures, systems and roles*, (2) *staff and facilities*, (3) *skills*, and (4) *tools*. The hierarchy involves a principle that it is not possible to achieve a sustainable change by improving skills or providing new tools if the structural aspects, such as undefined roles or insufficient staff and facilities, do not enable individuals to use the new skills and tools. Another element of the hierarchy is that changing structures, systems, and roles requires more time, due to their socio-cultural character, than the more technical provision of tools and organisation of training to improve the skills of individuals. The time dimension of capacity building introduced by Potter and Brough is an important addition to the Cooke's framework of research capacity building[31] discussed earlier. For the purposes of roadmap development, the four capacity building requirements in Potter and Brough's model can be combined to Cooke's structural levels of capacity building.

As previously outlined, the other dimension of the social change that we are envisioning in our roadmap is the perspective of behavioural change of individuals. For this, we need other theories. The Theory of Planned Behaviour (TPB) is a theory designed to predict and explain human behaviour in specific contexts[32]. According to Hardeman et al. (2002)[33] it is the most extensively studied social cognition theory that has relevance to intention and behavioural change. A central point of the TPB is that it separates *intention* to act from the actual *behaviour* (see Figure 4). Intention covers the motivational factors that influence behaviour; in other words it indicates how hard people are willing to try or how much of an effort they are planning to make, in order to perform the behaviour. The performance of certain behaviour is more likely, when intention to engage this behaviour is stronger. The TPB also specifies the cognitions predicting intention. One of these is the *perceived behavioural control*, which refers to people's perception of ease or difficulty of performing the behaviour. This perception may or may not reflect the *actual* behavioural control, e.g., the skills, resources and opportunities needed to perform the behaviour. The other two determinants of intention in the TPB are *attitude towards the behaviour* and *subjective norm*. The attitude towards the behaviour indicates the degree to which a person has a favourable or unfavourable view of the behaviour in question. The subjective norm, in turn, refers to the perceived social pressure to perform or not to perform the behaviour.[34]

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[30] Potter, C. and R. Brough, "Systemic capacity building: a hierarchy of needs", *Health Policy and Planning*, Vol 19, Issue 5, 2004, pp. 336-345

[31] Cooke J (2005), Figure 1.

[32] Ajzen Icek, "The Theory of Planned Behaviour", *Organizational Behaviour and Human Decision Processes, Vol.* 50, Issue 2, 1991, pp. 179-211

[33] Hardeman W., M. Johnson, D. Johnson, D. Bonetti, N. Wareham and A. L. Kinmonth (2002) "Application of the Thory of Planned Behaviour in behaviour change interventions: A systematic review", *Psychology & Health*, Vol. 17, Issue 2, April 2002, pp.123-158, p.124
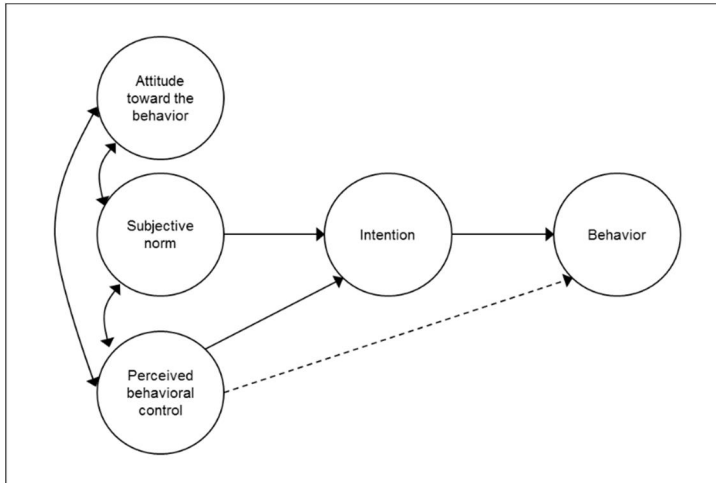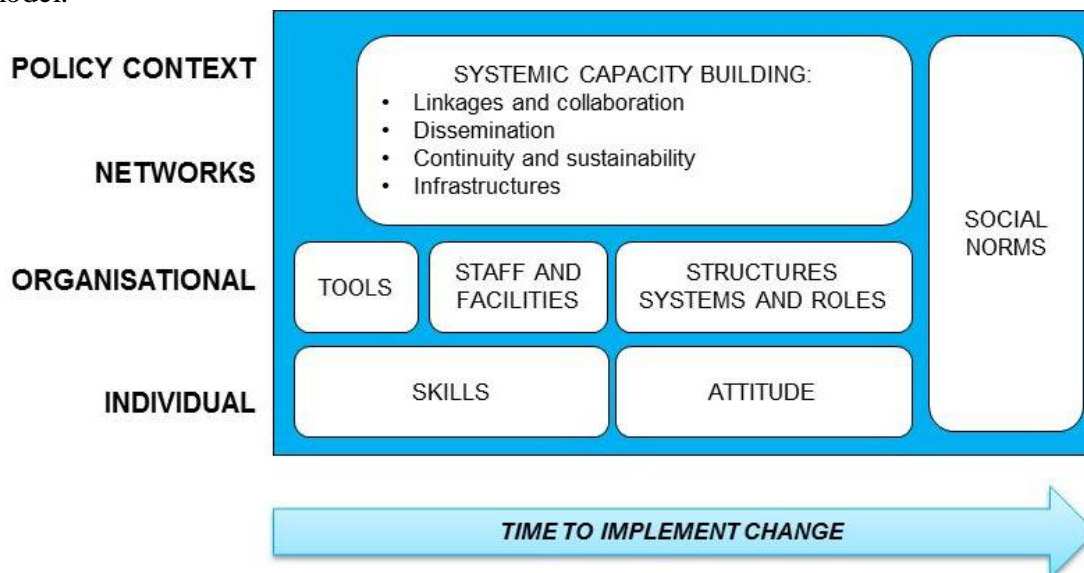
[34] Ajzen Icek, "The Theory of Planned Behaviour", Organizational Behaviour and Human Decision Processes, Vol. 50, Issue 2, 1991, pp. 179-211

Figure 4. Theory of planned behaviour[35].

As mentioned above, the TPB is a suitable model for predicting and explaining human behaviour. For example, Thoradeniya et al.[36] (2015) have used the TPB to examine managers' sustainability reporting behaviour. Hardeman et al.[37] (2001, 151) propose that due to the theory's concentration on the determinants of intention (i.e., motivation), it might also be useful for developing effective interventions aimed at behavioural change. This is a useful thought in relation to SATORI roadmap, because the purpose of the roadmap can partially be understood as a kind of intervention aimed at behavioural change. At a micro level, the implementation of ethics assessment procedures in research and innovation activities happens through changes in people's behaviour. When this micro perspective is combined with the systemic perspective of capacity building, as previously discussed, we can devise a comprehensive model for the implementation of a new social practise. Figure 5 shows this model.

Figure 5. Theoretical model for the implementation of a new social practise, such as improved ethics assessment practices.

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[35] Ibid.

[36] Thoradeniya P, J. Lee, R. Tan and A. Ferreira, "Sustainability reporting and the theory of planned behaviour", *Accounting, Auditing & Accountability Journal,* Vol. 28, Issue 7, 2015, pp. 1099-1137

[37] Hardeman et al., p.151

The model of Figure 5 has four structural levels (*policy context*, *networks*, *organisational*, *individual*) at which the change is supposed to takes place. The change appears differently at different structural levels, and the possibilities to contribute to the change are different at different levels. Another dimension is the *time required to implement change*. The basic principle for this dimension is that socio-cultural changes take more time than more technical ones. For example, it takes less time to develop people's skills than to change their attitudes, and it is more straightforward to introduce new tools and increase staff members or improve facilities than to make changes in organisational structures and roles. Systemic capacity building refers to actions and improvements that take place in a wider context, outside individual organisations. The role of policy context and policy making is crucial for capacity building, and various networks of organisations or individuals may play an important role, too. According to the Theory of Planned Behaviour, attitudes, subjective norms (i.e., the perceived external pressures to perform certain behaviour), and perceived *behavioural control* influence people's motivation (intention) to engage in certain behaviour. Behavioural control refers to the ability and opportunity to perform the desired behaviour. From the systemic perspective, we can think that ability or skills are individual characteristics and the opportunity is formed by the individual's position within his or her organisation. The latter aspect is noticed as structures, systems and roles in our model. Contrary to the Theory of Planned Behaviour, the notion of subjective norms is understood as a social construct and therefore it is extended to all the levels in our model. Social norms are intended to cover all the intangible aspects or principles and mental models that determine and influence the action and thinking of individuals and organisations. As we are dealing with deep-seated mental structures and tacit constructions, the changing of social norms may take generations, and it is therefore placed in the right-most end of the time axis.

The model in Figure 5 has formed the basic structure of the SATORI roadmap. It provides an understanding of the required change and desired outcomes from the actions proposed. The content of the SATORI roadmap is discussed in the following chapter.

5   SATORI VISION AND ROADMAP

The following SATORI vision statement presents a shared view on the desired future state of ethics assessment practices in the European Union. This vision is derived from the overall goal of the SATORI project and was fine-tuned in cooperation with various stakeholders during two SATORI workshops in the spring of 2016.

> *SATORI Vision:*
> In the European Union, there is a well-developed practice of Ethics Assessment, which ensures that the European research and innovation community follows high ethical standards in their R&I operations. The implemented practices, procedures and institutions for ethics assessment strengthen the socio-economic benefits of R&I, and are inspirational beyond the European context.

Figure 6 (next page) shows the SATORI roadmap. The middle layer, *Desired outcomes,* represents the path to the vision stated on the right end of the diagram. The elements on this path (indicated by the green boxes) are derived from the theoretical model described in the previous section. These elements represent the desired outcomes in six domains: tools, system-level capabilities, skills, responsibilities and monitoring, professional norms, and attitudes. Together, the desired outcomes in these areas will realise the SATORI vision.

The six types of outcome domains can be categorised as belonging either to the institutional level or to the procedural level. This institutional and procedural progress towards the SATORI vision is detailed in the top and bottom layers of the graphic of Figure 6. The *Institutional perspective* layer and the *Procedural perspective* layer contain the most important general steps, or actions, that need to be undertaken in order to realise the desired outcomes on the path towards the vision. These steps are based on (1) the work that has been done in the previous work packages and tasks in SATORI, (2) the results of the SATORI partners' workshop in Copenhagen on the 31st of May, 2016, and (3) the results of the expert workshop in Vienna on the 20th of June, 2016.

The colours used in the roadmap refer to the different structural levels of the actions and the types of stakeholders that are performing them. Orange represents the steps that are to be taken as a part of the Satori project. Grey indicates the actions that are to be performed by organisations and networks that have a stake in proper ethics assessment practices. And blue indicates actions that need to be taken by policy makers.

The following subsections outline the institutional and procedural perspectives and the various actions listed in the roadmap.
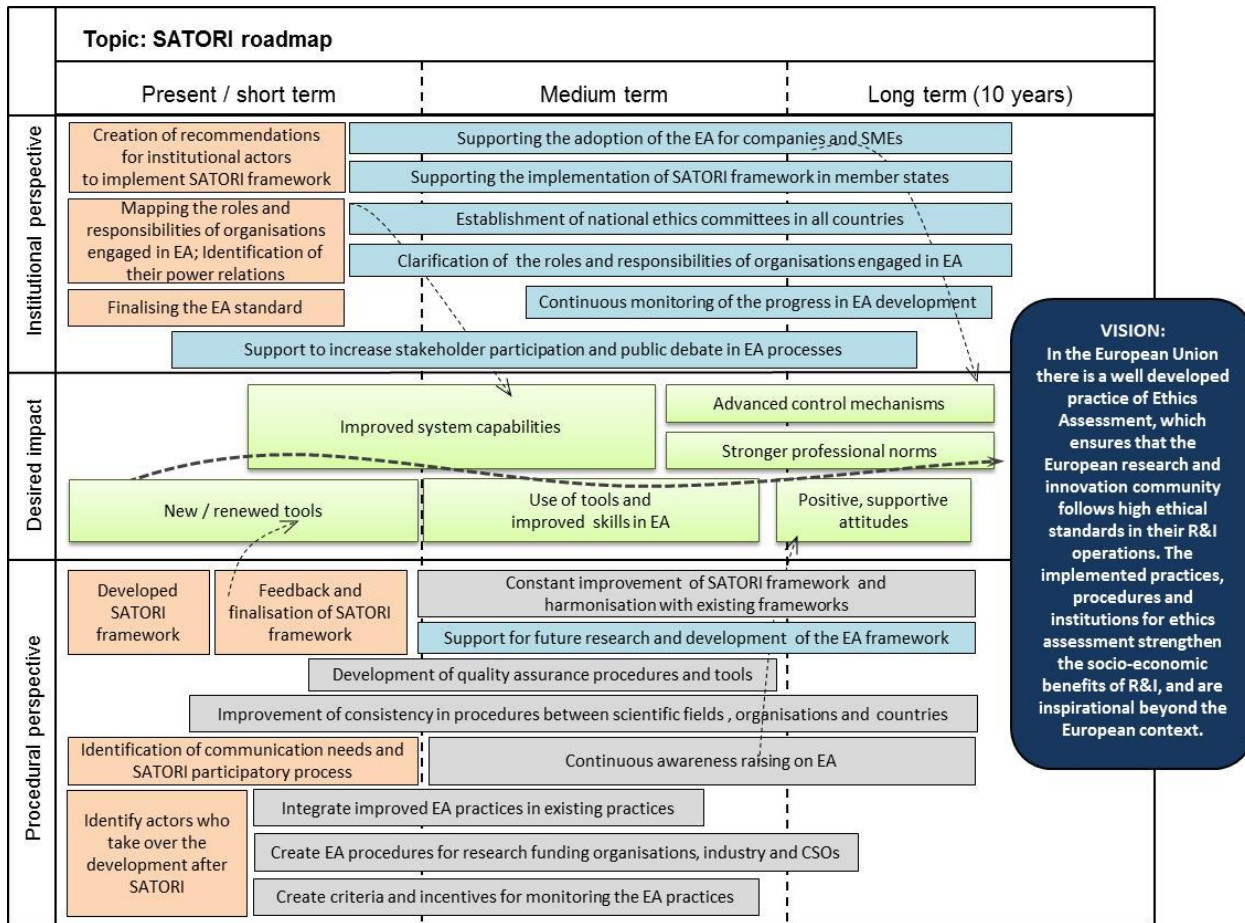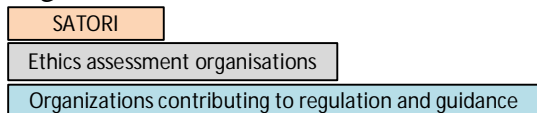
Figure 6. SATORI roadmap.

5.1 INSTITUTIONAL PERSPECTIVE

The institutional perspective refers to the operational environment's capabilities or outcomes – in terms of (1) *system-level capabilities in implementing ethics assessment*, (2) *responsibilities and monitoring of ethics assessment*, and (3) *stronger professional norms regarding ethics assessment* – as well as the actions that need to be taken in order to realise them. For this institutional perspective, Table 1 lists the most important desired outcomes and corresponding actions. The actions are categorized in three columns by the stakeholder roles identified above in Figure 6. After table 1, more detailed explanations are provided for each of the actions.

Desired outcomes	SATORI	Ethics assessment organisations	Organisations contributing to regulation and guidance
System-level capabilities in implementing EA	• Creation of recommendations for policy makers to implement the SATORI framework		• Supporting the adoption of the SATORI EA standards in academic research, industry, and SMEs • Supporting the

	• Finalising the ethics assessment standard		implementation of the SATORI framework in member states • Establishing national ethics committees in all EU countries
Responsibilities and monitoring of EA	• Mapping the roles and responsibilities of organisations engaged in ethics assessment • Identification of their power relations		• Clarification of the roles and responsibilities of organisations engaged in EA • Continuous monitoring of the progress in EA development
Stronger professional norms			• Support to increase stakeholder participation and public debate in EA processes

Table 1. Institutional perspective.

System-level capabilities in implementing EA from the institutional perspective

The most important aspect of the institutional perspective is to create the system-level capabilities for a systematic and harmonized implementation of ethics assessment structures and procedures. The SATORI project contributes to this outcome by finalising the EA standard, which is a strong starting point in building the capabilities. The standard promotes a harmonized understanding of EA of research and innovation across disciplines, countries and actors, and is aimed at improving its various (institutional) structures and procedures. EU guidelines should be developed to support its implementation in the EU member states.

On the national level the implementation of EA can be supported by establishing national platforms and national ethics committees (in in countries where such organisations do not already exist). National platforms could offer the possibility to discuss ethics related issues between different disciplines and stakeholders thus enabling the knowledge and best practices sharing. National ethics committees should act as the highest ethics guidance and policy body in the country, prescribing the general standards and procedures to be followed and occasionally making final assessment and decisions in challenging cases.

It is also important for organisations involved in EA policy and guidance to promote the implementation of the EA framework and standard. Research funding organisations are in a key position here in that they are often responsible for providing the financial means to develop new technologies and innovations that may raise ethical issues. Incentives for improved EA on the basis of SATORI proposals should be built into their funding systems.

Industry organisations – especially SMEs – are a special group in the field of ethics assessment because the present state of EA in these organisations is not as advanced as in research institutions. Therefore, industry organisations are to be addressed separately from the academic research community. It is important to do this in collaboration with industry associations and other network organisations.

Responsibilities and monitoring of EA

Another element in the institutional perspective is to define the responsibilities of EA and monitor its achievement. There is a need for a clear view on the roles and responsibilities of organisations engaged in EA. SATORI framework can contribute to the mapping of the roles and responsibilities and identification of their power relations. This information can be used by policy actors in the clarification of the roles and responsibilities on the national and international level.

The desire for consistency in quality of ethics assessment necessitates the continuous monitoring of the progress in EA development and the practices. This could for example be done by oversight committees or an ethics "ombudsman". For monitoring of the EA practices, criteria and incentives should be created. Funding organisations, for example, have a powerful position to do this in their activities. On the practical level, continuous monitoring of the progress in EA developments and the necessary revisions of the framework should be organised. The training activities should be monitored and minimum standards of ethics training should be created.

Stronger professional norms

Professional norms can be seen as an institutional factor because it entails education of researchers thus serving the desire that ideally ethics is a part of the professional attitude. An important principle that should be promoted by the entire research and innovation community is the stakeholder participation and public debate in EA processes.

5.2 PROCEDURAL PERSPECTIVE

Procedural perspective refers mainly to EA tools and procedures, the way they are used, developed further, implemented, and monitored. Table 2 summarises the procedural perspective of the SATORI roadmap, and is followed by a more detailed description for each of the actions listed.

Desired outcomes	SATORI	Ethics assessment organisations	Organisations contributing to regulation and guidance
New / improved tools	• Feedback and finalisation of SATORI framework	• Continuous improvement of SATORI framework and harmonisation with existing frameworks • Development of quality assurance procedures and tools	• Support for future research and development of the EA framework
Use of tools and improved skills in EA		• Improvement of consistency in procedures between scientific fields, organisations and countries • Integrate improved EA practices in existing	

		practices	
Positive, supportive attitudes towards EA	• Identification of communication needs and SATORI participatory process	• Continuous awareness raising on EA	
System-level capabilities in implementing EA	• Identify actors who take over the development after SATORI	• Create EA procedures for research funding organisations, industry and CSOs • Create criteria and incentives for monitoring the EA practices	

Table 2. Procedural perspective.

New / improved tools

SATORI project has developed a framework for ethics assessment and ethical impact assessment which are the basis for the CEN workshop agreement[38,39]. In addition to the CEN workshops, feedback and comments for improvement to the current version of the SATORI framework will be gathered through SATORI workshops, seminars and online public commenting procedures, as well as through case studies and pilots. The active interaction with the stakeholders will help in the finalization of the framework and will support its acceptance and application.

After the SATORI project has ended, EA organisations and EA regulation and policy organisations should aim to revise and improve the SATORI framework on a regular basis, taking into account recent changes in related frameworks and regulations. The starting point for the SATORI framework has been theoretical; there is no doubt that extensive real-world application of the framework will bring up further issues with the framework that may need to be addressed. Such issues can be due to, for example, new technological, social, regulation, and policy developments, including new emerging technologies that may generate new kinds of ethical issues, as well as developments in related frameworks which may result in harmonisation issues.

Other ethics related frameworks include RRI (Responsible Research and Innovation)[40] and CSR (Corporate Social Responsibility)[41]. The common denominator for the three approaches is the "responsibility". EA concerns research projects and new technologies, RRI is more process, stakeholder and policy oriented, and CSR is a meta strategy including all business decisions. Both RRI and CSR are much broader in nature than EA but EA is a part of them.

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[38] CWA SATORI-1:2016. Ethics assessment for research and innovation — Part 1: Ethics assessment unit. A CEN draft. NEN 2016. 35 p.

[39] CWA SATORI-2:2016. Ethics assessment for research and innovation — Part 2: Ethical impact assessment framework. A CEN draft. NEN 2016. 37 p.

[40] EC: "Responsible research and innovation is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation.", see https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation.

[41] The World Business Council for Sustainable Development (WBCSD): "Corporate Social Responsibility is the continuing commitment by business to contribute to economic development while improving the quality of life of the workforce and their families as well as of the community and society at large." See: http://www.wbcsd.org/work-program/business-role/previous-work/corporate-social-responsibility.aspx.

Therefore, EA could be an additional tool in both RRI and CSR. EA and RRI have the procedures in common whereas EA could be a tool to cover value chain aspects in CSR. The practical implementation of EA in RRI and CSR needs to be discussed and developed in collaboration.

Further development of ethics assessment structures and procedures calls for *quality assurance*, which raises questions such as: Who decides on quality? And who will approve the EA framework? To answer such questions, open discussion and collaboration is needed between different kinds of stakeholders in ethics assessment.

Use of tools and improved skills in EA

The SATORI framework aims to pave the way towards improved consistency in EA procedures within and between scientific fields, different kinds of organisations, and countries. Further development of practices to implement ethics assessment in different kinds of organisations is needed. This is especially the case for organisations performing ethics assessment that are not research ethics committees.

Training is another means to improve the consistency between different fields and kinds of actors. As a part of the SATORI project, so-called "mutual-learning workshops" have been organised to make different kinds of stakeholders familiar with the SATORI framework. However, systematic and continuous training will be necessary to generate the proper skills in EA among different actors. Furthermore, the need for ethics training in general should be discussed at the EU level and at the national level: the survey in SATORI[42] revealed that the meaning of ethics in practice is unclear especially in engineering and business environments even though it is taken into consideration under different names.

Since ethical issues, values, and principles are central to ethics assessment, it requires open discussion on ethical consequences of emerging technologies and innovations. European level thematic discussion groups or platforms could serve this purpose. At such platforms, the ethical principles, tools and best practices could be debated, as well as the needs for new practices and training.

The practical implementation of EA should be integrated with existing related procedures such as RRI (Responsible Research and Innovation), CSR (Corporate Social Responsibility) or quality management system. EA could be an additional tool in both RRI and CSR. The practical implementation of EA in RRI and CSR needs to be discussed and developed in collaboration. Ethics assessment should be built into the existing organisational structures so that few if any new institutional layers would be needed.

Positive, supportive attitudes towards EA

Positive, supportive attitudes towards EA are a corner stone for EA because decisions are made by humans and attitudes guide people's behaviour. One idea to promote awareness and positive attitudes is to identify communication needs and participatory processes in relation to

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[42] Shelley-Egan, C., P. Brey, R. Rodrigues, D. Douglas, A. Gurzawska, L. Bitsch, D. Wright and K. Wadhwa, "Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries", SATORI D1.1 including 5 annexes, June 2015. (see http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/)

critical issues, such as synthetic biology, stem cells or GMOs. These contradictory issues may help to engage and involve the public and simultaneously promote the necessity of EA.

Another way in which attitudes could be positively affected would be to raise awareness of the potential positive impact ethics assessment can have when it is an integral part of research and innovation projects. This may help to reduce resistance against, and doubts regarding the effectiveness, of ethics assessment. SATORI project could contribute to this by preparing appealing, easy-to-read presentation material (brochures, videos) including hands-on, practical examples based on the project results. The presentation and dissemination material should be adapted to different audiences and clearly point out the benefits of EA for the discipline, actor or field in question.

The participants of the stakeholder workshop highlighted that the target of the dissemination activities should be carefully identified. In the university, for example, the right addressee may be someone in the upper decision-making positions like rector, deans or heads of departments who can help to frame the issues further 'down' in organisations hierarchies. National associations of universities are also relevant target groups. They can contribute to the teaching and training of ethics which play an essential role in the attitude development.

System-level capabilities in implementing EA

Organisations and actors need tools, procedures and rules to apply the EA standard: practical EA procedures should be created especially for research funding organisations, industry and CSOs. The adoption of the EA standard in companies and SMEs should be supported and the possible alignment with existing activities such as RRI, CSR and quality management should be developed. Challenges in the practical EA application in organisations may arise due to different state of knowledge, different values and cultures as well as different priorities. However, these are the reasons why harmonisation is needed.

In summary, the system-level capability building will need new legislation and development of practices. Further research and development in collaboration with different actors enabled by public funding is needed.

6   RECOMMENDATIONS

The previous chapter has identified important outcomes for the development of ethics assessment, and actions required to realise these outcomes (and thereby the roadmap vision). In this chapter, we present more detailed and concrete recommendations, with corresponding actions, actors who should perform the actions, and timeframes in which to complete the actions. These recommendations are based on the workshop[43] results and more specifically on the analysis of the interview reports of SATORI WP1[44] (interviews with ethics assessment stakeholders) and the SATORI WP4 reports[45,46,47,48,49,50,51] on the state of ethics assessment at and recommendations for different kinds of organisations involved in ethics assessment.

These recommendations come together into the form of a system to put in place to facilitate the occurrence of ethics assessment across disciplines. An overview of this system is presented in Figure 7. It shows the different institutions that have a role to play in this procedure, and also maps out how they relate to each other. Detailed recommendations related to the establishment of these different *institutions* and of *procedures* to perform ethics assessment are given subsequently.

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[43] SATORI partners' workshop in Copenhagen on the 31st of May, 2016, and the expert workshop in Vienna on the 20th of June, 2016.

[44] Shelley-Egan, C., P. Brey, R. Rodrigues, D. Douglas, A. Gurzawska, L. Bitsch, D. Wright, & K. Wadhwa, "Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries", SATORI D1.1 including 5 annexes, June 2015. (see http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/)

[45] Wolfslehner Doris, Wessel Reijers & Sudeep Rangi, "Standards, tools and best practices for policy-oriented assessment and guidance of new developments and practices in research and innovation", SATORI Task 4.2.1 report, February 2016, 20 p.

[46] Benčin Rok, Gregor Strle, Sudeep Rangi & Dubravka Vejnović, "Standards, tools and best practices for guiding, assessing and supporting ethical professional behaviour by scientists and innovators", SATORI Task 4.2.2 report, March 2016, 33 p.

[47] Jansen Philip & Agata Gurzawska, "Standards, tools and best practices for the ethics assessment of innovation and technology development plans", SATORI Task 4.2.3 report, April 2016, 8 p.

[48] Brey Philip, David Douglas, Alexandra Kapeller , Rok Benčin, Daniela Ovadia & Doris Wolfslehner, "Models for Ethics Assessment and Guidance in Higher Education", SATORI Task 4.2.4 report, March 2016, 26 p.

[49] Warso Zuzanna & Dalibor Petrović, "Models for ethics assessment and guidance at CSOs", SATORI Task 4.2.5 report, March 2016, 16 p.

[50] Gurzawska Agata, Andrea Porcari, "Models for ethics assessment and guidance in industry", SATORI Task 4.2.6 report, March 2016, 34 p.

[51] Doris Wolfslehner, "Standards, tools and best practices for policy-oriented assessment and guidance of new developments and practices in research and innovation - Models for ethics assessment at research funding organisations", SATORI Task 4.2.7 report, 2016, 13 p.
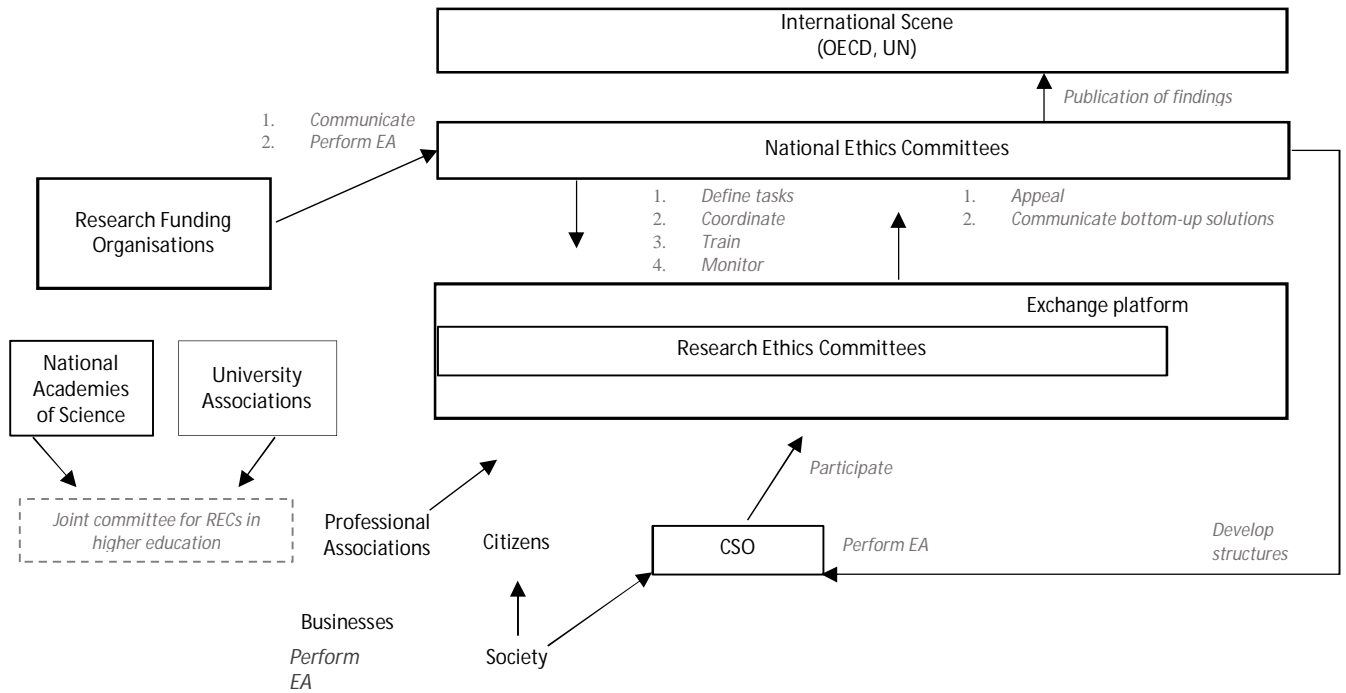
Figure 7. An overview of the system to be implemented

6.1   INSTITUTIONAL RECOMMENDATIONS AND ACTIONS

6.1.1   Recommendations for system-level capabilities

The following (Table 3) are recommendations and required actions for the improvement of system-level capabilities in implementing EA.

Recommendations	Actions	Stakeholders	Timeline
National-level coordination of RECs: Each country should have an institutional structure for the coordination of individual RECs in that country in terms of procedures and guidelines.	Establishment of NECs in countries where such organisations do not currently exist.	Governments, SAs, NECs	Medium to long term
	Definition of the tasks of national RECs: • The development of ethical guidance and assessment procedures to be implemented by RECs, and procedures for monitoring RECs activities • Functioning as a court of appeal, in cases when RECs decisions are being disputed.	Governments, SAs, NECs	Medium to long term
	Networking between RECs • The RECs in a particular country should consider establishing a platform for discussion and cooperation if the country in question does not have such a platform. • These networks can complement the top-down coordination by providing	RECs	Short term

	bottom-up solutions based on experience from day-to-day practices of committees.		
Set-up of RECs In higher education, one REC per institution should be established.	Universities and other institutes of higher education should establish RECs that are as centralised as possible. If further discipline-specific evaluation is needed, interdisciplinarity should be ensured.	Universities, RECs	Medium term
Clarifying the legal foundation of RECs operation: It should be clear in a legal sense when RECs are to be included in the ethics assessment practice.	Make the necessary legal provisions at the appropriate level—whether institutional, local, regional, or national—for when RECs are to be included in the ethics assessment practice. • In doing so, there is a need to avoid the "juridification of ethics assessment" by instituting RECs as more than clearing houses for legal compliance.	Local and national governments, research institutions	Short to medium term
Institutional set-up of NECs NECs should be established by law and as independent, multidisciplinary and pluralist ethics bodies with an equal gender distribution of members.	Governments need to establish NECs by law, ensuring a correct set-up.	Governments	Medium term
Broadening the focus of National Ethics Committees to include all other scientific fields besides the medical and life sciences.	Re-define the mandate / focus area of NECs and guarantee adequate resources.	Governments	Short to medium term
	Establishment of special sub-committees for different disciplines—including the natural sciences, engineering sciences, social sciences and the humanities fields.	NECs, professional associations	Short to medium term
	NECs should publish their findings in a language open for the international community in order to foster exchange and debate.	NECs	Short term
	National platforms could offer the possibility to discuss ethics related issues between different disciplines and stakeholders thus enabling the knowledge and best practices sharing.	NECs	Short term
Increased stakeholder and expert consultation by NECs	Institute a temporary sub-committee to investigate how to best include citizens, civil society organisations, external experts and possibly other groups in ethical decision-making process.	NECs	Short to medium term
	Development of organisational structures that allow for the consultation of citizens, civil society organisations, external experts and possibly other external groups based on the investigation results.	NECs	Short to medium term
Improvement of the capabilities of research funding organisations (RFOs)	Large research funding organizations should have the institutional organisation necessary to perform regular in-house	Large RFOs (spending more than 100 million	Short to medium term

to perform ethics assessment	ethics review of research proposals submitted to them: • Establishment of independent, multidisciplinary and pluralist ethics committees to perform ethics assessment	Euros a year)	
	Regular discussion and exchange of information among RFOs at the national and international levels on the topic of (good practices in) ethics assessment of new and emerging technologies.	RFOs	Short term
Establish ethical guidance and assessment units within research institutions.	Establish bodies within research institutions with the resources and a mandate to develop ethics guidance and assessment procedures and strategies, and to provide information and training on these procedures.	Universities and other research institutions	Short to medium term
	Universities and industry need to set up Ethics committees. NECs and SAs can help in setting up a new ethics committee. If they do not have the resources to establish an ethics committee themselves, they can outsource it.	Universities and other research institutions	Short to medium term
Strengthen the role of CSOs in ethics assessment	Support the development of an independent CSO that would focus on assessing public research and innovation agendas and cooperate with other CSOs in developing strategies of their own.[52]	EU, Governments	Long term
	Funding of the independent CSO.	Existing CSO networks, EU, Governments	Long term
	Formation of dedicated working groups or ethics assessment related networks by CSOs. • These networks could vary in terms of structure, level of interdependence, aims etc. • The purpose of networking would be to exchange information (knowledge and experience) and learn from each other (through sharing best practices, coordinating activities, obtaining common funding, organising advocacy campaigns, influencing the adoption of new regulative acts, etc.).	The existing CSO networks (e.g. the Euclid network)	Medium term
	Some CSOs should be further involved in research ethics committees as representatives of a specific vulnerable group (e.g. consumers or patients) or spokespeople for a specific interest (e.g. the animal welfare).	RECs, CSOs	Medium term

[52] Warso Zuzanna & Dalibor Petrović, "Models for ethics assessment and guidance at CSOs", SATORI Task 4.2.5 report, March 2016, p. 16.

	Organisation of training to CSOs who perform informal ethics assessment as an element of their other activities. • This training could be organized as an element of EU funded projects that concern Ethics in R&I and RRI.	CSOs, CSOs networks, EU	Long term
	CSOs should improve their expertise in ethics assessment by engaging experts in the EA procedures, establishing expert groups and engage in ethics capacity building.	CSOs, CSOs networks	Medium term
Ethics codes for universities Universities should develop a code of conduct, especially concerning conduct in research and innovation.	Universities should develop a code for ethical behaviour in research and innovation. This code should not focus on one discipline, but rather be general in order to allow an eventual discussion by a REC. After its establishment, the code has to be updated and distributed regularly.	Universities, RECs	Medium term

Table 3. Recommendations and required actions for the improvement of system-level capabilities in implementing EA.

6.1.2 Recommendations for responsibilities and monitoring

The following (Table 4) are recommendations and required actions for defining responsibilities and monitoring of EA.

Recommendations	Actions	Stakeholders	Timeline
CSOs who are involved in R&I more directly should consider establishing structures for internal ethics assessment.	Development a code of conduct and procedures for internal ethics assessment by CSOs.	CSOs, CSOs networks	Short term
Improve the monitoring of the compliance to the ethical principles	NECs should monitor for compliance with the ethical guidance they offer to ethics assessors. • Individual NECs should set up a special committee that evaluates, in general terms, the compliance to their ethical guidance.	NECs	
	NECs should be actively involved ensuring the quality of the ethics assessments made by REC members and other ethics assessors.	NECs	Short to medium term
	NECs should offer training programs for REC members and other ethics assessors.	NECs	Short to medium term
	NSAs should establish a compliance officer to monitor the number of mentions and citations of Academy results by policy, decision, and public actors.	NSAs	Short to medium term
	NSAs should try to develop closer connections to decision-makers, while	NSAs	Short to medium

	retaining their autonomy, to work in conjunction with policy and decision makers by establishing liaisons or programs to work alongside decision-makers.		term
Adequate funding of NSAs: There should be sufficient resources (administrative staff, budget, etc.) to facilitate the work of NSAs	The EC should encourage the establishment of National Science Associations as a part of its requirements for countries to receive funding for research and innovations projects.	EC	Short to medium term
	Creation of a multi-stakeholder platform on a global level, in which the UN, OECD, and the EU could collaborate in pursuit of harmonized NSA objectives. • This can build upon the existing work of associations that currently exist.	Governments, Governmental organisations (i.e. EU, UN, OECD)	Short to medium term
Developing of general standards at a national level for RECs in the higher education system	University associations and national academies of sciences should establish a joint committee to develop a joint framework that sets general standards at a national level for RECs in the higher education system. • Professional associations should be involved and consulted in the process and play a leading role in establishing discipline specific standards.	University associations and national academies of sciences	Short to medium term
Improve institutional structure of scientific integrity boards	The legal framework of scientific integrity should be clarified in terms of which organisations are responsible for particular aspects of the inquiry and investigation processes.	Universities, university associations and national academies of sciences	Medium term
	The independence of those investigating alleged misconduct should be protected so that their investigation is fair and impartial.	Universities, university associations and national academies of sciences	Medium term
	To encourage whistleblowers to report research misconduct when and if it occurs, institutions should put in place protections against retaliation against those who report misconduct	Universities, university associations and national academies of sciences	Medium term
Companies should recognise and commit to fulfil their corporate responsibilities (CR) through transparency and stakeholder engagement	Responsibility applies to all enterprises regardless of their size, sector, operational context, ownership and structure • Define the domains of influence and responsibility of an organisation over its impacts • Identify what are the relevant topics and prioritize the most important ones for the organisation • Apply due diligence process in the evaluation of impacts	Companies, Industry and Business Associations	Medium to long term

	• Set a strategy for ethics assessment, based on a structured, step-by-step, procedure (e.g. Plan, Do, Check, Act cycle).
	• Define responsibility for ethics assessment along all the hierarchy of the organisation
	• Ensure commitment of executives to ethics assessment
	• Ensure credibility of actions:
	  ▪ ensure transparency and accountability of the ethics assessment process
	  ▪ engage with stakeholders to evaluate and review impacts and actions; adopt multi-stakeholder approaches
	  ▪ regularly communicate results on ethics assessment (reporting)
	  ▪ provide ways for third part evaluation, external assurance of ethics assessment		

Table 4. Recommendations and required actions for defining responsibilities and monitoring of EA.

6.1.3   Recommendations for stronger professional norms

The following (Table 5) are recommendations and required actions for stronger professional norms.

Recommendations	Actions	Stakeholders	Timeline
Recognise responsibility for ethical professional behaviour.	Develop, revise, and publicise ethical codes of practice and conduct in research institutions.	Professional associations	Short term
	Universities and companies implement codes of conduct and practice for their students and employees. RFOs and GOs may also insist on those who receive funding should adhere to a specified code of ethics.	Universities, companies, RFOs, GOs	Short term
Raise awareness of ethical professional behaviour.	Develop ethical guidelines for specific fields and in each country	SAs, POs, universities, and NECs	Short term
	Encourage greater consistency in the ethical standards across different fields.	NECs and science academies	Short term
Raise awareness of ethical issues in research and encourage ethical behaviour.	Incorporate ethics training into university curricula and institutional training programmes.	Universities	Short term
	Industry groups, professional organizations, government organisations, and RECs may also contribute to the drafting of these standards and encourage their use by requiring researchers to follow them in the projects that they sponsor or review.	Industry groups, professional organizations, government organisations, RECs	Short term

	• provide and promote training opportunities and capacity-building on ethics assessment		

Table 5. Recommendations and required actions for stronger professional norms.

6.2 PROCEDURAL RECOMMENDATIONS AND ACTIONS

6.2.1 Recommendations for ethics assessment tools and frameworks

The following (Table 6) are recommendations and required actions for the development of ethics assessment tools and frameworks.

Recommendations	Actions	Stakeholders	Timeline
Joint framework for universities and institutions of higher education On a national level, standards for RECs should be established.	Institutions of higher education should establish a committee with representatives from various institutions to develop the joint framework.	Universities, science academies	Medium term
Effective and cost- and time-efficient use of the SATORI framework	Creation and development of a national knowledge repository of documents that are helpful in conducting ethical analyses according to the SATORI framework • e.g., documentation on how to apply the framework, lists of ethical principles, previous ethical assessments in various fields	NECs	Short term
	Standardisation of the review and audit procedures of SATORI's ethical impact assessment methodology as much as possible to decrease their administrative burden. • This can be done, for instance, by creating an online submission system that the assessor can use to submit his or her findings from the ethical impact assessment process.	RFOs, RECs and companies	Short to medium term
Research funding organizations should have adequate criteria and procedures for in-house ethics review and monitoring of proposals and projects.	Establishment of detailed procedures for in-house ethics review and monitoring (on the basis of SATORI's ethical impact assessment methodology set out in SATORI Deliverable 4.2) • These criteria and procedures must go beyond ethics assessment as required by law, and should also include aspects relating to research integrity, and scientific misconduct.	RFOs	Short to medium term

	Integration of the established ethics review and monitoring procedures in RFOs' proposal selection procedures.	RFOs	Short to medium term
Strategic corporate responsibility (CR) tools explicitly devoted to R&I activities (e.g. Responsible Research and Innovation tools) should be developed. These strategic tools should be integrated within a broader CR framework.	• A models for ethics assessment and guidance in industry should be integrated within already exciting CR framework (CR global initiatives, standards and principles) • This model should be multi-layered, providing general principles applicable to all types of actors as well as specific provisions suitable for different types and categories of actors (e.g. branches of industry, SMEs) • Ensure a flexible, modular, incremental process (tailored to the organisation type and needs) • Definition of minimum standards that become pre-requisite for EC financed projects	Companies, Industry and Business associations EU UN OECD Other actors engaged in CR	Medium to long term
Procedures within RECs RECs need to adjust their procedures according to the SATORI recommendations.	• A review by an REC should happen in three steps: an ethics self-assessment of the researcher, a pre-screening phase, and a screening phase. • Ethics clearance should be graded into "conditional ethics clearance", the recommendation of an "ethics assessment", and "refuse ethics clearance". The outcome of ethics clearance should be delivered in a written form.	RECs	Short to medium term

Table 6. Recommendations and required actions for the development of ethics assessment tools and frameworks.

6.2.2 Recommendations for the promotion of the use of ethics assessment tools and frameworks

The following (Table 7) are recommendations and required actions for the promotion of the use of ethics assessment tools and frameworks.

Recommendations	Actions	Stakeholders	Timeline
Ethics assessors should have sufficient skills in applying the SATORI framework and ethical theories and principles.	Institution and coordination of training programs • Training programs for ethics assessors should be developed on how to properly apply the	NECs, RFOs, RECs, research institutions and professional organisations	Short term

	SATORI framework as well as general ethical theories and principles.		
	Development of easy to understand online resources for training programs.	NECs, RFOs, RECs, research institutions and professional organisations	Short to medium term
Adoption of SATORI framework for ethics assessment in R&I activity	Promotion and training of the SATROI framework	SATORI	Short term
	Implementation of the SATORI framework and integration it with existing policies and procedures in EA.	Existing RECs	Short term
	Utilisation of the recommendations for best practice presented in the SATORI framework as guidance during the establishment of the unit's policies.	Newly established RECs and other Ethics committees	
	Implementation SATORI's Common Framework for Ethical Impact Assessment	RFOs, RECs, research institutions, and industry	Medium term

Table 7. Recommendations and required actions for the promotion of the use of ethics assessment tools and frameworks.

6.2.3 Recommendations for the promotion of positive attitudes and professional norms

The following (Table 8) are recommendations and required actions for the promotion of positive attitudes and professional norms.

Recommendation	Actions	Stakeholders	Timeline
There should be a greater general awareness of ethics and ethical issues among researchers who submit proposals and work on projects.	Increasing the role of ethical issues in the education of researchers.	Universities	Medium to long term
	Institution of programs that educate researchers on the ethical implications of their research through presentations and information materials.	RFOs, science academies, NECs	Medium term
	Provision of information on the ethical implications of research and possibilities or ethics assessment online.	RFOs, science academies, NECs	Medium term
Strengthening the Civil Society Organisations' involvement in ethics assessment and their function of an intermediary between science and society.[53]	Increased funding for participatory activities organised by CSOs.	CSOs networks, EU, governments	Medium term
	Organization of participatory activities, e.g. citizen meetings	CSOs	Medium term
Encourage a race to the top – responsible business	• Certification for socially responsible research, and real recognition of this certification	EU	Short to medium term

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[53] See SATORI Deliverable 4.2.5, p. 16.

	European Awards for social research and real visibility for these awards. • Particular attention and support should be given to SMEs		
Awareness of ethics in universities	In all scientific fields, higher education institutes should teach ethics to undergraduate, post-graduate and PhD students. Whether ethics are taught or not should be evaluated by accreditation committees.	Universities	Medium term

Table 8. Recommendations and required actions for the promotion of positive attitudes and professional norms.

6.3 A POLICY ORIENTED READING OF THE SATORI RECOMMENDATIONS

The recommendations detailed above show the role of a plethora of political actors. One should distinguish between the role of the European Union and the role of national governments.

6.3.1 The role of the European Union

The European Union has 4 major roles to play to see the SATORI framework brought to life (see Figure 8).

First, the EU should *incentivize* the creation of adequate structures at the national levels (National Ethics Committees or National Academies of Science when they do not exist).

Second, it should *support* the creation of CSOs involved in ethics assessment, which means make sure that these which are already in place are involved in ethics assessment, but also to fund new ones, and ensure the representatives of these CSOs are trained to perform ethics assessment.

Third, the EU, as a funding body, can define standards related to ethics assessments that condition eligibility to grants.

Fourth, the EU should promote the idea of ethics assessment to society and business. One should think of think of models on how ethic assessment is to be conducted with and for businesses.
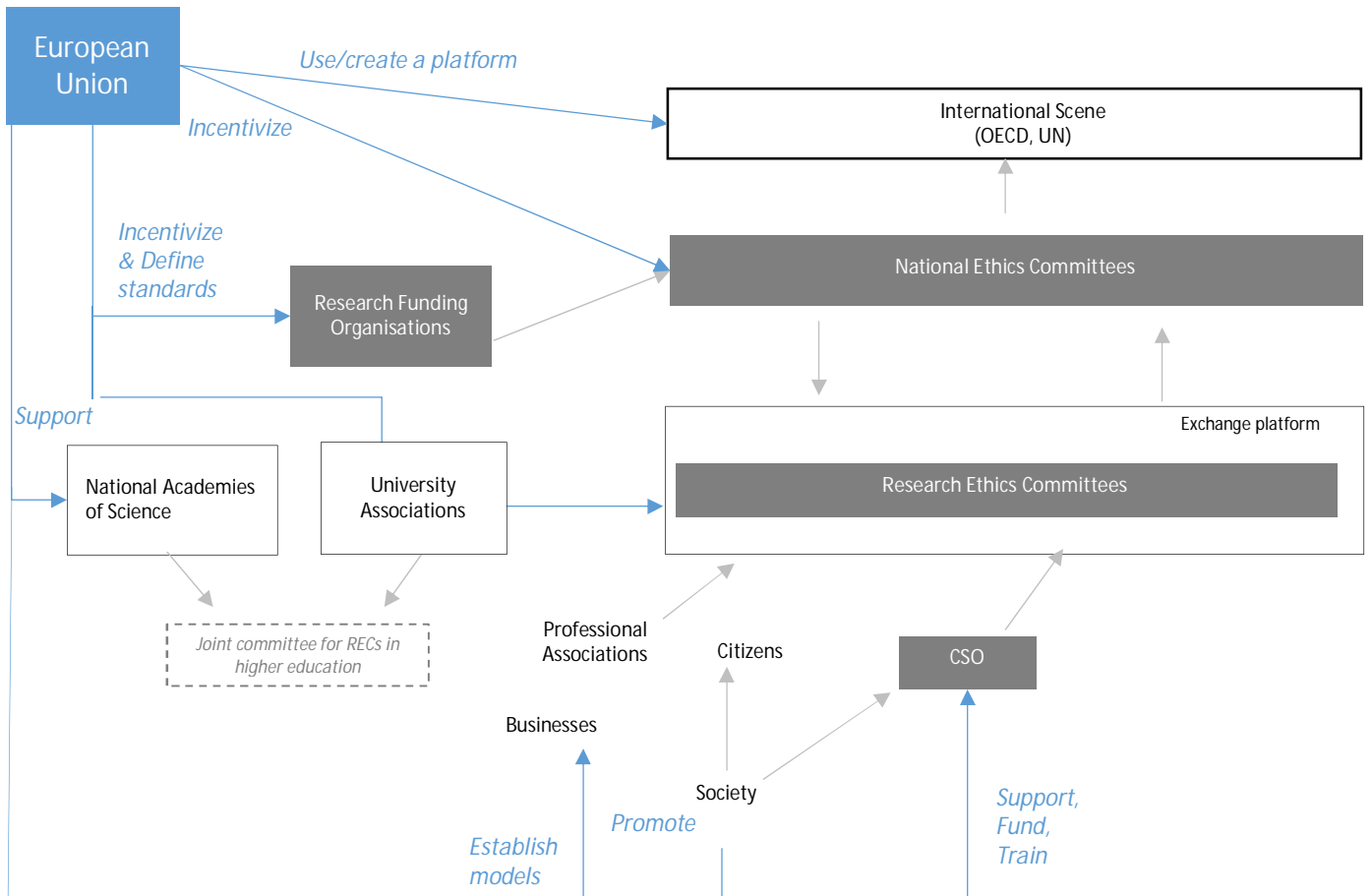
Figure 8. An overview of the role of the EU in setting up the institutions and procedures required by the SATORI framework

6.3.2   The role of national governments

National governments must make sure to create the bodies needed (National Ethics Committees, National Science Academies), support the creation of research committees and provide legal bases for these (see Figure 9).
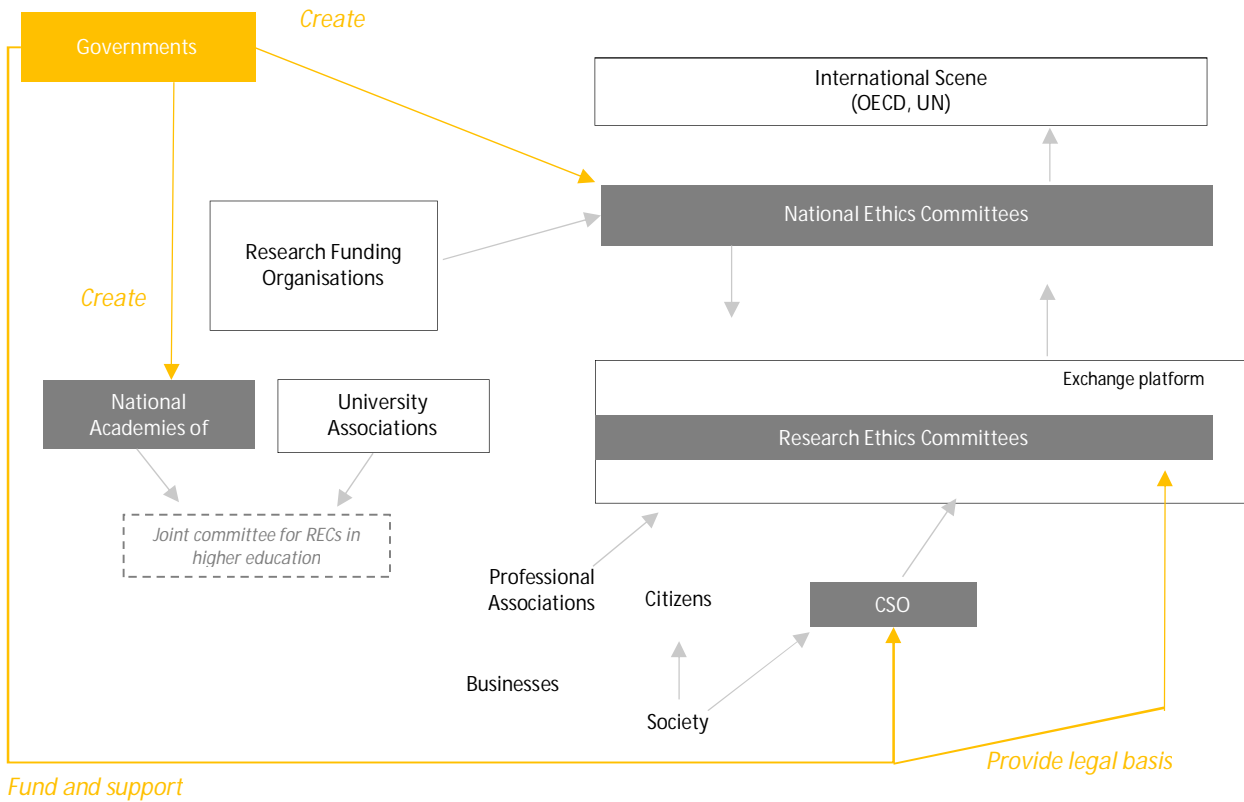
Figure 9. An overview of the role of the national governments in setting up the institutions and procedures required by the SATORI framework

CONCLUSIONS AND DISCUSSION

The aim of the SATORI roadmap process was to work out how the SATORI ethics assessment framework could be implemented in practice. First, a vision was formulated, and then the implementation of a new social practice was studied. A model for the implementation of a new social practice was constructed that describes the required steps at the policy making, network, organisational, and individual levels. This model was used as a basis for identifying the steps necessary in order to reach the vision.

The changes realising the necessary steps and ultimately the vision are of an institutional or procedural nature. The graphical presentation of the roadmap integrates the necessary steps with the actual institutional and procedural changes, thus dividing the roadmap in three levels: institutional and procedural changes, and the desired outcomes or steps that are realised by these changes. The necessary steps were identified on the basis of the developed theoretical model for the implementation of a new social practice – in this case, improved ethics assessment practices. Subsequently, the institutional and procedural changes required for the steps were identified. This was done (1) by using the results of the earlier work in SATORI and (2) by organising two SATORI roadmapping workshops. The earlier work included the results of more than 200 expert interviews and their analysis, among other materials.

The roadmap work was continued with the creation of more detailed and concrete recommendations, with required actions, actors responsible for the actions, and a feasible timeframe to fulfil the actions. The summary of the recommendations gained through the roadmap process is presented in Figure 10: it depicts the main results including the necessary steps and the most important actions by different actor groups.
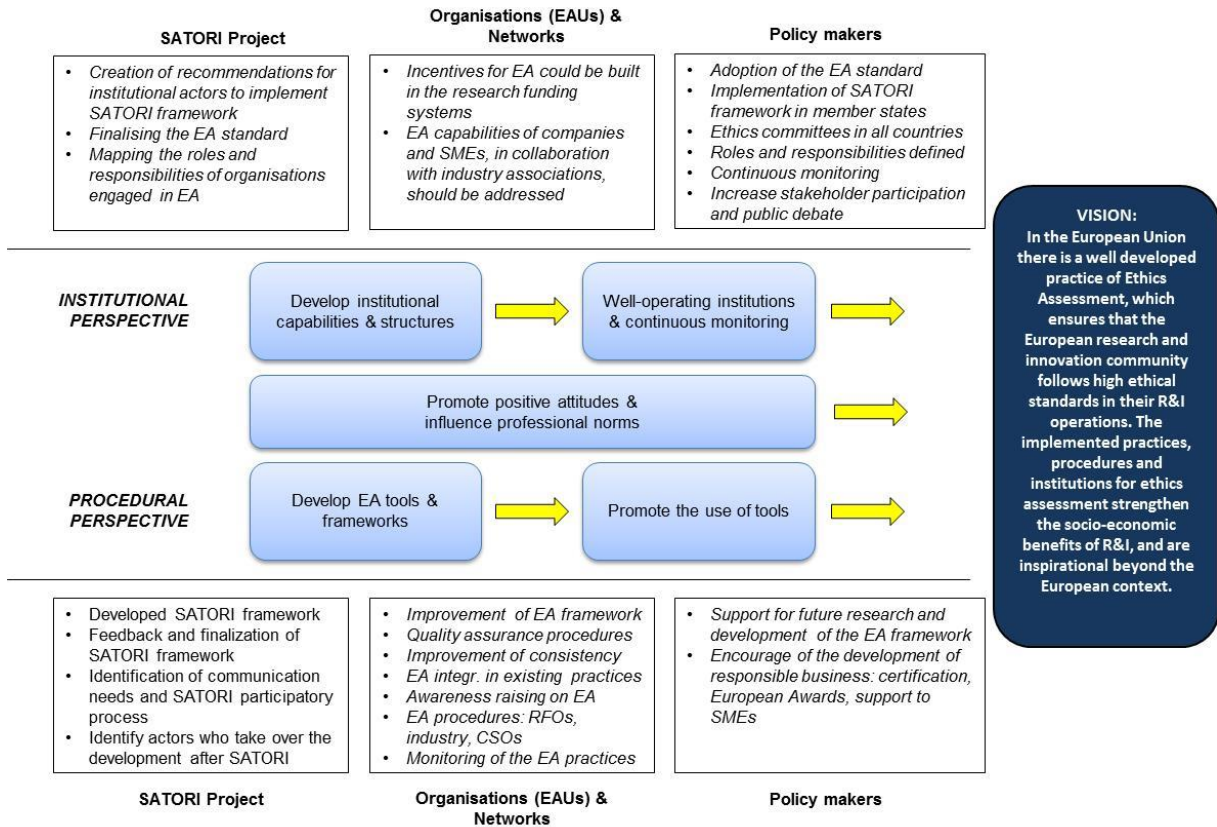
Figure 10. The summary of the recommendations gained through the roadmap process.

Roadmap reflects the opinions of the experts who participated in the work. In this case, the number of workshop participants was not very large. However, the knowledge that was available at the beginning of the roadmapping process was very substantial because the SATORI project had already been underway for two years and had resulted in a large number of expert interviews, reports, and workshops and seminars in which dozens of experts participated.

The SATORI project will continue for another year. Future work will include consultations with different expert groups which may reveal additional input to the roadmap.

7 ANNEXES

Table A1. Participants of the internal workshop held in Copenhagen 31 May 2016.

Name	Organisation	External (outside SATORI consortium)
Aleksandar Antovic	Bio Save Group	X
Rok Benčin	ZRC SAZU	
Marlou Bijlsma	NEN	
Lise Bitsch	DBT	
Philip Brey	UT	
Agata Gurzawska	UT	
Tilimbe Jiya	DMU	
Lars Klüver	DBT	
Raija Koivisto	VTT	(Facilitator)
Anna Leinonen	VTT	(Facilitator)
Rasmus Nielsen	DBT	
Lea Amby Ottosen	DBT	
Daniela Ovadia	EUSJA	
Andrea Porcari	AIRI	
Dino Tescher	EUSJA	
Dubravka Vejnovic	CPN	
Zuzanna Warso	HFHR	
David Wright	Trilateral	
Thamar Zijlstra	NEN	

Table A2. Participants of the stakeholder workshop held in Vienna 20 June 2016.

Name	Country	SATORI Partner
Marlene Altenhofer	Austria	
Philip Brey	The Netherlands	x
Mark Coeckelbergh	Austria	
Erich Grießler	Austria	
Barbara Grimpe	Austria	
Helena Kekki	Finland	
Raija Koivisto	Finland	x (Facilitator)
Anna Leinonen	VTT	x (Facilitator)
Johannes Rath	Austria	
Eva Singer	Austria	
Doris Wolfslehner	Austria	x