ERA4Health Partnership

D18.1. (3.1.1) RRI Guidelines

WP18

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Technical References

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1 PU = Public
SEN = Sensitive

D18.1. 3.1.1 RRI Guidelines

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GLOSSARY / LIST OF ACRONYMS

ERAB: Ethics & RRI' Advisory Board
ExCom: Executive Committee
JTC: Joint Transnational Call
RCN: The Research Council of Norway
RRI: Responsible Research and Innovation
SRIA: Strategic Research and Innovation Agenda
STAB: Strategic Advisory Board
WG: Working Group

EXECUTIVE SUMMARY

Responsible research and innovation (RRI) has emerged as one way to create space to consider the social, ethical, environmental and policy dimensions of science and innovation within the research and innovation process, and ensure that 'science' meets the needs of 'society'.

ERA4Health build on ERA-NETs that has implemented RRI in their networking activities and call processes, i.e. by developing RRI guideline for funders[5] and RRI Guideline for proposal writers and evaluators[6].

Implementing and developing RRI is a key action of the ERA4Health Partnership objectives. RRI actions will be promoted via integrated actions that for example promote cross-cutting training of relevant stakeholders and develop new organisational practices, to foster the uptake of the RRI approach by stakeholders, funders and research organisations.

ERA4Health emphasises that RRI is not a one-size-fits-all approach but must be adapted to the actual social and ethical issues raised by the R&I activities funded:

- RRI implementation in the Partnership is *fitted to the role as call developer and R&I funder*.
- The RRI Guidelines we want to further develop for R&I proposers and evaluators will be *fit to the type of R&I projects that ERA4Healt funds*.

This deliverable presents the "baseline" for ERA4Health RRI Guidelines approach in calls and ethical clearance of projects selected for funding in Joint Transnational Call (JTC)1 and JTC2. ERA4Health has successfully taken the first step towards an RRI implementation and ethical clearance. Other cross-cutting issues implemented are Open Science and Gender dimensions. ERA4Health will continue developing the partnership's practice in these fields through co-creation processes and collaboration between R & I funders, --scientists and -organisations, policy makers and other stakeholders.

[5] RRI_guideline_for_funders.pdf (healthydietforhealthylife.eu)

[6] EuroNanoMed III » ENMIII RRI Guidelines

1. PURPOSE AND OBJECTIVES

The vision for Pillar 3 of ERA4Health - Transversal Activities - is to foster and enhance shared learning and interaction across ERA4Health. Key activities for Pillar 3 include the development of research and innovation

- funding methodologies and sustainability
- ecosystems and capacity building activities
- responsible, ethical and open science

The pillar 3 contributes to all Specific Objectives (SO1-4) of this partnership.

Responsible research and innovation (RRI) has emerged as one way to create space to consider the social, ethical, environmental and policy dimensions of science and innovation within the research and innovation process, and ensure that 'science' meets the needs of 'society'.

Deliverable 18.1 is connected to WP18 (3.1) Responsible Research Innovation activities and other cross-cutting issues and the task 3.1.1 Establish and develop RRI Guidelines for ERA4Health partners and proposers to calls. Task leader is RCN, and many participants are involved (ISCIII, ZonMw, ANR, IT-MoH, ECRIN, RCN, DLR, AICIB, ASRT, FWO, MUR, NCBR, RCL (LMT), LCS, BMBWF, CSO-MOH, AEI, NWO, FWF, UEFISCDI, GSRI, BCM-SAS, FNRS, HRB, NKFIH, IFD) and task duration is M1-M58. This task will ensure that ERA4Health operates with a common understanding of RRI's goals; all calls support RRI from the beginning, proposers can deploy excellent and impactful approaches to RRI in their projects. The deliverable is also connected to WP23 Ethics requirements with the objective to ensure compliance with the 'ethics requirements' set out in WP23.

This deliverable presents the "baseline" for ERA4Health RRI Guidelines approach in calls and ethical clearance of projects selected for funding in Joint Transnational Call (JTC)1 and JTC2.

2. METHODOLOGY

ERA4Health build on ERA-NETs that has implemented RRI in their networking activities and call processes, i.e., by developing RRI guideline for funders[7] and RRI Guideline for proposal writers and evaluators[8].

Implementing and developing RRI is also a key action of the ERA4Health Partnership objectives. RRI actions will be promoted via integrated actions that for example promote cross-cutting training of relevant stakeholders and develop new organisational practices, to foster the uptake of the RRI approach by stakeholders, funders and research organisations. WP18 acts as a hub to advance and develop new RRI practices that will then be integrated into the other administrative and research activities of ERA4Health.

SO4 specify that ERA4Health will promote research 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 to ensure a true societal impact.

To achieve this, task 3.1.1 will develop RRI guidelines for ERA4Health partners, evaluators and for proposers to calls. These guidelines will in addition to RRI methodologies also cover Gender, Ethical and Open Science aspects. In the two ERA4Health JTC that have been published this first year, right at the beginning of the partnership, RRI was incorporated in the call texts with a short RRI request and a "mini RRI Guideline" in the Pre-proposal application form. The content was largely based on the Strategic Research and Innovation Agenda (SRIA) of ERA4Health.

2.1. IMPLEMENTATION OF RRI IN JTC1 AND JTC2

RRI in the call texts:
Explain how the project will demonstrate a commitment for investigating and addressing social, ethical, political, environmental or cultural dimensions of the proposed research.
The proposal template (application form) further elaborates on this and how RRI dimensions can be approached.

[7] RRI_guideline_for_funders.pdf (healthydietforhealthylife.eu)

[8] EuroNanoMed III » ENMIII RRI Guidelines

In application - Eligibility

Criteria Joint research proposals may be submitted by applicants belonging to one of the following categories: A. Academia., B. Clinical/public health sector, C. Enterprises, and
D. Operational stakeholders – e.g. citizens and/or citizen representatives, local communities, schools, municipalities, local/national NGOS, consumer organisations.
In line with the concept of RRI, operational stakeholders should be in a position to provide useful knowledge to the consortium, ensure the consortium's research is useful and translatable to their (or other) organizational contexts, and/or influence decision making or create change within their organisations. Operational stakeholders should be engaged in the research process from conception of the study to dissemination.

In the Pre-proposal application form: A "mini RRI Guideline"

In the pre-proposal application for the two JTCs included a "mini RRI Guideline" with the heading " Responsible Research and Innovation (RRI) and other cross cutting issues". The main objective was to guide the proposer a bit on how ERA4Health basically understands the RRI concept and the RRI approaches and actions that can be taken in a scientific proposal.
It was based on the ERA4Health SRIA and covered the following five themes:

a. General RRI aspects
   Explains shortly what Responsible research and innovation (RRI) is and how it is implemented in ERA4Health.

b. Stakeholder Involvement
   Proposal must describe role and contribution, level of involvement and explain reasoning behind stakeholder involvement.

c. For projects with high potential of applicability at short/medium term
   Expected time for market and transfer to patient towards clinical and public health applications, pharmaceutical/health device applications, other industrial applications including market and end user's scenario, quality of dissemination, exploitation and business plan.

d. Ethical considerations
   States the overreaching ethical standards to follow, including ethical self-declaration of Horizon Europe proposals.

2.2. ETHICAL CONSIDERATIONS AND CLEARANCE

ERA4Health will only fund research of the highest ethical standards complying with European Directive and the relevant national/regional laws, rules, and regulations. Each applicant to a ERA4Health call must comply with both ERA4Health ethics considerations and the national/regional/local regulations in question.

Within the application system, consortia are required to complete an ethics issues table, as well as supply an ethical self-assessment, a statement presenting ethics questions that the consortia actualise. Each consortium should explain how ethics issues will be treated in the proposed research project in the proposal form on ethics and legal issues and describe which participant(s) is/are responsible for the ethics issue. If an ethics permit is required, the applicants should include the status of the permit (not applied/under review/permit granted and date of submission/approval). This statement also pertains to data protection, human participation, and use of animals.

RESPONSIBILITY OF PROPOSAL PARTICIPANTS, FUNDING ORGANISATIONS AND ASSESSORS

All participants in a proposal must follow national ethical regulations for their part of the proposed work. All proposals appoint an ethics contact point for the consortium in the self-assessment. Ideally this person also oversees that the proposal holds cross-border high ethical standards.

Funding organisations participating in a call have no ethical assessment role if not having such procedures at the national level.

The ethical assessment performed in the framework of the ERA4Health Calls does not substitute the national ethical boards and procedures, and additional ethical authorisations might be required by some funding organisations according to national regulations. If identified, deviations from national ethics approvals must be reported to other funders of the consortium. The assessment should present strengths and weaknesses of the results, go beyond findings, and identify important underlying problems and/or priority issues. The final ethical clearance of funded proposals should be fully approved after documented necessary improvements done.

Decision: A final decision, based on the ranking list established by the Per Review Panel, available funding and the ethics evaluation results, will be taken by the national/regional funding organisations.

ETHICS APPRAISAL PROCEDURE

Each full proposal selected for funding will undergo an ethical clearance. The proposals will be shared with the experts in ethics assessment two weeks before the Ethics clearance meeting. The Ethics reviewers evaluate preselected proposals for funding alone, but have a pre-meeting with the JCS, supported by Pillar 3 leader, to agree on general approach. After a remote assessment of the proposals, a consensus concerning the ethical clearance of each proposal will be made by the two ethical experts in a meeting. The written recommendations of the board of the aforementioned experts will be forwarded to the JCS who will compile the feedback to applicants with the funding decision notification letters and to proposal highlighting the Ethical clearance. All reports will be inserted in the Deliverable "2A.2.4.X Joint selection list of funded projects".

2.3. OPEN SCIENCE

Importantly, all funding recipients must ensure that all outcomes (publications, etc.) of transnational ERA4Health-funded projects are published with Open Access. All research projects funded by ERA4Health are eligible to publish on Open Research Europe (ORE), the Platform of the EC1[9] at no cost. The new research data resulting from the project should be treated according to the FAIR2[10] principles, and deposited and shared, according to the national rules of the countries involved. To make research data findable, accessible, interoperable and re-usable (FAIR), a Data Management strategy for the proposed full projects is mandatory in the second evaluation stage. Projects selected to receive funding in the current call, will be requested to present a more detailed Data Management Plan (DMP) before month 6 from the official start of the project and an update of the DMP will be asked at the end of the projects.

[9] *https://open-research-europe.ec.europa.eu/*

[10] *https://www.nature.com/articles/sdata201618*

2.4. GENDER DIMENSION

ERA4Health strives to ensure that gender equality is taken into consideration for all aspects of ERA4Health calls. The JCS and the CSC take responsibility to ensure that an appropriate gender balance of PRP members and external reviewers is maintained. Gender equality is also an important consideration in research projects. The JCS will analyse the gender balance in the submitted and awarded consortium using the information reported by the applicants in the application form.

Consortia, where relevant, should describe how the gender dimension, i.e. how sex and/or gender analysis is taken into account in the project's content according to requested information in application forms and guidelines.

For guidance on methods of sex/gender analysis and the issues to be taken into account, please refer to the EC recommendations[11].

2.5. NEXT STEP

From June 2023 ERA4Health starts with D18.2 RRI Guidelines, to develop a more complete RRI Guideline document that will be an integral part of JTC3 and JTC4. This document will be developed in a co-creation manner including the inputs that will be received by the ERA4HHealth community (*survey* to and participation of the scientists, the STAB, and funders in a *workshop*). The core executive units in the RRI Guidelines development process are the Ethics and RRI` Advisory Board (ERAB), the subcontracted RRI advisors, as well as the ERA4Health RRI Working Group. These units are described in more detail in Deliverable 18.5: Working group RRI established (Public report).

ERA4Health emphasises that RRI is not a one-size-fits-all approach but must be adapted to the actual social and ethical issues raised by the R&I activities funded. Foundational, exploratory research will require a different approach to applied, high-TRL/clinical research.

3. RESULTS

[11] https://research-and-innovation.ec.europa.eu/strategy/strategy-2020-2024/democracy-and-rights/gender-equality-research-and-innovation_en

ERA4Health has a Deliverable D18.7 – D 3.1.3.1 RRI Impact reports. These reposts will be made by ERA4Healt partners in collaboration with our established Ethics and ERAB and RRI advisors. What impact the ERA4Health RRI practice and Ethics clearance will have will show here.

4. CONCLUSIONS

ERA4Health has successfully taken the first step towards an RRI implementation and practice and Ethical clearance in JTC1 and JTC2. Other cross-cutting issues implemented are Open Science and Gender dimensions. ERA4Health will continue developing the partnership's practice in these fields through co-creation processes and collaboration between R & I funders, -scientists and -organisations, policy makers and other stakeholders.

5. REFERENCES

SRIA: ec_rtd_he-partnerships-era-for-health-1.pdf (era4health.eu)

JTC1: CARDINNOV 2023 - ERA4HEALTH

JTC2: HEALTHEQUITY 2023 - ERA4HEALTH

WP13: Deliverable 13.1_ERA4Health_ STANDARD OPERATING PROCEDURE MANUAL (SOP) (Sensitive report)

WP18: Deliverable 18.5: WORKING GROUP RRI ESTABLISHED (Public report).

6. ANNEXES

The Pre-proposal application form: A "mini RRI Guideline"

Responsible Research and Innovation (RRI) and other cross cutting issues:

a. General RRI aspects (max 0,5 page)

Responsible research and innovation (RRI) 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 to ensure a true societal impact.

RRI implies that societal actors (researchers, health care systems, citizens, policy makers, industry, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society.

As the involvement of societal groups is essential in RRI it is often connected to co-creation, co-design and co-production – methodologies in which R&I projects are structured to include stakeholders from the outset (e.g. users or interest groups) – and is related to the general Open Science agenda. RRI can also involve interdisciplinarity, with the inclusion of expertise from the social sciences and humanities (SSH). Being inclusive also implies taking diversity seriously.

Implementation of RRI in ERA4Health:

Taking an RRI approach implies to take actions that may include to

a) Anticipate the future known and unknown risks associated with a science or technology;

b) Include a broad range of stakeholders in the development of science and technologies;

c) Reflect on the underlying assumptions and values driving a scientific research project; and

d) Respond to these processes by incorporating their outcomes into the design of research projects and funding programmes.

RRI is closely related to other cross-cutting issues, and actions can be taken that address both RRI and other important values, such as public/user engagement, open science or ethical assessments

Guidelines for RRI:
https://rri-tools.eu/ - provides numerous resources for practical RRI.
https://thinkingtool.eu/ - The Societal Readiness Thinking Tool guides you through the steps of including RRI in a project.

Explain how the project will demonstrate a commitment to investigating and addressing the social, ethical, political, environmental or cultural dimensions of the proposed research.

b. Stakeholder Involvement (max 0.5 page)

- Describe the role and contribution of operational stakeholders (e.g. patient advocacy groups, citizens and/or citizen representatives, local communities, schools, municipalities, local/national NGOS, consumer organisations.)
- Describe the level of involvement for each stage of the research
- Explain reasoning behind involving/not involving certain stakeholders

c. For projects with high potential of applicability at short/medium term (max 0,5 page)

Expected time for market and transfer to patient towards clinical and public health applications, pharmaceutical/health device applications, other industrial applications including market and end user's scenario, quality of dissemination, exploitation and business plan.

d. Ethical considerations

The proposal complies with ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct).

If research activities are undertaken in a non-European country, the applicants should verify that the research activities will follow the Ethical recommendations of the country where the research will be conducted as well as the EU Ethical recommendations. Full proposals will be checked by an independent ethical board. You can already check here the Ethical Issues potentially raised by your proposal.

Yes ☐ No ☐