MICROB-PREDICT

MICROBiome-based biomarkers to PREDICT decompensation of liver cirrhosis and treatment response

D8.1 Policy for integrating the six agendas (ethics, gender equality, public engagement, governance, scientific education and open access) of responsible research and innovation

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1. Executive Summary

The goal of this policy document is to define the agendas of Responsible Research and Innovation (RRI) and ways of implementation within *MICROBiome-based biomarkers to predict decompensation of liver cirrhosis and treatment response European research project* (MICROB-PREDICT). It is intended to analyze the measures that partners should take into account and develop to align the interest of all actors involved, including societal expectations from the very inception of the research interventions. The aim is to foster RRI at European level (HORIZON 2020), and the design of inclusive and sustainable research and innovation ecosystem.

Governance, ethics, gender equality, public engagement, open access and scientific education as the agendas of RRI are defined here offering measures for implementation. To develop this policy the contractual requirements between the MICROB-Predict Consortium and the European Commission have been reviewed and added when necessary according to the RRI issues. This report is not only for the MICROB-PREDICT Consortium but also for anyone interested in how this crosscutting RRI approach could be implemented, and offers guidance for other European projects.

2. Deliverable report

1 - Introduction

1.1- What is RRI?

Responsible Research and Innovation is a dynamic, iterative process in which all stakeholders in research and innovation become mutually responsive and share responsibility for both the process and its outcomes (RRI Tools). Scientific inquiry is a process not limited to the perspective of the researchers, and societal actors such as citizens, policymakers, business or third sector organizations can and should be involved during the whole research and innovation process.

The objective of RRI is to create high-quality science aligned with the values, needs, and expectations of society. Implementing RRI leads to a more engaged public, responsible actors, and responsible institutions. It also has benefits for research and innovation, as RRI strives for making science and technology more ethical, sustainable and socially beneficial.

To achieve these outcomes, RRI entails four dimensions of the research process that try to reflect the social, ethical and political stakes associated with technological and scientific advances. Diversity and

inclusion produce outcomes that are aligned with the values and expectations of society since they take into account different perspectives and expertise. Openness and transparency make the process of research and innovation more accessible to all actors, allowing people to discuss and scrutinize science and technology, which empowers them to make more informed decisions. Through anticipation and reflection it is possible to envision impacts and reflect on the underlying assumptions, values, and purposes of the research, allowing more responsible action. Finally, RRI entails responsiveness and adaptive change to respond to the views expressed by the stakeholders, changing circumstances or new knowledge.

Four dimensions of responsible innovation.

Dimension	Indicative techniques and approaches	Factors affecting implementation
Anticipation	Foresight Technology assessment Horizon scanning Scenarios Vision assessment Socio-literary techniques	Engaging with existing imaginaries Participation rather than prediction Plausibility Investment in scenario-building Scientific autonomy and reluctance to anticipate
Reflexivity	Multidisciplinary collaboration and training Embedded social scientists and ethicists in laboratories Ethical technology assessment Codes of conduct Moratoriums	Rethinking moral division of labour Enlarging or redefining role responsibilities Reflexive capacity among scientists and within institutions Connections made between research practice and governance
Inclusion	Consensus conferences Citizens' juries and panels Focus groups Science shops Deliberative mapping Deliberative polling Lay membership of expert bodies User-centred design Open innovation	Questionable legitimacy of deliberative exercises Need for clarity about, purposes of and motivation for dialogue Deliberation on framing assumptions Ability to consider power imbalances Ability to interrogate the social and ethical stakes associated with new science and technology Quality of dialogue as a learning exercise
Responsiveness	Constitution of grand challenges and thematic research programmes Regulation Standards Open access and other mechanisms of transparency Niche management Value-sensitive design Moratoriums Stage-gates Alternative intellectual property regimes	Strategic policies and technology 'roadmaps' Science-policy culture Institutional structure Prevailing policy discourses Institutional cultures Institutional leadership Openness and transparency Intellectual property regimes Technological standards

Source: Stilgoe J, Owen R, Macnaghten P. (2013) D*eveloping a framework for responsible innovation.*

To embed RRI in the research and development process, the European Commission has set out six key policy agendas for policymakers to consider: governance, ethics, gender equality, public engagement, science education and open access.

Governance can be seen as the umbrella term for activities that aim to address questions related to what processes and procedures can be implemented to ensure Responsible Research and Innovation. This key policy agenda deals with policies, rules and processes that affect the way in which powers are exercised. In the EU context, five requirements have been identified that underpin good governance: openness, participation, accountability, effectiveness and coherence (2001 EC White

Paper on European Governance). Governance permeates all the other five policy agendas of RRI. Ethics, gender equality, public engagement, science education and open access will be implemented taking good governance as the core of the concept of RRI.

2 - Ethics

2.1 - Definition

For all activities funded by the European Union, ethics is an integral part of research from beginning to end, and ethical compliance is seen as pivotal to achieve real research excellence (European Commission Online Manual). Research, including its outcomes and the way it is conducted, should be morally grounded and acceptable to society. Honesty, accountability, fairness and good stewardship should be core principles of research and innovation.

Ethics in RRI relates to three main areas, ethical research, research integrity, and societal acceptability. Ethical research conduct implies the application of fundamental ethical principles and legislation to scientific research in all possible domains of research. Research integrity means that research methods, activities, and processes are guided by standards, guidelines, and protocols; open to external scrutiny (for example, ethical bodies extended to societal stakeholders); and open to internal reflexivity (nurtured by a culture of open deliberative integrity). Social acceptability includes the consideration of the short-term and long-term implications of the research, and this should respond to actual social needs and reflect the basic values of society.

2.2 - Implementation

a) Informed consent policy for human subjects, human biological samples and personal data in MICROB-PREDICT

On the 30th of June 2019, the Informed consent policy for human subjects, human biological samples and personal data in MICROB-PREDICT was released and it is available in open access for anyone interested. “This policy describes the ethical and legal framework for the planned research interventions, the implications for research participants (patients and healthy volunteers) and obligations for those conducting research: First, we will elaborate on the information that potential study participants should have received in order to be able to decide whether or not to participate (‘informed consent’), and the implications this decision may have for their own personal situation. Second, in line with the requirements introduced by the General Data Protection Regulation (GDPR),

we will define and summarize the information that should be included in the information process and informed consent procedure when informing participants, collecting and using human biological samples and personal data for research purposes. Our information and informed consent policy respects also the main ethical and legal guidelines on ethics in research at international and European level and the research integrity that the Consortium should take into account for achieving the goals of the project, while respecting research subjects." (De Lecuona, 2019).

The informed consent includes:

- Information for potential human subjects in research and informed consent procedures.
- Information about personal data protection: privacy and confidentiality of potential participants in research.
- Information to donors of human samples from biological origin and personal data associated.
- Information about publication of MICROB-PREDICT results.
- Information about Doctoral Thesis in the framework of MICROB-PREDICT.

b) Codes of conduct applicable and research integrity policy including publications in journals (Deliverable 8.4)

Since assuring and promoting research integrity is a core issue for the MICROB-PREDICT Consortium, the Work Package dedicated to Ethics, Health and socioeconomic issues includes a report on the state of the art of the codes of conduct applicable and the research integrity policy including publications in journals. Due to the diverse partners involved, coming from the public and private research and innovation domain, and according to different traditions across Europe in research integrity, it is necessary to identify the codes of conduct and the policies on research integrity and ethics in research applicable. In 2017, the European Federation of Academies of Sciences and Humanities published the revised edition of The European Code of Conduct for Research Integrity for the European research community. The ALLEA Code, as a model for organisations and researchers across Europe, updated the European Code of Conduct on Research Integrity that is applicable for all members of the MICROB-PREDICT Consortium.

This compilation could also be necessary for the mentoring program, in order to teach mentees the right thing to do in research and how to handle allegations of misconduct in case there is any, as the European Union is fostering a culture on research integrity. Along these lines, MICROB-PREDICT will

have a compilation and provide an analysis of the common grounds shared by the partners in research integrity. This compilation will be available by the end of March 2020.

c) Contractual requirements about ethics

Article 34 - Ethics and Research integrity

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity) and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells). The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity (ALLEA, 2017).

This implies compliance with the following fundamental principles:

- reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;
- honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
- respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
- accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts and means

that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the 'ethics requirements' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the Commission (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

3 - Gender equality

3.1 - Definition

"Integrating the gender dimension in the content of research and innovation is an added value in terms of excellence, creativity, and business opportunities. It helps researchers question gender norms and stereotypes, to rethink standards and reference models. It leads to an in-depth understanding of both genders' needs, behaviours and attitudes. It enhances the societal relevance of the knowledge, technologies and innovations produced. It also contributes to the production of goods and services better suited to potential market." (How to address gender equality in Horizon 2020)[1].

To integrate the gender dimension in research and innovation content means taking into account the biological characteristics of both females and males and the evolving social and cultural features of

1 https://www.h2020.cz/cs/storage/53a22c0dd6e0572cf510aeb632015386136efc95?uid=53a22c0dd6e0572cf510aeb632015386136efc95

both women and men, girls and boys. The gender dimension invites researchers to conduct sex and gender analysis in the research process, when developing concepts and theories, formulating research questions, collecting and analysing data and using the analytical tools that are specific to each scientific area. (How to address gender equality in Horizon 2020).

Horizon 2020[2] addresses this integration through three objectives that underpin the strategy on gender equality at each stage of the innovation cycle:

a) fostering gender balance in research teams, in order to close the gaps in the participation of women
b) ensuring gender balance in decision-making in order to reach the Commission's target of 40% of the underrepresented sex in panels and groups (50% for Advisory Groups)
c) integrating the gender dimension in research and innovation (R&I) content which helps improve the scientific quality and societal relevance of the produced knowledge, technology and/or innovation.

The legal basis for the promotion of gender equality is enshrined in the three core documents of Horizon 2020:

- The Horizon 2020 Regulation
- The Rules for participation
- The Specific Programme implementing Horizon 2020

The European Commission (Gender Roadmap Shortguide) considers a Gender Equality Plan as a set of actions aiming at:

- Conducting impact assessment of procedures and practices to identify gender bias

- Identifying and implementing innovative strategies to correct any bias

- Setting targets and monitoring progress via indicators

3.2 - Implementation

a) Contractual requirements about gender equality

33.1 Obligation to aim for gender equality

[2] Guidance on Gender Equality in Horizon 2020 - European Commission

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

b) Project Proposal Gender Analysis

Strong female representation within MICROB-PREDICT. Four out of ten work packages are led by females (WP1, 6, 8 and 9). Females thus represent 40% of the votes in the Steering Committee. 32% of the partner teams in the project are (co-)led by females (partners 2, 10, 12, 13, 16, 19, 20 and 22.). One third of the votes in the General Assembly will therefore come from females. Altogether, presence of women on MICROB-PREDICT boards and participation in decision-making is clearly above average in the EU (28% in 2014, European Commission (2016), She figures 2015, p. 146"). MICROB-PREDICT is committed to a work environment that promotes equal opportunities across gender and prohibits discriminatory activities. To this end, the institutions of all partners in the consortium have taken measures to improve the under-representation of women in science and the gender inequalities that persist from hiring to advancing to higher career levels. In MICROB-PREDICT we will further promote equal career opportunities by providing

(a) a mentoring programme that incorporates elements designed specifically to support female early career researchers (WP9)

(b) by ensuring that working hour arrangements for staff employed will not disproportionately disadvantage those with caring responsibilities; and

(c) by the Project Management Office regularly monitoring gender issues from hiring to career opportunities and retention of staff.

Population of the study

The gender ratio of trial participants will reflect the gender ratio of patients with advanced cirrhosis in the 8 clinical centres. The expected gender ratio would be 63-65% males as previously described in the CANONIC study (Moreau et al., 2013).

Analysis of sex & gender issues

It has been demonstrated by several studies that women show a higher susceptibility to alcoholic liver damage (Gao et al, 2011). However, most patients with diagnosed advanced liver disease are male (Mandayam et al, 2004). Although these discrepancies have been well described for over a decade, the responsible pathophysiological mechanisms regulating these effects are still unknown.

Besides other factors, such as constitution, enzymatic activity and sexual hormones, the interaction of gut and liver, especially the fraction of alcohol that is metabolized entering the circulation, have been recently discussed to be impacted by gender. Since MICROB-PREDICT aims to achieve a holistic overview of the human microbiome possibly involved in the development of decompensation and ACLF, paired with the longitudinal observation approach, gender-specific differences will be identified. MICROB-PREDICT will be able to assess whether gender is a factor in the identification of signatures or key mechanisms in the development of decompensation or ACLF. Importantly, already some studies in this context were undertaken in the project. The coordinator of MICROB-PREDICT in cooperation with few partners has already investigated sex-differences in the development of renal dysfunction and ACLF, which were recently published (Lehmann et al., 2019) (Torner et al.,2019). Ultimately, different signatures could lead to the development of distinct biomarkers for men and women. Improved understanding of the gender-specific differences in the development of decompensation and ACLF will accelerate the progression towards personalized medicine.

3.3 - Monitoring

The Commission will monitor the implementation of gender as a cross-cutting issue, at various stages in the funding process. The following indicators will be used on an annual basis to determine the prevalence of gender as a cross-cutting issue:

- % of women participants in Horizon 2020 projects
- % of women project coordinators in Horizon 2020
- % of women in advisory groups, expert groups, evaluation groups and panels
- % of projects with gender dimension in the project design.

4 - Public engagement

4.1 - Definition

Public engagement is one of the key areas of the RRI approach, giving more weight to citizens and civil society organizations in the process of research and innovation, both in the definition of research needs and in its implementation. It is a tool to bring on board the widest possible diversity of actors, establishing iterative and inclusive participatory dialogues, to foster mutual understanding and wider acceptability of results.

Why the need for Public Engagement? As the RRI Tools initiative explains, “Involving stakeholders and the public in the process of research and innovation helps to ensure that the results match the values, needs, and expectations of society”. For the European Commission, in the context of Science With and For Society (Swafs)[3], the benefits of involving the broadest possible range of actors in research and innovation include the uptake of new and alternative forms of knowledge, as well as the consideration of a broader range of societal needs and perspectives, all of which are key towards helping tackle the complex and interconnected societal challenges that lie ahead.

The approach of public engagement contributes to enhancing creativity in research and innovation, increases the likelihood that research and innovation are societally relevant and provides a breeding ground to foster a more scientifically literate society and empowered citizens.

4.2 - Implementation

There are many ways in which the public can be engaged in the research and innovation process, but choosing the right tool will have to take into account many aspects of the project in hand. From actively initializing research with tools like Science Shops to shaping the R&I process, gather data through citizen science, or be part of the dissemination of R&I outcomes, public engagement can be personalized and adapted to many contexts.

The MICROB-PREDICT partner European Liver Patients' Association (ELPA) facilitates dialogue with patients and their families and dissemination to policy makers. ELPA is a representative organization of all European patient organizations for liver disease and it has 34 members in 27 countries throughout Europe. ELPA's aim is to promote the interests of people with liver disease and in particular to highlight the size of the problem, to promote awareness and prevention, to address the low profile of liver disease as compared to other areas of medicine such as heart disease, to share the experience of successful initiatives and to work with professional bodies such as EASL and with the EU to ensure that treatment and care are harmonized across Europe to the highest standards. ELPA, an active partner of MICROB-PREDICT, will participate in meetings, act as a consultant and actively participate in WP9 (Dissemination).

The European Association for the Study of the Liver (EASL) is a major European Association with international influence dedicated to the liver and liver disease. They have over 4,000 members from

[3] https://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=engagement

all over the world and provide an annual platform, The International Liver Congress™, for 11,000 liver experts to meet and discuss latest scientific research.

EASL has given rise to many international clinical trials and research collaborations to the benefit of patients all over the world. They have been working on EU advocacy and policy since 2009. EASL`s advocacy efforts have concentrated on raising awareness about liver disease in Europe, how to prevent and treat it and the role that EASL can play in doing this.

Their mission is to be the "Home of Hepatology" so that all who are involved with liver disease can realize their full potential to cure and prevent it.

EASL will support MICROB-PREDICT with dissemination to their established communication channels (WP9). With more than 40.000 contacts within the hepatology community, they will greatly facilitate uptake of new knowledge by the scientific community. EASL`s regular newsletters to more than 40,000 contacts within the hepatology community, a strong social media presence (6,500 facebook friends, 5,500 Twitter followers), 15 booths around the world all year where the work of MICROB-PREDICT will be presented, and EASL's strong media coverage will help to raise awareness for the project and its results. EASL will also contribute to guideline development in MICROB-PREDICT and will help to influence the national guidelines of national hepatology societies in Europe and world-wide.

A few questions can be useful in the development of Public Engagement activities:

- Why do you want to engage people with your research?

The levels of interaction and influence of civil society can range between discussing topics, consulting for a particular problem or approach, involving them in a more committed way, collaborating with different stakeholders, empowering the public, or even make them part of a direct decision approach

- Who do you want to engage? Who are the stakeholders that can be affected by the research or that can be interested in its outcomes?

For this particular issue, it can be useful to look at the analysis undertaken in the dissemination and communication outline (D9.1) where target groups and communication goals have been gathered and classified. A stakeholder mapping tool can also be a valuable resource to apply to each context to start the reflection process.

- How might you engage them?

From workshops to public forums, there are tools available depending on the degree of public engagement, the number of stakeholders involved or the online vs face to face format.

- Has it worked?
    - For instance, the Task 4 on the Working Paper 9 includes the following dissemination performance evaluation: “Together with the Impact Board a communication and dissemination plan will be developed in order to apply best strategies to reach out to stakeholders by various routes (e.g. social media). The Impact Board will interview MICROB-PREDICT partners at the annual GA-meeting concerning their IPR and dissemination plans for the next year. The findings will be reported for distribution among the stakeholders. Moreover, the Impact Board will measure and report on a 6- monthly basis communication channels like Instagram, Twitter and YouTube using the following measurements: likes, shares, demographics, comments, visits to the website, time spent on the website, unique visitors, site visit flow, and demographics. Based on the collected data, the Impact Board will propose strengthening or weakening different social media communication channels.”

A list of indicators and process evaluators should be decided beforehand to be able to evaluate the results of the activities chosen. These will be highly dependent on each of the projects, and a non-exhaustive list is provided in the References section.

The recommendations of the European Commission on how to implement public engagement in Horizon 2020 are as follows:

1. “Build participatory Research & Innovation (R&I) actions
   PE can be specifically called for or voluntarily built-in to projects to promote more societally relevant outcomes. Ideally, this engagement would be embedded in the research design and process from an early stage, and in an iterative fashion, so that the learnings can contribute to enriching the process and outcomes (citizen science actions could also fall under this category).
2. Provide inputs to influence EU R&I policy agenda
   Launching more widespread initiatives (similar to VOICES) involving citizens’ engagement that employs face-to-face as well as online participatory methods to provide input to policy and participatory foresight for selected themes. Such initiatives would require high-level commitment, transparency, and traceability of outcomes, timely and legitimized integration into our existing Horizon 2020 institutional mechanisms and strategy.

3. Support the development and implementation of thematic policies

   A major aim of R&I policy is to provide knowledge and evidence to support the design and implementation of thematic policies (e.g. environmental, health, transport) at national to the local levels, in particular in relation to societal challenges. Public engagement has its rightful place in science/policy/society interfaces supporting both thematic policy development and implementation.

5 - Science education

5.1 - Definition

Under Horizon 2020 it is a priority to build capacities and develop innovative ways of connecting science to society, helping to make science education and careers more attractive to young people. To achieve this it is crucial to invest in the interactions between the relevant actors in the field, the different levels of the education system, universities and other higher education establishments, civil society organizations, professors, teachers… The expected impacts of the science education approach for the Horizon 2020 programme are the development of a scientific citizenship, to attract more young people towards science and to develop RRI in higher education curricula.

One example of good practice in science education is the Scientix project, the community for science education in Europe, which "promotes and supports a Europe-wide collaboration among STEM (science, technology, engineering and maths) teachers, education researchers, policymakers and other STEM education professionals". In its website, the Scientix project lists all the different areas and resources where teachers, researchers and policy makers can benefit from their activities and events. Especially for researchers and project managers, there are resources that range from finding teachers or schools to collaborate with, participate in Scientix networking events or co-organise an event to increase the dissemination and participants.

5.2 - Implementation

One of the objectives of the MICROB-PREDICT dissemination, communication and exploitation plan (D9.1) is in line with the science education approach. Its goal is to attract talented scientists and students for the scientific fields relevant to MICROB-PREDICT.

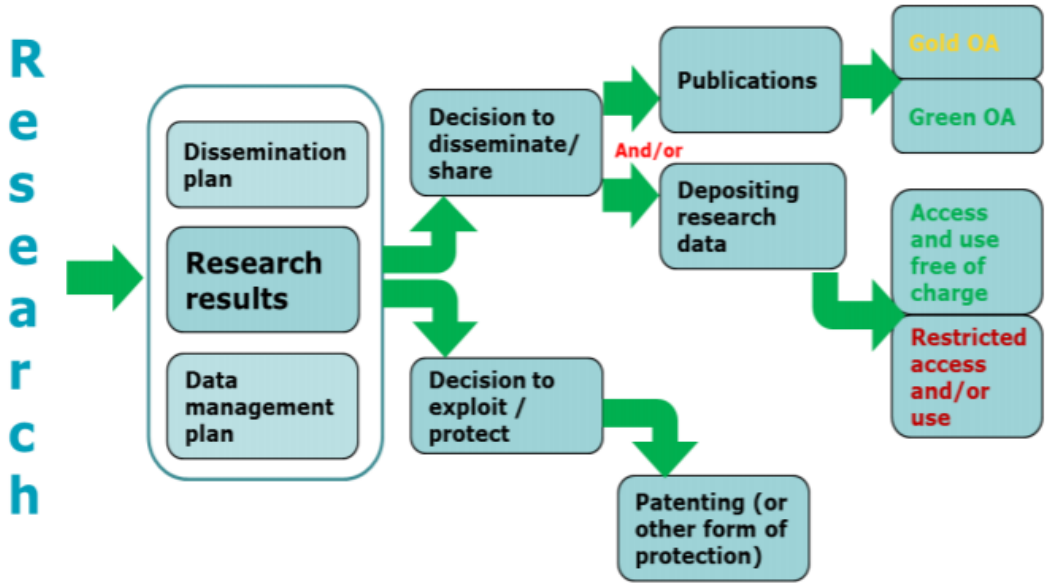
6 - Open access

6.1 - Definition

“Open access (OA) refers to the practice of providing online access to scientific information that is free of charge to the end-user and reusable. 'Scientific' refers to all academic disciplines. In the context of research and innovation, 'scientific information' can mean peer-reviewed scientific research articles (published in scholarly journals) or research data such as data underlying publications, curated data and/or raw data.

Self-archiving / 'green' open access – the author, or a representative, archives (deposits) the published article or the final peer-reviewed manuscript in an online repository before, at the same time as, or after publication. Some publishers request that open access be granted only after an embargo period has elapsed.

Open access publishing / 'gold' open access - an article is immediately published in open access mode. In this model, the payment of publication costs is shifted away from subscribing readers. The most common business model is based on one-off payments by authors. These costs, often referred to as Article Processing Charges (APCs) are usually borne by the researcher's university or research institute or the agency funding the research. In other cases, the costs of open access publishing are covered by subsidies or other funding models.”



Source: Guidelines to the Rules on Open Access to Scientific Publications and Open Access to Research Data in Horizon 2020

6.2 - Implementation

a) Contractual requirements about open access

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — 'disseminate' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving a notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the Commission before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge online access for any user) to all peer-reviewed scientific publications relating to its results. In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms “European Union (EU)” and “Horizon 2020”;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

Regarding the digital research data generated in the action (‘data’), the beneficiaries must:

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications, as soon as possible;

(ii) data which is relevant for addressing a public health emergency, if specifically requested by the Commission and within the deadline specified in the request;

(iii) other data, including associated metadata, as specified and within the deadlines laid down in the ‘data management plan’ (see Annex 1);

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data under Point (a)(i) and (iii), if the achievement of the action's main objective (as

described in Annex 1) would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.

As an exception, the beneficiaries do not have to ensure open access also to the research data under Point (a)(ii), if the Commission agrees to replace the open access obligation by special access rights for third parties that need the data to address the public health emergency. These access rights must include the right to access, mine, exploit and reproduce the data free of charge.

b) Standard acknowledgement

According to Art. 29.4 of the Grant Agreement any dissemination of results (in any form, including electronic) must:(a) display the EU emblem and (b) include the following text:

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825694.

This reflects only the author's view and the Commission is not responsible for any use that may be made of the information it contains." Link to EU emblem and guidelines for use.

3. Tables and other supporting documents

Basic documents:

- RRI Tools Guide
- European Commission Online Manual

Ethics

De Lecuona, I. (2019) *Informed consent policy for human subjects, human biological samples and personal data in MICROB-PREDICT (MS41)*

Casado, M., De Lecuona, I,m Patrao, M., Carvalho, A.S., Araújo, J (2016) *Declaration on research integrity in responsible research and innovation*, Ed. UB http://diposit.ub.edu/dspace/handle/2445/103268?mode=full

Gender equality

Guidance on Gender Equality in Horizon 2020

Roadmap to gender Equality plans in research and higer education - European Institute for Gender Equality - 2016

Public engagement

How to Include Engagement in Horizon 2020 - Webinar by the Engage 2020 - project

Science education

Science Education for responsible Citizenship - European Commission

Open Access

Guidelines to the Rules on Open Access to Scientific Publications and Open Access to Research Data in Horizon 2020

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