



D9.3
BUSINESS PLAN
FOR MIRRI-ERIC



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| Abstract: | This business plan describes the target groups of MIRRI-ERIC |
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| | and the value proposal to address their needs, how MIRRI- |
| | ERIC will be governed and managed to deliver the services |
| | and includes an analysis of the socio-economic impact and of |
| | future opportunities. |
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This document constitutes the Deliverable 9.3 of the project IS_MIRRI21 and describes in detail the strategy that the Microbial Resource Research Infrastructure (MIRRI), being a European Research Infrastructure Consortium (ERIC), will follow to reach its goals and to deliver its value proposal to its stakeholders, in order to become and remain a sustainable organisation.

This Business Plan has eight chapters including:

- 1. MIRRI-ERIC at a glance, containing the mission and goals of MIRRI-ERIC and serving as Executive Summary of this business plan;
- 2. the organisation and governance of MIRRI-ERIC;
- 3. an analysis of the different target groups and their needs;
- 4. the value proposal, with a description of the Collaborative Working Environment as a means of interaction with the different target groups, as well as the channels used to reach out the users;
- 5. a characterization of the targeted markets, together with a SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis and description of the main challenges facing competition;
- 6. a reference to the Financial plan, which is developed in detail in Deliverable 9.2. of IS_MIRRI21;
- 7. a description on how MIRRI-ERIC will implement and monitor its activities, with a risk analysis and contingency plan;
- 8. a discussion about future opportunities in terms of expansion of the membership and the development of sustainable strategic partnerships with other Research Infrastructures to improve and sustain MIRRI-ERIC's position.

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Abbreviations

ABS - Access and Benefit Sharing

CC - Culture Collection

CCU - Central Coordinating Unit

COVID-19 - Coronavirus disease

CWE - Collaborative Working Environment

EC - European Commission

ECCO - European Culture Collections' Organisation

EOSC - European Open Science Cloud

ERA - European Research Area

ERIC - European Research Infrastructure Consortium

ESFRI - European Strategy Forum on Research Infrastructures

FAIR - Findable Accessible Interoperable Reusable

GDPR - General Data Protection Regulation

H&F - Health and Food

IB - Industrial Biotechnology

IPR - Intellectual Property Rights

IT - Information Technology

KPI - Key Performance Indicators

LS - Life Science

mBRC - Microbial Domain Biological Resource Centre

MIRRI - Microbial Resource Research Infrastructure

MIRRI-IS - MIRRI Information System

M&O - Members and Observers

NN - National Node

PESTLE - Political, Economic, Sociological, Technological, Legal, Environmental

RI - Research Infrastructure

RIS3 - Research and Innovation Strategies for Smart Specialisation

R&I - Research and Innovation

SPOC - Small Private Online Courses

SRIA 2021-2030 - MIRRI "Strategic Research & Innovation Agenda 2021-2030"

SWOT - Strengths, Weaknesses, Opportunities, Threats

TNA - Transnational Access

T&E - Training and Education

UN - United Nations

USCCN - United States Culture Collection Network

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1. MIRRI-ERIC at a glance

The Microbial Resource Research Infrastructure – European Research Infrastructure Consortium (MIRRI-ERIC) is a pan-European distributed Research Infrastructure (RI). Through its motto, "microbial resources for a green, healthy and sustainable future", MIRRI-ERIC envisions a bright future for a greener, healthier and sustainable world, based on the preservation, study and valorisation of microbial resources and biodiversity.

In Europe, multinational collaboration is currently hampered by the fragmentation of policies, resources, data and expertise. Gaps in the current offer make it difficult to access strains cited in papers and databases. MIRRI-ERIC will create and consolidate a single, unified infrastructure to solve/mitigate these bottlenecks, allowing faster microbiological-related developments and discoveries.

MIRRI-ERIC promotes complementarity, reduces redundancy, and continuously improves the capacity of its partner microbial domain Biological Resource Centres (mBRCs) to preserve microbial materials, in a coordinated (non-fragmented), traceable and cost-effective way, contributing to the reproducibility, integrity and cumulative character of research.

MIRRI-ERIC's mission is to serve the bioscience and the bioindustry communities by facilitating the access, through a dynamic platform called the Collaborative Working Environment (CWE, chapter 4), to a broad range of high-quality microorganisms, their derivatives, associated data and services, with a special focus on the domains of Health & Food, Agro-Food, and Environment & Energy. The CWE brings together MIRRI-ERIC Partners and users from various stakeholder communities (chapter 3), promoting crowdsourcing, cross-sector interaction, excellence and innovation and boosts the possibilities to achieve common goals in research and development. The user-centered design strategy allows the CWE community to actively participate in the development of MIRRI-ERIC's strategies towards the provision of services to users. This ensures that products and services offered remain aligned with the target groups' expectations and meeting the effective needs of the scientific and entrepreneurial communities.

Combining resources, data, services, and capacity building about microbial resources under the same umbrella, MIRRI-ERIC harnesses the latent value of microbial biodiversity and improves microbiological science and innovation (**Figure 1**).

With the support of the Member and Observer countries that fund the infrastructure and the Partner organisations that constitute the infrastructure, MIRRI-ERIC will realise:

- a catalogue with broad coverage of high-quality microbial resources;
- a large amount of Findable, Accessible, Interoperable and Reusable (FAIR) data connected with the European Open Science Cloud (EOSC);

- coordinated and tailor-made service offer and pipelines;
- topic-driven expert clusters (applications, new technologies, legal issues, etc.);
- ambitious Training and Education (T&E) programmes.

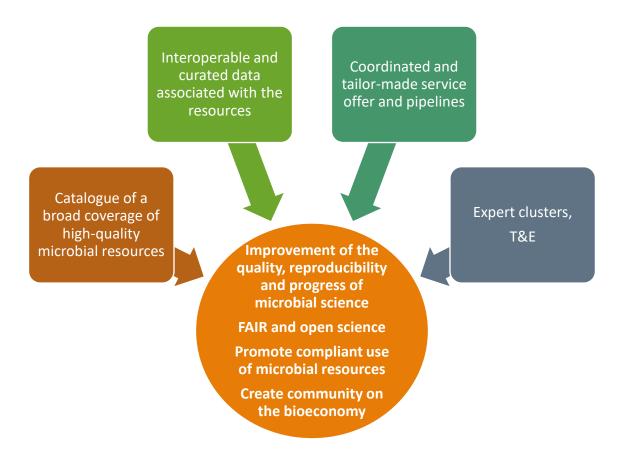


Figure 1 - The four main types of services constituting the MIRRI-ERIC offer to support users and providers of microbial resources and the most relevant outcomes

The long-term access to the biological materials on which the science is based will enable confirmation of results and facilitate high quality research and excellent science. Reliable resources associated with interoperable and curated data will be an added value supporting academic and industrial research and innovation. This will be complemented with high quality services, training programmes and expert advice, respecting and promoting the use of microbial strains under the legal framework (ABS, biosecurity) and following best practices.

Interaction with ESFRI peers and with other key initiatives and organizations all over the world (European Culture Collections' Organisation, World Federation of Culture Collections), will open

opportunities for collaboration and will expand the European catalogue of interdisciplinary services to users.

Using a PESTLE analysis, MIRRI-ERIC will keep its finger on the pulse to detect international trends and identify new markets. Research needs will be listed in its Strategic Research & Innovation Agenda (SRIA, **chapter 5**).

To operate, MIRRI has been constituted as a European Research Infrastructure Consortium (ERIC) (**chapter 2**), governed by an Assembly of Members and managed by a Central Coordinating Unit (CCU) shared by Portugal (statutory seat) and Spain (host of the CWE). National Nodes (NNs) in each Member country will coordinate the activities of the national partners (mBRCs, research institutions) providing services through MIRRI-ERIC. The coordinators of the NNs and the Executive Director of the CCU come together in the National Coordinators Forum, securing a smooth implementation of the annual work programme.

MIRRI-ERIC will apply a non-economic model based on the contributions of its Member and Observer countries, third party grants and revenues from provided services (chapter 6). Once MIRRI-ERIC is fully operative and has implemented all its structures, the income from grants and services is expected to increase, allowing further development and expansion of activities.

Contributing to the advancement of research and innovation (R&I) in Life Sciences (LS) and biotechnology, the societal impact of MIRRI-ERIC will be to strengthen the competitiveness of the European Research Area, to stimulate a competitive and resilient bioeconomy and create employment through the biotechnological discoveries in healthcare, sustainable agriculture and environment, food security, biofuel production and livelihoods (**chapter 5**).

2. MIRRI-ERIC organisation and governance

To operate, MIRRI-ERIC has been constituted as a European Research Infrastructure Consortium (ERIC), a specific legal form adapted to the business concept for not-for-profit RIs in the European Union, and is governed by the Member and Observer (M&O) countries following the provisions on the MIRRI-ERIC Statutes.

According to its Statutes, MIRRI-ERIC will be a distributed, but centrally coordinated, pan-European RI with three main organisational levels (**Figure 2**):

- 1. Strategic Decision-making: with the assistance of Advisory and Ethical Boards, the Assembly of Members, constituted by the Members with voting rights and Observers without voting rights, is the body by which the Members take collective decisions on matters relating to MIRRI-ERIC.
- 2. Executive level: those decisions shall then be managed and implemented by the Executive Director, as the legal representative of MIRRI-ERIC, together with the staff of the Central Coordinating Unit (CCU). The MIRRI-ERIC CCU consists of two distributed sections, the Statutory Seat situated in Braga (Portugal) and the CWE Hub located in Paterna (Spain).
- 3. Operational level: the CCU shall be the operational secretariat of MIRRI-ERIC, responsible for the general management and administration, organisation of meetings and outreach activities, and control of common services through the CWE. It serves also as the main point of communication with the stakeholders, through the Access Officer. Each Member will designate a National Node (NN) and a national coordinator overseeing the MIRRI activities of the Partners on its territory in alignment with MIRRI-ERIC. The national coordinators constitute together the National Coordinators Forum, a body chaired by the Executive Director, that ensures the efficient interaction between MIRRI-ERIC and the Partners. Current Partners are listed in **Table 1**.

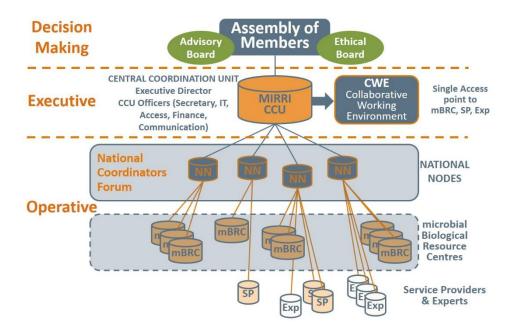


Figure 2 - MIRRI-ERIC operating as a distributed RI

Five European countries (Belgium-BE, Spain-ES, France-FR, Latvia-LV and Portugal-PT) have become Founding Members of MIRRI-ERIC, while four other countries have signed the Memorandum of Understanding, demonstrating their interest in becoming a Member of MIRRI-ERIC (Greece-GR, Italy-IT, Netherlands-NL and Poland-PL). Romania is preparing to become an Observer country (**Table 2**). The prospective countries are finalizing their national procedures in order to submit their request to join MIRRI-ERIC.

Table 1 - MIRRI-ERIC Members and Partners

| Country | Partner (acronym) | Partner (full name) |
|---------|----------------------|---|
| BE | | Belgian Coordinated Collections of Micro-organisms - Coordination cell (Belgian Science Policy) |
| | BCCM/DCG | Belgian Coordinated Collections of Micro-organisms - Diatoms Collection (Gent University) |
| | | Belgian Coordinated Collections of Micro-organisms - GeneCorner Plasmid Collection (Gent University) |
| | BCCM/IHEM | Belgian Coordinated Collections of Micro-organisms - Fungi Collection: Human and Animal Health (Sciensano) |
| | BCCM/ITM | Belgian Coordinated Collections of Micro-organisms - Mycobacteria Collection (Institute of Tropical Medicine) |
| | BCCM/LMG | Belgian Coordinated Collections of Micro-organisms - Bacteria Collection (Gent University) |
| | BCCM/MUCL | Belgian Coordinated Collections of Micro-organisms - Agro-food and Environmental Fungi Collection (Catholique University of Louvain-la-Neuve) |

| | BCCM/ULC | Belgian Coordinated Collections of Micro-organisms - Cyanobacteri Collection (Liège University) | | |
|----|--------------------------|---|--|--|
| ES | CECT | Spanish Type Culture Collection | | |
| LS | BEA | Spanish Bank of Algae | | |
| FR | CIRM-CFBP | International Centre for Microbial Resources - Plant associated bacteria collection | | |
| | CIRM-BIA | International Centre for Microbial Resources - Food associated bacteria collection | | |
| | CIRM-BP | International Centre for Microbial Resources - Pathogenic bacteria collection | | |
| | CIRM-CF | International Centre for Microbial Resources - Filamentous fungi collection | | |
| | CIRM-Levures | International Centre for Microbial Resources - Yeasts collection | | |
| | CRBIP-CNCM | National Collection of Cultures of Microorganisms | | |
| | CRBIP-PCC | Collection of Cyanobacteria of the Institut Pasteur | | |
| | CRBIP-CIP | Collection of Institut Pasteur (Bacteria) | | |
| LV | MSCL | Microbial Strain Collection of Latvia | | |
| PT | MUM | Micoteca da Universidade do Minho, Centro de Engenharia Biológica | | |
| | PYCC | Portuguese Yeast Culture Collection, Unidade de Ciências Biomoleculares Aplicadas, Universidade Nova de Lisboa | | |
| | ACOI | Algoteca de Coimbra, Universidade de Coimbra | | |
| | LEGE | Blue Biotechnology and Ecotoxicology Culture Collection, Centro Interdisciplinar de Investigação Marinha e Ambiental, Universidade do Porto | | |
| | UCCCB | Coleção de Culturas de Bactérias da Universidade de Coimbra, Universidade de Coimbra | | |
| | CIMOCC | Mountain Research Centre Culture Collection, Centro de Investigação de Montanha, Instituto Politécnico de Bragança | | |
| | VFMCC-INIAV | Agronomic, Veterinary and Food Microbial Culture Collections - Instituto Nacional de Investigação Agrária e Veterinária | | |
| | Biotropical Resources | Global Health and Tropical Medicine, Institute of Hygiene e Tropica Medicine, Universidade Nova de Lisboa | | |
| | CDB | Coleção do Departamento de Biologia, Centro de Biologia Molecul e Ambiental, Universidade do Minho | | |
| | IVDP | Instituto dos Vinhos do Douro e Porto, I.P. | | |
| | LRV/DRAg | Laboratório Regional de Veterinária dos Açores, Direçao Regional da Agricultura | | |
| | CNBC-IC | Cantacuzino National Institute for Research in Microbiology and Immunology | | |

Table 2 - MIRRI-ERIC Prospective Members (PM) & Observers (PO) and their Partners

| Country | Partner (acronym) | Partner (full name) | |
|------------|----------------------|--|--|
| GR (PM) | CCUoA-NKUA | Culture collections of the National and Kapodistrian University of Athens | |
| | ACA-DC | Agricultural College of Athens - Dairy Collection | |
| | BPIC | Benaki Phytopathological Institute Collection | |
| IT | TUCC (UNITO) | Turin University Culture Collections | |
| (PM) | DBVPG | Industrial Yeasts Collection | |
| | UMCC | University of Modena and Reggio Emilia Microbial Culture Collection | |
| | CNR-PLAVIT | National Research Council-Plant Viruses Italy | |
| | CNR-ITEM | National Research Council-Agro-Food Microbial Culture Collection | |
| | USMI | University Hospital (Ospedale Policlinico) San Martino | |
| NL | CBS | Collection of yeasts and filamentous fungi | |
| (PM) | NCCB | Netherlands Culture Collection of Bacteria | |
| PL (PM) | IAFB | Collection of Industrial Microbial cultures of the Prof. Wacław Dąbrowski Institute of Agricultural and Food Biotechnology | |
| | KPD | Collection of Plasmids and Microorganisms of the University of Gdansk | |
| | PCM | Polish Collection of Microorganisms | |
| RO | IBB | Institute of Biology Bucharest | |
| (PO) | MCUB | Microbial Collection of University of Bucharest | |
| | CMII-ICCF | Culture Collection of Industrial Importance Microorganisms-National Institute for Chemical Pharmaceutical Research and Development | |
| | MIUG-DJUG | Industrial Microorganisms Collection of "Dunărea de Jos" University of Galati | |
| | CNBC-IC | Cantacuzino National Institute for Research in Microbiology and Immunology | |

The Partners of MIRRI-ERIC will be mBRCs or institutions providing resources, services and/or expertise. Internal Partners are located in a Member or Observer country of MIRRI-ERIC. External Partners are located in a country that is non-signatory to MIRRI-ERIC. Both internal and external Partners sign the MIRRI-ERIC Partner Charter containing the criteria to be met by the Partners in order to ensure consistent high quality of the MIRRI-ERIC services.

3. Target Groups

MIRRI-ERIC's main target groups are the users and providers of microbial resources. The bodies governing, supporting or regulating these groups (e.g., the European Commission (EC) or the Policy makers) will also benefit from the services delivered by MIRRI-ERIC, indirectly by serving their user and provider communities and directly receiving expert advice on matters related with the use of microbial resources. Finally, MIRRI-ERIC will target a broader audience in the society, aiming to bring microbiological science closer to the citizens. Therefore, we can divide MIRRI-ERIC's target groups in the following categories:

- Users of microbial resources
- Providers of microbial resources Culture Collections (CCs) and mBRCs
- The EC and the Member countries of the RI, as well as prospective Member and Observer countries
- Policy makers
- Citizens
- Science communication professionals/journalists

3.1. Users of microbial resources

Research institutions and biotechnological companies using microbial resources.

High-quality, cost-effective and sustainable research is fundamental to reinforce Europe's position in a highly competitive global economy. A fundamental principle of the scientific method is experimental reproducibility to avoid critical negative socioeconomic impacts in case the same results cannot be obtained. A 2014 study based on workshops and surveys targeting authors publishing in microbiology journals indicated that only a small portion of microbial strains that are cited in papers are available in public mBRCs (Stackebrandt, 2014). More recently, a MIRRI internal study, carried out between 2015-2017, about microbial strains cited in 1100 LS databases indicated that less than 10% of the strains were preserved in CCs. In addition, almost no links were found between the strain datasheets in the CCs catalogues and the LS databases, resulting in a complete fragmentation of the data relative to a particular resource. This connection is essential to facilitate the replication of results, avoid the duplication of efforts and boost R&I in microbiology and biotechnology.

Users of microbial resources claim that the current offer, associated data and related services including expert advice, do not satisfy their needs (Van Hauwenhuyse, 2014a, 2014b). They have

difficulties in finding (1) resources cited in papers, (2) certain microbial taxa, especially fastidious microorganisms, (3) specialised services, and (4) extended datasets associated to the resources. Besides, they would find very useful (1) the delivery of innovative, specialised services and (2) the creation of expert topic-driven platforms. Furthermore, there is a lack of awareness about regulations related with the use of microbial resources (e.g. Access and Benefit Sharing (ABS), Biosecurity, Transportation) in the user community, urging the need to facilitate access to expert guidance and training on these matters.

The difficulty to obtain certain strains from qualified providers (i.e. CCs and mBRCs) drives users to share strains lacking the corresponding quality controls among colleagues, constituting a source of flaws and increasing the socioeconomic burden due to irreproducible research.

Besides these handicaps associated with the microbiological research in a broad sense, biotechnological companies in the areas of Health & Food, Agro-Food and Environment & Energy have difficulties accessing microbial strains suited for their processes. Moreover, finding counselling on how to cultivate, characterise and preserve microbial strains, and legal advice regarding their use (e.g. Intellectual Property Rights (IPR) or ABS issues), tends to present a challenge.

Currently, no single country offers complete coverage of microbial diversity and associated services and expertise. Therefore, an overarching European organisation of the nationally distributed infrastructures is required to make the best use of current capacity, bridge gaps and address the needs of biotechnology and bioindustry today. MIRRI-ERIC will play this role.

3.2. Providers of microbial resources

Institutions (public or private) preserving and sharing microbial resources. They can be CCs (repositories of microbial resources with limited quality control procedures) and mBRCs (advanced culture collections, providing microbial resources as well as databases with molecular, physiological, and structural information relevant to these resources, and other services associated with the characterization of microorganisms, all this following advanced Quality Management Systems).

Most European CCs / mBRCs' financial models are based on institutional and/or governmental support, research grants and income from supply of strains and provision of services. Government funding, when provided, is usually balanced against the income received for the various services and products offered by the collection, with additional income above plan being returned. This leaves very little for investment, to enable the collections to improve their coverage and incorporate new and advanced technologies. Harnessing the power of collections working

together is therefore essential to evolve for an efficient provision of services and microbial resources to the scientific community.

MIRRI-ERIC will increase complementarity, reduce redundancy, and continuously improve the capacity of its partner CCs / mBRCs to preserve microbial materials, in a coordinated (non-fragmented), traceable and cost-effective way.

3.3 The European Commission, the Member countries of the RI, and prospective Member and Observer countries

The EC launched in 2000 the European Research Area (ERA), with the ambition to create a single, borderless market for research, innovation and technology across the European Union. One pillar of this ERA is the European Strategy Forum on Research Infrastructures (ESFRI), supporting the establishment of pan-European RIs to provide Europe and the Members of the RIs (Member States, associated countries, third countries other than associated countries and intergovernmental organisations) with the most up-to-date research capacities.

A recently published White Paper (EC, 2020a) concludes that RIs are essential pillars of the ERA. RIs form the basis of the European R&I competitiveness and are major promoters of Open Science providing high-quality FAIR (Findable, Accessible, Interoperable and Reusable) data, needed to support the success of the European Open Science Cloud (EOSC).

For these reasons, RIs need to be reinforced and considered as strategic investments to address complex societal challenges. Therefore, the Members of the RIs (countries and intergovernmental organizations) need to coordinate their resources and services for the benefit of their scientific community, such as:

- cost-effective CCs and research centers;
- reliable research materials with significant scientific value for universities and industries;
- services with added value to already existing facilities in their territories;
- high-quality Training & Education (T&E) programmes;
- adhering to the national and regional Circular Economy and Bioeconomy roadmaps;
- adhering to environmental and scientific research ethical regulations.

MIRRI-ERIC's value proposition should convince prospective Member and Observer countries to officialise their interest and support for MIRRI-ERIC in a near future.

3.4. Policy makers

Policy makers regulate and implement legislation in various areas of specialisation such as LS, economics and political sciences.

Policy makers need (1) guidance based on reliable scientific results, (2) support raising awareness about the legal framework associated with the use of microbial resources, (3) assistance avoiding misinformation and (4) easier access to scientific experts. For all these aspects, they can call upon the expertise gathered within MIRRI-ERIC.

3.5. Citizens

Citizens comprise a heterogeneous group of individuals that would benefit from a facilitated access to simple, interesting, educational and relevant materials on the importance, applications and risks associated to the diverse world of microorganisms, as well as access to science-based public activities and events.

Within the group of citizens, teachers and students may need special attention, as they play pivotal roles in the foundations of a well-informed society, immune to fake news. For this, teachers from all levels of education (primary and secondary schools, technical degrees, university) need training and outreach material, scientifically relevant, and adapted to the different formative stages. Building knowledge about the different domains in microbiology is also crucial to attract future scientists and professionals to the field.

3.6. Science communication professionals/journalists

Most science communication professionals and journalists have, in the best scenario, only a broad knowledge of different scientific topics, so they need support to communicate trustable information, especially on sensitive issues.

Science communication (and communication in general) is facing some challenges in the era of internet and social networks. Nowadays, information spreads quickly and widely, in most cases before being filtered by experts, contributing to the reduction of the quality of the communication and the diffusion of messages that have not been corroborated or that are not correctly interpreted. Indeed, the EC has recognized this problem and has developed an "Action Plan against Disinformation" (EC, 2018a), in which one of the pillars is the need of raising awareness

and improving societal resilience to fake news, where independent researchers play a key role mitigating the negative impact of disinformation. Therefore, science communication professionals need fast access to accurate and reliable information, validated by experts and in a format that is easy to understand.

4. From Microbial Collections to Real-Life Innovations

MIRRI-ERIC will construct a global offer on microbial biodiversity linking data and expertise from e.g., ecology, climate, human, animal and plant health. For this, MIRRI-ERIC will offer its stakeholders the Collaborative Work Environment (CWE). This platform is designed to be a unique entry point to a broad offer of microbial resources and data, options to T&E, assistance through experts, aid in data analysis, hence providing the users with options of additional information that enrich the original query (**Figure 3**). The CWE will inform broad audiences about the importance of microorganisms in our daily life. In addition, MIRRI-ERIC experts can handle transversal aspects related with microbiology, facilitating the collaboration not only with researchers but also with the society, policy makers, etc.

4.1. MIRRI-ERIC's offer: The Collaborative Work Environment (CWE)

Table 3 indicates the correspondence between the products and services offered by MIRRI-ERIC and the needs of its target groups.

Table 3 - Correspondence between MIRRI-ERIC's services and the main needs of each target group

| | | MIRRI-ERIC PRODUCTS AND SERVICES | | | | | | |
|-------------|---|---|--|---|----------------------------|---|---|--|
| | | Digital content to increase knowledge about microbes and avoid misinformation | Catalogue of microbial resources and associated datasets | State-of-the-art facilities and tailor- made services | Expert Cluster platform | Advanced theoretical and practical training courses | Academic schemes for mBRC professionals | Workshops related to Quality Management and compliance |
| Т | Users of microbial resources | • | • | • | • | • | | |
| A R | Providers of microbial resources | • | • | • | • | • | • | • |
| G E T | The EC, the Member countries of the RI, and prospective Member and Observer countries | • | • | • | • | • | • | • |
| G | Policy makers | • | | | • | | | |
| R O | Citizens | • | | | | • | | |
| U P S | Science communication professionals/journalists | • | | | | | | |

The EC and the MIRRI-ERIC Member countries benefit from all services directly receiving expert advice related to policies involving the use of microbial resources and indirectly through their stakeholder communities (the society and the users and providers of microbial resources). The

society receives accurate information related to the microbial world through the public website. Finally, the main stakeholders benefiting from all the services are the users and providers of microbial resources, which take advantage from the whole offer. All these relationships are outlined in **Figure 3**.

The CWE is a virtual platform serving as the main communication channel between MIRRI-ERIC and all its target groups. A detailed description of the four CWE gates is provided hereunder.

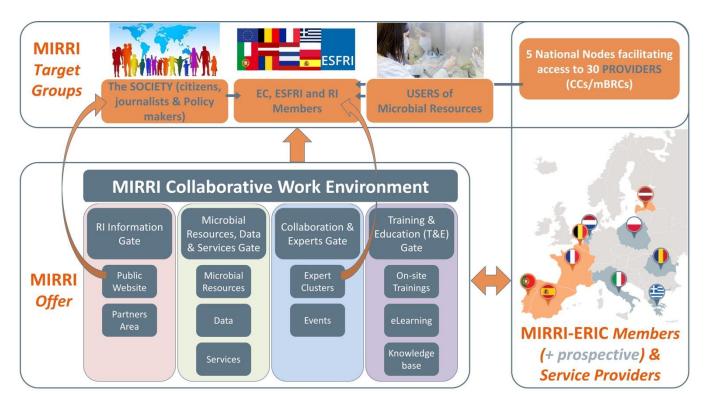


Figure 3 - Relationship between MIRRI-ERIC's target groups and the gates of the CWE

MIRRI-ERIC target groups have a single point of Access to the MIRRI-ERIC offer, the CWE, which facilitates the provision of services from the Partners. Orange arrows show the inflows/outflows between the target groups and the RI offer. Grey arrows indicate an indirect profit of the EC and RI Member countries by the benefits obtained from their communities (i.e. the society and the users and providers of microbial resources).

4.1.1. Research Infrastructure Information Gate

This gate will provide open access to <u>digital content to increase knowledge about microbes</u> <u>and avoid misinformation</u> in the society, adapted to different audiences (schools, policy makers, broad range of audiences).

By providing scientifically validated (digital) information, in an accessible way, MIRRI-ERIC will contribute to society's proper knowledge about microbes, nuancing the still existing and mainly negative perception of microorganisms (human, animal and plant pathogens), with the numerous positive and indispensable effects that microorganisms have in our daily lives. Other relevant topics for the community that are usually hotspots of misinformation, such as vaccines, will also be addressed by MIRRI-ERIC in simple informative materials.

4.1.2. Microbial Resources, Data and Services Gate

Online, open, and centralised access to the broadest <u>catalogue of microbial resources</u>, associated with largest <u>datasets of information</u>, embedded in the EOSC and following FAIR principles. **Figure 4** summarizes the complete offer of microbial resources, data, and data analysis tools.

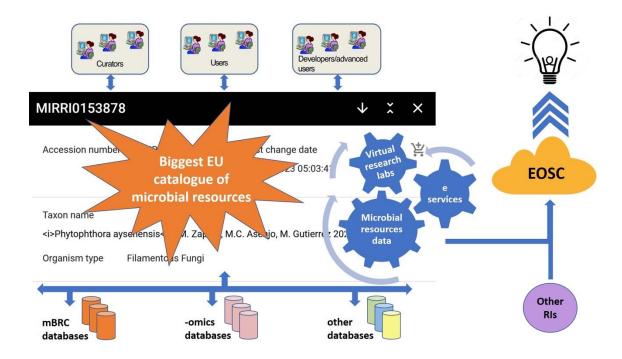


Figure 4 - The MIRRI-IS integrated solution maximizing the use of data associated with microbial resources to create innovative ideas

MIRRI-ERIC offers users and providers of microbial resources a single point of access to the biggest European catalogue of high-quality microbial resources, covering all types of microorganisms, such as bacteria, filamentous fungi, yeasts, eukaryotic viruses, microalgae,

bacteriophages, archaea, and other microbiological material such as cell lines, natural or construct-carrying plasmids, DNA libraries, and genomic DNA. New and potentially valuable strains covering gaps in the existing offer will be incorporated into the catalogues to be made available through a coordinated approach towards isolation and deposit of microorganisms in partner mBRCs (MIRRI-ERIC Accession Policy and MIRRI-ERIC Partner Charter).

From strains producing antimicrobials or other bioactive compounds for the pharmaceutical industry, to others that can be used in the production of healthier food products, in the biological management of agricultural soils and crops, in the bioremediation of polluted sites or contaminated effluents, or in the production of renewable fuels, to mention a few examples, MIRRI-ERIC is very likely to hold microbial resources matching every demand from researchers and bioindustries in the sectors of Health & Food, Agro-food, and Environment & Energy.

The microbial resources database (MIRRI-ERIC Information System, MIRRI-IS) hosting the catalogue is an integrated, high-quality, for most collections automatically validated, manually annotated, almost non-redundant microbiological resource database which provides relevant information and associated contextual data (metadata) about a particular microbial resource – e.g. taxonomy, ecology, pathogenicity, morphology, physiology, chemical characterisation, DNA barcoding or genomics. It is not merely a database of microbial resources, as it also provides tools for advanced analyses (i.e. Pairwise DNA alignment). Active links to key genome databases (NCIB and ENA) and taxonomic databases (AlgaeBase, BacDive, Mycobank, ICTV) add knowledge to the resources. The current degree of FAIRification based on Dataverse is 100% for both the "Findable" and "Accessible" requirements, while "Interoperable" at 60-70% and "Reusable" is at 50-60% ensuring connection with the EOSC, as well as integration with cross-disciplinary information, driving the innovation needs of the European bioeconomy.

In the frame of the Memorandum of Understanding that was concluded with United States Culture Collection Network (USCNN), MIRRI-ERIC and USCCN will grant each other access to their respective catalogues, that should be standardized, interoperable and respect The FAIR principles. Where appropriate, cross-referencing between the catalogues will be introduced.

Remote or Physical <u>access to state-of-the-art facilities and tailor-made services</u> and pipelines, going from bioprospection to validation of functional properties. Based on its partners' state-of-the-art facilities and top-level expertise, MIRRI-ERIC makes available a vast and diverse portfolio of high-quality services covering the value chain from bioprospection to preservation, identification, and valorisation of microbial resources. The different types of general services are divided into the following categories:

- Supply of microbial resources
- Deposit

- Microorganism isolation, preservation, and cultivation
- Identification
- · Phenotypic characterisation
- Molecular typing and phylogenetic analysis
- Next-generation sequencing (NGS) related services
- Screening, tests, and bioassays
- Taxonomic database tools
- Consultancy, Training and Contract Research
- Other services

Besides, MIRRI-ERIC also offers a catalogue of Application-Specific Services in the fields of Health & Food, Agro-food and Environment & Energy including solutions for the diagnosis of human, animal and plant pathogens, for the development of bio-pharmaceuticals, biofertilizers, biocontrol agents and bioplastics, for environmental bioremediation, production of bioenergy and the production of food or food-additives. A detailed description of the targeted market sectors and the current available services for each purpose is available in the MIRRI "Strategic Research & Innovation Agenda 2021-2030" (SRIA 2021-2030, MIRRI, 2021).

Users can also request tailor-made pipelines or combined services matching their needs.

The range of services provided will be enlarged as soon as MIRRI-ERIC generates outputs from the research strategy, aimed at delivering new capacities in emerging fields such as culturomics and preservation of microbial communities. Several Partners of MIRRI-ERIC are - together with other ESFRI research infrastructures - involved in the CanSERV, ISIDORe, AgroServ, MICROBE and BioIndustry 4.0 projects that aim to develop specialised RI services for the cancer, infectious disease, agro-ecosystems, microbiomes and industrial biotechnology research communities respectively.

4.1.3. The Collaboration & Experts Gate

The offer of technical and analytical services (Gate 2) is to be complemented with the access to a wide selection of experts in different topics related with the use of microbial resources through the **Expert Cluster platform**, an integrated set of online tools providing a unique environment for researchers in LS and policy makers to exchange knowledge (**Figure 5**).

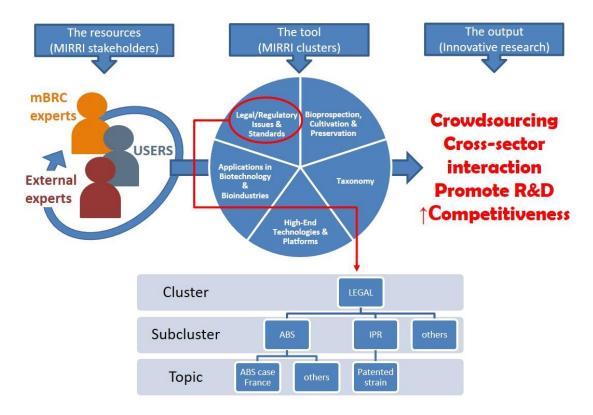


Figure 5 - MIRRI-ERIC expert clusters' approach to promote excellence and innovation in research by using microbial resources in compliance with applicable laws

The "MIRRI-ERIC Expert Clusters" will be organised around the key-topics of mBRCs' activities to support R&I processes at the demand of the stakeholders. Initially, five thematic clusters [Bioprospection, Cultivation & Preservation, Taxonomy, High-End Technologies & Platforms, Applications in Biotechnology & Bioindustries, Legal/Regulatory Issues & Standards] will be provided to the community, but the specific content of each one will follow the stakeholders' needs and new areas could be opened on demand.

Besides the expertise available in MIRRI-ERIC, leading experts in different fields (e.g. biosecurity, IPR, ABS) will be invited to join the MIRRI-ERIC expert cluster community with the purpose of enriching and sharing knowledge between the MIRRI-ERIC partners, academia and industry. The clusters are intended to provide advice, to develop operational best practices, to promote technology enhancement, to improve efficiency and effectiveness and to design and evaluate MIRRI-ERIC's T&E offer, among others. Different tools available through the CWE will facilitate the activities of the Expert Clusters:

- public rooms where all experts can participate and share ideas;
- secured rooms/e-mail contacts for bilateral confidential consultancy;
- videos and tutorials; and
- webinars, symposia, and workshops.

4.1.4. The Training and Education Gate

The T&E Gate of the CWE gives access to the MIRRI-ERIC training programmes towards different user categories (e.g., scientists, entrepreneurs/industrials, young professionals, partners), contributing to the capacity building within the scientific community as well as industrial users (**Figure 6**).

On one side, MIRRI-ERIC offers <u>advanced theoretical and practical training courses</u>, Small Private Online Courses (SPOC) and webinars targeting the needs of users of microbial resources.

Besides, MIRRI-ERIC will promote official <u>academic schemes to train mBRC and CC professionals</u>, like the European Specialization Course on mBRCs at UMinho-MUM, in collaboration with other MIRRI-ERIC partners and higher education institutions. The target audiences for these courses are Master students, PhDs, Postdocs and professionals who want to acquire high-level, international and research-oriented education in identification, preservation and valorisation of microbial diversity; integrate scientific competences and necessary skills to manage the mBRCs under quality control standards and complying with national and international regulations.

Finally, curators and managers of mBRCs will have access to <u>workshops related to Quality</u>

<u>Management and compliance</u>, including ABS and biosecurity, which are essential elements for mBRCs to meet the requirements of the MIRRI-ERIC Partner Charter.

Continuous professional development (for users)

- For mBRC users (academic scientists, industry)
- •On-site and remote (webinars, workshops, SPOCs, etc.)
- •Topics related with the use of microbial resources

Training of mBRC professionals

- •For students, PhDs, Postdocs and professionals
- ·Official academic scheme in collaboration with Universities
- Topic: integral management of mBRCs

Continuous professional development (for partners)

- For mBRC current or prospective partners
- ·Webinars, workshops, tutorials...
- •Topics: QMS, compliance

Figure 6 - MIRRI-ERIC Training & Education offer

4.2. MIRRI-ERIC channels to reach out to its target groups

The MIRRI-ERIC marketing plan is being implemented in several media. Inspired by its motto "Microbial resources for a green, healthy and sustainable future", MIRRI-ERIC is running promotional campaigns to strength its brand identity in social and public media, such as the MIRRI-ERIC LinkedIn company page, the twitter account @MIRRI_live and the Facebook account @mirri.esfri. MIRRI-ERIC targets companies offering microbial solutions and adding value to the health, food and agricultural sectors, among others, and serving educational/research institutes and individuals through its CWE, access programmes and T&E courses.

MIRRI-ERIC focusses its dissemination and outreach strategies on the different target groups as described under chapter 3 of this Business plan.

To ensure that microbial collections are used to implement real-life innovations, MIRRI-ERIC will pay special attention to cooperation with the industrial user community. Information about the needs and demands from the bio-industry will be systematically collected via surveys, analysis of on-demand-activities and presence on exhibitions and conferences. MIRRI-ERIC will ensure its representation in bioeconomy and industrial meetings of interest. MIRRI-ERIC – through the CCU but also through its National Nodes and Partners - will establish contacts with the industry at fairs and business federation meetings, or with invited sponsors at scientific congresses. If not done already, the National Nodes will join forces with their national microbiology associations to develop a dataset of talent pool, human resources and their background knowledge, CVs and to highlight experience with private-public partnerships.

MIRRI-ERIC must be included in the European bio-economy roadmap. The action 3.3.4. of the EC Bio-economy Strategy document (update 2018, DOI: 10.2777/792130, KI-04-806-EN-N), clearly identifies the importance for (i) a better integration of benefits of biodiversity-rich ecosystems in primary production through the specific support of agro-ecology and, (ii) for the development of microbiome-based solutions. For both elements of this action MIRRI-ERIC can provide the high-quality ex-situ resources from the microbial diversity of European soils and crop plants, and relevant expertise which will be needed to make actual progress. MIRRI-ERIC will underpin the value of its offer to the said action, and the role it should play in preserving newly isolated and characterized key-resources to secure research investments and future availability of relevant microbial biodiversity.

A database with contact persons, companies, their sector and main products will be developed and made available for internal RI-use, complying with GDPR policies. Initial contacts need to be developed further in follow-ups, newsletters, and visits. This can then be followed with student internships, detachments, development of and participation in common projects (e.g., Horizon Europe), training programs, licensing, knowledge and technological transfer, establishment of public-private partnerships in shared start-up daughter companies, etc.

Getting ex-students and postdocs into private companies helps partners increase the relevance of their education programmes, and helps building an alumni network in companies, which can be beneficial for further contacts.

5 Market Analysis

5.1. Socio-economic impact

High-quality bioscience research and innovative bioindustries are key contributors to tackle global societal challenges, towards a green, healthy and sustainable world.

There are studies of biomedical sciences indicating that a considerable fraction of published peer-reviewed scientific literature cannot be reproduced (National Academies of Sciences, 2019), causing a huge waste of public money. In 2015, a ground-breaking economic study claimed that about US\$28 billion a year was spent largely fruitlessly on preclinical research in the USA (Freedman et. al., 2015). Improper biological reagents and reference materials cause a whopping 36% of this irreproducibility. In other words, US\$10 billion per year are lost because of misidentified cell lines, contaminated microbial strains, or "borrowed" biological materials. For years, CCs have proven capacity building in microorganism's management and preservation through their very specialised staff and meticulous operations. However, there is still a lack of visibility, fragmentation of the offer and insufficient capacity of individual partners to deliver harmonised, reliable, high quality and integrated microbial-related scientific services throughout Europe.

The global market for microbes and microbial related products was estimated at 150B € in 2015 and up to 2023 has an expected annual growth rate of >10%. The EC estimates that the bioeconomy generated 2.3T € of turnover value and created 18 million full-time jobs in 2015 (Ronzon et al., 2018), reaching 1,460.6B € of value-added, which is 11% of the Gross Domestic Product in the European Union-28 (Kuosmanen et al. 2020). In 2013, the fraction of turnover value corresponding only to the industrial biotechnology (IB, a sector relying on the use of enzymes and microorganisms to produce bio-based products in diverse sectors), was 31.5B €, from which 8.4B € was generated in terms of value-added (EuropaBio Report, 2016). Furthermore, half a million jobs are associated with the IB in Europe and this number is expected to double by 2030. The economic impact generated by these sectors will certainly increase, as the EC calls to strengthen the sustainable bioeconomy valuing natural resources and diminishing environmental pressures, as well as increasing the use of sustainable renewable products, restoring and enhancing ecosystems' functions and biodiversity (Bioeconomy strategy, EC, 2018b). In this line, the EC has recently published the Biodiversity strategy (EC, 2020b), an ambitious agenda to protect and restore nature.

Harvesting the full value in microorganisms is fundamental to approach these challenges, as they impact different sectors, and MIRRI-ERIC will contribute to address them following its SRIA 2021-2030 (MIRRI, 2021) towards the main areas summarized in **Figure 7**.

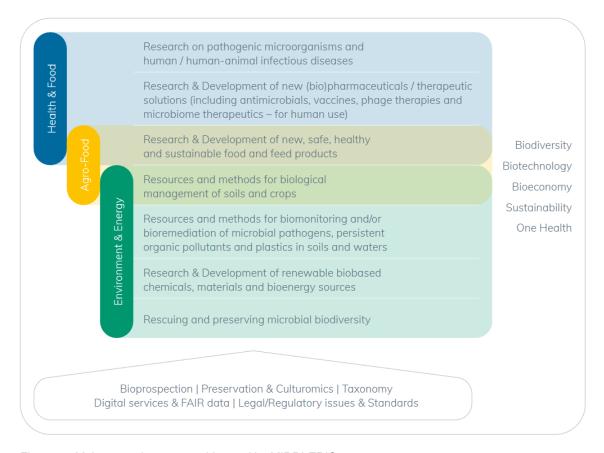


Figure 7 - Main strategic sectors addressed by MIRRI-ERIC

A non-exhaustive analysis of the socio-economic impact of some of the main areas where MIRRI-ERIC plays a role is summarized hereunder. A deeper analysis can be consulted in the MIRRI-ERIC SRIA 2021-2030 (MIRRI, 2021).

Infectious diseases and the growing concern for human and animal health

The World Health Organization estimated that 420,000 people die every year after eating contaminated food, resulting in the loss of 33 million healthy life years. Other threats related with public health are water-related infectious diseases and animal pathogens, since it is estimated that approximately 60% of human infections are associated to zoonoses. Recently, the world was hit by the novel coronavirus disease (Covid-19) pandemic that impacted the global economy through the costly use of medical care materials, low productivity, and forced lockdown in different countries. Implementation of prevention and mitigation measures is required to avert global health and economic crises. Besides the global emerging infectious diseases, there are the neglected infectious diseases affecting around 1 billion people in the world's poorest countries.

New (bio)pharmaceuticals / therapeutic solutions

Oncology, autoimmune and inflammatory diseases, diabetes and metabolic disorders, (neglected) infectious diseases, neurological and cardiovascular diseases, are currently the focus of an intensive R&I effort to deliver new therapeutic solutions, such as monoclonal antibodies,

recombinant growth factors, purified proteins, recombinant proteins, enzymes or hormones, cell and gene therapies, vaccines, immunomodulators, phage therapies, microbiome therapeutics, and many other product types. The global biopharmaceuticals market is highly competitive and is projected to grow by 9% through to 2025, reaching as much as 360-440B €. Alongside with this scenario, the pharmaceutical industry, together with academia, start-ups, and supported by governments, non-governmental organisations and charities have been developing new drugs and therapeutic solutions, to operate in financially less attractive markets. Several initiatives and programmes to illustrate what is ongoing are: (1) the Special Programme for Research and Training in Tropical Diseases (http://www.who.int/tdr/en/), (2) the Medicines for Malaria Venture (https://www.mmv.org), (3) the Global Alliance for Tuberculosis Drug Development (https://www.tballiance.org) or, (4) Drugs for Neglected Diseases Initiative (https://www.dndi.org).

Future of food innovation in balance with a resilient food system

Innovation in the food sector is oriented towards consumers that are more inclined to a healthy lifestyle and disease prevention. In fact, there is a growing demand for organic and healthy diets, including more nutritious and low-calorie food, customised food products, or food with health-promoting effects. Functional food is an emerging solution representing a huge market of 147B € (2021) that is expected to grow to 225B € in 2027, and 65% of this type of foods are elaborated with the help of microbes (i.e., bakery, dairy, novel vegetal fermentations). In addition, food and feed products need to meet the safety regulations and there is a great concern to ensure the food system sustainability, which are reflected in the Farm to Fork Strategy and the Food 2030 policy of the European Commission, both aligned with the Green Deal priorities. The agro-food chain generates about 700 million tons of waste each year in Europe. They are secondary raw materials which, in line with the transition towards a circular economy, can be exploited as carbon and nitrogen sources for microbial fermentation. Therefore, challenges such as agro-industrial by-products management and valorisation or foodborne-pathogen mitigation can also be addressed with the aid of microbes.

Healthy soil - healthy microbial ecosystem

The EC's Joint Research Centre has estimated that approximately 60-70% of soils in the European Union are unhealthy. Soil is an ecosystem containing large numbers of bacteria, fungi and other microbes; these contribute to 80-90% of the soil's biological activity and play a critical role in maintaining soil's health, ecosystem functions and crop production. Soil microorganisms can also affect human health, either directly via infection or by acting as reservoirs of antibiotic and antifungal genes than can be acquired by pathogens - for example, resistance to antifungal azoles administered to humans for treating aspergillosis has been linked with azoles used in agriculture. Healthy soils are required to fulfil the European Green Deal, the Common Agricultural Policy, the Water Framework Directive, the Habitats Directive, the Circular Economy Action Plan and the Soil Thematic Strategy.

Plant-microbe interactions for plant health and crop management

Plant-microbe interactions have dramatic effects on crop yield and economic viability. Microbes are important in nutrient transfer, nitrogen fixation, soil litter decomposition, solubilisation of inorganic minerals, stimulation of plant growth through phytohormones, antagonism towards pathogenic microorganisms, and mitigation of salt stress. Chemical fertilizers increase the cost of agricultural production and deteriorate soil quality. Use of beneficial microbes has a low cost and can reduce a crop's requirement of nitrogen by 50–70% and increase its yield by up to 20%. It is estimated that employing beneficial microbes could potentially reduce the usage of chemical fertilizers by half.

Biocontrol is the use of microbes or secondary metabolites produced by microbes to control pathogens; these can cause large reductions in pathogen numbers or pathogen virulence and thus reduce the dependence of farmers on harmful pesticides.

The potential of microbes to reduce the reliance on pesticides and fertilizers, as well as their ability to remediate contaminated soils means that they can have a major role in the development of sustainable farming systems and can thus play a major role in achieving the United Nations Sustainable Development Goals such as Zero Hunger.

Global environmental issues require immediate action

Pollution is one of the main causes of soil and water degradation and loss of ecosystem services: the accumulation of persistent pollutants from agriculture (agro-chemicals), industry (hydrocarbons, plastics, dyes), and civil society (pharmaceuticals, personal care products) led to negative consequences on climate change, alteration of water cycle, soil quality, and biodiversity with a strong impact on human health. The European Environment Agency estimates more than 2.5 million potentially contaminated sites; 340,000 sites are already identified and require remediation intervention. Managing contaminated land in Europe costs an estimated 6.5B € per year. Therefore, to reduce the European ecological deficit there is a pressing need to invest in new sustainable products and processes and to restore the ecological functions of lands, surface waters and oceans.

Attempts at remediating contaminated environments continue to be managed using conventional chemical-physical and often costly approaches. These methods are time consuming, invasive, disruptive to natural habitats and usually result in a rearrangement of the problems. Moreover, they are not applicable to tackle the problem of diffuse pollution of micropollutants (including microplastics) in soil and water. The environmentally safe and relatively inexpensive biotechnological methods of pollution control involving microorganisms (bioremediation) allow facing such issues in a sustainable way keeping into consideration the high number of sites that have to be treated.

Urgent need for renewable energy to afford climate change

Among the motivations behind the development of technologies to utilise renewable sources for the production of bioenergy are energy security and the drive to reduce national and global greenhouse gas production, as well as supporting the efficient utilisation of agricultural and forestry resources as part of a circular bioeconomy.

The natural resources can serve as replacements to chemicals and fuels derived from fossil fuel reserves, as well as in the production of bioalcohol (current bioethanol for automobiles and future longer chain alcohols for jet aircraft, for example), biochar and syngas. Specifically developed bacterial consortia, simultaneous and selective-degrading filamentous fungi, highly sugar-specific fermentative yeast strains, microalgae and more recently, co-cultivation methodologies have been developed to systematically remove high value components of the biomass for transformation into green chemistry precursors. These high value components find their application in the pharmaceutical, food and specialised chemicals industry.

5.2. Research strategy to meet the market needs

MIRRI-ERIC makes microorganisms and their potential available to society. The microbial resources, researchers, services and facilities in more than 50 repositories from 5 European countries (**Table 1**) and 5 prospective countries (**Table 2**) are a source of solutions to address some of the society's most pressing challenges: climate change, loss of soil fertility, air, water and soil pollution, renewable energies, protection of biodiversity, elimination of hunger and malnutrition, fight against emerging pathogens, search for new drugs and therapies. But they, also, generate new products for companies in an increasingly competitive market: new materials, ingredients, biodegradable products, improvements in process performance, health-promoting foods, etc. MIRRI-ERIC offers science and industry solutions aligned with global and European strategic agendas, such as the UN Sustainable Development Goals and the EC Horizon Europe, besides the ESFRI Strategy Report and Landscape Analysis, and national/regional Research and Innovation Strategies for Smart Specialisation (RIS3).

MIRRI-ERIC and its partner organisations are, therefore, on a privileged position to collaborate with the bioscience and the bioindustry communities and other RIs, on delivering the maximum value and impact from their projects, technologies and products.

5.3. Identifying new markets through environment scanning

In its quest for new markets, MIRRI-ERIC as a pan-European RI could be influenced by a myriad of factors on several levels. MIRRI-ERIC makes use of PESTLE (Political, Economic, Sociological, Technological, Legal, Environmental) analysis to identify the main factors. The current PESTLE analysis is included in **Annex 2**.

5.4. Position of MIRRI-ERIC in the European Research Area (ERA) and the ESFRI landscape

MIRRI-ERIC occupies a unique position and plays a singular role in the ERA and, particularly, in the ESFRI landscape, since (i) it is the only pan-European RI focusing on the preservation, study, provision and valorisation of microbial resources, and (ii) the broadness of its catalogue of microbial resources, associated data and services transversally crosses several highly-relevant R&I domains, including Health & Food, Agro-Food, Environment & Energy.

MIRRI-ERIC continuously analyses the landscape and scans the horizon in these domains to anticipate gaps and opportunities, aiming at better addressing the effective needs of its user communities, and helping them deliver the maximum value and impacts from their projects, technologies and products. This means, among other things, that MIRRI-ERIC is aligned and/or establishes potential links with relevant global, European and national/regional agendas, benchmarks and initiatives. An overview of these is given in **Annex 1**. The alignment between the MIRRI-ERIC areas of research and the Strategic Agendas and several ESFRI RIs is described in the MIRRI SRIA 2021-2030 (MIRRI, 2021).

5.5. Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis

Throughout its preparatory and implementation phases, MIRRI has been capable of accumulating a substantial number of relevant strengths, which set up the foundations for a competitive and sustainable RI in the long-term. Now fully entering the operation phase, some weaknesses remain, as they naturally occur in RIs with this level of maturity. It is important to highlight that these weaknesses have been properly diagnosed and monitored and are on their way to being adequately solved/mitigated.

MIRRI-ERIC's main strengths and weaknesses are listed, along with the context's opportunities and threats, on the SWOT analysis shown below (Table 4).

Table 4 - SWOT analysis of MIRRI-ERIC

Strengths Weaknesses • Establishment of MIRRI as ERIC brings a stable legal · Very limited financial capacity. structure, administrative advantages and reputational • Central Coordinating Unit (CCU) understaffed and with gains, along with new opportunities - e.g., on access to funding, on the external demand for resources and limited expertise in relevant topics (e.g. legal/regulatory services, etc. • National Nodes not yet formally constituted and/or • Participation of 10 countries (5 Members + 5 prospective Members/Observers) mobilizing ~50 mBRCs, CCs and research institutes. • Partner charter not yet signed by the (candidate) partners. · Availability of a broad range of high-quality microbial strains and associated data, as well as a comprehensive

• Top-level scientific expertise and leadership.

Environment & Energy.

· Adoption of a unified, long-term R&I vision, through the MIRRI's SRIA 2021-2030.

offer of services - important assets for researchers and

bioindustries in e.g. Health & Food, Agro-food, and

- During the Horizon 2020 project IS_MIRRI21, huge progress was made on the implementation and sustainability of the RI.
- · Recognition by the global mBRCs community as a key player to bring cohesiveness to the current disparate collections and resources in different European countries (also expandable to non-European countries).
- · Growing engagement of partners and interactions with stakeholders.

- affairs, finances/accountancy, project management).
- operational in some of the participating countries.
- Asymmetries in the level of engagement among the partners/people participating in MIRRI-ERIC.
- Specifications for technical design, operational procedures, monitoring key performance indicators, and operations of e-infrastructure services still not fully defined or not yet implemented.
- Catalogue of integrated services (workflows, pipelines), including in collaboration with other RIs, still under construction.
- Proactive enlargement and business development activities still not in place in sufficient scale.
- Limited track-record of many of the partners on interacting with or participating in collaborative projects with companies/industry.
- Lack of a signed agreement with BioAware and LifeWatch about the donation and in-kind contribution respectively for the provision of IT services to MIRRI-FRIC.

Opportunities Threats

- Ever-increasing need for cohesiveness and unification between collections and resources across countries.
- · Escalating demand for microbial resources, associated data and services from fast-growing scientific fields and market segments in the domains of Health & Food, Agro-Food, Environment & Energy.
- The high alignment of the MIRRI SRIA 2021-2030 with strategic agendas, such as Horizon Europe and national/regional RIS3, can bring new opportunities on access to funding, on attracting new countries and organizations, and on the external demand for MIRRI-ERIC resources and services.
- The unique position in the ESFRI landscape and the transversality of MIRRI-ERIC, intersecting several research areas, creates multiple opportunities for collaboration with other RIs, not only within the Health & Food domain, but also from the Environment, Data, Computing and Digital domains.
- Increased interest from the policy-makers and general public on microbes triggered by the COVID-19 pandemic.

- · Relatively limited visibility and perception of value of ESFRI RIs, in general, among the broad universe of stakeholders/users.
- The complexity of the internal, political processes associated to joining an ERIC can be a significant barrier candidate Members/Observers, many limiting/delaying the enlargement of the ERIC.
- Lack of foreseeable financial commitments to be obtained from non-founding countries participating in MIRRI.
- Potential non-inclusion of MIRRI National Nodes on the respective national roadmaps of RIs.
- Peripheral position of the hosting country in relation to important decision centers and relevant research and innovation ecosystems.
- Competition from other organizations providing microbial resources and services.
- Uncertainty and competition on the access to public funds and grants.
- Still insufficient recognition of the MIRRI-ERIC brand among some relevant stakeholders.

6. Financial plan

The income and expenses of MIRRI-ERIC under different funding scenarios are fully described in the Five-year Financial Plan, which constitutes another Deliverable of the IS_MIRRI21 project (D9.2.). The financial plan also describes the access to the services and pricing modalities of MIRRI-ERIC.

7. Implementation

7.1. Strategic axes

The activities of MIRRI-ERIC for the period 2023 - 2027 will be developed according to the following strategic axes/lines:

| | Research & Innovation, | | | | |
|-----------|--|--|--|--|--|
| STRATEGY | Anticipating future challenges and opportunities for research and innovation and setting up MIRRI-ERIC's strategic positioning towards scientific excellence | | | | |
| | Intelligence & Business Development, | | | | |
| | Anticipating the users' needs and the market trends and actively search and create new opportunities for business and collaborations | | | | |
| | Resources, Data & Services, | | | | |
| ACCESS | Growing and improving the offer of high-quality microbial resources, data and services, while making it every time more easily findable and accessible | | | | |
| ACCESS | Education & Training, | | | | |
| | Capacitating the present and future generations working with microbial resources (in mBRCs, academic/research institutions and industries), and promoting the citizens' literacy | | | | |
| | Operations & Quality, | | | | |
| OPERATION | Continuously improving the way MIRRI-ERIC and its partner organisations work together and operate on the interaction with the users, other stakeholders and third parties, aiming at operational excellence | | | | |
| | Partnerships & Enlargement, | | | | |
| OUTREACH | Attracting and retaining Members/Observers and Partner Organisations that can bring/deliver significant value to MIRRI-ERIC and its users, while strengthening the network and pursue valuable collaborations and partnerships | | | | |
| | Branding & Communication, | | | | |
| | Improving the reputation and the global recognition of MIRRI-ERIC among all its user communities and the overall society | | | | |
| | | | | | |

These strategic axes will be developed further in the five-year work programme and yearly work plans that are prepared by the Executive Director with the support of the National Coordinators Forum and approved by the Assembly of Members.

7.2. Key Performance Indicators, KPIs

7.2.1. KPIs to measure the impact of MIRRI-ERIC

MIRRI-ERIC will measure a series of indicators to monitor its performance as a research infrastructure. These indicators can also be used as proxies to measure impact of MIRRI-ERIC on economy and society. Most of these indicators can also be used to measure the impact of MIRRI-ERIC on the Partners' activities.

The KPIs are listed in **Table 5**, they will be measured annually. For KPIs with an *, also the 3-year trend will be monitored.

Table 5 - KPIs to measure activities of MIRRI-ERIC

| Objective | Indicator |
|--|--|
| Enabling scientific excellence | * Number of user requests (from profit and non-profit sector) for access to biological material |
| | * Number of samples of biological material distributed (to profit and non-profit sector) |
| | * Number of user requests/proposals (from profit and non-profit sector) for access to facilities |
| | * Number of granted proposals (from profit and non-profit sector) for access to facilities |
| | * Number of publications based on research performed using facilities/ resources of the RI |
| Delivery of education and training | The total number of person-hours for which people (internal and external to MIRRI-ERIC) have made use of training opportunities (on-site & on-line) provided by MIRRI-ERIC |
| | Number of people (internal and external to MIRRI-ERIC) that have made use of the training opportunities (on-site & on-line) provided by MIRRI-ERIC |
| Enhancing collaboration | Number of Members and Observers of the RI from EU countries |
| | Number of partners mBRCs that are part of MIRRI-ERIC |
| Facilitating | Share of users associated with industry |
| economic activities | Number of contracts/projects with industry |
| | * Outreach via website: |

| Outreach to the | number of usersnumber of page viewsaverage session duration |
|------------------------|---|
| public | * Outreach via social media (Facebook, LinkedIn, Twitter): - number of followers |
| | - number of interactions through social media |
| Optimising data use | * Number of catalogue records made available in MIRRI-ERIC catalogue of biological resources |
| | Number of participations of MIRRI-ERIC in policy-related working groups, committees and advisory boards |
| | Share of users (from profit and non-profit sector) from non-EU member countries |
| cooperation | Share of trainees (from profit and non-profit sector) from non-EU member countries |
| | Number of non-EU member countries officially collaborating with MIRRI-ERIC |
| | Sources of revenues (services, training, projects, other) and their respective contributions to investments and operational costs |

The CCU, where necessary with the help of the National Nodes, will gather the information needed to measure these indicators and evaluate their results annually.

7.2.2 Indicators to measure the operational targets of MIRRI-ERIC

In addition, MIRRI-ERIC has defined another set of indicators to monitor the internal operations of MIRRI-ERIC and the degree to which MIRRI-ERIC realises its objectives and integrates the activities of the Partner mBRCs. For the first five years, these indicators and their respective targets are presented in **Table 6**.

Table 6 - Indicators to measure the internal operational targets of MIRRI-ERIC.

| Indicator | Target |
|---|---|
| Number of Members and Observers participating in the infrastructure | Increase number of ERIC signatories by 4 countries by the end of year 5 |
| | Participation of MIRRI-ERIC in 4 projects by the end of year 5 |
| Number of collaborations with non-Members organisations | Collaboration with 2 non-Member organisations |
| | Formal collaborations with at least 3 other European RIs |

| Operation of CCU | All staff members for the CCU hired |
|--|---|
| Number of clusters of expertise | 3 clusters operational by the end of year 5 |
| Number of Partners that participate in the expert cluster forum | All Partners have designated at least one person as expert in forum |
| Number of new public accessions compliant with MIRRI- ERIC's Accession Policy | To be defined |
| Number of Partners contribute to the MIRRI-ERIC T&E program | T&E program established At least half of Partners contribute to the MIRRI-ERIC T&E program |
| Number of open calls for transnational access in which Partners representing MIRRI-ERIC are involved | To be defined (depending on external funding) |
| | Catalogues of Partners of founding Members available in MIRRI-IS one year after establishment of MIRRI-ERIC For other Partners: catalogue available in MIRRI-IS one year after becoming Partner |
| Number of Partner mBRCs having ISO 9001 certified (or equivalent) quality management system | All Partner mBRCs are ISO 9001 certified (or equivalent) after 3 years of partnership |

MIRRI-ERIC will regularly revise the indicators in function of their usefulness, to adapt them to a changing environment and to be in line with recommendations from the Advisory Board or good practices that will be developed by H&F working groups.

In addition to this internal monitoring of indicators, every 5 years, a scientific evaluation of MIRRI-ERIC activities, services and platforms will take place. The evaluation will be done by a panel of independent international external evaluators of the highest quality. This panel will produce and submit the evaluation report to the Assembly of Members.

7.3. Risk analysis and contingency plan

Unexpected factors and external risks can undermine and delay MIRRI-ERIC's ability to achieve the envisaged objectives. Recognizing potential risks, identifying mitigation options and articulating contingency measures enhance MIRRI-ERIC's ability to react to problems and to reduce their probability of occurrence.

Three major types of risks have been identified and evaluated: **(A) financial risks**, which include insufficient or delayed contributions by Members & Observers and other sources of revenue; **(B) implementation risks**, such as the delayed hiring of CCU staff, and the level of CWE users' satisfaction; and **(C) operational risks** covering low responsiveness of partners and failed service concept (expert cluster and training).

To evaluate the importance of each risk the following 4*4 categorisation matrix (**Tables 7 & 8**) was applied:

Table 7 – Risk categorisation matrix

| | | IMPACT | | | | |
|------------|--------------|-----------|--------------|-----------|--------------|--|
| | Risk Matrix | Minor (1) | Moderate (2) | Major (3) | Critical (4) | |
| Likelihood | Rare (1) | 1 | 2 | 3 | 4 | |
| | Unlikely (2) | 2 | 4 | 6 | 8 | |
| | Possible (3) | 3 | 6 | 9 | 12 | |
| | Likely (4) | 4 | 8 | 12 | 16 | |

Table 8 - MIRRI-ERIC risks and mitigation actions.

| Identification of Risks | Impact | Likelihood | Risk number | Mitigation for each risk. How? |
|--|----------|------------|----------------|---|
| A. Financial risks: | | | | |
| Insufficient or delayed contributions by Members and Observers | Critical | Possible | 12 | Develop a foresight plan based on the membership terms of each member and start negotiations for the continuation of membership one year before the expiration of the term. Develop a strategic dissemination plan for recruiting new M&Os highlighting the benefits of the ERIC. Increase revenues from other sources (grants, sponsoring, services, etc.), activities to encourage and increase the membership. |
| Insufficient funding by Third Party Grants | Major | Unlikely | 6 | Intensive interaction with other RIs and funding bodies, training for CCU staff in fundraising and grant management, active research of funding calls and other opportunities, increase the success rate by widening the partnerships. |
| Insufficient in-kind contributions | Critical | Unlikely | 8 | Sign agreement with in-kind contributor LifeWatch |
| Insufficient fees from services | Minor | Possible | 3 | Periodic market analysis and communication campaigns to disseminate the value of MIRRI-ERIC services. |
| Low revenues of sponsoring | Minor | Possible | 3 | Reporting on performance indicators of MIRRI-ERIC communication strategy (number of new website visitors, newsletter registrations, followers on social media, etc). Intensify communication and outreach campaigns. |
| B. Implementation risks: | | | | |
| Delayed hiring of CCU staff | Possible | Critical | 12 | Good planning of hiring procedures |
| CWE platform not satisfying user needs | Critical | Unlikely | 8 | Usability tests have been performed and the CWE has been improved according to feedback from users. It will be continuously improved matching user needs. |
| BioloMICS / ARIA unavailability | Major | Unlikely | 6 | Contracts / agreements with providers. Build up a new information system. |

| Difficult coordination and organisation of the EuroMIRC course | Major | Possible | 9 | Good coordination of Partners by the CCU. |
|--|----------|----------|---|---|
| C. Operational Risks | | | | |
| Low number of users | Critical | Unlikely | 8 | Dissemination plan and market demands must be systematically coordinated to develop MIRRI alongside the needs of users and partners and to address them adequately. The service and performance spectrum of MIRRI-ERIC, as well as user satisfaction, should be evaluated periodically. Training program developed in strong collaboration with mBRCs, universities and professional development associations. Active dissemination of the training offer in adapted channels for students, propose attractive curricula and tailor-made courses. |
| Failed service concept | Critical | Unlikely | 8 | Revise and update the service concept scientifically and practically. |
| Countries' contributions delayed delivery | Moderate | Possible | 6 | On-time delivery of requirements (work program and related budget requirements) - Send reminders. Adaptation of work programme. |
| Insufficient knowledge of MIRRI-ERIC by users - users still interact directly with mBRCs | Minor | Likely | 4 | Raising awareness about MIRRI-ERIC and the advantages it offers. Engage Partners to refer to MIRRI-ERIC on their websites. |
| Low responsiveness of Partners to provide services | Moderate | Unlikely | 4 | Continuous evaluation of benefits for Partners, communication about the economic potential of MIRRI services. |

The examination of the risk impact indicates that insufficient or delayed contributions by Members and Observers, possible delays in the hiring of CCU staff, the CWE platform not satisfying user needs, low number of users, and a failed service concept represent the most critical risks. It should be noted that these risks are highly depending on each other, and it is foreseen that active communication and outreach strategies will be implemented to mitigate as much as possible the financial and operational risks. Active and transparent communication strategies regarding the financial health of MIRRI-ERIC are foreseen in order to act quickly when a financial risk is detected.

8. Future opportunities

MIRRI-ERIC has the ambition to enlarge its membership (M&O countries) and partnership, recruiting important mBRCs not (yet) partners of MIRRI-ERIC and providing support to countries with important specialised collections for the implementation of quality standards needed to upgrade the CCs into mBRCs.

MIRRI-ERIC will develop sustainable strategic partnerships with other RIs. Cooperation with BBMRI-ERIC (human resources), EMBRC-ERIC (marine resources) and DiSSCo (scientific collections) on legal matters related to the Nagoya Protocol, access to resources, public-private relationships, implementation of data-processing and analysis tools, etc. will be beneficial for all RIs involved.

Interaction (e.g. in the frame of INFRASERV projects) with other Health & Food/LS RIs such as Instruct-ERIC, Euro-BioImaging and EU-OpenScreen ERIC will give the opportunity to increase knowledge on MIRRI-ERIC's own resources and to develop workflows of high-quality services integrating technologies of several RIs. Generating data on MIRRI-ERIC's own resources via high throughput screenings (e.g., metabolomics, imaging) will be invaluable in the increase of the attractiveness of the resources preserved by MIRRI-ERIC. Creating a strong community of service providers will bring the highest quality and complementary services possible to the MIRRI-ERIC users.

Since a key aspect of MIRRI-ERIC relies on sequence data of the holdings and their analyses, MIRRI-ERIC will also cooperate with ELIXIR, the infrastructure for life-sciences information and leader of the project EOSC-Life.

The IBISBA RI will develop new technologies and strategies for public and private researchers involved in the field of Industrial Biotechnology. It will be a perfect partner of MIRRI-ERIC by supporting the practical implementation of joint projects between MIRRI-ERIC partner mBRCs and their public or private users, helping to strengthen the possible industrial applications generated as a result of the collaboration. An example of a current project in this field is the HORIZON-INFRA-2022-TECH-01-01 Bioindustry 4.0, focused on the acceleration of bio-process development pipelines.

The SRIA 2021-2030 (MIRRI, 2021) and the participation of MIRRI-ERIC in the LS RI Strategy Group is facilitating the preparation of proposals for different Horizon Europe calls, including the development of common service workflows with other RIs.

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Annex 1 - Global, European and national/regional agendas, benchmarks and initiatives to which MIRRI-ERIC is aligned

STRATEGIC AGENDAS / FRAMEWORKS

- 1. NATIONAL/REGIONAL RIS3
- 2. HORIZON EUROPE CLUSTERS (Health / Digital, Industry and Space / Climate, Energy and Mobility / Food, Bioeconomy, Natural Resources, Agriculture and Environment)
- 3. HORIZON EUROPE MISSIONS (A Climate Resilient Europe / Conquering cancer / 100 Climate-neutral Cities by 2030 / Mission Starfish 2030 / Caring for soil is caring for life)
- 4. HORIZON EUROPE PARTNERSHIPS
 - 4.1. Health (European Partnership for EU-Africa Global Health / European Partnership for Innovative Health (Initiative) / European Partnership for Chemicals Risk Assessment / European Partnership ERA for Health Research / European Partnership for Personalised Medicine / European Partnership for One Health / Antimicrobial Resistance)
 - 4.2. Climate, Energy and Mobility (European Partnership on Clean Hydrogen / European Partnership for Clean Energy Transition)
 - 4.3. Food, Bioeconomy, Natural resources, Agriculture and Environment (European Partnership accelerating farming systems transition / European Partnership for Animal health / Agriculture of data / European Partnership for rescuing biodiversity to safeguard life on Earth / European Partnership for Safe and Sustainable Food Systems / European Partnership Water Security for the Planet)
 - 4.4. Partnerships across themes (European Partnerships Innovative SMEs / EOSC Partnership / European Institute of Technology Climate-Knowledge and Innovation Community (EIT Climate-KIC) / EIT InnoEnergy-KIC / EIT Health-KIC / EIT Food-KIC / EIT Manufacturing-KIC / EIT Raw materials-KIC / EIT Urban Mobility-KIC

ESFRI RIs

- 1. Environment
 - DANUBIUS-RI. International Centre for Advanced Studies on River-Sea
 Systems

- 1.2. DiSSCo. Distributed System of Scientific Collections
- 1.3. eLTER. Long-Term Ecosystem Research in Europe
- 1.4. EMSO ERIC. European Multidisciplinary Seafloor and water-column Observatory
- 1.5. LifeWatch ERIC. e-Infrastructure for Biodiversity and Ecosystem Research

2. Health & Food

- 2.1. AnaEE. Infrastructure for Analysis and Experimentation on Ecosystems
- 2.2. EU-IBISBA. European Industrial Biotechnology Innovation and Synthetic Biology Accelerator
- 2.3. METROFOOD-RI. Infrastructure for Promoting Metrology in Food and Nutrition
- 2.4. BBMRI ERIC. Biobanking and BioMolecular Resources Research Infrastructure
- 2.5. EATRIS ERIC. European Advanced Translational Research Infrastructure in Medicine
- 2.6. ECRIN ERIC. European Clinical Research Infrastructure Network
- 2.7. ELIXIR. A distributed infrastructure for life-science information
- 2.8. EMBRC ERIC. European Marine Biological Resource Centre
- 2.9. ERINHA. European Research Infrastructure on Highly Pathogenic Agents
- 2.10. EU-OPENSCREEN ERIC. European Infrastructure of Open Screening Platforms for Chemical Biology
- 2.11. Euro-BioImaging. European Research Infrastructure for Imaging Technologies in Biological and Biomedical Sciences
- 2.12. INFRAFRONTIER. European Research Infrastructure for the generation, phenotyping, archiving and distribution of mouse disease models
- 2.13. INSTRUCT ERIC. Integrated Structural Biology Infrastructure

Annex 2 - PESTLE (Political, Economic, Sociological, Technological, Legal, Environmental) analysis

P - Political: The current and potential influences from political pressures

- 1. ESFRI Roadmap
- 2. National R&I strategies
- 3. EC, which guided the constitution of the RI as an ERIC
- 4. MIRRI-ERIC Assembly of Members
- 5. Policymakers and national vs. European regulations

E - Economic: The local, national and world economic impact

- 1. Contributions from M&O countries
- 2. Funding redirected for health research due to the Covid-19 Pandemic
- 3. Availability of National and European Research funds
- 4. Non-for-profit business approach towards sustainability of RI
- 5. Inflation rate affecting direct costs (salaries)

S - Sociological: The ways in which changes in society affect the RI

- 1. Population and language of communication of the main Member countries
- 2. Covid-19 pandemic and its influence on MIRRI-ERIC's plans, employees and society at large
- 3. Ethical considerations
- 4. Outreach capacities to meet the needs of citizens and society

T – Technological: How new and emerging technology affects the RI

- 1. Digitalisation of databases from CCs
- 2. BioloMICS software to host MIRRI-IS
- 3. LifeWatch ERIC Common Facility in Spain to provide e-Tools and Virtual Research Environments
- 4. New emerging technologies that outdate the current systems and the need to improve service provision

L - Legal: How local, national and global legislation affects the RI

- 1. Protection of personal data of involved users
- 2. Nagoya Protocol
- 3. Biosafety and Biosecurity regulations
- 4. Access procedure adapted to the bioindustry needs (e.g. IPR, confidentiality)
- 5. ISO certifications
- 6. MIRRI-ERIC Statutes
- 7. Changes in organisational or institutional protocols for the Partner organisations

E - Environmental: Local, national and global environmental issues

- 1. Awareness about positive impact of microbes
- 2. Pests and soil treatment with microbes
- 3. Management of lab waste

