Roadmap for the development of a sustainable IBISBA infrastructure

Michael O'Donohue, Sonia Debeche, Pauliina Tukiainen

IBISBA 1.0

Industrial Biotechnology Innovation and Synthetic Biology Accelerator

Deliverable D3.4

Roadmap for the development of a sustainable IBISBA infrastructure

Planned delivery date (as in DoA): M50

Actual submission date: 28/02/2022, month M51

Workpackage: WP3

Workpackage leader: INRAE

Deliverable leader: Michael O'Donohue (INRAE)

Version: 1.0

Dissemination Level	
PU Public	X
CI Classified, as referred to Commission Decision 2001/844/EC	
CO Confidential, only for members of the consortium (including the Commission Services)	

This deliverable is part of a project that has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 730976.

TABLE OF CONTENTS

1 Summary

Addressing a gap in European industrial biotechnology, IBISBA's mission is to provide world-class cutting-edge research infrastructure services enabling the development of industrial biotechnology as a technological cornerstone of the circular bioeconomy. In this regard, IBISBA aims to contribute to the delivery of Europe's ambition to be the first climate neutral continent in 2050.

To fulfil its mission, IBISBA is building an interoperable network involving some of Europe's most significant, public-operated research infrastructures and the deployment of advanced digital networking tools. Belonging to IBISBA endows facilities with unprecedented collaborative capabilities that seamlessly link individual facility services and data assets within service workflows supporting whole R&D project life cycles. This means that IBISBA is uniquely geared to deliver translational research services, organizing the uptake and sharing of fundamental knowledge from different scientific disciplines to define new bioprocess concepts, build and test prototypes and perform pilot scale demonstrations.

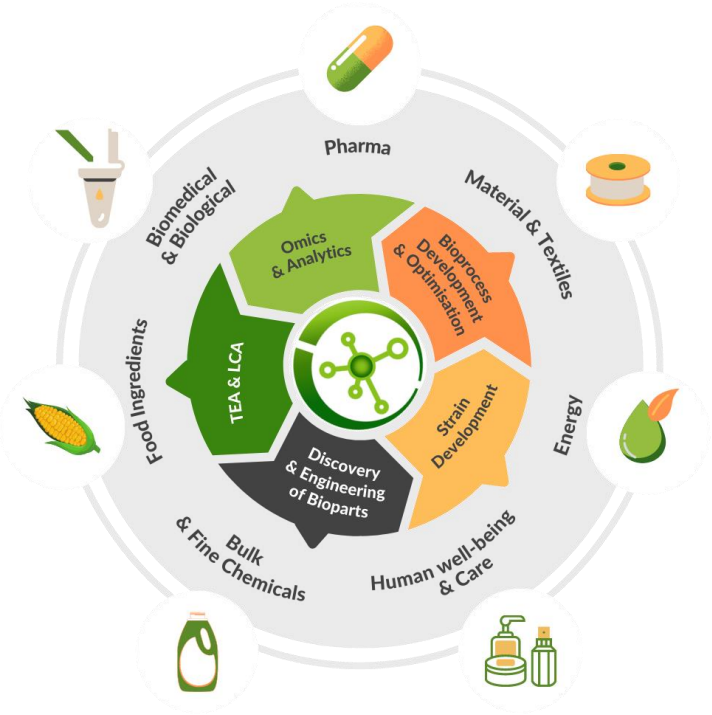
Since its origins in 2014, IBISBA has steadily grown in terms of numbers of partners involved, community maturity and organization. IBISBA's progress has been significantly boosted by funding received in the framework of two European Horizon 2020 projects (IBISBA 1.0 and PREP-IBISBA, grant agreement numbers 730976 and 871118 respectively) and by enhanced recognition following its inclusion in 2018 the European Strategy Forum on Research Infrastructures' roadmap. Presently, IBISBA is pursuing its progress towards a fully operational research infrastructure following a process that involves numerous preparative actions.

Considering achievements so far, this report is a non-scientific action plan that outlines 25 vital actions that must be successfully accomplished to deliver IBISBA's ambition, launching a legal entity before 2025 to achieve this. Some of these actions have already been reached, while other actions are ongoing or planned.

2 Introduction

2.1 Industrial biotechnology: advanced manufacturing for the circular bioeconomy

Industrial biotechnology is an applied field of research that feeds industry with new technologies based on the use of living organisms or their components (e.g., enzymes). These provide the catalytic power to drive processes designed to deliver manufactured goods or services to a very wide range of market sectors.



Industrial biotechnology embraces multiple disciplines and addresses a wide range of applications – curtesy of Mauro Di Fenza (IBISBA communications manager)

Since living organisms and their enzymes are responsible for the synthesis of the molecules and polymers that compose biological systems, they are exquisitely adapted to the modification of these. Therefore, living organisms and their enzymes are the ideal catalysts to drive new industrial processes that employ biomass feedstock. This is important, because unlike the fossil feedstocks of the petrochemical industrial, biomass is chemically complex, highly oxygenated and contains significant amounts of water. These characteristics require new, highly specific catalytic systems, unrelated to those previously developed to convert oil into manufactured goods.

The circular bioeconomy is an economically disruptive framework that postulates that future economic growth must better account for the finiteness of the Earth's resources and the imperative need to reduce greenhouse gas emissions and environmental dilapidation. To achieve this, the circular bioeconomy aims to deploy a range of advanced technologies that will support the use of renewable biobased feedstocks to replace fossil resources. The circular bioeconomy concept has recently received

strong support from the European Commission in the form of Europe's Green Deal[1]. This transformative policy is designed to respond to the combined menace of climate change and environmental degradation by renovating Europe's economic foundations. This involves a series of measures, including deep transformation of the manufacturing sector, aimed at delivering a modern economy that is competitive, carbon neutral, socially inclusive and a source of wealth and jobs.

Today's finely tuned petrochemical industry, a foundation stone of the present economy, is the result of two centuries of intense development fuelled by a progression of crucial discoveries in chemistry and chemical engineering through the 19th and early 20th centuries. Similarly, the development of industrial biotechnology relies on more recent progress in the field of biology, but also depends on advances in chemical engineering and in computer science. Both modern biology and computer science are recent developments that emerged in the latter half of the 20th century. Combined with chemical engineering, these two disciplines hold the potential to overhaul current industrial manufacturing, providing the basis for smarter, more flexible, and highly automated processes that will satisfy sustainability criteria and contribute to the success of Europe's Green Deal.

The use of industrial biotechnology by the manufacturing sector is already a reality. This can be illustrated by some emblematic products:

- Bioethanol is obtained through the fermentation of sugar feedstocks (e.g., from sugar cane or sugar beet), usually using the yeast Saccharomyces cerevisiae. Industrial production of bioethanol worldwide represented over 90 billion litres in 2018[2].
- Biobased plastics (e.g., polylactic acid and polybutylene succinate) present in a variety of products, such as yoghurt packaging, biodegradable cutlery etc. These compounds are most often obtained using microbial fermentation. According to www.european-bioplastics.org, the overall production capacity is 2.4 million tonnes worldwide.
- Biobased surfactants are compounds that reduce the surface tension of a liquid. They are frequently employed in the cosmetic and pharmaceutical industries. Many biobased surfactants are obtained through fermentation (e.g., rhamnolipids) using enzyme-driven processes (e.g., alkyl polyglucosides). The current production of biobased surfactants in Europe is approximately 1.5 million tonnes per year (https://www.ieabioenergy.com/wp-content/uploads/2020/02/Bio-based-chemicals-a-2020-update-final-200213.pdf).

Nevertheless, the potential of industrial biotechnology is enormous, because global demand for carbon-based chemicals and products is 450 million tonnes (embedded carbon) per year, with only 10% of this demand being met by biobased products[3]

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2019:640:FIN

[2] Bioethanol production volume by world region 2018. Published by N. Sönnichsen, Jan 27, 2021. www.statista.com

[3] Nova-institute 2021 – data available at www.renewable-carbon.eu

2.2 Current challenges in the field of industrial biotechnology

Hurdles to wider deployment of industrial biotechnology are numerous, but a major one is lack of knowledge, which justifies the necessity for intensified research in the field. The petrochemical industry is driven by industrial chemistry, which uses chemical catalysis to power sophisticated industrial processes. During the development of this sector, engineering approaches have successfully harnessed physical phenomena (e.g., thermodynamics, fluid mechanics etc) to design reliable, reproducible industrial processes. Modern industrial chemistry is thus rooted in physics and uses mathematical modelling to simulate and control processes. In this regard, industrial biotechnology resembles industrial chemistry, since it is also embedded in physics and chemistry, which underpin the understanding of biological processes. However, biology is less amenable to classical reductionist engineering approaches because, unlike machines, living systems are sensitive and resilient to environmental changes, possessing homeostatic capacity to re-establish themselves[4].

Despite the additional challenges related to the application of engineering principles to biology, the notion of bioengineering is well-established, with synthetic biology being a significant recent step in this direction. Synthetic biology is driven by a series of advances including easy access to synthetic DNA, a profusion of multi-scale biological data (e.g., genomics, transcriptomics and metabolomics data), genome engineering techniques etc, and the application of engineering principles such as modularity, standardisation, and design abstraction. Using the design-build-test-learn conceptual framework, synthetic biology practitioners aim to construct biological systems that display predictable behaviour and deliver functions in reproducible fashion. Considerable progress is being made in the field, but new knowledge and tools are necessary to account for the exquisite complexity of biological systems.

2.3 Emerging trends and opportunities

2.3.1 Industry 4.0

Computer science is a recent discipline that has given rise to a multitude of technologies and approaches that have steadily transformed industrial practices over the last 50 years, changing the way that products are designed, manufactured, and marketed. As a scientific discipline, computer science is remarkably inter-penetrable with other scientific disciplines. The consequence of this is that its impacts are numerous and varied, from the creation of internet, the development of artificial intelligence and robotics, to synthetic biology (e.g., the development of machine-readable languages that represent biological designs). One of the consequences of the computational and information technology revolution is the reappraisal of manufacturing concepts.

The industry 4.0 concept is hailed as a major upheaval of manufacturing philosophy. This concept, also known as the 4th industrial revolution, refers to a new vision for industry in which facilitating digital technologies are omnipresent. In industry 4.0, thanks to cloud computing and internet of things (IoT), manufacturing is distributed and automated, with processes being embedded in modular workflows that are executed by robots/automats. Moreover, process control is improved using both artificial intelligence (AI) and big data to introduce learning loops that help to perfection processes, while

[4] Woese, C. Microbiol Mol Biol Rev. 2004 Jun; 68(2): 173–186. doi: 10.1128/MMBR.68.2.173-186.2004

creating the basis for resilience. According to the industry 4.0 concept, manufacturing becomes more flexible and responsive to altered process conditions (e.g., variable feedstocks) and/or evolving markets needs and consumer demands.

Considering the state of the art in industrial biotechnology in the light of the industry 4.0 framework, it is readily apparent that this concept is very relevant to biomanufacturing. The promise of distributed operations is highly compatible with biobased industries that are likely to co-locate (to some extent) with biomass production, while greater flexibility and modularity are attractive features to deal with the intrinsic variability of biomass feedstocks. Likewise, the deployment of data driven AI as a complementary approach to equation-based modelling for the analysis and control of biological systems is an inviting prospect. Therefore, the rapid development of a bioindustry 4.0 concept is highly probable, or even inevitable. However, to develop bioindustry 4.0 as a workable concept considerable progress is necessary at all development levels, beginning with the adoption of distributed, automated processes, relying on the integration of virtual and physical systems, and standardization by research laboratories.

2.3.2 Environmental biotechnology meets industrial biotechnology

According to the International Society for Environmental Biotechnology, the term environmental biotechnology refers to the development, use and regulation of biological systems for remediation of contaminated environments (land, air, water), and for environment-friendly processes (green manufacturing technologies and sustainable development). Historically, despite their similarities, industrial and environmental biotechnologies have mobilized different scientific communities with the latter being invested to a much greater extent by chemical engineers specialized in the use of complex microbial consortia as biocatalysts for wastewater and solid organic waste treatment. The reason for this difference is that until recently, microbial consortia constituted a black box whose functions were understood and controlled mainly from a process engineering perspective. However, since the advent of metagenomics and more recently culturomics, the content of the microbial black box is being revealed and its functions better understood, both at the cellular and the ecosystem levels. Simultaneously, the circular bioeconomy concept has radically altered the status of waste streams, transforming them into valorisable feedstocks. This paradigm change means that waste treatment is now considered as a resource for added-value biomanufacturing, beyond the production of biogas for example. Simultaneously, industrial biotechnology-based solutions for the treatment of waste plastic materials or the valorisation of waste CO_2 streams are under development.

Overall, advances in the understanding of complex microbial systems and conceptual changes regarding waste are blurring the frontiers between industrial and environmental biotechnology. From a science and technology perspective, this is exciting because it extends the bioengineer's toolbox and diversifies solutions. From an applicative standpoint it implies that microbial consortia will increasingly be considered as viable options for a variety of market sectors (e.g., industrial chemicals, health and medicine, energy, and food and agriculture) rather than being restricted to environmental remediation.

2.4 IBISBA: a BIOINDUSTRY 4.0 testbed for Europe

The core principles of IBISBA are that industrial biotechnology is a key enabling technology of the circular bioeconomy and that its wide deployment will help meet numerous UN sustainable development goals and accelerate the transition towards a circular bioeconomy. To achieve this goal, IBISBA partners believe that a permanent research infrastructure capable of implementing new research practices and accompanying innovation projects is necessary.

To reach its goal, IBISBA gathers a multidisciplinary array of research infrastructure facilities from around Europe to deliver integrated responses to the needs of R&D in industrial biotechnology. This is achieved by developing the ability to design and operate infrastructure service workflows, integrating different expertise and project development scales. The underlying requirements to reach this objective being standardization and interoperability, a core goal of IBISBA is to assemble a highly integrated set of research infrastructure services, creating a common science and technology culture among its research facility operators. This involves the development of a shared business framework to support service delivery, while respecting the principle of subsidiarity for more routine research infrastructure operations.

The overarching ambition of IBISBA is thus to create a fully operational distributed research infrastructure, with geographically distributed facilities capable of performing the different operations that constitute the design-build-test-learn bioengineering cycle. This implies that IBISBA will integrate the services of research infrastructures embedded in scientific disciplines such as biology, chemical engineering, and computer sciences, providing the means to support the development of industrially relevant bioprocesses using advanced concepts (e.g., industry 4.0) and technologies, such as robotics and artificial intelligence. In doing so, IBISBA activities will progressively de-risk industrial biotechnology and thus promote its adoption by a wide cross section of industrial stakeholders.

The rest of this document provides an overview of IBISBA's pathway to operation. It will briefly describe the key milestones that have already been reached and describe the remaining ones required to reach the status of a fully operational European distributed research infrastructure.

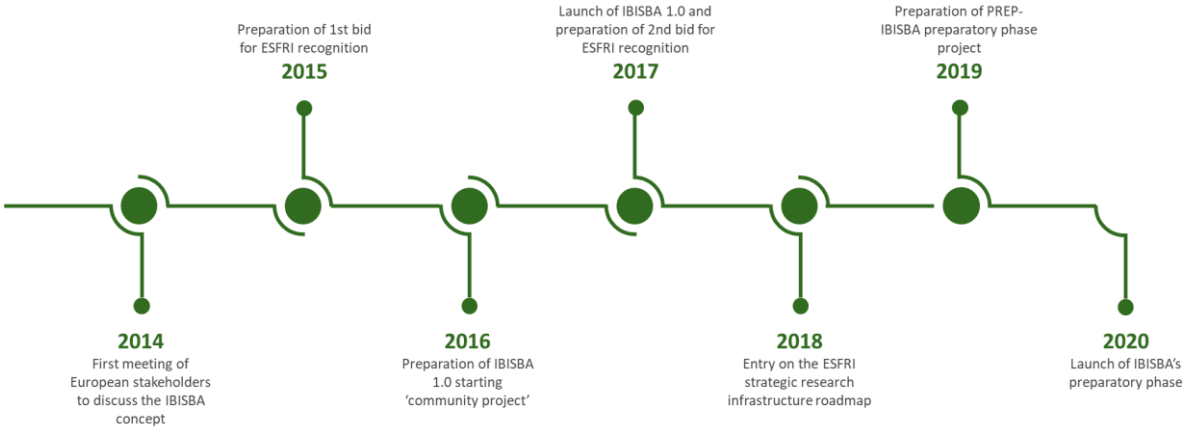
3 IBISBA, a landmark ambition

3.1 Tracing IBISBA's timeline so far

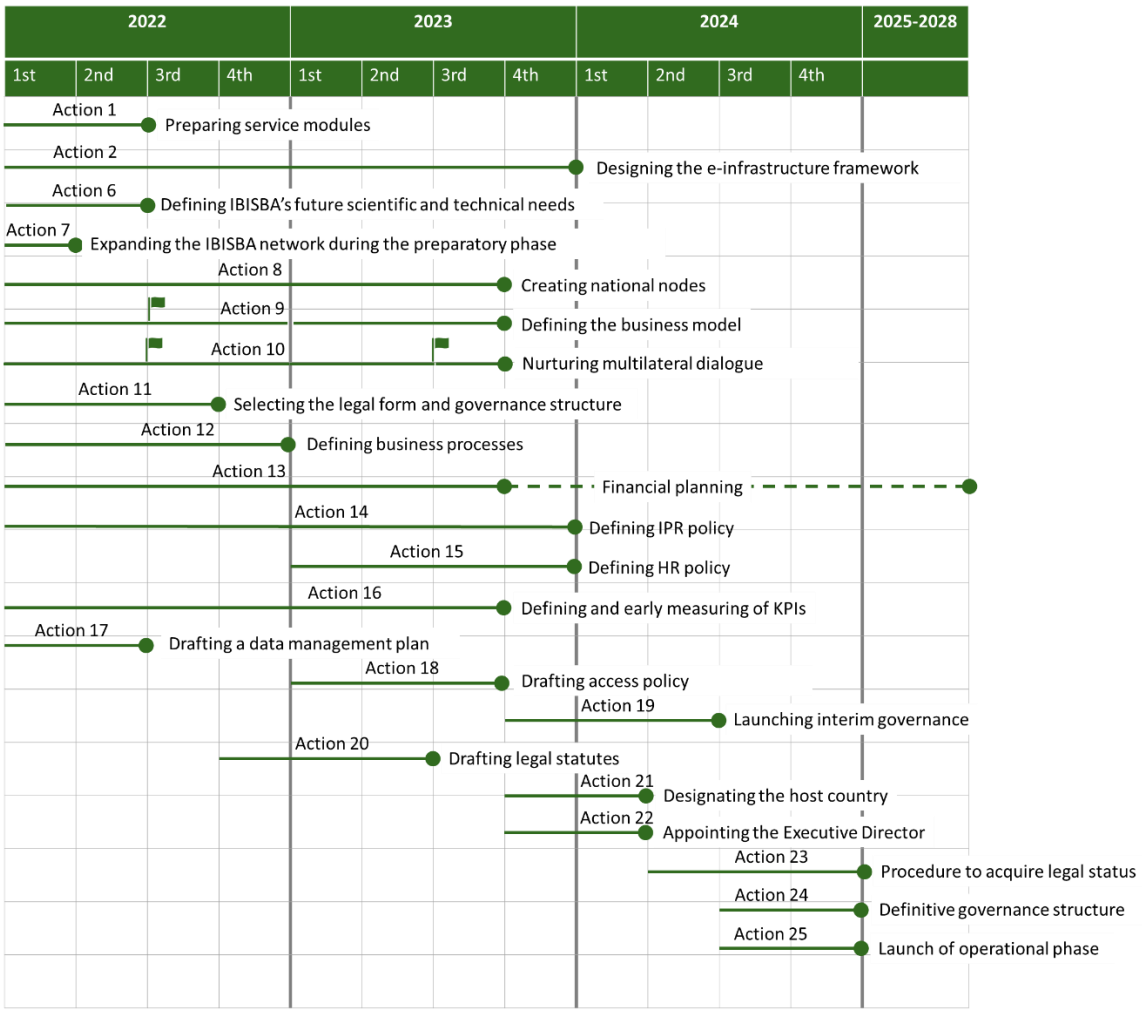
In 2014, a group of research scientists came together in Paris for the first time to discuss what was rapidly to become IBISBA. This first meeting established the need for a translational research infrastructure capable of translating fundamental research results into new bioprocess concepts, thus filling a gap in the R&D continuum, from basic laboratory research to industrial development. Following the meeting Paris, a core group of individuals and institutions began to lay the foundations of what is now IBISBA.

The first formal attempt to gain European recognition for IBISBA was launched in 2015, with France leading a bid to add IBISBA to the 2016 European Science Forum Research Infrastructure (ESFRI) infrastructure roadmap. Although this bid was unsuccessful, it laid the foundations for a project proposal that was submitted to the European Commission in 2016. Responding to a Horizon 2020 framework programme call (H2020-INFRAIA-2016-2017 Starting community), a consortium of sixteen

partners proposed a project entitled IBISBA 1.0. This project, programmed to last 48 months, was accepted for funding (Grant Agreement number 730976) and began in December 2017.



During the period 2016/2017, IBISBA partners also prepared a second bid to enter IBISBA onto the ESFRI roadmap. The second bid led by France and supported by 8 other European Union Member states was successful. This allowed IBISBA to enter onto the 2018 ESFRI roadmap, which was officially launched in September 2018. Following this success IBISBA partners prepared a bid for further funding from the European commission, this time responding the H2020-INFRADEV-02-2019-2020 call, the aim being to launch IBISBA's preparatory phase. The resulting 48-month project entitled PREP-IBISBA was accepted for funding and began in January 2020.



Summary of ongoing and planned actions. Actions already achieved are not shown.

3.2 Building network interoperability

3.2.1 Action 1 – Defining modular service building blocks

Objective	Provide the basis for the definition and execution of bespoke service workflows that respond to client needs.
Status	Ongoing
Expected delivery date	2nd quarter 2022 (first catalogue of modular services)

A majority of European research infrastructure whose strategic importance is recognized by ESFRI support progress in fundamental science. These infrastructures generally focus on and develop excellence in specific areas. Examples of such research infrastructure developing and delivering cutting-edge research services in specific science areas are ERIC-EURO-BIOIMAGING (state-of-the-art imaging services in biological and biomedical research), EMPHASIS (plant phenotyping), ERIC-

INSTRUCT (high-end structural biology services and techniques) and MIRRI (the preservation, systematic investigation, provision and valorisation of microbial resources and biodiversity). A smaller number of ESFRI-recognized research infrastructure focus on more applied, translational research. This is the case of ERIC-EATRIS, which provides services to support translational medicine.

Like ERIC-EATRIS, IBISBA's ambition is to support translational research. However, whereas EATRIS is specialized in medical research, IBISBA focuses on the wider field of industrial biotechnology. This means that IBISBA intends to provide a fully integrated research infrastructure acting as a R&D platform and crucible for innovation beneficial to several application areas. To achieve this, IBISBA must possess the ability to physically combine and reproducibly operate research infrastructure services within modular workflows that are designed in bespoke manner to fit the requirements of different R&D projects.

To achieve its ambition, the IBISBA community is working on the development of standards and harmonized research practices. These will ensure that IBISBA service facilities operate according to the same standards, and that the industrial biotechnology R&D community at large is provided with cutting edge, reliable R&D infrastructure services, and advanced tools and methods to improve their own research practices. Inthis regard, special effort is focused on the seamless linkage of research services. To tackle this question, the IBISBA community is devising a robust methodology to define and manage the hand-on/hand-off points of each service. The short-term ambition is to populate IBISBA's service catalogue with a first generation of service modules. Over time and through practice, it is anticipated that the methodology will evolve and the definition of each service module will be refined.

3.2.2 Action 2 – Designing and building a digital framework and e-tools for distributed operations

Objective	A conceptual framework for IBISBA e-infrastructure and its implementation
Status	Ongoing
Expected delivery date	4th quarter 2023

Irrespective of their field of specialization, European research infrastructures are pioneering the development and deployment of advanced data management solutions and computer technologies to support scientific excellence. Working closely with ELIXIR (https://elixir-europe.org/), other European research infrastructures are leading the way in terms of data FAIRization[5]. Similarly, since many European research infrastructures are distributed, these are also pioneering ways to perform research using advanced cloud computing technologies.

To implement its advanced research service offer, IBISBA aims to devise and share a wide range of concepts, advanced tools and methods that will unlock the potential of industrial biotechnology. These

[5] Wilkinson, M., Dumontier, M., Aalbersberg, I. et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci Data 3, 160018 (2016). https://doi.org/10.1038/sdata.2016.18

include strong focus on data management, developing domain-specific tools to ensure that data assets generated in the field of industrial biotechnology are both FAIR and fully machine exploitable. IBISBA also intends to tackle the question of data sharing among industrial biotechnology stakeholders, promoting the use of novel approaches, such as trusted data networks. Moreover, IBISBA aims to be at the forefront of efforts to digitalize industrial biotechnology (according to the industry 4.0 concept), developing for example digital twins, and demonstrating how cloud computing and Internet of Things can facilitate the development and operation of bioprocesses within distributed networks.

Early steps to build e-infrastructure capability include the development of the IBISBAhub (https://hub.ibisba.eu/). This is a complete data management platform used for IBISBA projects, but also available to other users wishing to better manage industrial biotechnology-related data. The IBISBAHub uses the ISA (Investigation, Study, Assay - https://www.isacommons.org/)[6] structure to organise data, providing different levels of accessibility and confidentiality.

Other ongoing work is focusing on the design of a comprehensive, multi-layer information system capable of supporting the different IBISBA distributed business operations. This includes a project management platform supporting an event-driven operating model and various e-tools to support R&D projects.

3.2.3 Action 3 – Establishing a one-stop shop

Objective	Create a single-entry point resource for IBISBA's user community and business process to support the delivery of integrated project services
Status	Achieved (One-stop shop is operational)

Historically, Europe is a world leader in scientific pursuits and technology developments, and its current scientific production remains superior to that of its global competitors [7]. As a result, Europe boasts a dense R&D landscape, composed of a multitude of organizations and funding agencies and a myriad of research infrastructures and facilities spread across the continent. Fortunately, a certain level of coordination and integration of European science is achieved by the European Research Area (ERA) ambition, which aims to better integrate research, innovation and technology across the EU, achieving this by enhancing cooperation between the EU, Member States, and stakeholders[8]. In this regard, under the supervision of ERA, ESFRI is charged with the responsibility of ensuring that research infrastructure capabilities across Europe are integrated and strengthened, thus extending the use of knowledge and knowledge-based technologies[9].

[6] Rocca-Serra et al. *Bioinformatics*, Volume 26, Issue 18, 15 September 2010, Pages 2354–2356, https://doi.org/10.1093/bioinformatics/btq415

[7] Veugelers, R. and Baltensperger, M., 2019, Europe –the Global Centre for Excellent Research. https://www.europarl.europa.eu/RegData/etudes/STUD/2019/631062/IPOL_STU(2019)631062_EN.pdf

[8] https://ec.europa.eu/info/files/pact-research-and-innovation-europe-factsheet_en

[9] https://www.esfri.eu/esfri-white-paper/esfri-vision-and-mission

In keeping with the mission of ESFRI, a common feature of most distributed research infrastructure is the operation of a single access portal, often referred to as a one-stop shop. Such a portal is designed to gather all information related to research facilities into a web-based single resource and provide users with a fast-track towards the appropriate research service. Moreover, one-stop shops often endeavor to complete the simplification process by adding streamlined back-office processes, allowing users to establish communication with research infrastructures without having to choose between a large number of people contacts. Finally, more advanced one-stop shops push customer service even further by ensuring that during the service contracting process users are not overwhelmed by an excessive number of interlocutors.

The IBISBA concept for a one-stop is one that goes as far as possible, including the ability to propose bespoke integrated services to customers. This ambition implies that IBISBA's one-stop shop is more than a web-based portal containing a catalogue of services. IBISBA's one-stop (http://ibisba-services.eu/) was launched in the framework of the IBISBA 1.0 project. It is conceived to offer customers a smooth browsing experience, the ability to compile a service wish list and access to an application form. Submission of the form to IBISBA initiates a business process allowing the customer to contact a business developer, and via this person, an array of research facilities. Likewise, the service is the entry point for access to bespoke integrated service workflows that are designed to meet client's project needs.

The creation of IBISBA as a legal entity will provide the opportunity to add new business processes. Regarding the one-stop shop, this will thus be an opportunity enhance integration even more.

3.3 Building IBISBA's visibility

3.3.1 Action 4 – Preparing a communication plan

Objective	Design an efficient communication strategy, defining how IBISBA will raise its visibility among stakeholders
Status	Achieved (communication in deployment phase)

Raising awareness about a research infrastructure's vision, mission and capabilities is a vital step towards its full operational launch. This is because a research infrastructure can only be fully functional when all of its stakeholders are thoroughly informed, understand its potential value, and enter a collaborative bilateral relationship. This holds for all IBISBA stakeholders, beginning with its clients and own internal facility operator community. It is also vital for policy makers to perceive the added value of IBISBA, identifying it as a partner for optimal deployment of research infrastructure, for the development of relevant science policy and to support innovation. Likewise, it is important for IBISBA to engage in dialogue with citizens, exchanging views on society's needs and expectations regarding biotechnology and raising the level of understanding about the advantages and limits of biotechnology in the context of the circular bioeconomy. Finally, considering the imperative need to train a new generation of biotechnology practitioners, it is crucial for IBISBA to be visible to early career stage researchers, providing them with access not only to cutting edge tools, but also advanced research practices. For all these reasons, a comprehensive communication strategy and plan are necessary to:

- raise awareness about the existence of the research infrastructure and its capabilities
- provide information relating to its purpose and convince that it is necessary
- galvanize the IBISBA facility operator community and build the basis for high commitment
- attract and maintain a wider client base
- create a basis for dialogue relating to industrial biotechnology
- incite early career stage researchers to engage with IBISBA

From the outset, IBISBA prepared a communication strategy whose purpose is to communicate to all its stakeholders. Regarding industry, special attention is given to SMEs because this group of stakeholders has consistently displayed appetite for IBISBA's service offer. Through its plan, IBISBA quickly developed vision and mission statements, which have been progressively altered over time to improve the impact of the underlying messages. These are aimed to be inclusive and relevant to a wide audience. Similarly, according to IBISBA's communication plan the opportunities offered by its website and social media resources have been exploited to disseminate information and create a basis for both permanent, 'cold' communication (e.g., permanent website features), combined with temporary, but more dynamic communication related to specific events (e.g., launch of calls for transnational access applications, direct promotion of IBISBA during international congresses, science festivals etc.).

IBISBA's VISION: Biotechnology is a game-changer, providing the technology building bricks for advanced industrial solutions impacting a wide variety of market sectors, including environmental services.

IBISBA'MISSION: Addressing a gap in European industrial biotechnology, IBISBA's mission is to provide world-class cutting-edge research infrastructure services enabling the development of industrial biotechnology as a technological cornerstone of the circular bioeconomy.

From an internal perspective, communication has undergone steady progression, building on the strong commitment of its research infrastructure facility operators. This has been helped by the launch of an internal newsletter and the task forces. The latter are small internal groups that are assigned work related to crosscutting issues that are not dealt within the framework of IBISBA EU-funded projects.

3.3.2 Action 5 – Developing a visual identity

Objective	Design visual elements for internal and external use that illustrate what IBISBA is about and create a stable link between IBISBA and its community and clients
Status	Achieved (visual elements in routine use)

Most modern, collective human enterprises develop corporate identity. This is because corporate identity translates complex strategy into simple, recognizable elements that symbolize the purpose and reputation of an organization. Key elements of corporate identity are straightforward, standardized statements about the organizations vision and mission and a logo, which can exist in multiple versions providing that the central features are stable and recognizable.

As part of the communication plan IBISBA has acquired a strong and now quite stable visual identity. The IBISBA logo was designed to convey the idea of a consistent, interlinked organization operating in a field that will promote green growth and sustainability. The logo and the mark 'IBISBA' are registered and all IBISBA partners are encouraged to use them. For this purpose, a graphical charter was also prepared and made available to all. Furthermore, IBISBA has adopted an easy to remember slogan: "sharing the way to innovation". This epitomizes IBISBA's philosophy and ambition to integrate research infrastructure strategies and thus better address challenges in industrial biotechnology.

In summary, the IBISBA community is now well endowed with a range communication tools that support the development of IBISBA's visibility among its stakeholders.

3.4 Extending the network

3.4.1 Action 6 – Defining IBISBA's future scientific and technical needs

Objective	Perform a scientific and technical analysis and generate a roadmap that identifies IBISBA's capacities and gaps, and provides a framework for growth
Status	Ongoing
Expected delivery date	2nd quarter 2022

A key feature of ESFRI-acknowledged European research infrastructure is their ability to support European excellence in all fields of science and innovation. To achieve this, European research infrastructures must be aligned with, and anticipate developments in their field, including regulatory and/or legal changes. Therefore, performing strategic analyses and road-mapping is ongoing task that constitutes a priority action for all research infrastructures.

Industrial biotechnology is a fast-developing area that is benefiting from a constant flow of new knowledge from life sciences research. Likewise, the field is strongly impacted by the digital revolution, with the deep digitalization of all R&D&I and operational stages of industrial bioprocesses already being clearly identified as a future prospect. Keeping apace of developments in industrial biotechnology is not a trivial task, because this not only requires careful analysis of current and future trends in the development of generic technologies, but also those that are specific to the many application areas of industrial biotechnology.

In the framework of PREP-IBISBA efforts are being made to appraise the current scientific and technical capabilities of IBISBA and make projections regarding future needs. The analysis sets out to perform a SWOT analysis, detect gaps in the current service offer and define IBISBA's unique selling point. As part of this study, a landscape analysis is being performed with longer-term projections (5 and 10 years) regarding needs being formulated. The final IBISBA strategic roadmap is expected in 2022. This document will be the first edition of a living document that will be regularly updated in coming years.

3.4.2 Action 7 – Procedure to expand the IBISBA network during the preparatory phase

Objective	Establish a procedure to incorporate new stakeholders into IBISBA's community
Status	Ongoing
Expected delivery date	1st quarter 2022

European distributed research infrastructures are generally quite extensive enterprises gathering together large numbers of research facilities (e.g. ERIC-EATRIS gathers facilities from over 115 academic centers across Europe, while ERIC-INSTRUCT gathers together facilities in 13 different countries, including the United Kingdom and Israel). While size alone is an insufficient criterion to measure the importance of a European research infrastructure, it does provide an idea of the extent of the community that supports the research infrastructure. Moreover, it also offers a guarantee of sustainability.

Since its early days, IBISBA has been actively supported by research and higher education establishments located in nine European countries. These entities provide strong support to IBISBA, mobilizing resources to ensure this. Therefore, IBISBA's current situation is healthy. Nevertheless, with the end of the preparatory phase in sight (i.e. end of 2023), IBISBA must look to the future, both with respect to its short-term sustainability and its growth. Regarding sustainability, until the creation of the legal entity and the implementation of the financial plan, IBISBA will require strong commitment and material support from its members. In this regard, IBISBA is aware that new members can provide new resources, skills and knowledge necessary to fill in science and technology gaps (e.g., in environmental biotechnology/microbial consortia and in computer sciences/artificial intelligence) and to succeed pre-implementation and implementation. Moreover, in the longer-term, new members provide the guarantee that IBISBA is adequately represented across Europe and that its service offer is sufficiently comprehensive (i.e., covering all relevant science areas and market sectors). Therefore, while awaiting the opportunity to create a legal entity, IBISBA's founders have drafted a Memorandum of Understanding (MoU). This agreement seeks to achieve two key aims:

1. Create a transparent basis for the addition of new members to the IBISBA community, irrespective of whether new parties are research and/or higher education establishments, or other types of entities
2. Secure and galvanize active support from both IBISBA's founding and new members

New parties can sign the MoU. In doing so they agree to abide by the rules and commit to the success of IBISBA. The MoU will remain valid at least until the acquisition of legal status by IBISBA. To access the MoU, a party (defined as a public or privately-owned legal entity) must obtain consent from the MoU's General Assembly. To do this, the request is addressed to the Secretary (currently michael.odonohue@ibisba.eu). The request explains the motivations of the candidate party and identifies the ways in which it wishes to commit to the success of IBISBA. Once received, the request is processed, and a decision reached within 45 calendar days. In the event of consent, the candidate party has 30 days to sign the accession document.

The MoU is now established and is being communicated to the IBISBA community, the aim being to inform all current participants of their organization's commitment. Likewise, the MoU will be publicly communicated, providing a means to attract new members and structure relations with organizations

that have previously voiced interest in IBISBA. So far, three new institutions have expressed interest to join IBISBA through the MoU. Among these, two are based in countries not yet involved in IBISBA.

3.4.3 Action 8 – Creating national nodes

Objective	Create national-based communities of research infrastructure facility operators able to contribute high level service to IBISBA's one-stop shop client offer.
Status	Ongoing
Expected delivery date	3rd quarter 2023

Distributed European research infrastructures are located in several European and associated member countries. In the vast majority of cases, they are formed by a central hub and several national nodes. In turn, nodes are national communities that operate several research infrastructure facilities, often involving several independent public entities (e.g. universities, research institutes, contract research organizations etc.). The nodes in a distributed research infrastructure engage collectively in joint programming and generate the services offered by the pan-European research infrastructure. In rare cases, nodes are fully absorbed by the central hub, but more usually nodes are well-defined national entities that smoothly interact with the central hub, while allowing its members to retain independent legal status.

It is anticipated that IBISBA's research facilities will be organized within national nodes (https://www.ibisba.eu/About/National-Nodes). The primary role of IBISBA's national nodes is to structure national research infrastructures in the field of biotechnology, building research service capability and interoperability, and providing IBISBA's legal entity with a well-identified national contact point. Additionally, IBISBA national nodes will endeavor to develop cutting edge research service offers, the aim being to compile a comprehensive catalogue of top-quality integrative services for IBISBA's clients. In doing so, the national nodes are expected to differentiate from one another, each developing unique selling points.

IBISBA's internal community of facility operators is still at an early phase, with different countries having reached different levels of organization and funding stage. Among the early movers are Italy, France, and the Netherlands. All three countries acknowledge the existence of national IBISBA nodes, with these appearing on their respective national strategic research infrastructure roadmaps, in 2016 for France, and 2021 for the Italian and Dutch nodes. Other IBISBA partner countries such as Belgium, Spain and Greece are actively pursuing the goal of creating national nodes, while Finland has recognized a bioeconomy infrastructure that includes IBISBA as a component.

For the creation of other national nodes in the future, IBISBA will carefully examine opportunities and look for synergy with existing IBISBA national nodes. Nevertheless, considering the current dynamics of the industrial biotechnology area, the diverse nature of its market applications and specificities of each country's needs, the potential for expansion and the creation of new national nodes has not yet reached its limit.

3.5 Preparing and organising IBISBA as a future operational legal entity

3.5.1 Action 9 – Defining the business model

Objective	Provide IBISBA with a clear definition of its business case and business model
Status	Ongoing
Expected delivery date	2nd quarter 2022; 3rd quarter 2023 (refined business model)

Like any enterprise, to clarify purpose and ensure sustainability research infrastructures need to develop a business model.[10] This involves answering a series of existential questions such as:

- What is the value proposition?
- How is value created?
- Who are the target users, clients or customers?
- What are the specific needs of the targeted users?
- Are profits generated?

In the case of IBISBA, this is a vital step, because IBISBA was originally founded in order to move academic collaboration in the field of industrial biotechnology away from a simple grant model (i.e., temporary funding) to a more stable, long-term model that will allow partners to capitalize on collaborative achievements, such as the development of common working standards and harmonization of business practices such as Intellectual Property Rights (IPR), and develop new advanced capabilities, such as integrated services for R&D projects.

Since the beginning of IBISBA 1.0, work on the business model was undertaken, although it is still incomplete. Nevertheless, finalization of the business model is currently underway. A key feature of the business model is IBISBA's ambition to operate as a non-profit entity. This because the future research infrastructure's primary purpose is to enhance research excellence, promote pan-European synergy, share innovation and derive greater returns on public investments in research infrastructure. On the other hand, while the development of some monetizable assets is expected, this is only a secondary goal for IBISBA.

Regarding IBISBA's uniqueness, it aims to be a science and technology integrator, creating the infrastructure capabilities necessary to absorb and translate fundamental knowledge, converting this into workable bioprocess concepts. In doing so, IBISBA aims to support the development of European biomanufacturing, exploring and developing new concepts, de-risking technologies, training a new

[10] Numerous sources. Examples are : Fecher et al., 2021 (https://doi.org/10.1093/scipol/scab026); Butter, M. INNO INFRA SHARE INTERREG project document ; Casadesus-Masanell, R. and Ricart, JE, 2011, Harvard Business Review (January–February).

generation of industrial biotechnologists and achieving Europe's ambitions in terms of green growth and manufacturing autonomy

This value proposition has been determined both by examining IBISBA's strengths and also by comparing IBISBA with existing infrastructures operating in its field worldwide. The users (clients or customers) of IBISBA are academic researchers developing new concepts that require a wide array of equipment and access to other disciplines, and private sector R&D operators. The latter group are especially exemplified by SMEs, attracted by the availability of cutting-edge research infrastructures and the associated expertise. From a more integrative perspective, IBISBA also uniquely offers users simplified access to integrated service workflows and provides the basis for showcasing of breakthrough technologies. Finally, IBISBA will operate on the basis of a mixed revenue stream combining stable funding sources with project-based temporary funding.

The definition of workable business model is now well underway and will be complete in 2022. However, a fine-tuned model will be delivered after the start of pre-implementation (i.e., 2023).

3.5.2 Action 10 – Building a multilateral dialogue with institutions and Ministry officials

Objective	Building the basis for consensus among IBISBA stakeholders
Status	Ongoing
Expected delivery dates	Steering Committee meetings 2nd quarter 2022 and 2nd quarter 2023

As Chapter 3 of the RAMIRI handbook rightly states, the launch of a European research infrastructure is the result of a lasting and stable agreement between stakeholders representing different countries and different interests[11]. In the context of a distributed research infrastructure, differences can be exacerbated by contrasting cultural practices and perceptions. Therefore, the patient establishment of dialogue between different stakeholders is an imperative step to ensure that consensus can be reached on vital issues such as the vision and mission of the research infrastructure, and its legal status and governance structure.

Since the beginning of the IBISBA construction process, multilateral dialogue between stakeholders has undergone steady progression. So far, key targets have been academics directly engaged in the design process, managerial representatives of organisations that operate research infrastructure facilities and national representatives. Upon the launch of IBISBA's preparatory phase in 2020, dialogue accelerated and in 2021 the first full meeting of IBISBA's Steering Committee was held. This committee is an assembly of Ministerial representatives from each country involved in IBISBA. Likewise, senior management structures of participant institutions (i.e. research facility operators) are regularly consulted. This whole process is designed to build consensus regarding major choices, such as the nature of the business model and how the ERIC will be organized and governed. Considering the wide

[11] Rizzuto, C. RAMIRI Handbook available at https://www.ceric-eric.eu/project/ramiri-handbook/chapter-3/

variety of participant entities (i.e., universities, public-funded research institutes, contract research organisations etc), this is a crucial process.

So far dialogue with IBISBA stakeholders has revealed a clear preference for the ERIC legal framework (*c.f.*, section 3.5.3) and established that the legal entity should be endowed with powers sufficient to fully deliver its value proposition (*i.e.*, that of a science and technology integrator, capable of delivering integrated service workflows in seamless way).

The 2nd meeting of the Steering Committee (June 2022) will provide the opportunity to consult members regarding both the business model and the proposed organizational scheme, notably the allocation of responsibilities between the central hub (ERIC) and the national nodes. It is expected that the committee will take a definitive decision regarding the target legal entity. Assuming that the ERIC framework will be approved, the process of designating the hosting country will be launched (see action 19).

Importantly, the different tasks foreseen in 2023 (IPR and access policy, hosting country, appointment of the Director, budget management and membership …) will provide content for the draft statutes of the future legal entity (irrespective of whether this is an ERIC or not). Assuming initial planning is robust, it will be possible to submit a preliminary draft of the statutes for approval at the 3rd meeting of the Steering Committee. In the event that the target is an ERIC, this 3rd meeting of the Steering Committee will officially launch the submission process to the European Commission.

3.5.3 Action 11 - Selecting the most relevant legal framework and governance and management structures

Objective	Select the appropriate legal framework and infer the necessary decision-making and management bodies
Status	Ongoing
Expected delivery dates	3rd quarter 2022

The legal and governance[12] structures of a distributed, European research infrastructure are vital. They define a research infrastructure's status within its business environment and determine the inclusive decision-making processes that allow smooth, professional operations. Moreover, they ultimately allocate responsibilities and define the relationships between the research infrastructure's different stakeholder groups. Most distributed, European research infrastructures operate along similar lines,

[12] RI-TRAIN training webinar

in as much that 19 out of the 29 ESFRI landmark distributed European Research Infrastructures[13,14] have adopted European Research Infrastructure Consortium (ERIC) legal status. In doing so they somewhat pre-determine their overarching organization. Research infrastructure's that adopt ERIC status are necessarily European joint-ventures that add value in the development of the European Research Area. ERIC's have the statutory seat located in one of its member countries (EU Member State or an EU-associated country). Moreover, as a minimum requirement ERICs should have an assembly of members (often called Assembly of ERIC Members), possessing full decision-making powers, and a Director General (or ERIC Director, or Board of ERIC Directors), appointed by the assembly of members. The Director is the legal representative of the ERIC[15]. The core governance structure is completed by an executive body.

Regarding IBISBA's legal and governance structures, a clear description of these must be delivered before work on the business model is completed. Therefore, work on defining IBISBA's legal and governance structures is underway and has already made good progress. Several options have been analysed and discussed with IBISBA's facility owner institutions and member country representatives. Currently, a clear preference for the ERIC legal framework is voiced by the majority. Regarding the governance and management structures, the definition of the most appropriate organisation is also underway.

3.5.4 Action 12 - Defining business processes

Objective	Identify and model essential business processes to supported integrated operations
Status	Ongoing
Expected delivery date	4th quarter 2022

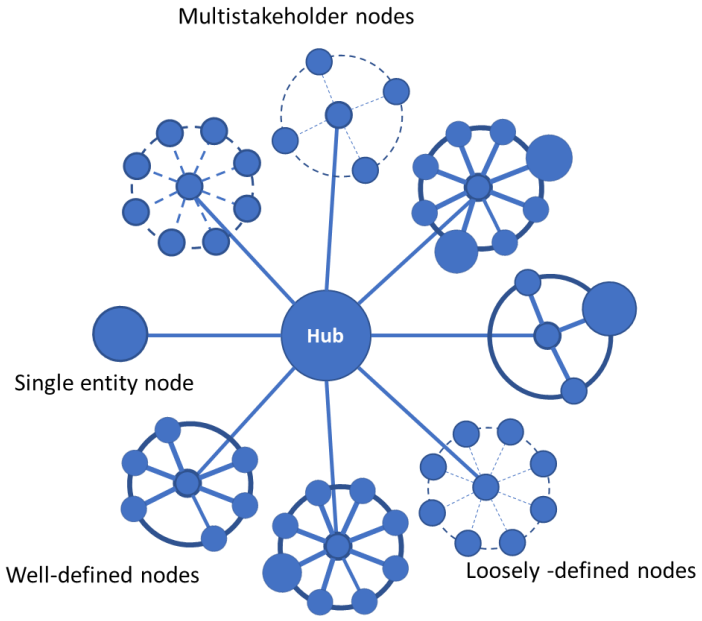
Often, the organization of distributed European research infrastructure follows an elaborate hub and spoke structure composed of a large number of independent research facilities, organized (or not) into nodes, present in different countries that are coordinated by a single central hub. The complexity of the model is variable, because organization of research facilities at the national level might be different. Generally, the research facilities are positioned in nodes that operate and cooperate within their nation states. However, the level of organization and cooperation at the national might not be

[13] From the Horizon 2020 EU-LAC ResInfra project report entitled "European RI funding and governance models relevant to EU-LAC collaboration" available at https://resinfra-eulac.eu/resinfra-deliverables/

[14] https://roadmap2021.esfri.eu/projects-and-landmarks. Since the above report was written the ANAEE-ERIC has become an ESFRI landmark.

[15] Kohler, E. et al., 2011, Governance of Large Scale Research Infrastructures: Tailoring Infrastructures to Fit the Research Needs ; COUNCIL REGULATION (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) ; various governance policies of current ERICs

identical in each country. Therefore, efficient coordination by the central hub requires considerable planning and effort.



Hub and spoke model for distributed European research infrastructure. Each node might be specific, both regarding its composition and organization. Smaller countries might only have one entity forming its node

For IBISBA to be successful, it is necessary to design robust business processes to deal with core areas such as:

- Customer relations: from first contact to contracting.
- Project execution: from project planning to project auditing
- Service quality
- Internal communication
- Administrative operations (management, human resources and finance)
- Governance and decision-making

To prepare business processes, IBISBA is currently engaged in a business process modelling exercise designed to define a certain number of workflows. Once defined, business processes will be readied for operation. Certain business processes will be translated into automated workflows that will be embedded in IBISBA's information system, while others will be manual procedures. These will form part of IBISBA's management handbook and, in some cases, will constitute parts of IBISBA policy (e.g., recruitment processes will form part of the HR policy).

3.5.5 Action 13 – Financial planning

Objective	Establish a realistic, sustainable financial plan for the first 5 years after the creation of IBISBA

Status	Ongoing
Expected delivery date	2nd quarter 2022 (Financial plan); 4th quarter 2022 (Marketing and Commercialization plan); 4th quarter 2023 (refined financial plan)

Research infrastructures are long term initiatives. Therefore, the financing of the whole cycle cannot be ensured from the outset[16]. However, it is important to at least establish a medium-term financial plan, keeping in mind overarching long term sustainability, as well as covering the financial needs of the specific stage before entering into the pre-implementation phase, when the funding from EU projects stops and the contributions for the new legal entity are not yet supplied. The financial plan for a research infrastructure is the consequence of the business case and model. Therefore, the business model must be defined before the financial plan, or at least in a simultaneous process. European research infrastructures are mostly financed by a combination of public funding sources, which include national funding (often for national nodes), member country ministries (charged with handling the 'shareholder' contribution), research and higher education establishments, the European Union and other diverse public funding agencies. Nevertheless, distributed research infrastructure can also generate revenues from the production of research services for full paying customers, from public-private partnerships, and from other monetizable activities.

Although the construction of buildings and the acquisition of equipment are often part of the financial plans of research infrastructures, this is not necessarily the case of distributed research infrastructures. This is because, these costs are often borne by the participating research facilities themselves and because distributed research infrastructure usually begin operations using existing facilities available in member countries. Nevertheless, other costs related to personnel, overhead services, maintenance, utilities, taxes and, perhaps in the longer-term, equipment acquisition, must all be accounted for.

IBISBA's business model is currently under refinement (c.f. 3.5.1). Therefore, although the core of the 1st financial plan is complete, it is also under refinement. In the case of IBISBA, focus is given to the costs and revenues related the operation of the legal entity, the costs of operating the facilities being put aside for the time being. However, at a later stage the financial plans of each facility will be examined in order to assess risks (i.e., a facility is no longer able to produce a cutting-edge service) and collectively anticipate the means to deal with these. Other steps in the process of defining the financial plan concern the preparation of a marketing and commercial plan. Finally, during pre-implementation the financial plan will be put into practice. This will provide feedback and allow readjustments before the beginning of implementation.

3.5.6 Action 14 - Intellectual property management guidelines

Objective	Draft and publish the central tenets of intellectual property management
Status	Ongoing
Expected delivery date	4th quarter 2023

[16] Rizzuto, C. Realising and Managing International Research Infrastructure (RAMIRI) Handbook. Chapter 4 (accessed at https://www.ceric-eric.eu/project/ramiri-handbook/)

Adopting a transparent policy for the management if intellectual property rights (IPR) is an obligation for all European research infrastructure. This requirement is recalled in the brochure entitled « ERIC practical guidelines[17] – "*An ERIC shall have in each Member State the most extensive legal capacity accorded to legal entities under the law of that Member State. It may, in particular, acquire, own and dispose of movable, immovable and intellectual property, conclude contracts and be a party to legal proceedings*". Underpinning this obligation is a need to ensure the IPR of research infrastructure shareholders and stakeholders, including its users, are correctly distributed and acknowledged. In the case of distributed research infrastructures, this is particularly important because background IPR are likely to be mobile among the different research infrastructure facilities and foreground IPR, produced in the framework of projects will often be the result of shared efforts and investments.

The preparation of IPR policy for IBISBA is underway. The key aims of this policy are not only to correctly allocate IPR generated through future IBISBA operations, but also to advance IBISBA's mission and ensure that the future legal structure is fully empowered to support the development of industrial biotechnology, working with both public and private sector stakeholders. For IBISBA's IPR policy, two specific features need to be considered. The first is IBISBA's ambition to operate integrated service workflows combining the services multiple research facilities. The second is related to IBISBA's potential to support R&D conducted by private sector entities, notably SMEs. For the first point, it is vital to establish clear rules regarding access to background IPR detained by individual facilities and foreground IPR that is useful for the overall operation of IBISBA. Regarding the second point, it is imperative to devise IPR policy that simultaneously promotes non-exclusive innovation, the attractiveness of IBISBA's services for public and private R&D players, protects European industrial interests, and contributes to IBISBA's sustainability.

3.5.7 Action 15 - Human resources policy

Objective	Defining all key elements of the human resources policy
Status	Planned
Expected delivery date	4th quarter 2023

Like any ambitious enterprise, European research infrastructures are only as good as the people who operate them. For this simple reason it is vital to ensure that research infrastructures are geared to provide the right environment to nurture their human assets. Developing this environment requires considerable skill and a lot of prior planning. Obviously, the exact HR organisational scheme depends on the business model that is being operated, but some commonalities are observed across infrastructure. In addition to the Director General, European research infrastructure usually have staff

[17] ERIC practical guidelines: Legal framework for a European Research Infrastructure Consortium. March 2015 European Commission, Directorate-General for Research and Innovation, Directorate B — Innovation Union and European Research Area, Unit B4 — Research Infrastructures

dedicated to communication, office management, project management and quality control, although the exact allocation of roles is specific to each infrastructure.

Beyond the organisational chart, HR policy for research infrastructure must cover forms of employment. In distributed research infrastructure, this is important, because some staff may be seconded from member organizations and others might be employed through service agreements. Additionally, HR policy must include guidelines for recruitment and include employer obligations, such staff management policy, continuous access to training, career development and advancement and staff evaluation.

Regarding IBISBA's HR policy, this has yet to be developed. However, the future policy must consider that although IBISBA is highly distributed, it aims to achieve a quite high degree of integration. Consequently, this will affect HR strategy. Like any distributed research infrastructure, IBISBA will require skilled managers capable of nurturing and maintaining buy-in from IBISBA's research facilities. It will require project managers to guarantee the smooth operation of integrated service workflows and IT specialists to support and develop the e-infrastructure that underpins business operations. Moreover, considering that IBISBA aims to engage with both public and private R&D practitioners, it will require a diverse set of business development capabilities to capture and address the specific expectations of each research infrastructure user group.

3.5.8 Action 16 – Defining and early measuring of KPIs

Objective	Elaborate and test a set of KPIs to measure research infrastructure performance
Status	Ongoing
Expected delivery date	3rd quarter 2023

To properly manage and ensure the sustainability of a research infrastructure it is vital to deploy an appropriate performance monitoring system. To achieve this, it is important to identify relevant Key Performance Indicators (KPIs). For European research infrastructures the process of identifying KPIs is facilitated work done by the ESFRI working group on monitoring of research infrastructures performance[18]. This work group recommends to develop KPIs to monitor nine umbrella performance categories:

1. Enabling scientific excellence
2. Delivery of education and training
3. Enhancing transnational collaboration in Europe
4. Facilitating economic activity
5. Outreach to the public
6. Optimising data use
7. Provision of scientific advice

[18] Report of the ESFRI working group on monitoring of research infrastructures performance. Accessed at https://www.esfri.eu/sites/default/files/ESFRI_WG_Monitoring_Report.pdf

8. Facilitating International co-operation
9. Optimising management

Each of these categories gives rise to a series of KPIs, with ESFRI proposing a total of 21 quantitative ones. The use of the ESFRI guidelines allows each infrastructure to carefully examine its own specificities and requirements in terms of monitoring and thus offers a framework for the development of a tailored set of KPIs.

During its preparatory phase, IBISBA has begun the process of defining KPIs, using the ESFRI guidelines to achieve this. In a first instance, a preliminary set of KPIs was determined to suit IBISBA's current needs and those of its stakeholders. Currently the deployment of early IBISBA performance monitoring is underway. As IBISBA progresses along its pathway to implementation, the KPI list will be monitored and revised according to needs. The delivery of a more complete set of KPIS is expected in 2023.

3.5.9 Action 17 - Preparing a data management plan

Objective	Draft and publish an overarching data management plan for the research infrastructure
Status	Ongoing
Expected delivery date	2nd quarter 2022

Presently all research infrastructures are designed for the intensive production of data and knowledge assets. To achieve this, research infrastructures generally rely on support from both internal and external computational resources and engage in numerous activities relating to data stewardship. In the case of distributed research infrastructure, these are also reliant on cloud computing and undertake significant amounts of data transfer between the different components of the infrastructure. Regarding European research infrastructure, these are at the summit of research excellence. As such, they are expected to lead the way in terms data management practices, adopting cutting edge standards and in some cases contributing to the development of new ones.

So far, IBISBA has received financial support in the framework of two Horizon 2020 projects. Both have resulted in the development of data management plans (DMP). This means that many guidelines for data management within IBISBA are established. Nevertheless, moving beyond project based DMPs, IBISBA partners are currently working on an overarching DMP that will serve as IBISBA's research infrastructure DMP. This will regularly undergo revision until and beyond the creation of the IBISBA-ERIC.

3.5.10 Action 18 - Defining IBISBA's access policy

Objective	Draft and publish the research infrastructure's access policy document
Status	Planned
Expected delivery date	3rd quarter 2023

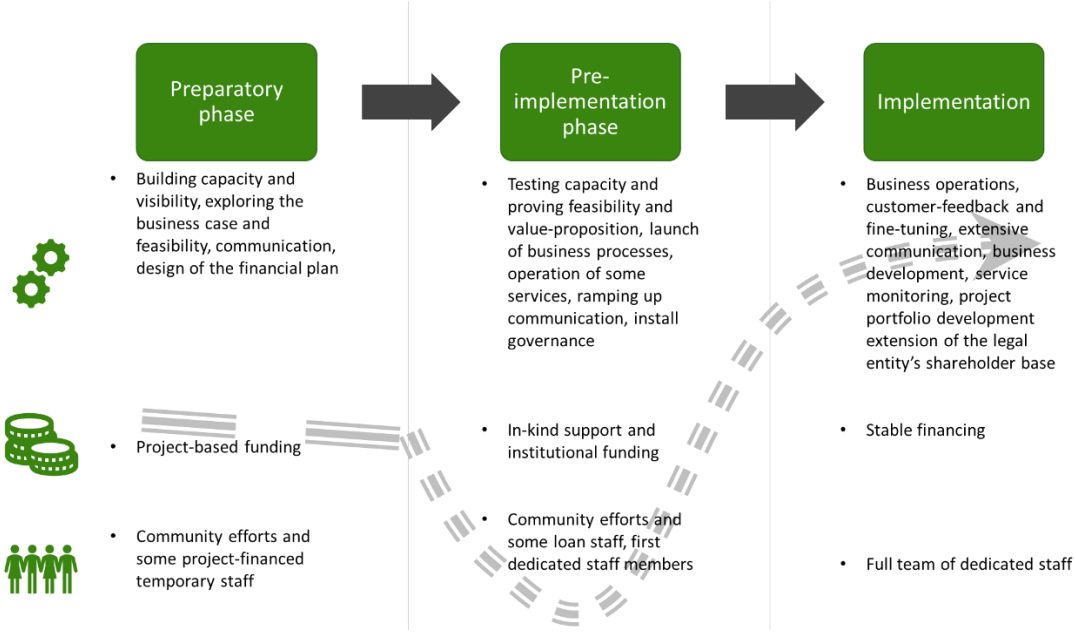
According to the European charter for access to research infrastructure[19] global access to research infrastructures promotes innovative research and development across the board. Therefore, favoring access is an important feature of research infrastructure management, which calls for explicit access policy. Access is defined as the ability to use physical, remote, or virtual services offered by research infrastructures. Similarly, access policy describes the conditions that must be fulfilled for a research infrastructure to grant access to users, irrespective of whether these are from public or private organizations. Logically, access policy statements relate to a variety of issues, including access costs, the way in which users should acknowledge the use of research infrastructure services, compliancy with ethical and regulatory affairs and engagement to practice non-discrimination.

During the duration of the IBISBA 1.0 project, IBISBA partners have operated a transnational access program, subsidized using European funds. This program provided the opportunity to experiment research infrastructure access management and establish rules for access. Consequently, IBISBA is well prepared to draft its future access policy. This will be based on a combination of hands on experience, best practice learnt from other research infrastructure and European and international guidelines relating to the subject.

3.6 Pre-implementing IBISBA

The pre-implementation phase (i.e., the period immediately preceding launch of the legal entity and the start of implementation) of any research infrastructure is an essential phase in the research infrastructure planning process, because it allows the testing of processes and structures that have been devised during the preparation phase. Regarding distributed research infrastructures, the pre-implementation is particularly delicate because it involves introducing and sharing business practices across the network. The successful uptake of these business practices will be central to the overall success of the pre-implementation phase. During the pre-implementation phase it is important to define performance indicators to measure progress towards full operational readiness. Another delicate feature of the pre-implementation phase is often the fact that this coincides with an end to public funding for the preparation phase, while membership funding is yet available. This is a real threat, because without adequate support, budding research infrastructures can remain stuck in the pre-implementation for an indefinite period.

[19] European Charter for Access to Research Infrastructures: Principles and Guidelines for Access and Related Services. European Commission, Directorate-General for Research and Innovation, 2016. doi:10.2777/52457. Accessed at https://op.europa.eu/en/publication-detail/-/publication/78e87306-48bc-11e6-9c64-01aa75ed71a1/.



According to Antonella Calvia-Goetz[20], setting a research infrastructure is akin to launching a start-up company. The process is characterized by several stages including an initial one (the Preparatory Phase), an intermediate one (the Pre-implementation Phase) and the final Implementation Phase. In the Preparatory Phase funding is quite often available, particularly thanks to the European Union's policy of supporting emerging research infrastructure that are designated strategic by ESFRI. However, just at the point when activities increase, funding often drops. This corresponds to the end of preparatory phase funding and the launch of pre-implementation.

3.6.1 Action 19 – Launching and operating IBISBA's interim governing bodies

Objective	Implementing an interim governance structure
Status	Planned
Expected delivery date	3rd quarter 2023 onwards (until switch to definitive governance)

As outlined earlier in this document, governance bodies are vital to any research infrastructure and the quality of the governance structure is paramount. Over complex governance structures render decision-making extremely laborious and inefficient, whereas over simple governance structures are

[20] Investing in Research Infrastructures: bankability, financial and business plans. March 9th, 2016. Accessed at https://www.esfri.eu/sites/default/files/EoE_09-03-2016_Calvia_Goetz_0[1].pdf

potentially exclusive and thus divisive, depriving certain stakeholder groups of a voice in the operation of the research infrastructure.

During the pre-implementation phase, programmed for 2023, the future statutes of the legal entity will be in submission phase (in the case of an ERIC, submission to the European Commission). Therefore, it will be both too early and legally unfounded to fully implement IBISBA's target governance structure. However, it will be timely to test governance structures and ensure that decision making is operational. To this end it will be useful to deploy a prefiguration of the supreme governance body, using the IBISBA's Steering Committee as a basis to achieve this. Likewise, the supervisory executive body can be constituted using the assembly of members of IBISBA's Memorandum of Understanding as the logical starting point. Finally, advisory bodies, such as the International Scientific and Technology Advisory Board will be launched at this point.

3.6.2 Action 20 – Preparing the legal entity

3.6.2.1.1

Objective	Drafting of the statutes of ERIC-IBISBA
Status	Planned
Expected delivery date	3rd quarter 2023

The creation of a legal entity to embody a research infrastructure is the result of a lengthy preparation process. Once sufficiently convincing business and governance models have been defined and the legal target identified, the process of preparing the statutes of the entity can begin. In the case of an ERIC, over a decade of experience of this legal model is making the creation of ERICs much less laborious, with many EU Member States now being familiar with the process. According to European Union documents, approximately nine months are required to create an ERIC.

For IBISBA, it is expected that the formal request to create an ERIC will emanate from the French government. Therefore, drafting of the statutes of the legal entity will require close coordination with French authorities. Regarding the content of the statutes, this will be largely determined by the mandatory elements, such as a description of IBISBA's purpose and its membership (which must be composed of at least three member countries, at least one being an EU Member State) , the rights and obligations of its members, the governance structure and various policies.

Launching the drafting process depends on the IBISBA's state of readiness and the willingness of the supporting countries to move forward. Ideally, drafting work will begin in the final quarter of 2022 and will be progressively completed in 2023, adding the different chapters (e.g., IPR policy, HR policy etc.) as they become available.

3.6.3 Action 21 – Designating the host country

3.6.3.1.1

Objective	Launch of the process to choose the statutory seat of IBISBA
Status	Planned

Expected delivery date	3rd quarter 2023

The launch of IBISBA's core business operations implies that one country will be responsible for registration of IBISBA as a legal entity. Assuming that the final choice of legal status is that of an ERIC, the host country will become the statutory seat for IBISBA-ERIC. Accordingly, the statutory seat will be responsible for the key administrative duties[21] required to support the normal running of IBISBA's governance.

In a first step towards designation of the host country, it is necessary to define a transparent, democratic process, using best practice from other infrastructures and ministerial dialogue as a basis for this. Accordingly, during the 12 months preceding the creation of the legal entity, the following procedure will be implemented

1. Public call for expressions of interest (EoI) – letters expressing interest will provide details regarding the candidate country's suitability. Suitability criteria will include sufficient experience of the legal processes required to register IBISBA as a legal entity, commitment from a significant part of the relevant national research community, and explicit support from government authorities and national funding bodies. In the case of an ERIC, other suitability criteria include the requirement for a country to be a European Member state or an Associated country[22].
2. Review of expressions of interest – all EoIs will be checked for compliance with host country selection criteria and, in the case of multiple EoIs, any differentiating factors will be noted.
3. Decision by IBISBA's supreme governing body – designation of the host country will be the sole responsibility of IBISBA's members. In the case of an ERIC this will be the supreme governing body composed of ministerial representatives of IBISBA member countries. To reach this decision, IBISBA's supreme governing body might appoint a panel of independent experts to make a recommendation.

3.6.4 Action 22 – Appointing the Executive Director

3.6.4.1.1

Objective	Recruit the legal representative of IBISBA capable of strong leadership and vision
Status	Planned
Expected delivery date	3rd quarter 2023

The Executive Director (hereafter 'Director') of a European Research Infrastructure is a key appointment, because according to Article 12 of ERIC Regulation No 723/2009, this person is the legal representative of the ERIC. In this role and under the supervision of the supreme governing body, the

[21] The detailed duties of the host country will be explained elsewhere.
[22] Article 8 of Council Regulation (EC) No 723/2009 "An ERIC shall have a statutory seat, which shall be located on the territory of a member which shall be a Member State or an associated country"

Director is responsible for the operation of the research infrastructure. Likewise, he/she is responsible for the preparation of a long-term vision, ensuring that the research infrastructure remains relevant and aligned with the expectations of its governing bodies and its user community.

In the case of IBISBA, an Executive Director will be recruited as soon as this is possible and no later than immediately after the creation of the legal entity. For the recruitment process, IBISBA will adopt best practice, first launching a call for suitable candidates. The whole recruitment process will be handled by the supreme governing body, using the services of an external service provider and taking advice from experts if that is deemed necessary.

3.7 The implementation phase

3.7.1 Action 23 – Launching the legal entity

Objective	Launching the process to acquire legal status recognition
Status	Planned
Expected delivery date	From 1st quarter 2024

Finalization of IBISBA's scientific and technical design, financial plan and statutes proposal will provide the basis to apply for ERIC status. Currently, it is expected that this stage will be reached at the end of the 3rd quarter 2023, with the hosting country (for VAT exoneration and various fiscal benefits) being designated at this time. In this case, the hosting country will file an application to the European Commission. It is expected that the whole application procedure will take several months to complete. Therefore, the launch of IBISBA-ERIC as a legal entity is not expected before the 2nd quarter 2024.

3.7.2 Action 24 - Implementing the definitive governance structure

Objective	Implement the governance structure as laid out in the IBISBA statutes
Status	Planned
Expected delivery date	From 2nd quarter 2024

Assuming that the operation of the interim governance structure is successful, upon creation of IBISBA as a legal entity, the target governance structure will replace it, adding governance bodies wherever necessary. The supreme governance body (*i.e.*, General Assembly or Assembly of Members) will be composed of representatives of countries that adhere to and fund (*i.e.*, shareholders) the legal entity. Assuming that not all countries will be ready to engage from the beginning, it is possible that applicant countries will be invited to participate in the activities of the supreme governance body, but only as observers, devoid of voting rights.

3.7.3 Action 25 – Achieving operational status

Objective	Move IBISBA to full operational status and creating the basis for its recognition as an ESFRI landmark research infrastructure
Status	Planned
Expected delivery date	From 2nd quarter 2024

According to the ESFRI life cycle for strategic European Research Infrastructure, the operation phase should be fully effective within 10 years of the research infrastructure introduction onto the ESFRI roadmap. At this point the research infrastructure should reply to all of the key performance criteria.

IBISBA was introduced onto the ESFRI roadmap in September 2018. Therefore, it is expected that it will operate as a fully-fledged distributed research infrastructure before 2028. To achieve this and allow IBISBA to become a Landmark ESFRI acknowledged European distributed research infrastructure it is expected that IBISBA will move to implementation during the course of 2024. This assumes that the legal entity is created by then. Implementation involves a move to full operation, meaning that the entity becomes fully capable of delivering it business model and fulfilling all aspects of it mission. To successfully achieve implementation, many actions must be deployed. Many of these will be the concrete results of the preparatory actions described above. Beyond these, it will be vital to implement measures to anticipate and handle different types of risk. The correct deployment of KPI monitoring will be part of this action, ensuring that a sufficiently wide-ranging set of KPIs are deployed to cover all business processes.

4 Conclusion

The IBISBA 1.0 project provided the means to accomplish a large number of preliminary tasks necessary to better define IBISBA as a research infrastructure. Network building activities and the transnational access programme have created opportunities to develop shared practices and experiment collaborative approaches. The results of these activities provide a solid platform from which future actions can be launched.

Since the beginning of IBISBA 1.0, IBISBA has advanced along its pathway towards full operation. It is currently in preparation phase and pre-implementation phase is expected to begin in 2023, coinciding with the preparation of the statutes for IBISBA's legal entity. To smoothly approach and successfully surmount this major hurdle in IBISBA's life cycle a series of preparatory measures are necessary. Accordingly, this document proposes 25 actions, some of which have already been achieved, that are vital to ensure the successful launch of IBISBA. The IBISBA assembly of members is fully committed to the execution of each of these actions and to the operational launch of IBISBA during the course of 2024.

5 Partners involved in the work

INRAE prepared and wrote the deliverable. Input has been obtained from work performed by a variety of IBISBA 1.0 beneficiaries working in its different work-packages. After drafting, VTT contributed to the content and proofreading of the document until its finalization.

6 Report authors

This report was drafted by Michael O'Donohue, IBISBA 1.0 project coordinator (INRAE). The draft document was improved with input from Sonia Debeche (INRAE) and Pauliina Tukiainen (VTT).