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(Summary)

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Contributions to Increasing the Quality of a Non Reimbursable Research-Development-Innovation Infrastructure

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Part I. Current State of the Research Ecosystem

Chapter 1. Research and Innovation in a Global Context

Socio-economic life is based on knowledge, and, particularly in recent years, knowledge gained more attention and is perceived as a strategic advantage and a key element of organizations, to be included in products and services available on the market. Under these circumstances, concepts such as knowledge-based organizations, intelligence-based organizations or knowledge creating organizations are increasingly frequent in the relevant literature [1].

The knowledge-based organization is today an important research topic. Most researchers focus on one or more aspects related to this concept, such as: the types of knowledge, organizational learning and knowledge, the specific processes that allow acquiring knowledge, the application, storage and transfer of knowledge and the organizational strategies, aimed at supporting and/or improving the use of knowledge inside and outside the organization [2,3].

Management applies to all types of organizations and all managers at all organizational levels. The principles of management are used today not only to manage business, but in all aspects of life, such as governmental, military, social and educational institutions. In essence, management is the same process in all forms of organization. But its complexity can vary widely depending on the size and level of organization. Management is the essential element that brings to life any organization [4].

Management makes evolve continuously the performance at the organization, team and individual levels, depending on the preset performance indicators, and the use of assessment results to constantly reach objectives, with the following characteristics [29]: a) management is goal-oriented; b) management is continuous; c) management is time-oriented; d) management is a group activity; e) management integrates human, physical and financial resources.

Research and innovation are the foundation of sustainable development in any relevant field. These activities support the concept of sustainable development and promote it at the local, regional, national, and international level. The ultimate impact of research and innovation processes can be quantified, estimated and evaluated by means of different direct results – finished products, patented ideas, sustainable entrepreneurial stimulation, medium-term sustainability, changes in public policies, improvement of processes, or indirect results, such as the long-term sustainability of infrastructures that have the scope of activity mentioned above, and healthy and competitive private development.

Research methodology represents a guide for the research activity and the manner in which it is conducted. It is considered that, by its descriptive and analytical capacity, methodology describes and analyzes methods, highlights limitations and resources, clarifies premises and their consequences, while relating their potentialities to the twilight zone, i.e. the frontiers of knowledge. The advantages of research methodology according to Rudestam and Newton [5] are: a) advancing the human being; b) providing tools for conducting research; c) developing a critical and scientific attitude, observation-oriented thinking; d) enriching the research process and providing opportunities for in-depth study and understanding of the topic; e) improving the ability to evaluate and use research results reasonably; f) developing the ability to learn and think critically.

Innovation and innovation management

Despite the vast literature available, it is very difficult to give a comprehensive definition of innovation and to clearly describe its nature. Innovation is a multidimensional concept that includes varying meanings and definitions depending on the perspective of different disciplines, some of which coexist in emerging fields, such as innovation studies [6], while in others they are considered “outsiders” [7,8].

Innovation = Invention × Commercialization, innovation equals the commercialization of the invention, according to the formula proposed by Bill Aulet from MIT.

The needs of innovation are a new idea and an entity that will commercialize this idea and add value to it. The value of the idea is not superior to the value of the possibility of commercialization, as they are valuable only combined.

It is considered that, for the innovation to exist, the existence of a new idea and the presence of an entity that will commercialize the idea and add value to it need to be confirmed. The value of the idea does not prevail over the possibility of commercialization as value can only be obtained by the successful combination of both.

Innovation can materialize in various manners, starting from the comprehension of innovative products or the entering of new markets to the development of complex variations in the business model, The effects of innovation thus depend on the manner in which each change project is performed, as well as on the capacity of management to achieve their integration into an intelligible strategy. Innovation management is a multilateral task that, by its strategic and operative principles, leads to a systematic change process [9].

One decade ago, a report published by the Organization for Economic Cooperation and Development (OECD) highlighted the emergence of a “new nature of innovation” which makes it different from the innovation of the industrial age. According to this report, there are four trends or drivers that explain the gradual transformation in the way companies innovate, namely: global challenges and changes in the public sector and welfare policies, global knowledge, collaborative networks, and new ways to co-create value for customers and leverage knowledge about users.

Practically, innovation management defines specific processes, structures, resources, methods, and tools for planning, developing and validating innovation projects. Furthermore, the ‘system’ concept suggests that actions are not isolated, that solving specific innovation problems is done from the perspective of:

Technology Transfer

In recent years, technology transfer has become an area of interest for the European Commission (EC), similar to the US system that funds R&D activities by more than $100 billion, and an encouragement to the private sector to develop technologies with high commercial potential through cooperative agreements or state partnerships. As a consequence, at the initiative of the EC, the Competence Center on Technology Transfer (CC TT) was set up in 2018, launched by the Commission Joint Research Center (JRC). It has become the recognized reference for expertise in the field of technology transfer, representing the European Commission and the European Union institutions, providing services related to TT policy, as well as services that support these activities through operational assistance, both at institutional and Member State level. Technology transfer is currently a field of the future, a link between research and the final consumer, with great potential for development in the coming years; however, at national level, technology transfer is in an early stage and requires a large amount of development and state support.

The Technological Readiness Level (TRL) was developed in the period 1970-1980. The National Aeronautics and Space Administration (NASA) introduced this scale as a discipline-independent merit program to enable a more effective assessment and communication of the maturity of new technologies. It was subsequently generalized to any project, and not necessarily to aeronautical or space projects, from the initial idea to its deployment. However, there is an increasing use of TRL as a planning tool for innovation management, as the specificity of the health sector brings the need for clarity in these predefined stages.

TRL conversion in the health sector

From basic research activities to preclinical trials: TRL 1-4.

In the first stage, scientific results are reviewed and evaluated as a basis for characterizing new technologies. Researchers generate a base of scientific knowledge (***TRL-1***). The main focus is on the problem itself, as the intense intellectual work consists of compiling and generating research ideas, hypotheses, and experimental designs into scientific "original studies". This naturally leads to the development of new or improved protocols or research plans. As the problem is thoroughly studied, hypotheses are formed and preliminary studies are established to define parameters and identify candidate concepts and/or therapeutic strategies (***TRL-2***).

Hypothesis testing and data collection begin to explore alternative concepts and to identify and evaluate technologies that support the development of medicines/medical devices. As the first screening results are identified and the initial synthesis of candidates is ongoing, limited *in vitro* and *in vivo* models are applied to establish the initial proof of concept. Identification of the access sites (candidates) locations and mechanisms of action, together with the initial characterization of the results obtained in preclinical studies, is performed in the **TRL-3** stage.

The next level starts with the first preclinical studies, using animal models to identify and assess potential safety and toxicity issues, adverse events, and side effects. At this level, exploratory studies are conducted to establish the formulation, the routes of administration, the synthesis method, the physical and chemical properties, the metabolic pathway, and excretion/elimination. Results from formulation studies, laboratory tests and pharmacokinetic studies are used to demonstrate the proof of concept and the safety of candidate formulations (***TRL-4***) [154,155].

The new proposal of a medicine/medical device corresponds to the ***TRL-5*** *level*

Pharmaceutical opportunities are selected during the intensive period of non-clinical and preclinical research studies involving parametric data collection and analysis in well-defined systems. The candidate pilot batch is manufactured for further development and provides the basis for a manufacturing process compliant with the Good Manufacturing Practices (cGMP). At this level, GLP safety and toxicity studies in animal model systems are used to assess pharmacokinetics and pharmacodynamics. Available results are compiled in the technical data project, which contains data from animal pharmacological and toxicological studies, proposed manufacturing information and clinical protocols for Phase 1 clinical trials. Furthermore, a decision point is reached where it is determined that there is sufficient data on the candidate product in the technical data package to justify the preparation of a new investigation application for a new medicine (IND)/medical device (CDRH) [10,11].

Clinical studies are classified within the limits of TRL 6-8.

Before the start of clinical trials, the pre-IND and PMA meeting is held with the European Medicines Agency (EMA) and/or the US Food and Drug Administration (FDA-CDER) to verify the overall adequacy of the information and data in support of the submission of the new application. Following approval of the application, Phase 1 clinical trials are conducted to demonstrate the safety of the candidate in a small number of persons, under carefully controlled and intensively monitored clinical conditions. At this level, production technologies are demonstrated through cGMP qualification at production scale. As the pharmacokinetic and pharmacodynamic data meet the clinical safety requirements to support the design of well-controlled, scientifically valid Phase 2 studies, the TRL-6 level is followed.

Phase 2 clinical trials are conducted to demonstrate initial efficacy (preliminary evidence) and to capture additional safety, toxicity, and immunogenicity data. By the end of the Phase 2 clinical trials, a pre-Phase 3 meeting is set to discuss the results of the Phase 1 and Phase 2 trials and the clinical objectives and/or the surrogate efficacy markers and testing plans. Protocols or trial plans provide a record of agreements and a basis for the sponsor to proceed with the Phase 3 clinical trial or the surrogate trial plan. An updated IND/PMA application is then submitted, amended by a new clinical protocol to support the Phase 3 clinical trial or surrogate trial plan (TRL-7).

The safety and efficacy of the candidate medicine/device are tested in Phase 3 clinical trials or in surrogate trials. The trials are conducted to assess the overall risk of the administration of the candidate product and to provide an adequate basis for labelling the medicine/medical device. Process validation is completed and is followed by batch consistency and reproducibility studies. The new IDN/PMA application is prepared and submitted to the EMA/FDA. Once a letter of approval is issued, after FDA / EMA review, TRL 8 is reached [12,13].

Product launching and monitoring in the market - TRL 9

In TRL-9, the new pharmaceutical medicine/medical device can be distributed and marketed. Post-marketing surveillance (non-clinical or clinical) studies may be required and are designed. Phase 4 studies, such as safety surveillance, studies supporting use in special populations and clinical trials are conducted [12,13].

Chapter 2. Research Infrastructures

Research infrastructures, or RIs, are an unprecedented asset in Europe for science, industry, and society in general. Over the years, approximately 550 RIs have participated in the EU framework programmes, with a total investment by (mostly national) funders of around €100 billion, with annual operating and maintenance costs between €10 and €15 billion. Every year, more than 50,000 researchers use these infrastructures and their data, producing up to 6,000 new impactful papers.

At the same time, RIs are a drive for excellence, providing a continuous benchmark for research and attracting the best minds from around the world: 32% of RIs in Europe say that more than half of their researchers come from outside the host country. As such, these research infrastructures are locally challenging universities, researchers, and scientists for improvement. They also induce mobility – the free movement of people and ideas across the EU, an important element in defining the research scope at the EU level and in the European knowledge market.

Moreover, research infrastructures create innovation ecosystems, being catalysts that bring together research, education, and industry to promote innovation. RIs setting up and operation require constant interaction between industry suppliers, education institutions and researchers, increasing their competitiveness at the international level.

There is growing recognition that the infrastructure supporting scientific activities is founded on modern research in many, if not most fields. Furthermore, in disciplines such as physics and astronomy, there is a long history of planning, building, and operating the infrastructures that are necessary for the development of science in these fields. However, life sciences and humanities, to name only two examples, are rather new in this field. As such, the *Member Organization Forum on Research*

Infrastructures (MOFRI) of the *European Science Foundation* - ESF launched in January 2010 a first attempt to bring together the national agencies throughout Europe for joint discussions about the policies on research infrastructures [14].

IR facilities may be *dispersed*, i.e., located in different organizations and/or countries, or *localized* in a single place or even *virtual*. Infrastructures may include scientific equipment, scientific collections of documents, archives, databases, or any objects that can be used for research purposes [15].

The research infrastructure setting up and development mechanism was efficiently used by the European Union (EU) to create a unified research area. The creation of worldwide research infrastructures made it possible to combine the scientific potentials of various countries and to interconnect individual research tasks with the overall purpose to achieve development at the Union level. The European Strategy Forum for Research Infrastructures (ESFRI) was created in 2002 with the purpose of creating a unified European strategy for scientific research [16].

The Forum's activities aim to overcome the fragmentation of national and regional infrastructures' efforts in various research areas and to integrate European infrastructures into a global system. Among its activities, the Forum develops and regularly updates the Roadmap for the Development of European Infrastructures in different fields of interest. Most research infrastructures are funded, managed, and operated at national or regional level and provide services mainly to national research communities [17].

*R*egulation (EU) no. 651/2014 of the European Commission provides the following definition: *"Research infrastructure means physical facilities, human resources and related services that are used by the scientific community to conduct research in their respective fields and covers the main scientific equipment or sets of structured scientific instruments, generic information and communication technology-based infrastructures such as grid, computing, software and communication, or any other means necessary to conduct research. Such infrastructures may be 'single-sited' or 'distributed".s*

Taking into account the above definitions, the definition developed by ERIC (the *European Research Infrastructure Consortium*) of the research infrastructure was further simplified to be introduced and implemented in the MERIL project, as follows: *"a European Research Infrastructure is a (virtual) facility or platform that provides the scientific community with resources and services to conduct top-level research in their respective fields"*.

These research infrastructures can be unified, distributed or e-infrastructures, and can consist of a national or international network of facilities or networks of interconnected scientific instruments.

A research infrastructure can be divided into different domains with the following definitions:

- the *national research infrastructure* consisting of the facilities funded in support of research by a varied range of users from several institutions or sectors. The research infrastructure can consist of large facilities, usually single-sited (reference facilities) or networks, distributed at national level, and activation capacities [18].
- the *institutional research infrastructure*, which is the research infrastructure set up inside an institution. It is funded mainly from the institution's resources, including support from the research block grant and the infrastructure, equipment, and facilities linkage scheme. These facilities may involve collaboration, but not at the national level [19].
- The *personnel (human capital) infrastructure* means the number and relevant characteristics of the persons employed (such as general and specific education, qualification for various positions). Population is a stock and workforce variable that is changing depending on the birth rate, death rate

and migration (the quantitative aspect of the personnel infrastructure), as well as on the characteristics of the active population (the qualitative aspect of the personnel infrastructure).

At national level, according to the Romanian Committee for Research Infrastructures (Comitetul Român pentru Infrastructuri de Cercetare, CRIC), infrastructures can be a) in the project/design stage; b) in the construction stage; c) in the operation stage; d) in the decommissioning stage.

However, the following are not classified as infrastructures with a role in R&D: individual equipment, universities or research institutes, research programs and/or research networks.

Instead, research infrastructures include a) major scientific equipment or sets of instruments; b) scientific collections, archives or data; c) computing systems and communication networks; d) any other research and innovation infrastructure of a unique nature, open to external users [20].

Research generates knowledge, which is used to benefit society by opening up new business opportunities. The capacity to support a competitive advantage in generating new knowledge and new scientific knowledge, in particular, is the foundation of the strategic plans of many nations that position themselves for growth in a highly competitive global economy [22, 23]. Certain countries started ten years ago: *"We cannot know where scientific research will lead us. Consequences and spin-offs are unknown and cannot be known until they happen. But one thing is certain: if we do not explore, others will, and we will be left behind. This is the reason I have asked the Congress to allocate more money to research. It is an indispensable investment in the future of America"*[24].

Some of the key relevant aspects in terms of research infrastructures are:

- *The existence of international research infrastructure* that are complementary to the existing ESFRI RIs (and the key international initiatives with dimensions and scope of work that would make them eligible for the ESFRI Roadmap, such as CERN). The purpose is to find a definition able to determine when an infrastructure can be considered to exist from the RISCAPE perspective. Extremely strict criteria could be applied, for instance, limiting this definition to RIs with legal personality, which selection would leave outside the system certain very important European research infrastructures and would not necessarily reflect the manner in which RIs are organized worldwide. Similarly, the choice of a very wide definition (for instance, defining an RI as any group with a common name and a web page or social media hashtag) is not constructive.
- *Temporal persistence* should also be defined. In many cases, landscape analysis is meant to be used for a certain period of time, therefore future activities should also be considered. In the same way, a major existing RI could be included in the scope of the analysis but, if it is to be closed soon, the activity analysis may no longer be useful.
- The *relationship* with user communities may also be an important requirement in defining the scope. Since an analysis of the area in which the infrastructure operates may require some sort of portfolio of services intended for use with a global scientific audience outside the target organization, this definition of the scope can be particularly important.
- The *scope* of the product is to ensure that products (data, access, methods, etc.) are appropriate for use in the analysis of the planned landscape. This could indicate that RI products are connected to scientific research and the RI is not an organization that only has non-scientific products.
- The *geographic relevance* (or location) is crucial in selecting infrastructures in certain cases. Due to scientific, political, or other reasons, the analysis can focus on certain fields or ignore certain fields. This limitation may be political rather than geographical, in which case the "location" could indicate a characteristic, for example, a moving observer or a web-based instrument, irrespective of their real location. A regional approach (in a global sense) can be used to monitor the intensity of levels of

engagement with the RIs in various regions. This is different from the “coverage” and can be used to identify “hub” locations. Jurisdiction can be relevant for collaborative actions.

- *Access* and openness can also be considered a key element in terms of encouraging international collaboration, meaning the possibility to attract the best researchers in the world, to define new generations of interconnected infrastructures and to ensure worldwide interoperability.
- The *need for impact/meaning* is a global requirement meant to determine the global role of the infrastructure in the respective field. The main idea behind this requirement is to ensure that the aspects related to usage and the RI position are considered in the process applied to include them in the analysis.

Part II.

Contributions to the Structural Modeling of the Needs of Research Infrastructures

Chapter 3. Socio-Statistical Analysis of Research Infrastructure Management

Needs at management level, identified within infrastructures

Research infrastructures are increasingly important for modern science in many research disciplines, from the humanities and social sciences to life and natural sciences, physics, and engineering. As the number of research infrastructures is growing and their importance becomes increasingly evident, questions about how to fund, organize and manage these infrastructures have become important points of interest for the managers of research organizations.

More than 75% from the respondents to the needs identification questionnaire have more than 10 years of experience and a senior management position in the organization, the fewest respondents being young researchers or persons with less than one year within the organization. The respondents' perception of their relationship to the organization they belong to is detailed in, most respondents being in a senior management position, followed by approximately one third in a management position (Figure 3.2). The structural analysis of the group was necessary to validate the answer and to prove that they had been provided by persons with an overall view on the activities, challenges and strategies of the represented organization.

About one third of respondents held, according to a subjective assessment, a position that either generated knowledge at the request of personnel or determined by the situation on the ground, or were part of the research team or generated knowledge at the request of management, and were holding, at the time of responding to the questionnaire, an executive position in the organization they were representing when they responded to this questionnaire.

From the perspective of the organization hosting the infrastructure, 67% of respondents are public institutions, among which more than 52% have a major scope of business where the infrastructure provides research services in the health sector, followed by privately funded institutions operating in the materials sector (Fig. 3.3). The smallest percentages of respondents were represented by institutions in the public and private sector or institutions governed by public law. In terms of the scope of business, the ICT, bioeconomy, environment, food, and nuclear physics sectors were represented by almost equal shares.

More than 66% of respondents identify public funds as the main source of revenue, while private funds are only designated in a share of 28.8%. Moreover, over 35% of respondents are not aware of the actual share of the private funds used, while 20% among those who identify them report a share of 75% corresponding to private funds.

In order to evaluate institutional performance in a possible subsequent correspondence with the size, funds, and number of researchers, in the part of the questionnaire related to operation, participants were asked three questions about the results of the research activity:

- the amount of **ISI impact factor articles** resulting from the infrastructure's activity in the reference period of the last 3 years of activity,

- **the number of patents registered in the last 3 years**

- **the number of new products/services** launched by the organization in the last 3 years

One third of respondents are not aware of the number of patents registered in the last 3 years or the amount of ISI impact factor articles published, and, surprisingly, more than 25% declare that they do not know the innovating products/services of the organization.

From the perspective of the materialization of revenues from patents registered in the last 10 years, their amount is reflected in Fig. 3.8. **About three thirds of respondents do not know the answer to this question** regarding the values related to the use of patents in the last 10 years, although a large part of respondents are senior managers in the institutions with length of service of more than 10 years.

Specific needs of the RDI infrastructure identified by respondents

Organizational needs are the requirements identified to drive an organization forward. The analysis of these needs allows comparing the current capacities within the organization with those needed to meet future development goals. In the questionnaire provided to respondents, they were asked to mention the organizational management needs in the institutions where they work. More than half of respondents mentioned that it was "quite likely" necessary to better plan tasks and working time (Fig. 3.42). In addition to the aspects related to working time, more than half of respondents considered that the organization they belonged to needed clearer procedures, which must be followed by every employee, as well as a more transparent development strategy.

In terms of human resources management within organizations, 76.47% of the persons who answered the invitation to respond to the questionnaire agreed that the basic need for research infrastructures was predictable funding, by means of regular national competitions in smart specialization fields. An appropriate financial motivation for the activity performed, as well as ensuring proper working conditions, by maintaining equipment and purchasing consumables, are also important priorities according to respondents.

As regards market-generated needs, 58.82% of respondents agreed that participation in international research projects is an extremely important goal for the development of the organization. Collaboration with universities and researchers from other fields was also identified among needs by the respondents.

Respondents' opinion on the priorities for resource management in their respective organizations

The priorities identified by respondents are:
1. Predictable funding (periodic competitions planned in smart specialization fields)
2. Consumables for the research activity
3. Proper financial motivation for personnel, depending on their respective positions
4. State-of-the-art-equipment
5. Long-term funding of research programs
6. Centralized maintenance of equipment
7. Qualified human resources and desire for further training of the young professionals
8. Personnel willing to improve their professional performance
9. Funding to support human resources in research

Chapter 4. Structural Modeling of Needs for the Management of Internal Processes of RDI Infrastructures

Research digitalization is no longer just an option but a necessity, an example being the Covid 19 pandemic, which led to an accelerated process of digitalization at all levels. The adoption of digital technologies improves research efficiency, transparency, and impact.

In order to achieve a full digital transformation in the long term, it is necessary to redefine research organizational mindsets, processes, and competences, so as to align these with the premises of digitalization. It has been proved that the digital environment requires agile workflows, an approach focused on testing and learning, decentralized decision making and greater reliance on business ecosystems.

Existing digitalization solutions meant for European research infrastructures

In the European Union, there are many digital solutions aimed at improving research infrastructures and facilitating collaboration between researchers across the region. These digital solutions cover a wide range of aspects, from data and information management to dissemination of research results and communication between research teams. Below are some examples of existing research infrastructures in the EU:

- **Research E-Infrastructures**: These include high-performance data centers, advanced communication networks and distributed computing services. They facilitate the efficient storage, processing and transfer of research data and ensure access to powerful computing resources to support complex, data-intensive research.
- **Online research and collaboration platforms**: There are many digital platforms that allow researchers to collaborate and work together virtually. These platforms facilitate the exchange of information, documents, and research data, allowing researchers to collaborate from different geographical locations and share their knowledge in real time.
- **E-labs and analysis tools**: EU research infrastructures provide online analysis tools and e-labs, allowing researchers to access specialized tools and equipment for complex remote experiments and analysis. This increases accessibility and allows researchers to collaborate with laboratories in other countries or institutions.
- **Databases and research portals**: The EU hosts a number of research databases and portals that provide access to relevant and up-to-date information on research projects, scientific publications, datasets and educational resources. These are essential to facilitate communication and dissemination of knowledge in the scientific community.
- **E-learning platforms and online courses**: There are digital platforms offering continuing education courses, seminars and distance learning programs for researchers and students in various fields. These platforms help develop digital skills and improve research capacity.
- **Open science and open data policies**: In the EU, there is a growing trend towards open science and open data policies in research. This means that research results are made freely available to the general public, and research data are available for use and verification by other research teams.
- **Project funding and management platforms**: Digital platforms facilitate applications for research funding and managing research projects, ensuring efficient and transparent management of resources and results.

Existing web platform at the level of national research institutions

At national level, we find the need to create and develop such research infrastructures. The platform that is currently managing the existing research infrastructure at national level is the EERTIS Platform - Engage in European Research and Technology Infrastructure System (https://eertis.eu/), an online platform that brings together private and public European research and technology infrastructures.4.3 Software models and flows development

The management software of the research infrastructure is mainly meant for facility managers, operators in the field of research and innovation, and research and funding organizations, aiming to allow these to better decide on how to provide modern and proper conditions to users of research infrastructures, as well as to better assess the quality of operation of these institutions. Therefore, the management software of the research infrastructure will facilitate for the researchers within the institution and their external collaborators from the sector and industry the identification of, and access to, research facilities, equipment and systems within the infrastructure, thus allowing:

- to provide the best research results by using the most appropriate equipment,
- a simple and uninterrupted approach to identify, access and operate research infrastructures of any type
- support for the own strategy of the entity to expand the quality and scope of the mutually beneficial engagement with the industry
- to facilitate opportunities of collaboration with top researchers
- to use to the largest extent and to ensure operational efficiency of the research equipment of the entity, as well as to obtain more revenue.

The software solution for the management of research infrastructures starts from the supply of information about the activities at the level of the research infrastructures, such as information about the equipping of research infrastructures, data about the personnel and existing equipment of the research institution.

The first step in creating the solution is to create an appropriate architecture that allows collecting, storing, accessing, and searching data about research infrastructures.

Based on experience, the software should meet the requirements of the EOSC or ERTIS system. It should contain a well-defined workflow for data entering and validation and a user interface to search for and access data. Dynamism and flexibility are also key features. Another aspect to be considered is the implementation at architecture level of a flexible classification scheme system, allowing to use several international and national classifications applied in the classification of research infrastructures.

The basic essential components of a research infrastructure are: databases (data collections), media repository (active data storage), research data repository for data publication with DOI allocation, publication database, web-bases information platforms (the entity's website), intranet, reference databases, profile pages for references of research projects conducted (destination pages), as well as websites on various topics. In addition, the system should also include recording, research, evaluation and editing tools (such as the research IT system, the media research portal, the investigation system, the generic labeling and reporting system), relying on basic components.

The work flows required to use the infrastructure have an essential role in the infrastructure optimization. For this purpose, specific process definitions will be prepared, tested and implemented to guarantee a standardized management of research data. This stage includes first of all the transparent documentation and definition of the systematic procedure used to integrate the distributed collected data into the central collection management system, creating online forms for sending (meta)data to the research data repository and preparing recommendations to regulate the use of the research infrastructure management software in future research projects.

The funding of research data management software is not viewed (yet) in general as a part of the standard research process and is not included in the normal research budget, and the specific nature of this type of management and the budgetary area for funding data facilities are not yet clearly defined.

European cloud services for *open science* are a means of combining human activities and research products. Infrastructure digitalization involves the implementation of digital technologies and tools to support and improve research processes, data collection and analysis, and collaboration and communication between scientific communities.

Existing software solutions that can be integrated into a RDI infrastructure in the health sector

There are many existing software solutions for certain processes in healthcare R&D infrastructures. These cover a wide range of aspects, from clinical data management and data collection to data analysis and collaboration in medical research.

Analysis of existing solutions

Existing solutions do not cover fully the needs of a RDI infrastructure at national level and are not customized for integration with the specific Romanian management procedure, but they can be integrated into a dedicated product.

The development of innovative software for the management of research infrastructures can offer significant benefits to researcher communities and academic institutions by integrating the following new ideas.

- Integration of new technologies in the use of facilities related to the use of RDI infrastructures equipment
- Virtual assistance for research
- Data interpretation technologies
- Efficient energy management.
- Resource sharing platform

Chapter 5. Social-Statistic Analysis of the Expectations of the Business Environment regarding Research Infrastructures

Research ecosystems /Clusters

The 'cluster' concept was introduced in 1990 by Michael Porter, considered to be the founder of economic policies bases on cluster development; his definition is the following: *Clusters are geographical concentrations of interconnected companies and institutions in a particular field. Clusters include a group of related industries and other important entities in terms of competition. They include, for example, suppliers of specialized products such as components, machinery and services, or providers of specialized infrastructures. Clusters often extend downstream to various distribution channels and customers, and laterally to producers of complementary products and industries linked by common skills, technologies, or developments".*

Types of clusters

Depending on their field of activity, clusters can be divided into:

- RDI clusters
- humanitarian clusters

Regarding the classification of clusters in terms of size and geographical distribution, in the health sector, in Romania, they can be divided into:

- metaclusters: MEDRO – Romanian Network of Clusters in the Medical Field (Rețeaua Română de Clustere în Domeniul Medical) is a metacluster that includes the medical clusters in Romania, being constituted out of the need for exchange of information and best practices on addressing the medical field and related sectors, as well as increasing the visibility of the clusters in the network, at national and European level. The main goal of the metacluster is to raise awareness at national level of the importance of funding the health sector from the perspective of research and innovation. The entity brings together six of the eight clusters in the health sector in Romania.
- national clusters: ROHEALTH – the Cluster for Health and Bioeconomy, develops at national level competitiveness and innovation, and promotes and encourages cooperation between companies, organizations, universities, and public entities resulting in increased economic competitiveness in the fields of health and bioeconomy. The activity of the organization follows the principle of expertise subsidiarity, the cluster being organized in eight thematic groups, as follows: Health Policies, Medical Equipment and Instruments, Materials for Health, E-health and Education, Translational Medicine, Bioeconomy for Health, Social Responsibility for Health, and Health Research Infrastructures, respectively. (https://rohealth.ro/).
- regional clusters: the Medical Cluster "Sănătate România" (Health Romania); the Innovative Cluster "Pentru Sănătate Dunărea de Jos" (For Health Lower Danube) Galați; the Transylvania Regional Balneary Tourism Cluster; the Health Cluster in South-West Oltenia Region; the Health Tourism Cluster in South-West Oltenia Region; LifeTech City; the Biotechnology Cluster in North-East Romania (bioROne). the Regional North-East Innovative Cluster for Molecular and Structural Imaging (Imago-Mol);

Europe hosts approximately 2,500 strong clusters [245], i.e., statistically defined regional concentrations of related traded industries that perform above average for employees, enterprises and regions. The effects of clusters become visible when the presence of related industries in a specific location reaches a critical mass. About 45% of all the jobs in the traded industries are located in strong clusters. Employees in strong clusters earn on average salaries 11% higher than their colleagues in the same industries but outside clusters. This reflects the higher productivity companies can obtain within clusters. Strong clusters recorded a 0.2% annual increase in employment in the post-crisis period (2008-2014), while the traded industries located outside strong clusters recorded an average decrease of 1.7%. Research conducted in the US showed that the creation of new businesses is higher in strong clusters and that the new companies have higher chances of success and growth if they belong to strong clusters [246]. Finally, regions with a higher share of employment in strong clusters record higher levels of overall prosperity [247, 248, 249].

The role of clusters in the sustainable development of members' research infrastructures

Research clusters play a pivotal role in promoting innovation and collaboration by bringing together academia, industry and government to work together on advanced research initiatives. They aim to encourage knowledge exchange and collaboration between organizations, covering various sectors, from technology to renewable energy, and use the combined resources of their members to approach complex problems, thus contributing to the acceleration of research and development.

In addition to knowledge exchange and collaboration, clusters attract talents and investments and become centers for projects that entail high risks and provide major benefits. This makes them more attractive for researchers, innovators, and entrepreneurs, generating innovation and economic growth. Clusters also benefit from private and public investment, as governments and investors recognize their potential to create innovative solutions and stimulate economic growth. Finally, clusters contribute to sustainable development and to obtaining competitive advantages at the global level. By facilitating interdisciplinary collaboration and supporting startups and SMEs, they promote economic diversification and an entrepreneurial culture. The alignment with the UN's Sustainable Development Goals underlines their contribution to solving the challenges of society and the environment, highlighting the importance of continuing investments and support for the development of research clusters at global level.

During the definition stage of innovative projects, the cluster plays an essential role in the generation of ideas and the identification of challenges and opportunities. In an environment that reunites professionals and experts from the same field, synergy among the cluster members facilitates the exchange of ideas and the generation of innovative solutions. At the same time, the cluster offers the opportunity to identify market needs and demands, relying on the feedback and experience of its members. Therefore, innovative projects can be developed with a better understanding of the real needs of users and final beneficiaries.

Innovation hubs

Innovation hubs are dynamic and stimulating environments where innovators and entrepreneurs can collaborate, experiment, and develop innovative ideas able to have a significant impact. By facilitating collaboration, providing resources and support, and promoting technology transfer, innovation hubs contribute to the development and implementation of innovation in various fields, stimulating economic growth and solving complex societal problems.

Digital Innovation Hub - DIH

A Digital Innovation Hub – DIH is a complex initiative aimed at supporting and stimulating innovation and digital transformation within enterprises, organizations, and communities. These hubs are designed to facilitate access to state-of-the-art expertise, technology, and digital resources, with the purpose of accelerating innovation and ensuring competitiveness in the global market.

Infrastructures' perspective

The chart illustrates a series of needs identified for the Research, Development and Innovation (RDI) infrastructures based on question 50 of questionnaire II, in percentages that reflect the extent to which these activities are essential within an organization.

Inclusion in international research consortia; ***Participation in international projects; Collaboration with universities (0.94):*** Almost all organizations (94%) consider that it is necessary to participate actively in international research networks and in collaborations with other academic institutions. This indicates a strong orientation to integration within the global scientific community and underlines the importance of partnerships to advance research.

Collaboration with researchers from other research fields (0.91): Interdisciplinary collaboration is also considered crucial, as 91% of organizations recognize that it is necessary to stimulate innovation and approach complex research issues.

<u>**Collaboration with the private environment (0.88**):</u> Most organizations (88%) are aware of the value of collaboration with the private sector, which can improve the applicability and impact of research and may lead to a better commercialization of innovations.

<u>**Supporting technology transfer by specific programs**</u>; Quick adaptation to market demand (0.82): A clear tendency towards technology transfer and adaptability to market needs, as 82% of respondents consider these aspects as being important for the success of the organization.

Development of a marketing department (0.74): A significant share of organizations (74%) recognizes the importance of marketing in promoting research and its results.

Active presence in specialized international fairs (0.68): Participation in international fairs and exhibitions is seen as being important by approximately two thirds of the organizations, which suggests a need for visibility and networks in the wider international community.

Outsourced marketing services to promote research results (0.65): Marketing outsourcing is considered useful by most organizations, indicating a tendency to rely on experts outside the organization to help disseminate and promote innovations and discoveries.

The analysis of the infrastructures' answers regarding the expectations from public strategies and policies shows a strong recognition of the need for consistency and stability in the field of national research. A high percentage of 85% of ***participants underline the essential importance of the identification of real national needs for new knowledge, technologies, products and services, indicating an awareness of the importance of strategic investments in innovation and development***, a need that can be identified by sustained interaction with the market.

An equal share of respondents (85%) highlight the need for the existence of a coherent national research policy. This suggests the need for a unified and harmonized framework that would direct and support research efforts at the national level.

At the same time, the ***need to ensure research continuity and political stability*** is recognized with the same percentage of expectations (85%) for both aspects. This reflects the perception that long-term progress in research depends on a stable political environment and a continuous support for research initiatives, which are not interrupted or compromised by political changes or instability.

The professionalism of authorities is also considered vital by 85% of respondents, with a small difference regarding the professionalism of authorities (82%). This indicates the need for expertise and competence among those that develop and implement research policies, as well as among those that manage and coordinate research projects.

Moreover, there is a **recognition by 71% of respondents of the need to create a notified body in Romania, dedicated to activities in the field of health infrastructures**. This suggests the desire to have a specialized institution that would coordinate and support the certification of medical innovation products at national level.

Finally, we can see a ***lower recognition (65%) of the capacity of the National Agency for Medicines and Medical Devices (ANMDM) to have available the resources required to hire sufficient properly paid***

personnel able to respond to applications for certification within a competitive time limit compared to other countries in Europe (that are not EU Member States). This suggests concerns related to the Agency's capacity to attract and maintain the qualified personnel required to manage efficiently the research projects at international level.

Economic operators' perspective

As entrepreneurship is based on the principle of value extraction, its basic prerogative is to take risks that go beyond the normal risks encountered in an ordinary business. From an economic point of view, entrepreneurial activity is carried out by the entity that has the ability to translate inventions or technologies into products or services.

Barriers identified in the innovation in the health sector

Long period between idea conception and market launch: Innovation in the health sector often requires a long process of research and development, testing and approval. The rigor of these phases extends the period between conceiving an idea and bringing a product to the market.

High costs associated with product development: Significant financial investments are required to fund research, clinical testing and the development of innovative medical products. These costs can discourage small developers or can be a significant financial risk for companies.

Complex and strict regulations: The health sector is subject to strict and complicated regulations. The necessary approval from regulatory agencies can be a laborious process, while non-compliance with rules can result in delays or even the failure of the project.

Strict requirements regarding patient/human safety: As the health of patients is at risk, regulations impose high safety standards for medical products. These requirements increase the complexity of the development process and may lead to additional costs in order to meet the safety standards.

Complicated product certification procedures: The certification of medical products often requires complex and rigorous procedures to ensure that these products meet the quality and safety standards. These processes may involve collaboration with certification organizations and regulatory authorities. The new European regulations on certification were introduced in response to the significant changes in the global business and technology environment. These changes include fast technological innovations, the globalization of supply chains and increasing concerns regarding sustainability and environmental impact. Therefore, the European Union recognized the need to update and revise the existing regulations to adapt to these new realities. ***The complex and regulated nature of the medical sector imposes strict requirements and high standards to ensure the safety and efficacy of innovative products.***

The complexity of necessary knowledge, including in the field of clinical trials: Innovations in the health sector require a wide expertise in fields such as medicine, biology, and clinical sciences, to name only a few. The collection and interpretation of data from clinical trials are complex challenges, adding another layer of difficulty to the innovation process.

Another obstacle is the lack of funds required for preliminary market testing, competition analysis and, last but not least, the evaluation of trends in the field with regard to products, as well as the anticipated impact at patient level. A relevant example in this field is a product developed by a Romanian manufacturer, the product being in the cellular testing phase, where a thorough analysis of the market, competition and trends resulted in the continuation of research.

Socio-statistical analysis

Among the 76 companies operating in the medical field that answered the questionnaire, a significant share of 73.7% confirmed that they are involved in research, development or innovation activities, thus underlining their commitment to advancing and permanently improving this sector. In addition, when asked about their interaction with research infrastructures in the public environment, such as those associated with universities, research institutes or public hospitals, in the context of the development of their products and services, an impressive percentage of 72.4% of these companies answered that they had already had such interactions (Fig. 5.6). This statistic highlights a positive tendency towards collaboration between the private and the public sector in the medical field, underlining the importance of synergies in promoting innovation and progress in this field. These collaborations can include various forms of partnerships, such as access to specialized equipment and resources, knowledge, and expertise exchange, as well as joint development of research projects able to generate breakthrough innovations in healthcare.

Among the economic operators, the **use of specialized services** proved to be diversified and oriented to supporting business growth and innovation.

The analysis of their preferences in the choice of services reveals the following trends:

1. **Technical support and expertise/know-how** (65.45%): This service is the most used and indicates a great need among economic operators for technical assistance and transfer of specialized knowledge. This can include consultancy in various technical fields or assistance in the implementation of new technologies.
2. **Collaboration and networking opportunities** (58.18%): This preference underlines the importance of relationships and partnerships in the business environment, offering companies the opportunity to interact and create beneficial relations for their growth and expansion.
3. **Access to specialized equipment** and **Product/solution testing** (54.55% for both): These services are crucial to companies and allow them to use state-of-the-art equipment and to test products under the best conditions, without the need to invest directly in such resources.
4. **Support in the preparation of scientific articles** (49.09%): This service suggests a focus on research and development, encouraging the publication and dissemination of discoveries and innovations in the scientific and industrial community.
5. **Data management and analysis** (47,27%): This preference reflects the growing need to process and interpret large amounts of data, which is a crucial aspect in the digital world allowing informed decision-making.
6. **Access to specialized databases and resources** (43.64%): Access to resources enables companies to rely on existing information and research, thus saving time and resources in the innovation process.
7. **Personnel training in the company's field of research** (25.45%): This service underlines the need to develop and continuously update employees' skills, aligned with the advances in the relevant field.
8. **Support in protecting intellectual property** (21.82%): This reflects an increased awareness of the importance of protecting innovations and copyright in the competitive business environment.
9. **Support in identifying qualified human resources in the relevant field** (20.00%): This reflects the need to attract and retain specialized talents, which are essential for the long-term growth and success of companies.
10. **Specialized human resources with temporary assignments inside the organization** and **Support in the qualification of the organization's employees** (18.18% for both): These services

indicate the recognition of the importance of expertise exchange and continuous development of employees by means of educational programs, including academic projects.

It is interesting to note that **the use of services for the preparation of the documentation required for the CE marking of products and services was not reported**, which may indicate either that the need is less important in this field, or a lack of awareness of the importance of this aspect for the commercialization of products or services in the European Union.

Economic operators have clearly identified their preferences for services that may support and improve their business activities (Fig. 5.8).

The following list details the desired services and reflects in percentages the interest expressed by these operators:

1. **Collaboration and networking opportunities** (100%): This indicates unanimity with regard to the value recognized by economic operators of the opportunities to create successful partnerships and to connect to other entities in the industry thus opening the way to innovation and mutually beneficial growth.
2. **Product/solution testing** (76,27%): A significant majority stressed the importance of access to services that allow a thorough assessment of the new products and solution before market launch, to ensure quality and compliance.
3. **Access to specialized databases and resources** (69.49%): Almost seven of ten operators highlighted the need to access information and resources that may offer an advantage in research and development, as well as in strategic decision-making.
4. **Technical support and expertise/know-how** (66.10%): The recognition of the fact that technical expertise is crucial for innovation success and adaptation to changing markets is obvious from the percentage of those who request such services.
5. **Access to specialized equipment** (61.02%): Advanced and niche equipment is often costly and difficult to obtain, which is why more than half of economic operators require access to such tools to expand their research and production capacity.
6. **Data management and analysis** (61,02%): An equally high percentage of economic operators underlined the need to manage and analyze efficiently large data volumes, which is an essential element in the digital era to support data-based decisions.
7. **Support in identifying qualified human resources in the relevant field** (52.54%): More than half of respondents indicated that they need help in finding and recruiting the talents they need to sustain their growth and innovation.
8. **Personnel training in the company's field of research** (45.76%): Almost half of the operators value the development of their employees' research skills, indicating that an investment in human capital is an essential component of their development strategy.
9. **Support in protecting intellectual property** (42.37%): A significant percentage of economic operators consider it is important to secure their innovations and ideas as intellectual property, which reflects the importance they attach to innovation and intellectual property.
10. **Specialized human resources with temporary assignments inside the organization** (38,98%): This service, requested by almost 40% of operators, suggests that there is a clear need to borrow temporarily talents and specific skills for special project or to supplement existing teams.
11. **Support in the qualification of the organization's employees** (35,59%): More than one third of the companies recognize the value of supporting the education of their employees by graduation projects or doctoral theses.

The innovative nature of investment materializes in product and process innovation.

The development of an innovating software for the management of research infrastructures can offer significant benefits to researcher communities and academic institutions by integrating the following new ideas:

- The existence of an institutional memory spacer customized to attract the request of services from the private environment.
- Training modules to educate young researchers on diverse topics:
    - The use of certain equipment and laboratories
    - Authoring an article
    - Intellectual property
    - Communication within an international research team, etc.

All these elements together with the use of virtual reality (VR) and augmented reality (AR) to create training experience and to view research infrastructures allow researchers to virtually explore laboratories, equipment, and facilities before booking or planning experiments.

Chapter 6. Case Study – SIMPLE RDI SPIN-OFF

As the product does not exist in the market and in order to determine a double benefit, one solution would be ***the development of an innovative software for the management of research infrastructures – institutional memory and training module*** by means of a spin-off of an existing RDI institution so that, post-development, it is possible to commercialize this product to third parties without exceeding the permitted (20%) percentage of RDI economic activities. At the same type, such a long-term solution would bring benefits in terms of its scaling and maintenance.

Funding needs

The funding needs were estimated and presented in the form specific to existing funding in the RDI market and integrates the following types of expenditure, expressed in lei (Table 6.1).

Financial plan

Assumptions underlying the forecasts

The following aspects were considered in the preparation of the economic-financial analysis:

- The length of the project shall be 18 months.
- The submission of the project is planned for the first quarter of 2024, the financial analysis having considered 2024 and 2025 as implementation years, to facilitate data interpretation.
- During the implementation period, 4 FTE (full-time equivalent) jobs are expected to be created, software engineers, technology development engineers, IT and AI specialists. For the project ***operation period*** (after completion of project implementation), the team shall be formed of 4 persons, representing 4 FTEs, i.e. sales agents / RDI AI Module implementation expert.
- The company to be set up aims to obtain revenues from the following types of activities:
    - ✓ License lease (rent/year) to public RDI institutions
    - ✓ License lease (rent/year) to private RDI institutions
    - ✓ License lease (rent/user/) to private companies

- The value added tax considered in the analysis is 19%.

- The economic-financial forecast is based on 5 years, i.e. 2026 - 2030.

Forecast financial statements

Revenue and expenditure were based on the following assumptions:

- the revenues obtained by the company in the period 2025 - 2030 are those described in the preceding subchapter
- the expenditure for raw materials and consumables for the operation period are the expenses required to implement the RDI module with the AI component and were estimated according to the activities/operations to be carried out in the implementation of the solution.
- the expenditure for other materials (including for services of external parties) for the operation period consists of the expenses included in the project budget and the expenses estimated for the operation period
- the category "other expenses for external supplies (energy and water)" include expenses related to utilities (administrative expenses, rent, etc.)
- the expenditure corresponding to depreciation and amortization considered a depreciation/amortization period of 3 years for IT equipment and intangible assets (licenses and software)
- the category Other expenses: (accounting, marketing, human resources, legal, etc.) for the operation period was estimated according to the services to be provided.
- the calculation method is linear depreciation/amortization.
- no other revenue or expenditure is expected in the analyzed period

The project budget was divided for the two fiscal years (2024 and 2025) as follows:

Expenditure designation	2024	2025
ELIGIBLE EXPENDITURE	**991,656.25**	**1,038,500.00**
Expenditure for research and development activities (industrial research and experimental development)	**455,000.00**	**455,000.00**
Personnel-related expenses	455,000.00	455,000.00
Expenditure for purchase of research and development services		-
Expenditure for purchase of raw materials and materials necessary to conduct research-development activities		-
Expenditure for launching research results into production and technology building	**338,325.00**	**295,000.00**
Personnel-related expenses	295,000.00	295,000.00
Expenditure for purchase of tools, plant and equipment strictly necessary for the introduction of research results in the production cycle	31,325.00	0.00
Expenditure for purchase of raw materials and materials necessary for launching research results into production and technology building	0.00	0.00
Expenditure for purchase of intangible assets necessary for the introduction of research results in the production cycle	12,000.00	0.00
Expenditure related to innovation	**1,000.00**	**101,000.00**
Expenditure related to innovation	0.00	100,000.00
Expenditure for support services for innovation	0.00	0
Expenditure for information and publicity for the project	1,000.00	1,000,000
General administrative expenses (overheads)	198,331.25	187,500.00

Expenses for the mySMIS digital certificate		
INELIGIBLE EXPENDITURE	**-**	**9,520.00**
Final audit of the project	-	9,520.00

Cash flow table

The forecast cash flow of the company is analyzed for the three components – operational, investment-related, financial, and considers the following aspects:

- The contribution to the company share capital is 270,000 lei for 2024 and 207,700 for 2025, representing the co-funding related to eligible expenditure and the contribution to ineligible expenditure. The resulting total contribution is 477,700 lei. This amount is expected to be reimbursed starting from 2025, over five years (until 2030).
- The company does not expect to sell assets in the analyzed period (2024-2030).
- The grant is divided for the two implementation years (2024-2025). The value is expected to be reimbursed during these years, as the beneficiary estimates that it will use the Application for Payment mechanism in parallel with the Applications for Reimbursement.
- There are no new purchases of tangible fixed assets estimated during the operation period, and there are no new purchases of intangible fixed assets estimated during the operation period;
- The company does not expect to take out long-term loans during the analyzed period.
- The receipts from operating activities, including VAT, were forecast at 100% of the amounts included in the revenue and expenditure presented above; the value added tax is 19%.
- The amounts corresponding to expenditure for raw materials and materials, other materials (including external services), energy and water, and salaries are those included in the revenue and expenditure, plus the value added tax of 19% (except for salaries, which are not subject to this tax).
- The spin-off to be set up will recover the VAT related to eligible expenses in the project, as it will be set up as an enterprise not subject to VAT and is expected to become subject to VAT in 2026.
- <u>The net cash flow for the analyzed period is positive.</u>

Financial profitability indicators

The main purpose of the financial analysis is to calculate the project performance indicators.

The method used in the preparation of the financial analysis is the discounted net cash flow. Therefore, non-cash flows such as depreciation, amortization and provisions are not considered.

We present below the funding sources for the project variant including the grant. The private contribution of the company consists of a minimum of 20% of eligible expenditure plus ineligible expenditure. The total value of the project is 2,040,676.26 lei, and the value of the grant is 1,663,508.13 lei.

Funding sources for a project with grant, in lei

PROJECT BUDGET ITEMS	VALUE
TOTAL PROJECT VALUE:	**2,040,676.26**

INELIGIBLE PROJECT VALUE:	***9,520.00***
ELIGIBLE PROJECT VALUE:	***2,031,156.26***
REQUESTED GRANT	*1,663,508.13*
APPLICANT'S ELIGIBLE CONTRIBUTION	*367,648.14*
Contribution in cash	367,648.14
Contribution in kind	N/A
Loan	-

Financial profitability indicators

Project sustainability was analyzed for the 'project with grant' scenario in the analyzed period, taking into account the following elements. Investment value, Funding sources, Operating expenditure.

The cash flow should demonstrate financial sustainability, namely that the project is not at risk of lacking cash resources.

Solvency and viability are ensured if the cumulated result of the net cash flow is positive throughout the analyzed period. We present below the table containing information about the financial sustainability of the investment, over the two implementation years followed by the five years of the analysis.

B/C ratio

According to the guide for the cost/benefit analysis of investment projects prepared by the European Commission, DG Regional Policies, the B/C ratio is VAN (I)/VAN (O), where "I" represents incoming flows and "O" outgoing flows. If B/C >1, the project is compatible because the benefits, measured by the current value of all incoming flows are higher than the costs, measured by the current value of all outgoing flows.

The benefit/cost ration for this Spin-off project is **1.40**

|In conclusion, the project is feasible and the need for the grant is justified. The incoming flow of the project is higher than the outgoing flow, which means that benefits can sustain the project operating costs.

Chapter 7. Analysis of the Market for the Product Resulted from Research in the Context of Identified Services

The market segment targeted by RDI SIMPLE is the market of software products.

The RDI SIMPLE software is an innovative software with AI component for the integrated management of research infrastructures, with significant benefits for researcher communities and research institutions due to the integration of new ideas.

Target group of the service at national level

Research and Development Institutions (RDI): In accordance with Law no. 319/2003 on scientific research, technological development and innovation in Romania, the National Institute for Research and Development (Institutul Național de Cercetare-Dezvoltare, INCD) is a specific form of RDI, recognized and funded by the state. These institutions have the mission to carry out scientific research and technological development to promote innovation and progress in various fields.

National Research Institutes: Romania has numerous officially recognized national research institutes, which are mentioned in the specific legislation for each field. For example, the National Research and Development Institute for Biomedical Products Medicine and Engineering (Institutul Național de Cercetare-Dezvoltare pentru Medicina și Ingineria Produselor Biomedicale, ICMB) is one such institute operating in the field of health and biomedicine.

Universities and University Research Centres: Universities in Romania are regulated by the National Education Law no. 1/2011, which sets out their structure and role in research and development. Most universities have departments and research centers carrying out scientific research and innovation activities.

Research Centers in the Private Sector: Private companies in Romania can establish research and development centers, according to the provisions of Law no. 64/1996 on scientific research and technological development in the economic sector. These centers aim to develop innovative technologies and products for the benefit of the companies concerned.

Non-Governmental Research Organizations (NGOs): NGOs that engage in social, economic or environmental research are regulated by Law no. 21/1924 on associations and foundations. These organizations can provide expertise and research in various fields and collaborate with public and private institutions.

Research Laboratories: Research laboratories may be part of universities, research institutes or other entities. They are important for experimental research in fields such as physics, chemistry, biology and engineering.

Romanian Academy Institutes: The Romanian Academy is mentioned in the Romanian Constitution and is regulated by Law no. 1/2011 on the organization and functioning of academies and academic societies in Romania. The Institutes of the Romanian Academy carry out research in a variety of scientific fields and have the role to promote knowledge and innovation.

European level

According to ESFRI, the European Strategy Forum for Research Infrastructures, established in 2002 and bringing together national governments, the scientific community and the European Commission (EC) to support a coherent and strategically driven approach to Research Infrastructures (RIs) in Europe (Roadmap 2021 - Strategy report on research infrastructures), the updated and complete list of infrastructures contains 22 ESFRI PROJECTS and 41 ESFRI LANDMARKS. There is a growing need for new types of Research Infrastructures (RIs) responding to specific challenges, such as climate change and environmental sustainability, which cannot be allocated to a single scientific discipline. These RIs require multiple locations and mobile or virtual capabilities. They need to be designed and deployed not only in the EU, but on a global scale that matches the scope of the problems addressed. At the same time, the RIs in traditional disciplines are becoming bigger and require an increasing number of participating countries and significant financial resources, both in the UE and worldwide. Expectations regarding the contribution of research to wider policy objectives are also increasing. Now, it is important to stimulate the impact of the growing number of interconnected RIs that form a new RI ecosystem, which not only serves research, but also leads to a stronger integration of RIs in the innovation ecosystem and in many other fields.

Target market size

Target market size The RDI SIMPLE software is targeted at universities, research institutes and governmental organizations interested in improving the management of research infrastructures.

The potential for growth of the market for software products that integrate AI is large, according to https://www.gartner.com/en/newsroom/press-releases/2021-11-22-gartner-forecasts-worldwide-artificial-intelligence-software-market-to-reach-62-billion-in-2022. A study conducted by McKinsey Global Institute [https://www.mordorintelligence.com/industry-reports/global-artificial-intelligence-market] highlights that the application of artificial intelligence (AI) could add approximately 13 trillion dollars to global economy by 2030, which would correspond to an annual growth of global GDP by approximately 1.2%. As regards this tendency by region, the image below shows that in Europe this increase is small. 7.1).

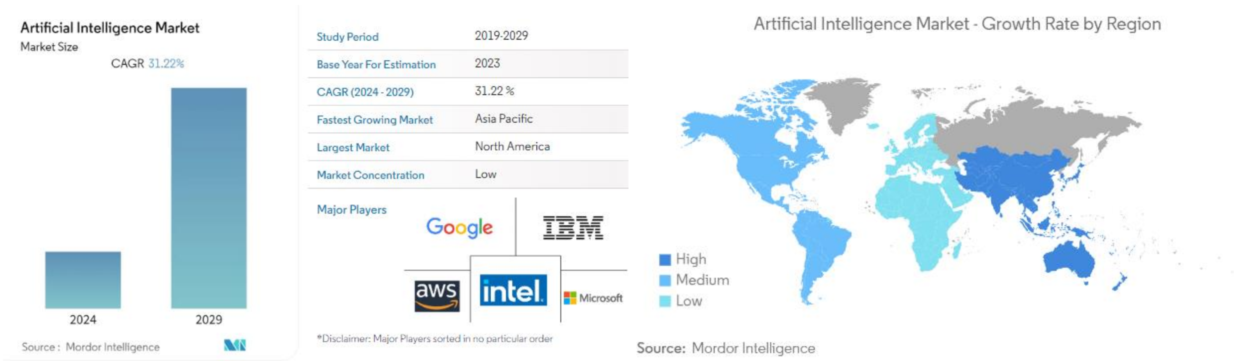

Fig. 7.1 The potential for growth of the market for software products that integrate artificial intelligence

The potential for growth of the market for software with AI component is also supported by the needs for development, namely:

- Companies seek to automate processes and tasks to improve efficiency and reduce costs. AI systems can offer more advanced and adaptable automation solutions.
- AI software applications can offer users customized and adaptive experiences, which is an increasing demand as consumers become more demanding in terms of customized services.
- As more and more data are available, companies need advanced data analysis tools. AI solutions can identify patterns and extract important information from complex data.
- AI technologies play a crucial role in the identification and prevention of cyber threats. The demand for AI-based security solutions is increasing, to counteract increasingly sophisticated attacks.
- In the medical field, AI solutions can be used for faster and more accurate diagnosis, medicine discovery, patient data management and healthcare services improvement.
- The development of autonomous vehicles and driver assistance technologies require advanced AI algorithms to ensure their safety and efficiency.

- The use of robots and automated systems in manufacturing benefits from AI technologies to optimize processes, reduce errors and increase productivity.
- For online learning, AI solutions can facilitate the learning process by providing individually customized materials, feedback, and assistance.
- AI applications, such as virtual assistants and chatbots, are increasingly used for customer support and to improve interactions with users.

Description of the direct influence of economic, political, legislative, technological, and social factors

a) The context of the software industry

The European Commission compares European countries using a set of criteria relevant to measuring the level of digital development, using the Digital Economy and Society Index – DESI: “human capital”, “connectivity”, “integration of digital technology” and “digital public services”. Romania ranks last in Europe, as the only criterion where we are at an average level compared to European countries is “connectivity”. The dimensions “human capital” and “state of digital technology integration” are at half the level of the top countries. The major underperforming area is “digital public services” (Fig. 7.2), where the lack of reform and digital project puts us in the last place, with 25% of the level of top performing countries in Europe.

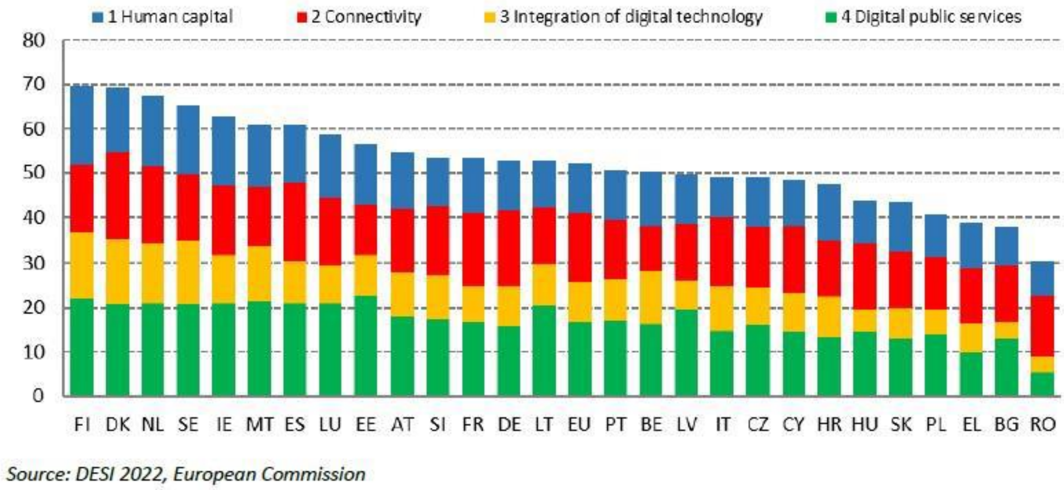

Fig. 7.2 DESI distribution in the European Union

The software and IT sector in Romania is a main topic in public discussions, reflecting its importance in the context of the expanding digital economy. Discussions are focused on the development of public services, business opportunities, integration of skilled workforce, the interest of the international market interest and the attractiveness for foreign investment, underlining the essential role of digitalization for economic progress. More than two decades ago, this was considered to be a niche field with unexplored potential. The political initiative adopted in the early 2020s, which exonerated from income tax employees in direct production, was a major step generating significant growth and an increasingly strong presence of the software and IT sector in national economy.

Based on the current trends and the market dynamics, the sustained growth of the Romanian software and IT sector is expected to continue in the coming years. Technological innovation, the growing demand for digitalization in all economic sectors and the increasing interest of foreign investors contribute to an environment that supports this growth.

Bucharest remains the largest contributor to the market volume at national level, with approximately 60% of the market over the years, but its supremacy is slightly declining. It is followed by the North-West region (Fig. 7.3). All the other regions are below 10%, with slightly better results in the West, North-East and Central regions, which have the potential to gain a larger market share in the future. The South and South-East regions are at the lowest levels, with a constant contribution over the year that only reaches 1% or 2%.

b) National political and legislative context

The income tax exemption for IT and research professionals was introduced in Romania in the early 2000s as an incentive for the development of this sector.

The measure aimed at attracting and retaining highly qualified specialists in the country, thus contributing to increasing national competitiveness in technology and research. This favorable taxation policy was a key factor in the rapid expansion and continued success of the Romanian software and IT services industry.

Law no. 25/2023 on the voluntary integration of Romanian research, development and innovation organizations into the European Research Area and on the amendment of Government Ordinance no. 57/2002 on scientific research and technological development

regulates the voluntary integration of research, development and innovation organizations in Romania in order to reduce the high degree of fragmentation of the national research and development system, encouraging them to pool their own resources and related infrastructures in order to improve their scientific performance for better integration into the European Research Area. According to Article 3(1):

Research organizations may integrate on a voluntary basis in one of the following ways:

- association in research, development and innovation consortia, hereinafter referred to as RDI consortia;
- merger;
- transfer of national research and development institutes, hereinafter referred to as NRDI, to the coordination of public higher education institutions.

The RDI SIMPLE software would be essential in supporting the efficient implementation of Law no. 25/2023 and to facilitate the collaboration and integration of research organization in the European Research Area, by the efficient management of resources, performance monitoring and assessment, facilitation of collaboration and communication, and ensuring compliance with the law and international standards. At the same time, it could support communication between research teams and project coordinators and the training of young professionals, which would contribute to the streamlining of activities.

Social aspects

Tax facilities and technology progress stimulated the development of human capital in the Romanian IT and research sector and reduced the “brain drain” phenomenon by retaining local talents.

However, the sector lacks specialists, this issue being aggravated by the relatively small number of university graduates in the relevant fields compared to the demand in the EU. This discrepancy underlines the need for increased attention to education and vocational training, to support the continuous growth of this industry.

Competitive advantages of the chosen solution

The research infrastructure management software would include features for resource planning and monitoring, research project administration, data and scientific publications management, as well as facilities for collaboration and knowledge exchange. It could also integrate modules for financing and budget management, research progress monitoring, result reporting and ensuring compliance with ethics and legal standards, etc. In essence, it would aim to facilitate research processes, increase researchers' productivity, and facilitate interdisciplinary and international collaboration.

Currently, there is no such product in Romania, at the level of research institutes. An analysis of the digitalization of institutes (INFLPR – the National Institute for Laser, Plasma and Radiation Physics, IFIN-HH – the National Institute of Physics and Nuclear Engineering "Horia Hulubei", IFTM – the National Institute of Materials Physics) led to the identification of the following existing digital solutions:

- The iConsalt IT system dedicated to national research and development institute, which can contain:
  - Daily time sheet records (Evidență Pontaj Zilnic, EPOZ)
  - ERP module for expense reimbursement (Decontarea cheltuielilor, DECO)
  - ERP module for payroll (Evidenta si calcul salarii, ESA)
  - ERP module for external backup in a different location (Salvare Externa date in Altă Locație, SEAL)
  - ERP module for records of research-development agreements (Evidenta ConTracte CERCETARE - DEZVOLTARE, ECTC)
  - ERP Module for records of receipts (Evidenta InCASari, ECAS)
  - ERP software for records of public procurement plans (Evidenta Plan Achizitii Publice, EPAP)
  - ERP software for records of vehicle fleet (EVidenta Parc Auto, EVA)
  - ERP software for invoicing (FACturare, FAC)
  - ERP module for balance sheet (BILant Contabil, BIL)
- Online booking systems for equipment use
- Zoom/Teams licenses
- Teamviewer/Origin/ Mathlab/Labview/Avantaje etc. group licenses for individual data processing and equipment remote control.
- Electronic register (Regista by Zitec)

With all these digital solutions implemented in institutions such as INFLPR, IFIN-HH and IFTM, there are still fields where digitalization is not developed. These fields include the integrated management of research project life cycle, from conception to publication and commercialization, advance systems for research data management that support big data analysis and artificial intelligence, and digital platforms for extended collaboration. There is a lack of digital tools for the training of young research specialists. This includes the lack of e-learning platforms adapted to research-specific needs, as well as the absence of modules that operate as a digital archive of the research facility, thus facilitating knowledge and experience transfers between generations.

Marketing plan

Strategies to approach the market of the RDI SIMPLE product

Criterion	Strategy used	Explanation
Depending on the quality level of provided services	Adaptation strategy	The provided services, in addition to basic experience, will be adapted depending on the requirements of each market segment
	Differentiation strategy	The services provided will be differentiated from competing ones as they will take into account the specific characteristics of the research organizations they are targeting, namely public RDI institutes, private RDI institutes, private companies carrying out RDI activities.
Depending on the renewal frequency of the software product	Product optimization strategy	The product will be optimized/adapted permanently to respond to the needs of clients and to be aligned with the new technologies that will be developed, so as to provide the best user experience.

Pricing strategy or policy

The pricing strategy for RDI SIMPLE is presented in Table 7.7.

Table 7.7 Pricing strategy for RDI SIMPLE

Criterion	**Chosen strategy/model**	**Arguments in support of this choice**
Price formulation method	Cost-oriented strategy Value-oriented strategy	The company aims to recover its initial RD costs, the operational costs, and the costs of further development (new features, functionalities, etc.). At the same time, it will also consider the value perceived by potential clients, considering the benefits offered by the RDI SIMPLE solution.
Price evolution in time	Penetration prices	In terms of the price evolution in time, the penetration price strategy is the most logical one, as, at the beginning, the application will need time to be accepted by potential clients, will only have basic features and can be supplemented in time with new functionalities that will be reflected in increased prices.
Selected price model	User-based prices Feature-based prices	In the first years after the product launch, we will apply user-based prices and, in time, after new features and functionalities are added, we will apply a mix of the three selected models.

Criterion	Chosen strategy/model	Arguments in support of this choice
	Level-based prices	

Sale and distribution strategy

As the RDI SIMPLE product is targeting organizations and less the market of final consumers, when determining the sale and distribution strategy, we have considered the features of the B2B market.

Promotion and public relations strategy

As the RDI SIMPLE product is targeting the B2B market, the promotion and public relations strategy should be adapted to this market (Table 7.8).

Table 7.8 Promotion strategy for the RDI SIMPLE product

Item No.	Promotion and public relations method	Desired effect
1	Website & SEO	To inform potential clients about the RDI SIMPLE product, pricing models, software benefits and general information about the company, and search engine optimization.
2	Social media: LinkedIn	To permanently inform potential clients and existing clients about the product, news, etc. Paid promotion campaigns will allow us to target the relevant market segment, namely public and private research organizations.
3	Google Adwords: paid ads on Google	To present the product when users query search engines looking for software products of this type
5	Paid articles in journals/media	To inform potential clients about the new software launched on the market.
7	Participation in national and international events	To participate in the same events as the targeted market segment and to present the demo during such events.
8	Sales force	If potential clients are informed about the new software by means of the other methods, the sales force will contribute to actual sales by the relationships they will create.

Chapter 8. Final conclusions, main contributions, and directions for further research

Main contributions

1. Research and Innovation in a Global Context
    - Analysis of the innovation concept and innovation types
    - Conversion of the technological readiness level in the health sector: pharmaceutical development and medical device development
2. Research Infrastructures
    - Classification and relevant key aspects in the field of research infrastructures

- Analysis of the RDI infrastructures in the health sector in Romania
- Analysis of European strategies with regard to research infrastructures

3. Socio-statistical analysis of research infrastructure management

Development, collection, and analysis of information by means of the questionnaire aimed at identifying existing needs at management level within infrastructures from the perspective of:

- Institutional performance
- Human resources
- Challenges created by the COVID-19 pandemics for the management of RDI infrastructures
- Specific needs of the RDI infrastructure identified by respondents
- Needs generated by the market
- Respondents' expectations with regard to public strategies and policies
- Respondents' opinion on the priorities for resource management in their respective organizations

4. Structural Modeling of Needs for the Management of Internal Processes of RDI Infrastructures

- Analysis of the existing management models at international level for RDI infrastructures
- Identification of existing digitalization solutions meant for European research infrastructures
- Analysis of the manner in which new and modern technologies can be used in the development of a research infrastructure management software
- Analysis of the existing software solutions that can be integrated into a RDI infrastructure in the health sector

5. Social-Statistic Analysis of the Expectations of the Business Environment regarding Research Infrastructures

- Analysis of the existing research ecosystems – clusters and innovation hubs
- Identification of the role of clusters in the sustainable development of members' research infrastructures
- Identification of obstacles to innovation in the health sector
- Approach of European regulations regarding the certification of medical devices
- Questionnaire-based analysis of the RDI infrastructures' perspective on development opportunities in relation to the economic environment
- Questionnaire-based analysis of the economic operators' perspective on development opportunities in relation to RDI infrastructures

6. Case Study – SIMPLE RDI SPIN-OFF

- Identification of resources and funding needs, development of the financial plan and calculation of financial profitability indicators.

7. Analysis of the market for the product resulted from research in the context of identified services

- Analysis of the market segment, the target group for the service and the product resulted from research
- Development of the marketing plan

Final conclusions

Research is considered a long-term investment that over time will benefit the organizations involved in any field if this vision is shared by all stakeholders in the system. The possibility to access R&D funds meant for underdeveloped or developing countries increased investments in this field at global level and is reflected in the growth of qualified workforce in this field and personnel training level, and the continuous change in the local, national and international regulations and policies. Moreover, the number of bodies that control this regulation has increased as well, and a good knowledge of the changes that occur every year in legislation or guiding principles is indispensable.

Collaboration between entities in view of organizing research-development projects facilitates the simultaneous development of entities and can also be achieved by means of non-governmental organizations or clusters.

Furthermore, technology transfer, either internal, within the industry, directly inside the company, including the delivery to production of internally developed systems or equipment, technical services inside the company and purchased products customized before commissioning within the company, or external, such as processes from or into other organizations, including the purchase of technology from external sources, technology licenses granted to other organizations and associations at multiple levels, including the development of cooperation and consortia in the industry, is essential for the proper functioning of these non-governmental structures.

Entrepreneurship is the element that facilitates the sustainable funding and the functionality of these entities. It is an essential element for economic progress, as it identifies, evaluates, and seizes business opportunities, creates new companies and/or renews them to render them more dynamic, and leads the economy by innovation, competence, and job creation, improving the general well-being of society.

Research infrastructures beyond 2020 – they are sustainable and efficient ecosystems for science and society.

Synchronization and alignment of policies and investments in the research infrastructures at various levels – although a complete synchronization is not necessary for national facilities, but a higher level of alignment is necessary to ensure the consistent development of the European research Infrastructures ecosystem. The ERIC regulation has a positive impact on the investment lever, targeting stronger financial agreements and resource pooling. However, the fiscal interpretation of the ERIC regulation still requires clarity and a coherent approach. At the same time, a certain level of alignment between human resources policies and social security regulations would increase the attractiveness of research infrastructures for expert personnel.

The development of stronger and seamless funding mechanisms for the research infrastructures throughout their life cycle – the funding mechanisms of the research infrastructure are sub-optimal due to gaps in financing, where European, national, and other sources of funding are not sufficiently available. These gaps are mainly found in the pre-construction and pre-operational phase. A coherent approach of funding is required, which should cover the entire life cycle of research infrastructures and provide a better alignment and synchronization of the various funding instruments.

The improvement of the research infrastructure impact as knowledge hubs – a clear message is required about the impact of investments in research infrastructure on citizens. Service orientation and the consolidation of the role of research infrastructures in education and training are good methods to demonstrate the return to citizens. Research infrastructure approach industrial and social needs, strictly observing their role as one-stop shops for social and economic activities beyond science.

The needs identified in the market sector cover, in fact, the gaps in the management area, as there are requests for “inclusion in international research consortia; marketing for research; participation in international projects, collaboration with universities, collaboration with the private environment, active presence in specialized international fairs, development of a marketing department, fast adaptation to market demand”, when, in fact, these needs are normally covered by the marketing and technology transfer departments.

The funding of research data management software is a challenge in the current context of research. Traditionally, this is not considered an essential component of the standard research process, therefore it is rarely included in the usual research budget. However, given the evolution of digitalization and the need to efficiently manage a growing volume of research data, the importance of appropriate management software is becoming increasingly obvious.

One of the reasons why the funding of this type of software is undervalued is the lack of a proper awareness of the benefits it may provide to researchers and research institutions. A well-developed management software can consolidate and streamline the entire research process, ensuring data integrity and accessibility, facilitating collaboration between researchers and optimizing data analysis and interpretation.

The digitalization of research institutions brings the following advantages and disadvantages:

- Advantages of research infrastructure digitalization:
    - Improved efficiency: Digitalization allows researchers to easily store, manage and access data. This means that research processes can be significantly accelerated as researchers are able to analyze data much faster than allowed by traditional methods.
    - Improved collaboration: Digital platforms facilitate remote collaboration between researchers and research institutions around the world. This increases synergies and develops stronger research networks.
    - Increased accessibility: By digitalization, research results and data become more easily accessible to the general public or other researchers. This contributes to increasing research transparency and can facilitate collaboration between various fields of research.
    - Cost reduction: Digitalization can reduce the costs related to hard copy documents storage and management. At the same time, the optimization of administrative processes can generate significant money savings.
    - Advanced analysis: By using advanced data analysis documents, such as machine learning or artificial intelligence, researchers can obtain more thorough insights from research data. This allows them to develop more complex research and obtain more detailed and accurate results.
- Disadvantages of research infrastructure digitalization:

    - Data security: Digital data can be vulnerable to cyber attack and loss of data. This can compromise the confidentiality and integrity of research information and require additional security measures.
    - High initial costs: The implementation of digital infrastructures often requires significant investment in equipment, software and personnel training. These initial costs can be an obstacle for organizations with limited resources.
    - Technology complexity: The introduction of digital technologies can be difficult and require considerable resources to ensure a smooth and efficient transition. It is important to allocate the appropriate resources to manage this complexity.
    - Dependency on technology: Organizations can become too dependent on technology, which can expose them to risks in case of technical issues or system failures. It is important to develop backup plans and to constantly monitor the digital system.
    - Unequal access: Not all research organizations have access to high quality digital resources and technologies. This can create inequalities in scientific research and development, where organizations that are smaller or are located in less developed regions have fewer digital resources available.

In conclusion, digitalization in research infrastructures will bring many benefits, but it must be managed carefully to prevent potential disadvantages and risks. The careful planning and implementation of the digitalization process can contribute significantly to improving research efficiency and quality in research organizations.

Directions for further research

The main directions for further research resulting from the thorough investigations presented in this thesis are:

- **Creation and implementation of innovative software modules** for the management of research, infrastructure and innovation (RDI) infrastructures, adjusted for the specific requirements of the RDI market.
- A thorough study of the **trends and evolution in the dynamics of small and medium enterprises** (SMEs) within industrial clusters.
- **Development of new and improved models for support ecosystems** that facilitate innovation and intersectoral collaboration within RDI infrastructures.
- **Implementation of artificial intelligence in the management of RDI infrastructures**: A thorough research is necessary regarding the manner in which artificial intelligence systems can be integrated to improve decision making, efficient use of resources and predictability in the management of RDI infrastructures. This could include the development of algorithms that predict resource use tendencies, workflow optimization for research and innovation and interface customization for various users, from researchers to administrators.
- **Digitalization impact on RDI infrastructures**: Digital transformation opens up new possibilities for collaboration and innovation. Studies could explore how digitalization can enhance interdisciplinary and interinstitutional collaboration, for instance via virtual data sharing platforms and digital laboratories. At the same time, it could analyze the challenges in terms of confidentiality and security that occur together with the large-scale storage and analysis of research data.
- **Sustainability strategies for RDI infrastructures**: Research can identify the most efficient practices to ensure the sustainable operation of RDI infrastructures. This can include the development of solutions to reduce energy consumption, waste management and recycling of research equipment. At the same time, business models could be explored in support of sustainable investment and integrating the principles of circular economy.
- **International cooperation in RDI infrastructures:** It is vital to understand how international cooperation can accelerate innovation. Research can approach the manner in which international partnerships influence technology transfer and access to funding and attract talent. At the same time, it can evaluate the role of RDI infrastructures in facilitating multidisciplinary collaboration to address global challenges such as climate change or pandemics.
- **RDI infrastructures as incubators for technology entrepreneurship:** RDI infrastructures can play a crucial role in supporting entrepreneurial innovation. Research could investigate how RDI infrastructures can support startups by access to equipment and high technology, expertise and mentoring. At the same time, it could evaluate how these infrastructures can be the pivot of innovative regional ecosystems and how they can contribute to the transformation of scientific discoveries in commercial products and services.

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