04
A Multisector Strategy for Industry and Innovation

Creating a single-cell based biomedical innovation ecosystem in Europe, involving start-ups, established small, medium and large enterprises as well as research and technology organisations will form a solid basis for establishing personalised or precision medicine as the new standard of care. Only a pan European integration of efforts within the public and private sectors will offer sustainable, transformative solutions. Most of the technologies at the core of the LifeTime vision are at the Technology Readiness Level (TRL) of proof of concept, or validated in the laboratory, such as single-cell multi-omics, spatial transcriptomics, high-throughput imaging and single-cell computational models. These need to be further developed and integrated together with industry partners to a TRL where they have been tested and demonstrated in a clinical environment.

To join all necessary European stakeholders, the Industry Strategy introduced in this Strategic Research Agenda (SRA) identifies key priority areas divided into five industry engagement platforms: i) technology adoption and development, ii) strategic partnerships, iii) networking brokerage, iv) entrepreneurship and v) expert advising. Appropriate framework conditions including intellectual property (IP) policies for firms in the EU should ensure successful implementation and operation of these platforms as outlined in section 7.6 to be able to succeed and compete globally.

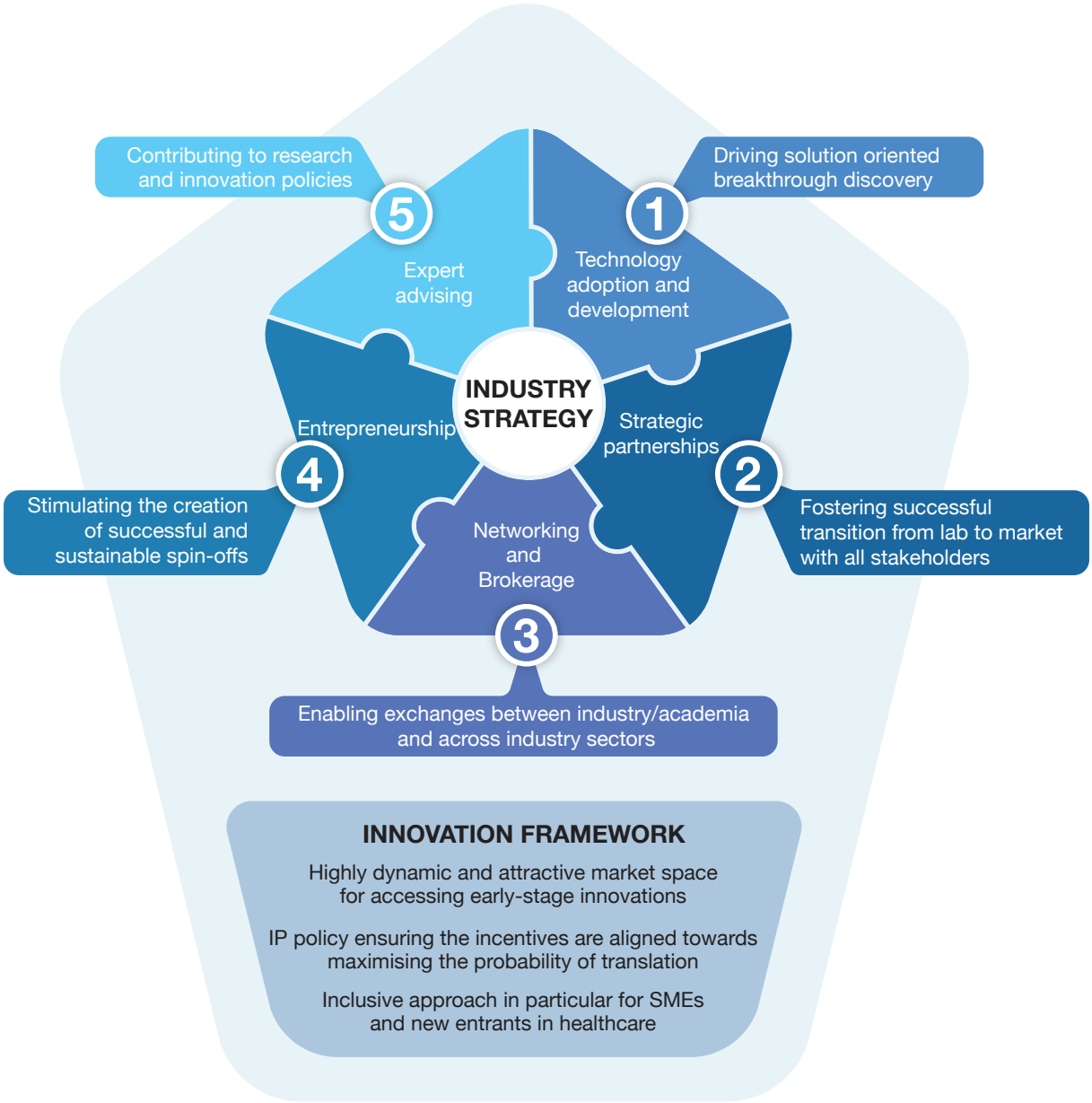
LifeTime has a unique potential for developing innovative technologies and discovering new drugs or diagnostic opportunities with a realistic chance of significant value creation. This could be very powerful in generating innovation, creating spinoffs and supporting sustainable and inclusive growth of companies, regions and countries (section 2.4).

In order to deliver on the ambitious objectives of this SRA, European public and private sectors need to join forces. LifeTime recommends addressing the key challenges described below to ensure a major role of the industry sector in the proposed path to transform healthcare for all citizens. Establishing five industry engagement platforms will facilitate involvement and coordinated co-operation between all stakeholders and foster the development of a competitive health industry in Europe. LifeTime will apply single-cell multi-omics to pathology, develop single-cell resolved organoids models for personalised treatment and advance early-stage technologies such as molecularly empowered predictive machine learning. This not only requires intensive collaboration between academia and industry partners from the following areas but also strong interactions with the finance industry to improve overall framework conditions for innovation, including access to finance (risk capital and other alternative sources of financing):

- **Single-cell technologies:** sample isolation/preparation, microfluidics, sequencing, epigenomics, proteomics/metabolomics, etc.
- **Pharmaceuticals:** target identification, drug development, new therapies, translational medicine, etc
- **Medical diagnostics:** biomarkers, assays, devices, point of care testing, etc.
- **Biotechnologies:** CRISPR-Cas, organoids, subcellular analyses, etc.
- **Imaging technologies:** advanced microscopy, live imaging, deep imaging, etc.
- **IT & Data sciences:** infrastructure, high performance and cloud computing, secure data management, bioinformatics, analytics, AI & machine learning, etc.

To maximise the impact of this SRA, LifeTime has developed an Industry Strategy addressing the following major bottlenecks:

- **Absence of a comprehensive platform driving multi-sector collaboration and enabling all stakeholders to participate in creating transformative healthcare solutions**
- **Insufficient engagement of industry in lower TRL Research and Innovation (R&I) projects**
- **Lack of awareness of the latest advances and available solutions across sectors and too high threshold for implementing emerging technologies limiting technology diffusion across Europe**
- **Cultural barriers limiting exchange between sectors, insufficient knowledge and data flows between disciplines and actors**
- **Complex environment of health innovation, highly regulated industry and very cost-intensive Research and Development (R&D) not offering quick returns on investment**
- **Low access to risk capital, bottlenecks in providing financing to new companies, risk averse European investors**



LifeTime Industry Strategy and Innovation Framework

In addition to the implementation of the five proposed platforms, LifeTime recommends creating an innovation framework for innovative ways of interacting and sharing risk between stakeholders, supporting public/private partnerships and business creation. The ultimate goal is to organise a highly dynamic and attractive market space for accessing early-stage innovations from LifeTime. The IP policy should ensure the incentives are aligned towards maximising the probability of translation into product and service development trajectories with add-on investment from the private market.

4.1 Accelerating Technology Adoption and Development

Technological innovation has always been a major driver for breakthrough discoveries. Therefore, LifeTime proposes to develop a technology adoption and development platform across Europe, in collaboration with industrial technology providers with the aim to lower the threshold for scientists in both industry and academia to implement emerging technologies in their pre-clinical and clinical research. It would create a win-win situation whereby users can test innovative or disruptive technologies for applications in their research much earlier and developers can feed these experiences back into their developmental pipelines. This will ensure that future products deliver what researchers require to accomplish their goals. We have identified the following key elements:

- **Scouting and early-access programmes** for new, emerging technologies developed by industry or academia. A screening system should enable the earlier discovery of innovative technologies that can potentially impact LifeTime research and promote start-ups. This will form a basis for a long term and interactive matching process with the goals of the LifeTime community. Early-access programmes should accelerate the adoption of the scouted technologies at various development stages in academic or industry laboratories. Based on competitive calls, LifeTime recommends to provide grants to scientists working on the proposed disease roadmaps (section 3.2) to support implementation of these new technologies in their research. Different funding rates could apply for different categories from non-commercialised technologies in the prototype phase to recent commercialisation (e.g. < 3 years). Moreover, commercial agreements with technology providers offering competitive product pricing would be in the interest of both companies and research institutions.

- **Open technology innovation laboratories** to create a bridge between external early-access prototypes and commercial ready to use technologies by enabling direct expertise and knowledge exchanges between technology developers and researchers. There should be dedicated laboratory space with technology specialists working alongside interested researchers to launch the technologies, perform troubleshooting, train scientists, manage the collaboration with companies and help LifeTime researchers make strategic implementation decisions after careful technology evaluation. Industrial partners (e.g. biotech and pharma companies) could also be granted access to these innovation lab platforms under well-defined conditions that appropriately cover commercial aspects. Open laboratories can lead to joint new developments of future commercial value that should be protected by appropriate agreements.

- **Technology co-development projects:** The technological developments proposed in section 3.1 can only be realised in collaboration between the public and private sector. Technology companies from the fields of single-cell analysis, imaging and IT/data science are very interested in LifeTime's vision and eager to co-develop technologies with academia. For them it is crucial to see current and future directions in their respective fields, determine priorities and requirements for scaling up and

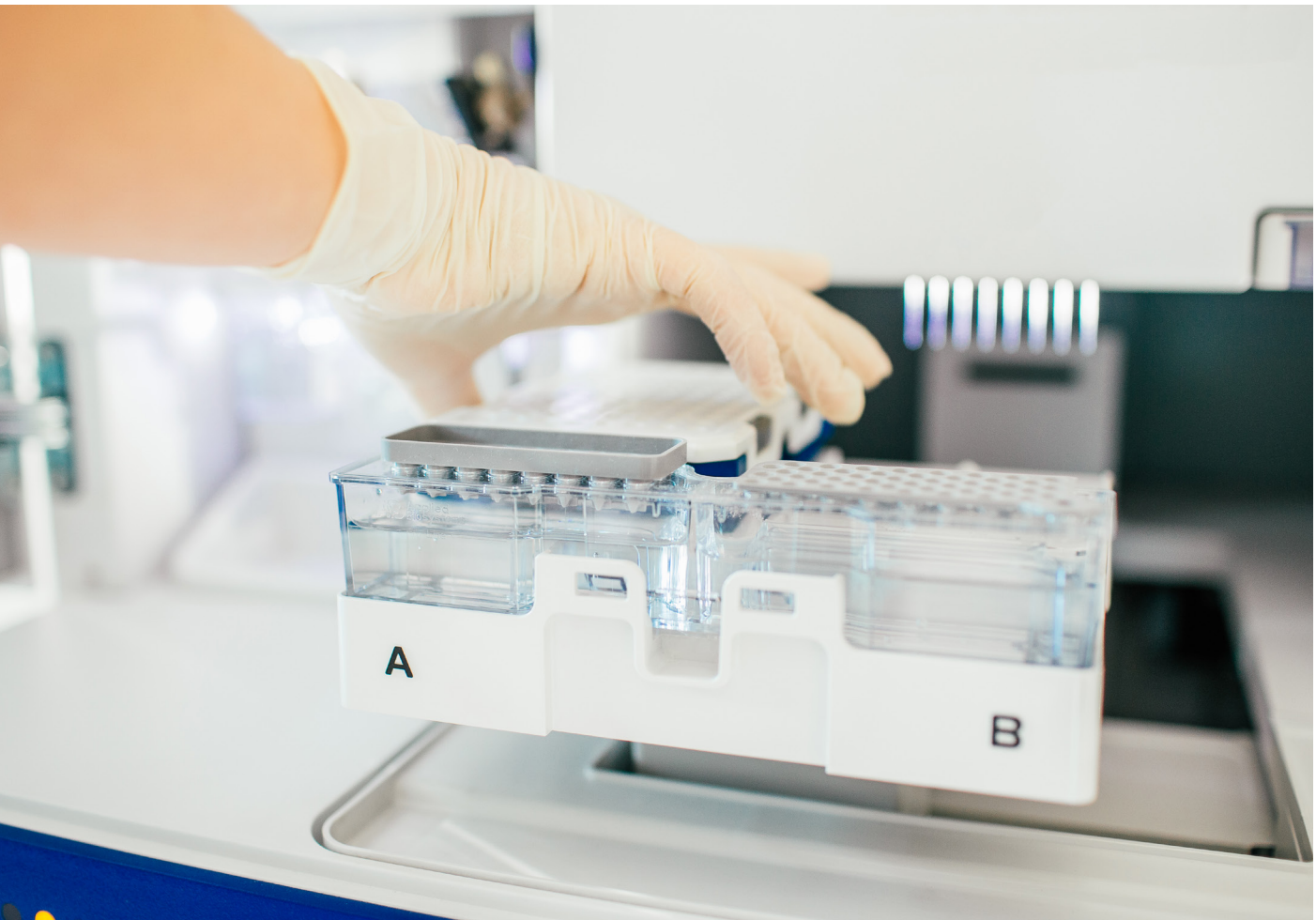
integrating new technologies. Many single-cell technology companies (liquid handling platforms, single-cell transcriptomics, proteomics, epigenomics & multi-omics, RNA-protein interactions, etc.) welcome the co-development of pipelines, instruments, protocols and novel applications in joint projects. They are also willing to support the commercialisation of technologies coming from academia. Some also offer their infrastructure to scale up/further develop (e.g. to create diagnostics based on multi-omics analysis of liquid biopsies) technologies and concepts from academic labs (e.g. providing a platform to multiplex assays). Focused, multi-stakeholder consortia across industry sectors in partnership with academia can leverage new opportunities and help to bring down cost, and increase efficiency.

The proposed technology adoption & development programme offers attractive benefits for many industry supporters of LifeTime. It provides them with an early indication of what is needed to take the technologies to market or into the clinic. Moreover it enables testing and evaluation of new technologies from different sectors or academic developers in their own R&D efforts. Different companies could also synergise more between each other, with such a platform - combined with the network support (section 4.3) - serving as a catalyst. This would also be beneficial for technology developed by academic groups which would be identified, tested, and presented to collaborating companies earlier in their development pipeline.

4.2 Fostering Successful Transition from Lab to Market

LifeTime recognises the importance of strategic partnerships between public and private sectors. These should involve all relevant stakeholders in the value chain and span the entire biomedical innovation cycle from discovery research, technology development, and implementation into hospitals and the healthcare industry. Building on the success of the Innovative Medicine Initiative (IMI) and seizing opportunities arising from the newly developing EU public private partnership - European Partnership for Health Innovation or EU health PPP - joint projects between academia and industry from different sectors should be supported. Covering the cycle of innovation from high-risk research to higher TRLs as well as bridge and integrate the different sectors of pharma, biotech, imaging and data sciences would bring strategic innovation potential. Significant support is required for basic single-cell biology, for multi-omics research and imaging, for organoid-based disease models and for the translation of novel computational approaches to single-cell biology data as well as their integration into clinical studies. We recommend that public-private partnerships deal with the following aspects in a collaborative effort:

- **Benchmarking, standardisation:** Multi-centre, multi-site studies and benchmarking initiatives for instrumentation, as well as experimental approaches, are crucial for industry. Common standards will facilitate the technology development and its scalability following the identified priorities outlined in section 3.1 for each of the technology areas. Through shared procedures and goals, common standards will boost research outcomes and market uptake of innovation. Among different technology areas, companies are calling in particular for standardisation of data format, transfer, storage and analytic software.



- **Translational research:** The proposed disease roadmaps (section 3.2) including the generation of advanced patient-derived disease models, identification of biomarkers and novel drug targets should be implemented by inter-sector collaborations ensuring that new insights in basic biomedical research are translated rapidly and efficiently, to maximise impact on patients' lives. Improving collaboration among all actors from the translational research value chain, including patients, scientists, clinicians, physicians, regulators and industry is therefore essential.

- **Sharing of samples:** Creating "cohorts" of patient-derived disease models for longitudinal analysis requires access to patients from whom cell samples are available and which can be linked to functional medical imaging, genetic and clinical data. The availability of relevant human biological material is often a bottleneck for both academia and industry, especially for longitudinal analyses and the development of advanced personalised disease models. To accelerate research, biotech and pharma companies as well as academic researchers absolutely need high quality human samples. This requires the development of unified, controlled access systems.

- **Large scale cohorts and clinical trials:** Longitudinal studies of disease onset and progression will lead to improved understanding of disease mechanisms. This will enable rational stratification of patients on the basis of biomarkers empirically linked to pathogenic mechanisms, the systematic identification of key molecules/pathways for drug targeting and/or repurposing and early disease detection and better prediction of disease prognosis. Together, these insights are poised to transform the design of clinical trials. Academia and industry should collaborate to bridge clinical with molecular/cellular endpoints and therapeutic approaches on the basis of validated patient-specific disease mechanisms.

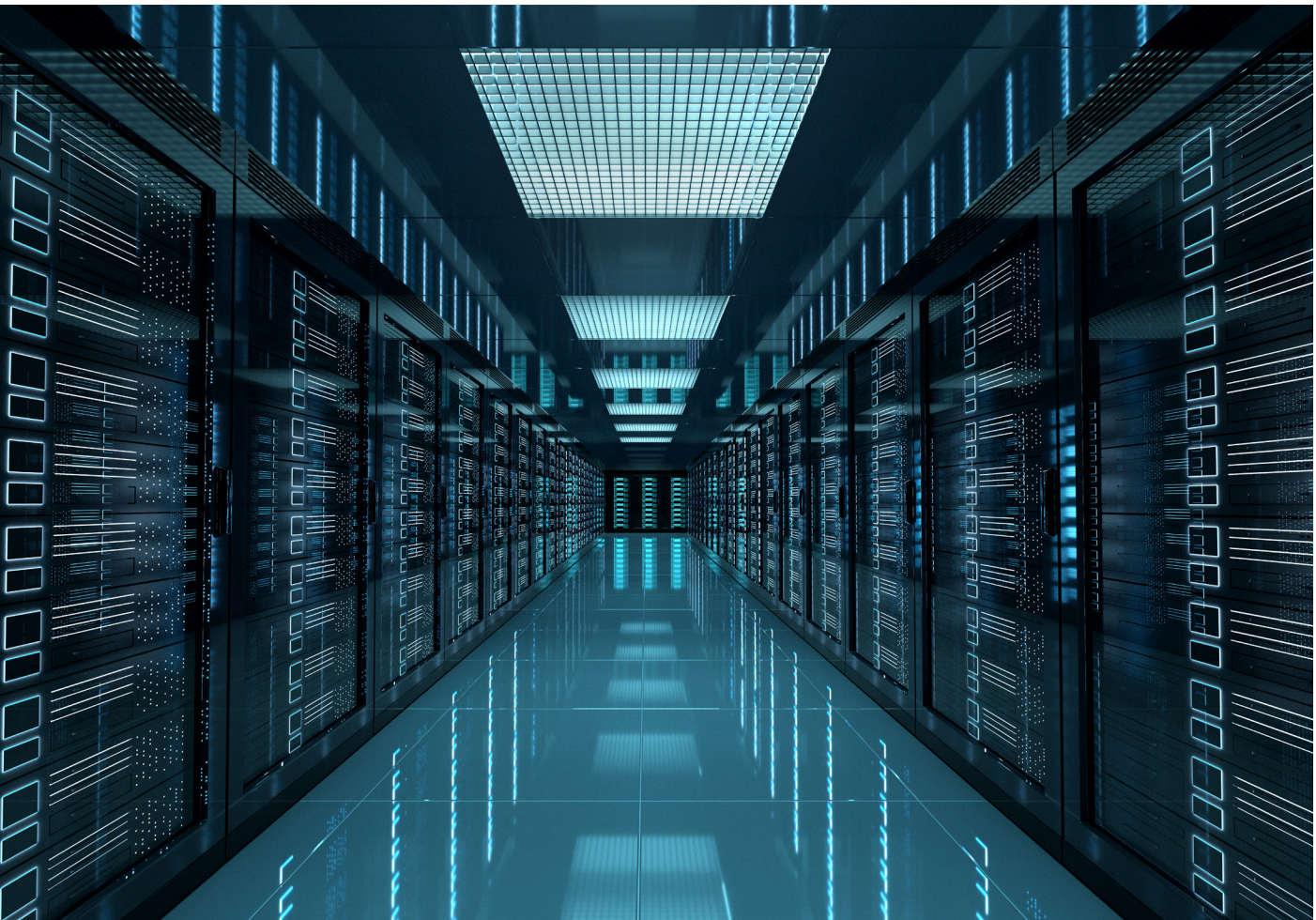
- **Raw data repositories:** Joint industry/academia efforts should also focus on building repositories of data including raw data (single-cell, imaging), pre-clinical model treatment and/or clinical treatment outcome data. These data should, as much as possible, aim to comply with European Open Science and Innovation standards and the Findable, Accessible, Interoperable and Reproducible (FAIR) data principles. Data access needs to support quality control and data queries in line with agreed intellectual property rights. Beyond project-based collaborations, partners need to plan the sustainability of controlled FAIR data access and wherever patient data is generated or used, it should be integrated across studies in a legally and ethically compliant way, including requirements of the European General Data Protection Regulation (GDPR).

- **Secure data management:** Highly sensitive personalised data (e.g. genetic information, clinical data and medical imaging data) are collected and stored locally at hospitals and institutes, but derivatives of these data need to be made available in a secure and GDPR compliant way to all relevant stakeholders. Only a consolidation of data from multiple sites can leverage the power of subsequent AI-based analytics and therefore a secure data management concept is most important for the success of LifeTime. It needs to address, amongst others, different levels of data sensitivity and user-permissions (e.g. for clinicians, researchers and industrial partners), FAIR data, and an intuitive access platform.

Here, a European decision on how to handle clinical and omics data will be critical. Several companies in Europe as well as some EU-initiatives are working on solutions for this complex problem and should be supported as much as possible to scale their solutions to international level. The development of secure data management for LifeTime has the potential to be a cornerstone of European efforts towards ethical AI and a prime example for successful AI applications of clinical data worldwide.

- **Computing infrastructure:** Public-private partnerships should foster pioneering technologies (e.g. faster processing, in memory computation, AI-specialised hardware, etc.) to shape the next generation of the European medical and biodata compute infrastructure. The scale of the data that will be generated by the programmes proposed by LifeTime, the cross-disciplinary and international organisation combined with the ambition to pioneer novel analytics using AI, requires joint efforts across sectors and to connect and to build on existing European infrastructures and initiatives as much as possible (e.g. EMBL-EBI, ELIXIR, EOSC).

- **Data analytics and AI:** A priority should be to transfer algorithms, pipelines and processes from academic centred research in Europe to foster a strong private European sector in this discipline with a particular emphasis on supporting precision medicine efforts. It will also be critical for academia to develop new avenues to enable this sector to flourish and to become part of the required analytical ecosystem. To reduce the dependencies on the Big Seven in AI and to foster European efforts, developing a culture that integrates the private sector in data analytics into initiatives such as LifeTime will be key. This would also provide this sector sufficient space to develop commercially successful products, even if these seem to compete with efforts currently centred around academic institutions.



4.3 Enabling Exchange Between Industry and Academia and Across Different Industry Sectors

Identification and engagement of the most appropriate industrial and translational partners from the private and public sectors is crucial for implementing the potential strategic partnerships introduced above. Moreover, new collaboration opportunities that have not initially been anticipated will and should arise. Therefore, LifeTime recommends creating a networking brokerage platform for individuals, academic and industry organisations that share the goal of developing and integrating breakthrough technologies and applying them in the clinic for the benefit of patients. This platform would also support the technology adoption platform (section 4.1) and could include the following engagement activities:

- **Regular cross sectoral meetings:** LifeTime supporting companies would strongly welcome more opportunities for networking and knowledge exchange forums between partners from different fields that share the same vision and the continuation of the dialogue/exchange process initiated by LifeTime. To share experiences and ideas with all sectors interested in specific clinical or biological topics, we recommend the organisation of more focused cross-sectoral meetings (e.g. histopathology of cancer samples that would bring together single-cell and imaging-associated academics with diverse companies also working in the field of AI). Biohackatons where contributors work on specific challenges proposed by some participants could also be organised.

- **Exchange programmes:** In addition to meetings, LifeTime also put forward the need for programmes supporting cross sectoral exchanges of individuals not only between academia and industry but also between fields, for instance between IT and pharma. It is clear that optimising interactions requires a better understanding of different development timelines and distinct business models that exist in various industries.

- **Training/education:** Besides staff exchanges and more other activities, LifeTime Education and Training Programme (section 6) should engage industry partners. High-quality training courses and materials provided by Europe's leading experts in technology, innovation and entrepreneurship will be both developed with and accessible to industry partners.

- **Open innovation community:** Clear guidelines for an open innovation framework should enable the open sharing of well defined non-competitive results and data to foster new ideas and accelerate research progress.

- **Communication forum:** LifeTime communication channels that are tailored to industry needs will enable smooth information exchange between all members of the open innovation community (vacancies, latest technology offers, funding calls for academia/industry collaboration, etc.).

- **Public funding consulting:** Industry sectors that are not or are less involved in IMI so far welcome new opportunities for public/private collaboration funded by the EU and other research funding organisations. However, access to such programmes is often a challenge for many companies lacking experience and resources. To foster public/private collaborations and support their funding competitiveness, dedicated support staff could facilitate this process: help identify partners, prepare grant applications, etc.

- **Interaction with regulators:** LifeTime expects market entry of new products and services in precision medicine to follow a more complex path compared to previous procedures. To bring such products and services faster to market, we will promote interactions between regulators and academic partners (e.g. regarding medical device regulation, which will affect many technology developers) as an integral part of the application for market approval in a regulated market. LifeTime recommends the development of a framework for such fruitful collaborations between academia and industry when it comes to interactions with regulators.

4.4 Stimulating the Creation of Successful and Sustainable Spin-offs

LifeTime is committed to stimulate the creation of successful and sustainable spin-offs based on technologies invented/developed by the initiative's partners and beyond. In addition, LifeTime will continue to engage with investors such as venture capital funds as well as private equity specialised in the healthcare and life science sector to enable them to participate in the various industry engagement platforms. It proposes the following activities:

- **Nurturing entrepreneurial culture:** The diverse activities of the LifeTime Education and Training Programme (section 6) as well as of the other industry engagement platforms will contribute to develop an entrepreneurial culture. Academic partners will benefit from a supportive environment with multiple opportunities to obtain real-life business world experience.

- **Pre-seed/pre-incubation fund:** Given the high need to support innovation projects across high-risk fields, LifeTime recommends to engage with different funders, including venture capital funds, business angels, private equity, corporate ventures and public sources such as the European Investment Bank (EIB) to create a specialised LifeTime innovation fund. This would fund few, well-chosen innovation projects per year especially fostering technology bundling and enabling proof of concept studies before the founding of a new company.

- **Support for founders:** LifeTime will assist entrepreneurs with evaluating and developing the company concept and fundraising. The LifeTime industry engagement platforms will help founding projects to find appropriate management and infrastructure, and support the early phases after the company creation.

4.5 Reciprocal Expert Advising

From the start, LifeTime has interacted with and sought feedback and advice from key stakeholders in various industry sectors. Reciprocally, LifeTime research and clinical experts can inform and advise industry partners about the latest technology developments in their field, key challenges and most promising applications. LifeTime has an opportunity to function at the intersection of academic and industrial research, mediate closer interactions between the two sectors while advising in both directions:

- **Industry advisory board:** Collecting strategic feedback and understanding the specific needs as well as challenges of various industry sectors is key to ensure that LifeTime strategy and operations are relevant for industry partners. We recommend that the Industry Advisory Board LifeTime has started to establish should regularly issue recommendations during LifeTime's further development (section 7.3). It includes experts from single-cell and imaging technology providers, the biotech, diagnostics and pharmaceutical industry, as well as the IT and data science sector.

- **LifeTime expertise:** LifeTime experts can contribute to defining strategic Science & Technology agendas and help to identify critical priorities for the development and applications of breakthrough technologies (e.g. EU Health PPP planning and future topics definition).

Beyond this expert advising platform, LifeTime stakeholders from industry and academia can form an advocacy group acting as a strong body able to influence healthcare transformation in the next years by shaping national and international R&I policies.

4.6 Creating a Globally Competitive Innovation Framework for Companies in Europe

The successor of the Innovative Medicine Initiative, the next EU public private partnership - or EU Health PPP - could offer a framework for some joint projects between industry and academia (section 7.4) The increased involvement of other health industry sectors in the cross-sectoral private consortium compared to IMI is a very good starting point. Furthermore, the disease interception objective of LifeTime aligns closely with the EU health PPP strategic aims. Both initiatives have identified the better understanding of disease mechanisms as a major societal challenge. As of now, the new EU health PPP seems to be less focused on more fundamental research and early development/integration which is vital for emerging technologies as proposed by LifeTime. However, numerous representatives from the private sector have expressed interest in participating in these activities. It is also widely acknowledged that early industrial involvement is critical for a successful transition from the laboratory to the market and early development of industry standards with international partners (section 1.5).

Therefore, we are facing an unparalleled opportunity to expand the ecosystem of players related to the scientific objectives of LifeTime in particular with participation of small and medium-sized (bio)tech companies and new start-ups. To include the European computational, data, and software industry better is another important aspect. The open source policy in the academic biomedical field can often generate a difficult environment for commercial products to flourish. Yet, data analysis is one of the most promising growth areas for the coming decades, which will require a strong European private sector with sufficient start-ups, small and medium-size enterprises (SMEs) to provide data analytics and AI to users in the biomedical field.

Legal aspects and in particular IPR regulations should be adapted to the operational and business models as well as research and development timelines of companies not involved in IMI so far in order to define the best co-development pathways. For example, data science and analytics companies still experience the biomedical sector - in comparison to other sectors - as a high-risk area, which is a clear barrier for engagement of many IT and data science companies in Europe, particularly for start-ups and SMEs. Yet, this area might be one of the most promising growth markets in the 21st century for Europe. Therefore, to develop a European precision medicine sector, the ultimate goal should be to link the development cycle of pharma, imaging, biotech, diagnostic, digital and single-cell technology companies. To incentivise tech companies compared to pharma organisations, there could be a shift from the previously shared use of any discovery in IMI projects. An adapted legal framework established between the academic and industry partners could allow for some inventions to be protected and used for commercial applications. This should provide the opportunity for players in the industrial ecosystem to acquire IP, even on an exclusive basis, enabling companies to justify the investment needed for development and commercialisation.

Some industry sectors will also need support mechanisms to understand better the opportunities offered by public funding programmes such as the EU Health PPP. Companies from the non-medical imaging, ICT and AI industry interested in working in the health sector but not organised in European trade associations such as EFPIA or COCIR would for instance welcome dedicated staff to facilitate their engagement. This is specifically true for SMEs which do not have the resources to invest into call watch, partner search and proposal preparation (section 4.3).