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1 Definitions and Scope

1.1 What does the Spin-off culture encompass?

The concept of "culture" originates from anthropological literature where initially, the focus was primarily directed towards indigenous populations. The shift in the application of cultural concepts towards organisations and management emerged in the post-war era in the United States. Researchers started to perceive organisational culture as a function of successful performance. Subsequently, interest in organisational culture has flourished across various fields and industries, including notable contributions within the healthcare sector. This expansion has led to organisational culture becoming a complex and elusive construct, characterised by divergent interpretations. Many different scholars proposed their definitions and approached organisational culture in variety of ways.

Nonetheless, two primary schools of thought can be identified regarding organisational culture. The first school perceives culture as an inherent characteristic of an organisation, representing its essence. The second school views organisational culture as a set of variables or attributes that an organisation possesses and can actively manage. These two perspectives shape how culture is understood and approached. Recognising this distinction is crucial as it determines whether culture can be deliberately manipulated and controlled or if it emerges organically as a result of the organisation's constituents.

It is also worth recalling at this stage one of the five main Sano strategic project objectives is the issue of Entrepreneurship, focusing on fostering an entrepreneurial culture within Sano to promote translation of research and enhance the innovation potential.

At Sano, we adopt the viewpoint that organisational culture is not a fixed feature, but rather a dynamic process that can be intentionally shaped to yield positive outcomes through continuous learning and agile responses to change. In this context, we envision spin-off culture as an enrichment of the existing culture at Sano.

The concept of spin-off culture at Sano revolves around bridging the gap between the culture of academic search for knowledge and understanding, and the market-driven culture of entrepreneurial activity, not only to directly facilitate the commercialisation of scientific endeavours for economic and business growth, but also to equip Sano alumni with a set of skills valuable in their future business projects. It serves as a powerful force for innovation, unlocking new opportunities and instigating meaningful change through experimentation and creativity. By nurturing a spin-off culture, Sano aims to foster an environment conducive to entrepreneurial activities, enabling the translation of research findings into practical applications that benefit both the organisation and society at large.

Table 1. Scope of spin-off culture.

Components	Description	Examples in
Entrepreneurial Mindset	A mindset that embraces innovation, risk-taking, and a proactive approach to identifying and seizing opportunities. It involves encouraging employees to think creatively, challenge the status quo, and pursue new ideas.	Encouraging researchers to explore commercialisation opportunities for their computational medicine innovations.



Components	Description	Examples in
Knowledge Transfer and Collaboration	The exchange of knowledge, expertise, and resources among employees, teams, and external stakeholders. It involves creating an environment that fosters collaboration, encourages cross-functional teamwork, and facilitates the sharing of knowledge and ideas.	Organising regular research seminars, workshops, and collaborative projects to facilitate knowledge sharing and collaboration among researchers.
Agile Decision-making	The ability to make timely and effective decisions in a fast-paced and uncertain environment. It involves empowering employees to make autonomous decisions, promoting adaptive decision-making processes, and leveraging data and insights for informed decision-making.	Implementing agile project management approaches to enable rapid decision-making and efficient execution of computational medicine research projects.
Innovation and Research Commercialisation	The process of transforming research and innovative ideas into tangible products, services, or solutions with commercial value. It includes activities such as intellectual property protection, market analysis, product development, and strategic partnerships for successful commercialisation.	Establishing transfer procedures and commercialisation process to support researchers in patenting and market growth.
Risk Management and Resilience	The ability to identify, assess, and manage risks associated with entrepreneurial endeavours. It involves implementing risk management strategies, fostering a culture of resilience and learning from failure, and adapting to changing market conditions and challenges.	Developing a risk management framework to evaluate and mitigate potential risks in computational medicine research projects and investments.
Professional Development	A culture of continuous learning and improvement that encourages individuals and teams to acquire new knowledge and skills, embrace feedback, and actively seek opportunities for growth and development. It involves promoting a learning mindset, providing training and development programs, and recognising learning achievements.	Offering professional development programs and training opportunities to enhance the computational and research skills of the institute's researchers.
Enterprise Structure and Financing	The ability to navigate through the landscape of entity types, organisational structures, funding models, shares vs. loans, types of venture capital available.	Organising tailored trainings and seminars on the practical issues of running a business to increase awareness and promote good practices.



1.2 Spin-offs, Spin-outs and Start-ups

In the academic literature, we may come across many terms that define a spin-off. The correct and optimal definition of this concept consists of several facts. A spin-off represents an entity that was created by separating from a parent organisation in order to undertake an activity that was difficult or impossible within that organisation. Clearly, then, there is a significant role for the so-called 'parent institution', i.e. the institution from which the knowledge and people come, which significantly builds the competitive position of the new entity. It is crucial to emphasise that building and developing behavioural attitudes and an internal pro-innovation culture in spin-off organisations is an important determinant of their competitiveness.

We can distinguish between four different types of spin-offs from a Public Research Organisation (PRO; e.g. an “organisation that is either owned by the government or receives a significant share of funding from the government and that aims [...] at providing research results as a public good”) (cf. Frietsch et al., 2021, p. 4-6¹):

- **IP-based spin-off:** The main purpose of the spin-off is to commercialise IP that has been generated at the PRO based on an IP contract between the PRO and the spin-off. PROs may bring in their IP either by taking a share in the company or by selling or licensing-out the IP to the spin-off. IP-based spin-offs include both firms that are entirely owned by the PRO, joint ventures between the PRO and other firms or individuals, and firms founded by researchers from the PRO based on an IP contract with the PRO. In this document, only IP-based spin-offs involving a researcher in the founding team are considered.
- **Research-based spin-off:** A company established by researchers from the PRO with the main purpose to commercialise results of research and development (R&D) activities that were performed by the researchers at the PRO, but not involving an IP contract between the spin-off and the PRO. Such spin-offs may occur, for example, in case the R&D results cannot be protected by legal measures on which an IP contract can be based, or in case the PRO is not interested in establishing an IP contract. Due to the existence of NDA agreement between Sano and all its researchers, this type of spin-off would only be possible by direct agreement between Sano and the company founders, to lift the constraints of the NDA for a particular area of research.
- **Expertise-based spin-off:** A company established by researchers from the PRO that rests on the individual capabilities and competencies of the founders that are not the direct result of an R&D activity, but rather represent the accumulated knowledge of researchers obtained during their work at the PRO. Such knowledge may include methods, contacts and networks and other types of work experiences. Due to the existence of NDA agreement between Sano and all its researchers, this type of spin-off would only be possible by direct agreement between Sano and the company founders, to lift the constraints of the NDA for a particular area of research.
- **Other spin-off:** A company established by researchers from the PRO which is not intended to commercialise R&D results or knowledge generated or obtained during the researchers' work at the PRO. Such spin-offs are often motivated by the researchers' desire to work independently, to explore new ideas or to enter into a new phase of their personal development. While such spin-offs are not directly linked to the transfer of knowledge from the PRO, they nevertheless may contribute to an indirect knowledge transfer in case the knowledge obtained by the founder at

¹ <https://publica.fraunhofer.de/entities/publication/03b3b203-0bd8-49b7-a442-09e54ffd07b2/details>



the PRO is utilised for developing the spin-off's business activities at a later stage in the firm's development. This will particularly be the case when the spin-off follows a knowledge-based or innovation-driven business model.

A **start-up** is a newly formed business with particular momentum behind it based on perceived demand for its product or service. The intention of a start-up is to grow rapidly as a result of offering something that addresses a particular market gap. Start-ups leverage the effects of scale, automation, replication, either mass production or digital delivery, to pursue exponential growth. In this they differ from more traditional newly established companies, which invest in more long-term, linear expansion, mostly due to the inherent cost model of the offered product or service.

Therefore, not every spin-off is a start-up, especially spin-offs based on active income model (CROs, consultancy, education, and similar) are usually not considered start-ups, since it is difficult to attain exponential growth in a model which relies strongly on expert involvement in the delivery of every single instance of product/service. However, in the domain of Sano, where AI, automation and digital delivery are common, spin-offs may often want to pursue the start-up route of exponential growth to quickly attain the scale sufficient for breaking even.

2 Motivation – Why Entrepreneurial Culture is important for Sano?

2.1 Sano Mission Perspective

The mission of Sano is conducting scientific research or development works in an international scientific environment, at the highest scientific level, taking into account high ethical standards, in particular good scientific practices, and knowledge dissemination. The centre performs basic and applied research on computational methods, techniques and technologies for prevention of disease, patient diagnosis and treatment.

Sano has formulated a set of standards and values that concern and contribute to the development of entrepreneurial attitudes at Sano. The set of standards that have been implemented at Sano influence the actions taken by Sano members when conducting all their activities also taking into account the development of innovation. This set of values relates to:

Passion: Passion in what we do, engagement in Sano operations, taking responsibility, providing initiative, being happy at work.

- Passion drives Sano's urge to be pro-active and entrepreneurial.

Innovation: Boldness in articulating and pursuing novel ideas, courage to think outside the box.

- To become actionable, innovation needs the focus and commitment provided by spin-off mindset.

Integrity: Directness, openness, tolerance and respect. Scientific integrity (we do not cut corners).

- Integrity is the bottom line of successful innovation – the one that truly works and makes a demonstrable difference.

Diversity: Diversity in backgrounds, cultures and opinions of Sano employees. Promotion of women in STEM.



- Sano's diversity translates into an environment that is a melting pot of problem-solving ideas.

Sano, as a non-profit NGO engaged in scientific research and development in the field of computational methods for personalised patient diagnosis and treatment, can benefit from building a spin-off culture and embracing an entrepreneurial mindset for several reasons aligned with its values:

- **Accelerating Impactful Innovation:** By fostering a spin-off culture and entrepreneurial mindset, Sano can accelerate the translation of its scientific research into practical solutions. The entrepreneurial approach encourages researchers to identify commercialisation opportunities, explore novel ideas, and take calculated risks to bring innovative computational methods and technologies to market more efficiently. This can lead to faster development and implementation of solutions that have a tangible impact on patient care and personalised medicine.
- **Increasing Knowledge Dissemination:** Embracing an entrepreneurial mindset enables Sano to disseminate its research findings and technological advancements more effectively. By commercialising their innovations, Sano can reach a wider audience beyond the scientific community, making the knowledge and expertise developed within the institute accessible to healthcare providers, industry partners, and the general public. This knowledge transfer and broader dissemination contribute to the mission of Sano to impact society positively.
- **Fostering Collaboration and Networks:** Building a spin-off culture encourages collaboration and the formation of networks within Sano and with external stakeholders. Entrepreneurial activities often involve interdisciplinary collaborations, industry partnerships, and interactions with investors and other entrepreneurs. These connections can provide valuable opportunities for Sano researchers to exchange ideas, access diverse expertise, and form relationships that amplify the impact of their research. Such networks can also help Sano attract funding, secure partnerships, and stay at the forefront of advancements in computational medicine.
- **Attracting and Retaining Top Talent:** Establishing a spin-off culture and promoting it as a part of branding activities can make Sano an attractive workplace for top talent in the field of computational medicine. Researchers, scientists, and professionals with an entrepreneurial spirit may be drawn to Sano's dynamic environment, where they can apply their research expertise to develop innovative solutions with real-world impact. The opportunity to be involved in spin-off ventures or entrepreneurial activities can provide researchers with unique career development opportunities, job satisfaction, and a sense of ownership over their work.
- **Enhancing Sustainability and Autonomy:** Developing spin-off ventures can provide Sano with a sustainable revenue stream to support its research activities. By commercialising intellectual property or forming strategic partnerships with industry stakeholders, Sano can generate additional financial resources, reducing its reliance on traditional funding sources. This financial independence can grant Sano greater flexibility in setting research priorities, attracting talented researchers, and maintaining its scientific excellence in the long term.
- **Driving Mission Alignment:** By building a spin-off culture and teaching entrepreneurial mindset, Sano can align its research objectives more closely with its mission and values. The entrepreneurial approach emphasises proactive problem-solving, bold ideas, and taking responsibility — qualities that resonate with Sano's values of passion, innovation, integrity, and diversity. This alignment ensures that the entrepreneurial activities of Sano researchers are in line with the foundation's overarching goal of conducting high-quality research that contributes to personalised patient care and advances the field of computational medicine.



- **Product Development:** Fostering a spin-off culture will also highlight the relevance of product development efforts as perfectly aligned with Sano's mission, enabling the organisation to refine research findings into tangible products and services that can be deployed in real-world healthcare settings, thus advancing the accessibility and effectiveness of personalised patient diagnosis and treatment.

By embracing a spin-off culture and entrepreneurial mindset, Sano can leverage its research expertise, scientific integrity, and passion for making a difference to drive innovation, increase societal impact, foster collaboration, and create a sustainable ecosystem that supports its mission in computational medicine. Building and sustaining the entrepreneurial culture, both internally and externally, is part of Sano's **Deliverable 2.3: Strategic Plan**, where it is addressed in sections 3.4: *Support for entrepreneurial activities* and 4.8: *Create entrepreneurial activities*. Spin-off ventures are also included in Sano's phased development approach, as described in **Deliverable 6.1: Business Development Plan**. Entrepreneurship-driven commercialisation is part of the Consolidate - Sustain phases (see section 1.1.7: *Phased Development*). This is also an issue important to Sano's fundraising strategy, as detailed in **Deliverable 2.4: Fundraising Plan**, where fostering entrepreneurial spirit, resulting in the creation of spin-offs, is ultimately to bring additional tangible and intangible benefits to Sano in the long term.

2.2 Sano Researcher Perspective

Sano is dedicated to attracting and retaining top talent in the area of computational medicine, creating an environment that fosters translation of research expertise into innovative solutions with real-world impact. Key motivations of Sano researchers to embrace the entrepreneurial mindset are the following:

- **Fostering Innovation:** Embracing an entrepreneurial mindset encourages researchers to think creatively, take risks, and explore unconventional approaches. It fosters an environment where researchers can challenge existing paradigms and explore novel ideas that may have significant implications for the field of computational medicine. Through entrepreneurship, researchers can push the boundaries of their research and catalyse innovation in healthcare.
- **Creating Tangible Impact:** Researchers in computational medicine are driven by a desire to make a difference in healthcare. By adopting an entrepreneurial mindset, they can directly contribute to the development and implementation of solutions that address critical medical challenges. Building a startup or collaborating with existing companies allows researchers to create tangible products, tools, or services that have the potential to improve patient outcomes, enhance diagnostic accuracy, streamline healthcare processes, or enable personalised medicine.
- **Collaboration and Networks:** Entrepreneurial activities often involve collaboration with multidisciplinary teams and building networks with industry professionals, investors, clinicians, and regulatory experts. Engaging with the entrepreneurial ecosystem allows computational medicine researchers to broaden their networks, tap into diverse expertise, and create partnerships that can accelerate the development and adoption of their research innovations. This network can also provide valuable job opportunities for students who are interested in pursuing careers in computational medicine or related fields; thereby they may gain access to internships, research positions, or employment opportunities in startup companies, healthcare organisations, or research institutions.



- **Customer-oriented viewpoint:** Direct interactions between researchers and potential 'customers,' including clinicians and industry partners, allow researchers to gain first-hand insights into the needs, challenges, and practical requirements of the medical environment. By actively seeking feedback and understanding the perspectives of end-users and industry partners, researchers can tailor their innovations to address specific medical needs and industry demands effectively. This customer-centric approach not only enhances the commercialisation potential of the research, but also fosters meaningful collaborations that lead to the development of impactful solutions for healthcare and personalised medicine.
- **Accessing Resources:** Building a startup or engaging with entrepreneurial endeavours can provide researchers with access to additional resources. This includes funding opportunities, business expertise, mentorship, and collaborations with industry partners. Such resources can help researchers bring their computational medicine solutions to market more effectively, overcome barriers to implementation, and scale their impact.
- **Autonomy and Influence:** Embracing entrepreneurship empowers researchers to take ownership of their work and pursue their vision independently. By starting their own ventures or actively participating in entrepreneurial activities, researchers can shape the direction of their projects, choose the problems they wish to solve, and maintain greater control over the development and implementation of their computational medicine solutions.
- **Achieving Recognition and Financial Rewards:** Embracing entrepreneurship can provide researchers with opportunities for recognition and financial rewards. Successfully developing and commercialising computational medicine solutions can lead to accolades, awards, and visibility within the scientific and entrepreneurial communities. Moreover, if the venture becomes successful, researchers may also benefit from financial gains through equity, licensing agreements, or revenue generated by their spin-off company.
- **Attracting Research Sponsors:** By actively participating in entrepreneurial endeavours, researchers can attract potential research sponsors. Companies, organisations, or government agencies interested in advancing computational medicine may be more inclined to provide funding or support to researchers who have a track record of successfully translating their research into commercially viable solutions. Entrepreneurship can act as a catalyst for attracting sponsors and collaborators who share a common interest in advancing the field.

Importantly, embracing the entrepreneurial mindset does not mean researchers have to abandon their academic pursuits. Sano will promote the idea to maintain a balance between entrepreneurial endeavours and the career in research, leveraging entrepreneurial experiences of Sano researchers to enhance their scientific efforts, attract funding, and foster collaborations with industry and academia.

2.3 Sano Advanced Partners Perspective

Klaster LifeScience Kraków (KLSK), which by definition aims to build bridges between science and business, recognises that for better results Sano should include an entrepreneurial approach in addition to a strictly scientific approach at every stage of its development. Giving attention not only to scientific part of Sano development but also to the practical application of its results will allow Sano to better realise its potential and increase its impact on the outside world.

Building a spin-off culture with the help of KLSK is evident in the various sub-activities:



- **Funding:** KLSK facilitates access to funding for entrepreneurs who intend to establish their companies in Małopolska through active cooperation with incubators, local governments and fundraising partners. This makes it possible to provide Sano with up-to-date information on various sources of funding, such as grants, venture capital funds and innovation support programmes.
- **Training:** KLSK organises projects and training programmes to enhance entrepreneurial skills from the topics of business modelling, effective business-science collaboration, marketing strategies, intellectual property rights management, regulatory compliance and financial management.
- **Motivation:** KLSK organises events to inspire and motivate each other to share challenges, success stories, panel discussions and mentoring programmes. By fostering a sense of community and motivation in the industry, KLSK aims to motivate others to achieve and overcome obstacles.
- **Focus:** KLSK focuses on the development of the LifeScience field in Małopolska and Poland, concentrating on effective integration, supporting entrepreneurship and innovation in the area of life science and creating conditions for effective commercialisation of R&D results. By focusing on these specific industries, KLSK is able to leverage expertise and resources to create a targeted and impactful support system for scientists and entrepreneurs in the region.
- **Methods:** KLSK employs a variety of tools that are a key part of supporting the building of a spin-off culture in Sano. These methods include access to networking through a digital collaboration platform, access to the KLSK resources and experts, access to mentoring and coaching programs within EIT Health Hub Poland, access to training and events. In line with the KLSK motto 'because innovation comes through collaboration', it should be emphasised that the implementation of entrepreneurial mindset fosters the establishment of external collaborations with the private sector, government institutions, other scientific organisations and the local community. Such collaborations contribute to the exchange of knowledge, resources, intellectual capital and competencies, which can lead to strategic partnerships, research and commercial projects.
- **Acceleration:** KLSK, through active collaboration with entities inside the cluster, offers access to accelerator programs (subject to admission through competitive calls) designed to accelerate the growth and success of organisations. These programs provide intensive mentoring, guidance and support to entrepreneurs, helping them refine business models, develop market strategies, secure financing and navigate regulatory frameworks. In addition to this, the cluster provides access to a broad network of industry experts, investors and experienced entrepreneurs, thereby allowing networking with the right people in Sano should the need be defined.

KLSK's direct access to Polish clinics, industries and investment capital enables it to harness its resources, develop competences, promote collaboration and support commercialisation processes, for Sano. To support the Centre, KLSK engages in a number of activities that aim to create a favourable business ecosystem for spin-off companies in the scientific and medical sectors.

The **University of Sheffield (USFD)** has developed a significant presence in *in silico* medical research, now spanning many academic disciplines and disease areas, and it considers its purpose in Computational Medicine predominantly to be the quest to improve patient care through the use of computational models, tools and workflows. One exploitation mechanism supported by USFD is the commercial translation of a technology developed in research, via the creation of a spin-off company, to nurture the technology's development through to a marketable product.



Awareness of the journey of a technology from research idea to marketable product helps to shape the research questions, directions, and processes to be more aligned with the production of technologies that could have a realistic impact on healthcare sector, through several mechanisms:

- Being more aware of the end-users' needs, ensuring that the technologies are addressing real-world problems in a manner that can be practically implemented.
- Identifying and appropriately protecting the Intellectual Property underlying the technology.
- Understanding the regulatory requirements and processes the technology must comply with to reach the market.
- De-risking the technology by instigating market assessment and analysis at an early stage in the technologies' development.
- Putting the supporting documentation and quality systems in place to meet the regulatory requirements, adding value to the intellectual property.

Awareness of the stages of a technology's journey to the marketplace can contribute to the readiness of that technology, its potential value and its likelihood of becoming successful.

For USFD, a secondary motivation is the possibility of generating a significant income stream, allowing the institution to reinvest in further technical developments, so enabling additional innovations to reach the market.

Along these lines, USFD has expertise in its technology transfer offices (TTO), including the Healthcare Gateway² and access to external expertise through the Royal Society Entrepreneur in Residence and Regulatory Expert in Residence, details of which have been made available to Sano to promote good practice. Independently of the EC-supported Sano project, USFD cooperates with Sano's research teams, and is open to the possibility of spin-offs based on joint USFD/Sano IP, where there would be joint interest and benefit. USFD would also derive benefit from the experience of supporting a Sano spin-off.

The **Fraunhofer-Gesellschaft (FhG)** is the leading organisation for applied research in Europe. Research for practice that generates direct economic and social impact is its central mission. Its contract partners and clients are industrial and service companies as well as the public sector. At the same time, Fraunhofer plays a mediating role between basic and applied research and is one of the most important players for knowledge and technology transfer in Germany. Along with the continuous development of R&D capacity and scientific excellence, Fraunhofer Gesellschaft, as a key element of the innovation system that aims at applied research and development and the transfer of technology into practice, acts highly market and user oriented. This involves:

- availability and continuous development of significant entrepreneurial and business-related skills of its scientists,
- understanding of the market mechanisms and users' needs and requirements as well as
- active engagement with industrial partners and potential users.

This model has proven highly effective in terms of generating and transferring new technologies and is a central success factor for the FhG as innovation leader in Germany and beyond. As such, it therefore represents a highly relevant role model for Sano. The success story of the FhG highlights

² <https://www.sheffield.ac.uk/medicine-dentistry-health/facilities/healthcare-gateway>



that rather than exclusively focusing on basic science and academic R&D, an active development of the skill set and capabilities is necessary to ensure that the R&D is responsive to users' needs and problems and market mechanisms are fully understood.

Sano as provider of largely new to the market and user-disruptive technologies follows to a large extent a technology push strategy, which requires a careful market and technology transfer approach. This demands different competencies, methods and information. "Technology push" projects possess a very high market uncertainty that results from the novelty of technologies, their new-to-the-market and new-to-the-user nature. For technology providers, such as Sano, this leads to the necessity to develop and implement mechanisms and methods for the effective reduction of uncertainty. Only this way can they be sure that in place of "happy engineering", a technology-development is implemented that is orientated towards potential application fields and their market needs. A significant part of these core competencies lies in the process know-how, and, in this context, how project management can be effectively organised. The project management of CM technology-driven development projects must be orientated around the application context and market-related characteristics of the technology under development.

Sano can hugely benefit from the support from the project partner Fraunhofer ISI in multiple ways:

- Sharing of expertise and evidence on successful innovation processes and practices in the field of medical technology through the Fraunhofer ISI team. Fraunhofer ISI is one of leading innovation research institutions in Europe with over 50 years' experience in application-oriented R&D.
- Providing guidance on user-oriented research as well as the management of R&D projects to improve the efficiency of R&D processes, reduce risks and uncertainties and increase chances for product success. This also involves sharing of the expertise on the business oriented and the overall innovation friendly culture.
- Providing methodologies for the development of sustainable R&D and business strategy.
- Sharing its knowledge and expertise on how to ensure and improve acceptance and trust in CM technology as one of main aspects for successful technology uptake and dissemination.
- Provide support in how to achieve and increase social and economic impacts and provide technologies with higher social value.
- Joint R&D with Fraunhofer institutes in technology fields relevant for Sano to support learning processes and promote knowledge transfer. Highly significant in this context is sharing of practical knowledge on successful technology transfer and translation into practice as well as cooperation with users. An example of such potential cooperation partners is the Fraunhofer institute for digital medicine MEVIS.³

2.4 Society and Sano Environment Perspective

The essential function of building an adequate spin-off culture in an organisation like Sano is to understand how to provide an effective and sustainable pathway to commercialise research outcomes and translate them into real-world applications. To generate socio-economic impact and to be a meaningful player of the innovation system, Sano has to work towards the transfer of its research and development through different channels. The impact from technologies that Sano develops can

³ <https://www.mevis.fraunhofer.de/>



primarily be achieved, when it is translated into industrial and clinical practice for an efficient utilisation by and for relevant stakeholders. Another route is more direct to the society, by providing knowledge, prevention-related advice, lifestyle and behavioural guidelines. One major route for this is the research utilisation and commercialisation through patents, licensing and spin off firms. Along with the development of R&D capacity and scientific excellence, to focus specifically on the applied R&D and the transfer of technology into practice is therefore of importance for Sano. Expected impacts from successful technology transfer and business activities can be achieved mainly through the Technology Transfer Pathway in the economic and market domains through the provision of technologies, services and other business and user related competencies. The broad technology uptake and use would also lead to considerable societal benefits through the route of the impact pathways, such as Advancing Personalised Medicine for Better Health, Contributing to the Digital Transformation of Healthcare, and Improving Translation between Healthcare and Research. When successfully transferred into practice, Sano's technologies can generate broad socio-economic impact. First of all, they may create new business opportunities, stimulate growth of innovative businesses and contribute to the overall innovative capacities of the economy. This can lead to economic benefits such as improved productivity, promotion of innovation driven growth and competitive power, and incentives for new investments. When broadly implemented and used, effective Computational Medicine technologies can have important social impact helping improve clinical outcome, enabling better and more timely diagnosis, targeted and optimised treatment and help prevent illness. Not less relevant is the bench-to-bedside translation of proven research outputs and a better recognition of patient and clinical needs by the research community, thereby leading to more suitable solutions becoming available for healthcare faster. The technologies provided can help improve efficiency of medical personnel and clinical workflows. Sano and its spin-offs' activities can considerably contribute to an increased acceptance of Computational Medicine benefits by patients and thereby a potential positive attitude towards sharing their data for research and trusting Computational Medicine based solutions. Ultimately, this leads to the accelerated development of advanced data driven innovations and solutions becoming available for healthcare faster (and cheaper) and meeting patient and clinical needs better than the existing solutions are able to do it.

3 Supporting Entrepreneurial Mindset at Sano

Entrepreneurial Mindset is being taught at Sano by continuously nurturing individual, positive attitudes towards the commercialisation of research results in order to promote the translation of research and increase innovation potential. In the latter case, Sano aims to position itself as an innovative and business-oriented organisation that is keen to support entrepreneurs with knowledge-based solutions. These objectives are achieved as a result of the various measures taken at Sano as presented in this section.

First and foremost, it should be emphasised that building an entrepreneurial mindset at Sano is a process that requires commitment from both the researchers and employers and the institution itself. This involves a specific set of attitudes, behaviours and characteristics that are associated with an understanding of the entrepreneurial spirit. It is a way of thinking and approaching situations that enables individuals to identify opportunities, take calculated risks and create value.



Yet, in today's dynamic and competitive business environment, developing an internal entrepreneurial mindset in research organisations such as Sano helps with achieving success and maintaining a competitive advantage in the area of translation. However, there are many barriers that have to be faced in the process of developing such attitudes:

1. Traditional Research Paradigm - which should be understood as a lack or shortage of commercial skills due to the very nature of the organisation which is directed to prioritise scientific discovery, knowledge generation, and academic excellence over entrepreneurial pursuits. Academics and researchers have limited knowledge of the methods and tools that can be used to commercialise research results. The indicated barrier is directly related to the lack of required competences such as lack of managerial skills, lack of knowledge of available business models, lack of marketing skills to present solutions and evaluate the adequacy of the offer, ignorance of the principles of intellectual rights protection;
2. Low level of cooperation between research and business (industry) - without close cooperation between research and business (industry), there is a risk that research projects may focus on topics or approaches that have limited relevance to existing end-user needs. This can result in a gap between research outcomes and the market demands, making it challenging to develop viable academic spin-offs that address real-world problems. This approach is linked in particular to the concern of insufficient sources of information regarding opportunities for commercial activity, but most importantly this may simply arise from the fact that curiosity-driven science does not concern itself with the immediate applicability of the acquired knowledge;
3. Financial barriers related to lack of seed capital and high investment costs which are related to perceived (from the potential investor's point of view) lack of profitability, which may be caused by many reasons: actual inadequacy of the offering to the current market situation, difficulty in properly communicating otherwise suitable business case to the investors (see the skillset discussion above), pitched solution being too early in development, and fierce competition for the limited funding available for entrepreneurial activities;
4. Misunderstanding of legal principles related to the safeguarding and control of intellectual property. Research institutions and individual scientists may have inadequate or limited support or expertise in managing intellectual property, particularly in terms of what needs to be kept confidential and what the principles of ownership are – which is especially true for intellectual property based on digital-only assets;
5. Running spin-off and commercial activities can involve bureaucratic procedures – often tied to the nature of money acquired for the seed funding – which can affect flexibility as well as slow down decision-making. Scientists may not understand this which ultimately may result in psychological barriers such as low motivation, risk aversion, low self-esteem.

Introducing an entrepreneurial mindset from the outset will allow Sano employees to overcome these challenges that come with developing academic spin-offs.

3.1 Trainings and Courses

Securing appropriate opportunities for personnel development is one of the core objectives of Sano, and the idea behind the concept of the development of a Centre of Excellence. What is more,



developing the basis for encouraging professional development among staff is an essential element of an internal training policy involving Sano's support for entrepreneurship. The actions taken in this area are intended to respond to the challenge of low entrepreneurial skills among researchers. In essence, a key role in this process on behalf of Sano is the collaboration of the Sano Human Talent Manager with Advanced Partners in terms of formulating training programmes, mentoring and support, access to resources that enhance business awareness, problem-solving skills and strategic thinking, can encourage entrepreneurial thinking in the organisation. This approach is included in Sano's policy towards human talent, as outlined in **Deliverable 4.4: Review of Human Talent Management Policies** (sections 5: *Training* and 9.1: *Alumni management*).

Sano has only recently approached the stage of its development where we turn more of our attention to productisation, and commercialisation of technology. The introduction of "startup culture" and teaching researchers the "entrepreneurial mindset" are two major objectives that we aim to achieve in the next stage of Sano development. Up to this point we focused the newly hired Sano researchers on starting their research projects, training research-related skills and tools, and putting their minds to the research questions. As Sano currently approaches a stage where our ongoing research project portfolio is saturated (in terms of personnel and operational capacity), our attention will move towards training the involved researchers with the "entrepreneurial mindset".

It is important to understand that proposing these kind of growth opportunities for Sano researchers does not only motivate them to create Sano spin-off companies – which are among the likely vehicles to bring innovation to market – but it also teaches them efficient ways of communication with entrepreneurs, industry and private funds. These researchers, who want to become successful in the innovative market of medical technologies, need to learn the "languages" of these other actors of the value chain.

To this end Sano has prepared and updated two major documents, which are milestones for developing such skills of researchers: the Training Policy and the 2023 Training Plan.

The Training Policy was prepared as a result of observation of the current situation, identification of barriers with the intention of presenting corrective measures for the Training Policy internal regulations. The condition for achieving the formed objectives of the Training Policy is its effective implementation, and this requires adapting the proposed solutions and tools to the actual needs of an organisation like Sano. An important issue is also the introduction of new regulations on the Training Policy, in particular, the planning of training, the rules of participation in training and the possibility of using training budgets. It is important to break down the different types of training, while also taking into account the different sources of funding.

Earlier, most of the training conducted was of an ad hoc nature, reported during the fiscal year in connection with the training needs at that time in a team. The implementation of a broadly defined Training Policy will transform this model into consistent and continuous development of training plans adequate to the identified training needs, in accordance with clearly outlined principles. This will require commitment from all Sano employees, especially Team Leaders and the Human Talent Team.

The Training Policy is Sano's first comprehensive approach to the entire framework of teaching Sano personnel in professional and soft skills – entrepreneurial skills included. The policy provides a process of consulting, proposing, accepting, implementing and revising annual the Training Plans of Sano. It



also provides several formal ways of accessing training opportunities to Sano researchers and support staff members. Using this process, the 2023 Training Plan was devised.

Training Plan 2023 includes the following learning opportunities for Sano researchers regarding skills necessary to collaborate with entrepreneurs:

Table 2 List of learning opportunities for Sano researchers

Held by Sano Partners
<ul style="list-style-type: none"> • Business Model Thinking (KLSK) • Innovation Training Cycle (Fraunhofer)
Held by external training service providers
<ul style="list-style-type: none"> • From scientist to businessman - business basics, startup, spin-off, spin-out • Management of research and scientific projects (PRINCE2®) • Business ethics • Communication and dissemination of scientific research results • Open access and FAIR principles in the presentation of scientific research results • Management of scientific data • Copyright in scientific practice • Networking and establishing international scientific cooperation • Efficient collaboration

Trainings and Courses – plan for the future:

- Implement the 2023 Training Plan (ongoing): organise workshops, seminars and training sessions
Monitoring:
 - Internal: create ongoing surveys of training needs and on-going updates to the training plan. (Specific training necessary for the scope of activities required by the role);
 - External: continue to monitor training opportunities for its employees and collect information on completed courses from its employees, create and maintain an internal database of high quality trainings, trainers, courses;
 - Individual: assess every new employee for training needs., create a schedule for three years, review annually;
- Based on the knowledge accumulated from the monitoring and the implementation of the 2023, and evolving needs, proceed with preparation and implementation of 2024 and future Training Plans;
- Periodically update the Training Policy in case adjustments are considered beneficial (e.g. based on experiences acquired from implementation of subsequent Training Plans);
- Realise individual trainings.

3.2 Informal Mentoring

Fostering an entrepreneurial culture within Sano requires a supportive and encouraging environment. One such measure is the introduction of what amounts to individualised coaching and mentoring. Thanks to Kraków's Sano Partners having a well-established connection with Incubators, Hubs and



VCs, the choice of experts who can act as mentors is wide. The key, however, is to define the activities that will fall under the term informal mentoring.

Mentoring program: Sano aims to establish a mentorship program where experienced entrepreneurs, industry experts, or successful researchers can provide guidance and support to potential entrepreneurs. This program will involve one-on-one mentoring sessions, group workshops, or informal networking events to facilitate knowledge sharing, skill development, and fostering an entrepreneurial mindset.

Entrepreneur-in-Residence (EIR) program: Sano already collaborates with a successful entrepreneur in the area of computational medicine and plans to transform this collaboration into a role of Entrepreneur-in-Residence at Sano. The EIR will be available to provide valuable insights, mentorship, and practical advice to researchers and potential entrepreneurs within Sano. EIR will also host workshops and engage in one-on-one consultations to guide researchers in the process of spinning off their ideas and building successful ventures.

Pitching competitions: Sano will organise regular pitching competitions to encourage researchers to present their ideas, innovations, and entrepreneurial projects. These events will provide a platform for researchers to refine their pitching skills, gain exposure to the startup ecosystem, receive feedback from judges, investors and fellow entrepreneurs, potentially attracting partners or collaborators.

Advisory panel and expert consultations: Sano will create an external advisory panel consisting of investors, entrepreneurs, industry experts, and professionals from the startup scene. Researchers with entrepreneurial aspirations will have the opportunity to consult with this panel for guidance on business strategy, market viability, fundraising, and other aspects of building a successful venture. The advisory panel will provide insights and recommendations based on their expertise and experience.

3.3 Acceleration and Incubation

In the context of Sano and the development of its Spin-off culture, the acceleration procedure is understood as the scaling and development of a spin-off company in order to develop competitive advantage and profit-generating opportunities, while incubation focuses on nurturing and developing the spin-off at an early stage, partially within the parent organisation (Sano). The efforts to accelerate the innovation development in selected projects and incubate them into viable business opportunities will **start at Sano** and gradually **involve external partners** and institutions.

Cross-functional project teams: Within Sano, cross-functional project teams are assembled to support entrepreneurial initiatives. These teams comprise individuals with diverse skill sets, including technology experts, management professionals, designers, marketing specialists, and intellectual property experts – all seconded from internal resources of Sano. The teams complement the potential entrepreneurs (Sano researchers) to provide assistance in various areas, such as technology development, product design, market research, and IP strategy.

Prototyping and proof-of-concept support: Sano will offer resources and support for prototyping and proof-of-concept activities to reduce the risks of projects selected for acceleration. If necessary, this will include internal funding for early-stage development. Sano will also provide guidance on



developing minimum viable products (MVPs) and assist the teams in conducting proof-of-concept analyses to validate the feasibility and potential impact of their entrepreneurial projects.

Investment readiness and pitch deck preparation: Sano will provide training and resources to the entrepreneurial teams on investment readiness. This will include internal workshops on crafting effective pitch decks, conducting market research, financial planning, and understanding investor expectations. Sano will also use its resources to assist the teams in preparing investment pitch decks and facilitate connections with potential investors or seed funding sources.

Market feedback and validation: finally, Sano will encourage the entrepreneurial teams to actively seek market feedback on their ideas or solutions, including insights from potential users, clinicians, or industry stakeholders. This feedback will help to refine the solutions, identify market opportunities, and make the entrepreneurial projects more appealing to investors and potential customers.

Beyond those internal activities, Sano will **forge partnerships or collaborations with external incubators/accelerators** that specialise in supporting early-stage startups. This approach can leverage the resources, networks, and expertise of these organisations to provide additional mentorship, access to investors, and entrepreneurial training opportunities for the entrepreneurial teams. Sano and KLSK exchange knowledge on an ongoing basis about available programmes that Sano as an organisation, or individual Sano researchers, could access. Monitored programmes include:

- [EIT Health](#)
- [Polish Agency for Enterprise Development](#)
- [Krakowski Park Technologiczny](#)
- [Startup Hub Poland](#)
- [HugeThing HQ](#)
- [Akcelerator Innowacji NOT](#)
- [Polski Fundusz Rozwoju](#)
- [Mother and Child Startup Challenge](#)

As a result of acceleration programmes, Sano employees can gain new skills and competencies as well as mentoring support, which will allow them to refine their business ideas. These activities will accelerate the development of their emerging business projects and increase the chances of implementing the proposed solutions on the market.

The choice of an incubation or accelerator programme requires a number of conditions to be taken into account, which are driven by the very nature of the market and Sano's business. The factors to be considered include:

Mission, Values and programme objectives: to verify that the incubation/acceleration programme is in line with Sano's mission, vision and values.

Access to resources and competences: to examine what specific resources, competences and infrastructure the incubation/acceleration programme offers and to what extent expectations in this respect are met.

Funding: to consider the source and degree of funding available.

Intellectual property: to look into the management and protection of intellectual property, in particular the question of who will own the rights to the assets created, whether the programme will offer support for the protection of IP and how the information provided is protected in terms of confidentiality.



Networking opportunities: to evaluate the potential of specific programmes to provide outreach to the industry, healthcare, VC.

4 Supporting Early Stages of Product Development

Currently, Sano is still at a fairly early stage in the development of its products and services, but with the start of each project, the individual research groups have access to advice in formulating their offer from the business perspective, in particular this includes advice on deciding on the optimal business model, defining target group(s), establishing legal/IP groundwork, assistance with commercialisation and fundraising opportunities, including successful grant acquisition.

A careful preparation of the technology transfer helps overcome potential barriers and risks. A strong market and user orientation from the very beginning of the development process is essential for the economic success of a new solution under development. This involves a good understanding of customers' needs and requirements, competitive situation and the nature of the market. Past experience demonstrates that performing the adequate amount of early product development and basing its design on facts related to the target environment of operation, significantly contributes to the product success. Market and user focus, while crucial initially, should prevail throughout the entire R&D project, and the users' inputs, having a vital role in the design of the product and its specifications, should continue throughout the entire product life-cycle. Important activities that support early stages of the product development are:

- market assessment – a market study to assess market potential and desired product attributes; users'/customers' needs & requirements research;
- analysis of the competitive situation;
- technical assessment – technical appraisal of the project, assessing technical feasibility and identifying technical risks.

As presented in Section 3.3, this task will be undertaken by the cross-functional project teams, established horizontally (i.e., across various Sano departments) for the purpose of supporting early stages of spin-off development (that is, the *incubation phase*).

One of major success factors impacting positively on both profitability and reduced time to market is the question how well the product is defined at early stages of the development. This definition includes:

- the target market;
- the product concept and the benefits to be delivered to the user (including business plan and business model);
- the positioning and business strategy for the implementation of the product (including the target price); and
- the product's features, attributes, requirements, and specifications.

Moreover, the definition serves as a communication tool: all functional areas have a clear definition of the product to be communicated to involved stakeholders. This definition also provides clear



objectives for the R&D team members and their support, so they are more target-oriented and they are able to proceed at a greater pace towards their objective.

The process of product development in the medical market generally should involve several key elements:

- concept/idea generation
- incubation and acceleration activities
- market research
- intellectual property considerations
- regulatory compliance considerations
- business modelling
- investment risks
- collaboration and engagement with industrial, academic and VC partners

The sections below describe how Sano and Advanced Partner will support a spin-off in all these/selected steps of this process.

4.1 Assessment of the Innovation Potential

Sano and its Partners engage in a comprehensive process to assess the innovation potential of research items generated by Sano research activities. This process begins with the **identification of elements that exhibit commercial potential**. Research support team at Sano performs continuous internal scouting to pinpoint intellectual property/proprietary knowledge that may emerge from research efforts, with focus on those with promising applications and marketability.

Following identification, the **technology readiness level (TRL) is assessed** for the selected research items. This involves determining the stage of development and evaluating the maturity of the technology. Sano's team conducts a thorough examination to understand the progress made, the technical challenges that need to be addressed, and the remaining steps required to reach a market-ready state.

Feasibility confirmation plays a vital role in the assessment process. Assisted with Sano's business development team, the researchers outline a plan for **proof-of-principle studies and experiments** to validate the feasibility of the concept. With follow-on research based on this plan, the scientific basis is established to demonstrate that there is a potential to solve real-world problems of the medical environment.

The approach to evaluate potential benefits to healthcare of identified research items will be inspired by the British experience, where NICE (National Institute for Health and Care Excellence) established 3 conditions that must be met by health technologies to be classed as innovative:

1. **The novelty condition:** the technology must display "innovative characteristics" or be of an "innovative nature".



2. **The substantial benefits condition:** the innovative nature of the technology must bring substantial health benefits to the patient, also referred to as a “*step-change* in the management of the condition”⁴.
3. **The demonstrable and uncounted benefits condition:** the substantial benefits brought by the innovative characteristics of the health technology must not already be captured in the incremental cost-effectiveness ratio (ICER) calculation of the technology under scrutiny and they must be “demonstrable and distinctive”⁵.

Once the innovation potential of a research item is assessed, the subsequent steps towards spin-off development will be taken as described below.

4.2 Planning IP Protection and Commercialisation Options

The role of intellectual property at Sano has already been referred to several times in Sano documents, in particular in **Deliverable 6.2: IP Management Policy**. In addition to this, Sano aims to define internal clear guidelines for the management, use, and protection of IP assets within the organisation (SOP *RD-01: Internal Intellectual Property Regulations*). This is important from a broader perspective, as thoughtful IP protection contributes to many opportunities, including monetising one's innovations through licensing, selling IP rights, or establishing strategic partnerships, among others. Failure to consider IP can result in loss of control over assets or uncontrolled use by third parties.

In the context of spin-off creation in computational medicine, having a robust IP protection plan is crucial to safeguarding the innovation and maximising its commercial potential. Consideration of IP management and protection may help the spin-off to attract investors. Having a potent IP portfolio demonstrates the value and business potential of the spin-off. Therefore, very often, the factor of IP awareness and adequate IP management is taken into account when looking for innovative companies with secured IP rights that can generate high returns on investment.

The key Sano actions in **planning for IP protection** include:

Identifying IP assets: each of the commercially relevant computational medicine developments at Sano will be analysed to select relevant intellectual property assets that they may represent. This includes patentable inventions, but also non-patentable IP like algorithms, software, databases, and other elements that may be eligible for protection.

Documenting know-how: the valuable know-how and expertise developed during the early stages of computational medicine research will be identified. This includes methodologies, processes, techniques, and best practices that are not necessarily patentable but contribute to the innovation's competitive advantage.

Evaluating patentability: for invention-type IP elements, the patentability of the innovation will be assessed by conducting prior art search and evaluating the novelty, non-obviousness, and industrial

⁴ National Institute for Health and Care Excellence. Single technology appraisal: User guide for company evidence submission template. London: NICE; 2015.

⁵ Charlton V, Rid A. Innovation as a value in healthcare priority-setting: the UK experience. Soc Justice Res. 2019;32(2):208–38. <https://doi.org/10.1007/s11211-019-00333-9>



applicability of the invention. Whenever relevant, patent attorneys and/or experts in computational medicine IP will be consulted to guide this process.

Filing patent applications: if necessary for the sake of innovation's competitive advantage, patent applications will be prepared and filed for the inventions that meet the patentability criteria. This step will require the researchers (inventors) to work closely with patent attorneys specialising in computational medicine to draft strong and enforceable patent claims that cover the key aspects of the innovation.

Other forms of IP protection: suitability of copyrights for software code, trademarks for brand elements, and trade secrets for confidential information will be considered as an IP alternative or complementing to patents in each case of Sano's innovation candidates. A quick guide to the various ways in which access to the technology can be controlled (or exposed) is given in the **Annex A: Protection Options (7.1)**. A structured guidance on the forms of protection that may be appropriate at each stage of the TRL chain of development (IP grid) has been provided in **Deliverable 6.2: IP Management Policy** (section 3.3: *Invention Maturity (TRL Development) vs. Appropriate IPR Protection Steps*).

Once the research items of high market potential have been identified (see Section 4.1), their underlying principles proven and IP issues addressed, Sano will take a focused approach to explore **commercialisation options**, identifying practical applications, potential users, and technology recipients within this domain. In order to accomplish this, Sano conducts targeted market research and engages with experts in the computational medicine field, seeking to understand the specific areas within healthcare and medicine where the innovation can be applied, the target users (such as medical industry, clinicians, or patients) who could benefit from the technology, and the potential impact it can have in improving healthcare outcomes. This analysis will guide the subsequent steps in commercialisation planning for effective market positioning of the innovation. Possible IP exploitation pathways are outlined in the **Annex A: Exploitation Pathways (7.2)**.

Based on the market profiling and segmentation, commercial potential of the innovation can be gauged through more detailed market analysis, considering factors such as the current and projected market demand (dynamics), the competitive landscape including existing products or services, the potential customer base encompassing industry, healthcare providers and organisations, as well as revenue generation models via licensing or direct sales. A summary of the approaches to obtaining income from the asset is presented in the **Annex A: Payment Models (7.3)**.

The output of those activities will be a set of detailed commercialisation strategy documents, as outlined in **Deliverable 6.3: Products, services and business development report** (section 2.6.5. *Developing and implementing focused commercialisation strategies*).

4.3 Increasing Technology Readiness Level

Sano and its Partners can support researchers in advancing the technology readiness level (TRL) of their research items. This can involve providing access to resources, facilities, or expertise required for prototyping, proof-of-concept development, and validation of the innovation. Sano and its Partners



can facilitate collaborations with industry partners, technical experts, or research institutions to help researchers overcome technological challenges and reach higher TRLs. By increasing the TRL, the innovation becomes more attractive to investors, potential partners, and customers.

Any organisation aiming to propose financially viable products to the market (certainly including spin-offs) needs to have a clear strategy of doing so, which could be expressed, among others, through a set of linked KPIs for monitoring the progress. Robust and clear strategy should include:

- Strategic target areas defined – areas of strategic focus on which to concentrate new product efforts. The goal is to select strategic fields rich with opportunities for innovation – those that will generate the business's future engines of growth.
- Clearly defined product innovation priorities, goals and objectives.
- The established link between the product innovation goals and the business goals.

Using the TRL scale enables a systematic approach to estimate, compare and meet technology requirements at different R&D development stages. Since there are no standardised lookup tables for medical technology TRL, we provide a practical guideline to TRLs below, in order to avoid misinterpretations. It can be used to better manage the progress of technology towards its maturity for successful deployment for the intended end users.

Table 3. *Guideline for a better management of technology towards its maturity.*

TRL	Description	Relevant questions	Evidence required
1-2	Basic research	What are practical applications for this R&D and/or innovation and what is its added value?	Examples of potential applications. Why it is suitable for these applications? Who will be potential users? How different user groups can benefit from the new solution? How the new solution can address the unmet or underserved needs?
3	Proof of concept	What are the key functionalities and elements of the intended solution? How do they meet the needs of potential users identified previously?	Creation of laboratory prototypes and proof of concept for the intended solution. Demonstration and validation of the prototype and its key elements with potential users.
4	Elements and functionalities validated in laboratory environment	Does the laboratory prototype created integrates all key elements necessary to address a particular problem for the intended application context? Does it have all functional aspects and can be operated according to what users would expect?	All functionalities and elements are integrated, demonstrated and sufficiently tested with potential users. Adequate metrics which allow to conclude if (to what extent) the prototype works as expected, are proposed and used.
5	All elements and components integrated and demonstrated in laboratory environment	Has a prototype been built and tested to successfully demonstrate all required functionalities and performance in application context? Do you have metrics to conclude that the prototype is a success? Are there customers for this technology? What are their specific	Metrics that describe functionalities and performance of the technology (i.e. integrated elements/components) and how well it meets the requirements and needs of users or goes beyond their expectations. Internal demonstration (i.e. in laboratory and not yet in the target environment) of these specific benefits and added values to potential users and customers.



TRL	Description	Relevant questions	Evidence required
		requirements for the solution and its integration in their practice?	Business case for a particular customer group describing how new solution can benefit users in a specific application context, how it meets functional and performance requirements and needs of different user groups and how the value can be realised. Business case should also include a strategy how the solution is to be commercialised and integrated into clinical practice, incl. presentation of implementation cost and revenues expected.
6	Prototype demonstrated in relevant environment	Is the prototype consistent with all of the agreed-upon requirements? Has the prototype been demonstrated successfully in the target user environment?	Metrics and benchmarks that prove the success of the demonstration The demonstration must be representative of the customer's specific needs
7	Prototype demonstrated in operational environment	Are the customer and supplier in full agreement that requirements are completely established and in final form? Has a prototype been integrated within the users' workflow/operational processes platform and demonstrated to function as expected? Did users confirm this? What final modifications need to be done?	Final set of users' requirements and metrics that confirm that they are fully met. Description of all elements of functionality and performance that were demonstrated. Description of the demonstration and how the prototype integrates within the user's operational system. Final modification needs identified and addressed. If applicable, product accreditation completed.
8	Technology proven in operational environment	Has the final product been qualified for final delivery to the customer? Does the customer agree that the product is qualified and ready for final delivery?	Proof that customer accepts the product in its final form or requires some further modifications. Pre-market application submitted and approved for medical device (when applicable). Support structure in place to address technical issues and assist users (software, hardware).

Further detailed discussion of TRL-related opportunities appears in **Deliverable 6.1: Business Development Plan** (section 1.3: *Technology & Readiness Levels*).

4.4 Understanding of the Applicable Regulatory Route

Sano and its Partners can help researchers gain a clear understanding of the regulatory landscape relevant to their innovation. This includes identifying the applicable regulatory frameworks, understanding the regulatory requirements and approval processes, and navigating through compliance considerations. Sano and its Partners can provide guidance on engaging with regulatory agencies, accessing regulatory expertise, and planning for regulatory milestones throughout the product development pathway. Understanding the regulatory route early on helps researchers align their development efforts with the necessary requirements and timelines. It is also important for decisions regarding structuring the future spin-off company, and the distribution of effort between Sano and the company, as elements of the compliance acquisition path relate to the provider rather



than directly to the product (e.g., certification of the provider of the technology regarding the product development, deployment and improvement life cycle).

Details on the applicable regulatory routes, including a case study for Clinical Decision Support Systems (CDSS), are given in **Deliverable 6.1: Business Development Plan** (section 7.2: *Implementation of Section 2 - Channels*). The following series of questions help define where the innovation is located in the regulatory framework.

1) Is it a Medical Device?

MDR Regulation (EU) 2017/745, Article 2:

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following purposes:

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or disability,*
- *(...)*

For devices that lie on the border of being a medical device, it may be advantageous to declare the non-medical uses at the early stages of development, to allow data to be collected about its safety and utility, before investigating the medical device claims. For example, health and well-being, non-medical usage or use on animals not humans. It is important to understand precisely which specific functionalities and modes of use qualify the product (in its planned final shape) as a medical device.

2) Is it Medical Device Software?

MDCG 2019-11 *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR:*

Software used to process, analyse, create or modify medical information and records is medical device software. Software used for storing, retrieval and transmission of patient data, information and records is not medical device software as it is not ‘processing’ data.

3) Device Scope: Is it a Medical Device (MD) or an In Vitro Diagnostic (IVD)?

MDCG 2019-11 *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR:*

Software intended specifically to be used with an in vitro diagnostic medical device to enable its intended use is an In Vitro Diagnostic (IVD).

Is the device or software used to measure samples away from the body or is it acting on the patient? This will determine which regulations apply.

4) Device Risk Classification

Assessment of the consequences of the device failing from low risk of harm to death will determine the device risk classification and regulations that will be apply. **Table 4** illustrates the banding of device risk classifications against the UK, EU and USA regulations for MDs and IVDs.



Table 4. Device Risk Classification.

Level of Risk		Existing CE Devices		Existing CE Devices		USA
		UK UKCA	EU CE	UK UKCA	EU CE	
		MDD 93/42/EEC Annex IX 18 Rules	MDR 2017/745 Annex VIII 22 Rules	IVDD 98/79/EC Annex II	IVDR 2017/746 Annex VIII 7 Rules	US FDA Website
Highest	Death	III	III	Annex II List A	D	3 – PMA (21 CFR 814)
	Serious Harm	IIb	IIb	Annex II List B	C	2 – 510(k) (21 CFR 807)
	Harm	IIa	IIa		B	
Lowest	Low Risk of Harm	I Measuring	I Reusable	Self -Testing General Classification (80%)	A (10%)	1 – Self Declared
		I Sterile	I Measuring I Sterile			
		I	I			

AI and Healthcare Regulations

In addition to the existing regulations for Medical Devices, the recognition of the increasing importance and impact of Artificial Intelligence on the healthcare domain has prompted the discussion and development of regulations for the use of Artificial Intelligence in healthcare. Sano should be aware of these developments and account for them in the regulatory requirements for their innovations. Further, Sano has the opportunity to contribute to these discussions, shaping the policies and regulations from the basis of its expertise and vision in this domain.



5 Supporting Company Creation and Early Development

Sano is motivated to see the fruits of its work have real-world impact through the translation of research ideas developed as innovations to products which improve patients' well-being in the healthcare system. This journey is not straight-forward and there are market and technological risks that need to be negotiated. A financial risk is the so-called 'Valley of Death' (see **Figure 1**) moving the innovation from the research domain, which is well resourced with tax-payers money, through research funding bodies to a successful product, which is well resourced by private investment and ultimately self-funding and profit-making through sales, or licencing depending on the details of the business model adopted. Organisations which are able to see their products cross the Valley of Death will eventually enjoy greater percentage of success in the translation, and in consequence will have stronger beneficial impact on the economy and society. Therefore, it is important for Sano to provide adequate assistance for its entrepreneurial researchers to take that step.

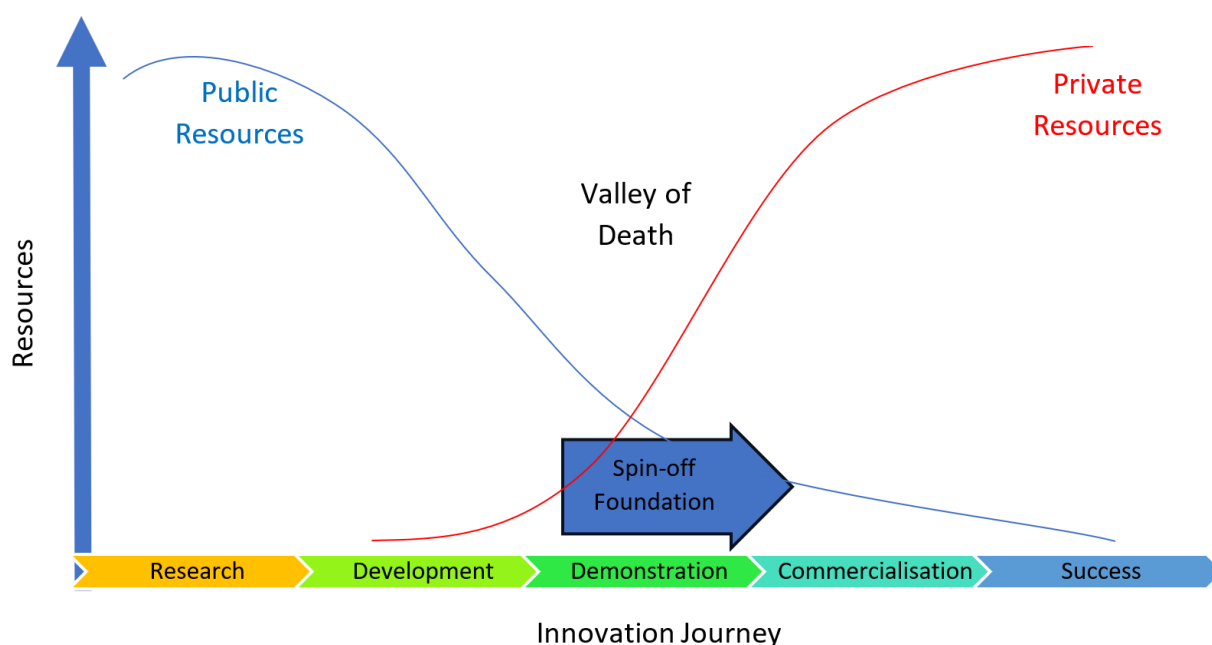


Figure 1. The 'Valley of Death' between the public investment in research and private investment in a successful product.

Sano is responding to this challenge with the acceleration and incubation programmes described in this document (Section 3.3). As explained, the researchers will be assisted along the entire way presented above by a multidisciplinary team with diverse technological, finance/fundraising, legal and business skills to take the innovation forward, and maximise its chances of arrival to the stage where the prospect is sufficiently de-risked for a private investment targeted at deployment (incl. certification where required) and "productisation". Sano can support the spin-off with its own expertise in these areas to shepherd the spin-off through these early stages and remove some of the financial pressures by for example continuing to protect the IP on behalf of the spin-off.

It is also worth noting that the issue of the Valley of Death, especially prominent in medical technologies where costs and risks are much higher than in many less-sensitive markets, was noticed by R&D funding authorities. As a result, we now witness the introduction of funding programmes



targeted at precisely helping the most promising innovations overcome that difficulty. Examples from Poland include:

- ABM (*Agencja Badań Medycznych*) programmes which sponsor pre-commercial clinical trials, not only for drugs but also for medical devices, CDSS software included -> an opportunity for a technology to reach much higher TRLs and significantly progress through the compliance pathway for a subsequent private investment to become more probable.
- FNP (*Fundacja na rzecz Nauki Polskiej*) Proof-of-Concept and PRIME programmes. PoC sponsors costly validation (higher TRL) while PRIME funds spin-off creation and business case development efforts. Both programmes are very adequate for the entrepreneurial endeavours of Sano researchers.
- NCBR (*Narodowe Centrum Badań i Rozwoju*) Bridge Alfa fund-of-funds instrument, which joins public funding with matching private funds in order to lessen the level of financial risk for the private investors, and therefore increase the likelihood of promising new companies (spin-offs included) crossing the Valley of Death to financial liquidity, and the break-even point. The first iteration of this instrument was already saturated in the former EU financial perspective, but there are indications that the instrument will be re-enacted in the current financial perspective.
- key funding programme of the EU, Horizon Europe (HE) has one of its three pillars dedicated to innovation: Pillar – Innovation Europe, with a budget of €13.5 billion out of HE's total budget of €95.5 billion, with the purpose of stimulating market-creation breakthroughs and ecosystems conducive to innovation. This has three components:
 - European Innovation Council: Supporting innovations with breakthrough and disruptive nature and scale up potential that are too risky for private investors. It has complementary instruments to bridge the gap from idea to market: Pathfinder, Transition and Accelerator. The Accelerator funding is aimed specifically at single SMEs and start-ups.
 - European Innovation Ecosystems: Connecting with regional and national innovation actors.
 - European Institute of Innovation and Technology (EIT): Bringing key actors (research, education and business) together around a common goal of nurturing innovation.

This shows a commitment to support innovations through the early stages of their development at a European level.

The cross-functional teams will assist Sano researchers in acquisition, where desirable and possible, this additional support to help them bring their innovations closer to market and exploitation, and their companies to private investment and stable financial future.

Sano can also provide the flexibility in employment contracts and conditions to allow some members of staff to meet their commitments to both Sano and the fledgling spin-off company.



5.1 Optimal Technology Maturity Level at Transfer

Sano and its Partners can define the target technology maturity level at which research projects or technologies are considered ready for transfer to a spin-off company⁶. This can be based on factors such as feasibility, proof-of-concept, intellectual property protection, optimisation towards regulatory acceptance, and market potential. To allow Sano management and its researchers an informed decision in this regard, Sano and its Partners establish guidelines and criteria to ensure that technologies are sufficiently developed and have the potential for commercialisation.

Sano approach towards assessment of technology maturity in relation to Technology Readiness Levels has been outlined in **Deliverable 6.2: IP Management Policy** (section 3.3: *Invention Maturity (TRL Development) vs. Appropriate IPR Protection Steps*).

Design Control

The journey of the innovation from conception to market requires the implementation of Design Control and a Quality Management System. **Table 5.** The Innovation Journey from conception to post-launch mapped out against Technology Readiness Level with Quality Management Activities. **Table 5** illustrates the journey to market mapped against the TRL with Quality Management triggers. The timely implementation of a Quality Management System and documentation, such as the technical value can add value to the innovation through de-risking the innovation for investors.

The earlier stages TLR1-3 are iterative with a great deal of experimentation, whereas later stages are working through the consequences of a selected solution.

There are several possible stages of the presented process at which Sano could transfer IP, through licencing or selling, to the spin-off Company. Notably, at the end of TRL4 Product Development, when there is a specific product design that has been selected and reproducibly described with a Technical File, and when the User Design Requirements were documented. Having this documentation in place represents a maturity of the product from initial conception and allows subsequent owners to proceed without necessarily repeating the earlier Proof of Market, Feasibility and Concept stages.

However, there is a consideration that at this stage the product has not yet been proved to be safe and effective, which are costly processes, possibly requiring clinical trials and the scaling up of production facilities, the latter possibly less of an issue for purely software products. By retaining control and management of the IP and its protection at this early stage, Sano can protect the spin-off from these costs, until its investment and cash flow is sufficient to cover them (see the incubation idea presented in earlier chapters).

Other exit points after TRL7 and the safety and clinical assessments have been made or TRL8 around the launch of the product or post launch. At these stages the value of the IP will have increased as the risk to the investors have reduced.

However, consideration of Sano's positioning as a research institute and relatively limited experience of the later stages of regulatory accreditation, product development and market launch would argue towards the earlier transfer of IP to the spin-off company. This would allow the spin-off and its

⁶ For the sake of brevity, "transfer" here is understood as any kind of handover of technology or know-how from Sano to a spin-off company, for further development and exploitation. In practice, arrangements like licencing are possible, in which case no formal "transfer" of ownership takes place.



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collaborators and contractors to take responsibility for the certification process and product development. A possible scenario would be for Sano to ship licenced (or transferred) software from Sano to the spin-off company as SOUP (“Software Of Unknown Provenance”) for which the ISO- and IEC- certified company will take the formal post-market responsibility – then any further agreements regarding insurance, guarantees, costs of fixes and improvements, service-level agreements (SLAs) etc. could then be made between the company and Sano independently from the restrictions of the processes regulated by the standards.



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Table 5. The Innovation Journey from conception to post-launch mapped out against Technology Readiness Level with Quality Management Activities.

Phase	TRL#	Medical Device Stage	TRL Description (As per Table 3)	Regulation and Documentation Activities	QMS Activities
0) Conception	NEW	Eureka		Identified a new clinical need for known technology OR Invented a new technology for a known need	
1) Develop conceptual designs to meet clinical need	TRL1	Proof of Market	Basic Research	Document clinical and commercial need. Perform scientific literature review and initial market survey	
	TRL2	Proof of Feasibility	Basic Research	Discuss idea with a wide group of people. Identify fundamental User Requirements. Create basic models for demos and to test hypothesis	
	TRL3	Proof of Concept	Proof of Concept	Document User Requirements, Design Requirements and Risk Assessment . Create and test multiple prototypes.	Create Technical File Design Review
	TRL4	Product Development	Elements and functionalities validated in laboratory environment	Improve manufacturing methods. Prove designs function as intended. Distil multiple designs through testing.	ISO 13485 Certification? Design Review
2) Verification & Validation of chosen design	TRL5	Pre-Clinical Assessment	All elements and components integrated and demonstrated in laboratory environment	Validate Manufacturing/SW. Qualify Approved suppliers. Functional and Analytical Performance testing. Risk assessment Review. Perform Design Freeze.	Design Review
	TRL6	Product Safety Assessment	Prototype demonstrated in relevant environment	Biocompatibility. Sterility assessment. Electrical safety. EMC. Data security.	Design Review
	TRL7	Clinical Assessment	Prototype demonstrated in operational environment	Regulatory Ethics. Ethics Review. User Testing inc. Usability Engineering. Complete clinical performance testing, Phases I / II / III as applicable to device risk class.	Design Review
3) Place Product on Market	TRL8	Final Verification / Validation Review Launch Activities	Technology proven in operational environment	Review changes made since Design Freeze & revalidate product as required. Risk Management Report. Complete Technical File. Approval gained. Production release. Control of distribution. Post-Market Surveillance (PMS) Plan. Post-Market Clinical Follow-up / Post-Market Performance Follow-up (PMCF/PMPPF) Plan.	Final Verification / Validation Review Design Review



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Post-Launch	MARKET	Post Surveillance	Market		PMS, PMCF/PMPF, PSUR Manage feedback, Customer Complaints, Vigilance. Design Change Control	
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5.2 Business Modelling

Sano and its Partners can provide support in developing robust business models for spin-off ventures. This can involve helping researchers identify market opportunities, assessing the competitive landscape, defining value propositions, and formulating sustainable revenue models. Sano and its Partners can offer guidance and resources for researchers to understand the market dynamics, customer needs, and potential business strategies for their technology or solution.

Business modelling from the perspective of an emerging entity may have a significant impact on many aspects of the business. It includes helping to identify and describe the future business model, assessing existing competition and end-user expectations of a particular product or technology, identifying the revenue model, marketing channels and key partners.

As an institution and internal structure, Sano not only provides the substrate for researchers to develop their innovations, but also, with a defined training strategy and Advanced Partner support, teaches them how to effectively analyse and plan the business-related aspects, which is crucial for the future commercialisation of their innovations.

However, for such activities to be effective, it is necessary to include awareness building among researchers of the role that business modelling plays in the effective development of innovation. For this reason, a Training Policy (referred to in section 3.1 of this document) has been developed, which incorporates a range of training courses to ensure that this awareness and entrepreneurial base is sharpened and that the support of Sano and Advanced Partners is used appropriately.

As a spin-off develops towards market entry, the technology or idea will typically need to be further developed with a focus on specific commercially viable market applications. It will also need to develop production processes, establish supply chains and value networks, and crucially, its business model. Universities provide business planning tools and template documents to spin-offs post-foundation, e.g. for business planning, cash flow forecasting, business model generation, and to facilitate investment.

Building a Business Plan

Perhaps the single most significant step in preparing for any journey to market is the preparation of a Business Plan, a written document that outlines the goals, strategies, and operational details of a proposed business. It serves as a roadmap for the organisation, providing a comprehensive overview of how the business intends to achieve its objectives, attract customers or clients, generate revenue, and sustain profitability. A well-developed business plan typically includes the following components:

Section	Content
Executive Summary	An overview of the business, its mission, and the key highlights of the plan.
Company Description	A detailed description of the company, its legal structure, industry, products or services, target market, and competitive advantages.
Market Analysis	An examination of the target market, including its size, growth trends, customer demographics, and competitive landscape. This section also includes an analysis of the business's position within the market.



Section	Content
Organisation and Management	An outline of the company's organisational structure, key management team members, their roles and responsibilities, and relevant expertise.
Product or Service Line	A detailed description of the products or services offered, including their features, benefits, and unique selling propositions. The IP position.
Marketing and Sales Strategy	An explanation of how the business plans to attract and retain customers or clients, including marketing activities, pricing strategies, distribution channels, and sales forecasts.
Financial Projections	A presentation of the financial aspects of the business, including sales forecasts, projected income statements, cash flow statements, and balance sheets. This section also includes information about funding requirements, capital expenditures, and return on investment.
Operations and Management	A description of the operational processes, facilities, equipment, and technology required to run the business effectively.
SWOT Analysis	An assessment of the business's strengths, weaknesses, opportunities, and threats. This analysis helps identify areas of advantage and potential challenges that need to be addressed.
Risk Management	A discussion of the potential risks and challenges that the business may face, along with strategies to mitigate or manage those risks.
Implementation Plan	A timeline and action plan outlining the steps and milestones needed to implement the business strategy effectively.
Exit Strategy	A plan for the eventual exit or transition of the business, including options such as selling the company, merging with another entity, or succession planning.

A business plan is a dynamic document that should be regularly reviewed and updated as the business evolves. It serves as a crucial tool for internal decision-making, securing funding from investors or lenders, attracting partners or key personnel, and communicating the business's vision and strategy to stakeholders.

Key areas to be considered as part of the development of the model behind the Business Plan for a putative spin-off are described below. Many of these seem superficially obvious and even trivial, but detailed research into the essence of each issue will be rewarded by a better appreciation of risk.

Technology Assessment

The assessment of the potential of an innovation has been discussed in Section 4.1.

Market Assessment: Top Down – General, macroscopic data

- Is there a market?

Assessing the existence of a market for a new product idea involves conducting market research and analysis. This includes understanding customer needs and preferences, evaluating competition, analysing market trends, and assessing potential demand and profitability. Factors such as target audience size, purchasing power, market saturation, and potential barriers to entry are crucial in determining if a viable market exists for the new product idea.



- Is there a product opportunity?

Assessing the potential for a new product concept involves considering factors beyond market research. It requires evaluating the competitive landscape and identifying any gaps or unmet needs in the market. Additionally, analysing emerging trends, technological advancements, and changing consumer behaviours can provide insights into whether there is room for a new product concept. Understanding the competitive advantage, uniqueness, and value proposition of the concept is essential in determining its potential success.

Target Product Profile: Bottom up – Focused, microscopic data

- What is the product specification?

When writing a product specification, several key issues must be considered. Firstly, clarity and specificity are crucial to ensure that the intended functionality and features are accurately communicated. Secondly, the specification should be comprehensive, covering all essential aspects of the product. Thirdly, it is important to strike a balance between providing sufficient detail and allowing flexibility for potential modifications. Lastly, the specification should align with technical feasibility, cost considerations, and customer requirements. IP disclosure must be avoided.

Asset Positioning

- Where will the product fit in the market?

Pitching a new product in a crowded market requires a strategic approach. Firstly, focus on highlighting the unique value proposition and differentiation of the product. Clearly articulate how it solves a specific problem or meets a distinct customer need. Secondly, emphasise competitive advantages, such as superior quality, affordability, or innovative features. Thirdly, tailor the pitch to resonate with the target audience and leverage compelling storytelling to captivate their attention. But in Computational Medicine if these are the approaches that remain after a market assessment, it's probably inappropriate to continue the development.

- How and when will it be used?

Accurately describing the circumstances in which a product is to be used involves providing clear and concise information. Begin by defining the target audience and their specific needs or challenges. Then, outline the specific scenarios or environments in which the product will be most effective. Consider factors such as user demographics, industry requirements, technological compatibility, and any limitations or special considerations that may apply to ensure an accurate description. In healthcare, the clinical condition is a key factor.

Key Information

No business discussion about any putative venture should take place without the proponents having an absolute grasp of these key issues:

- Technical details of invention
- Patentable elements
- Risks
- Unique Selling Point/Proposition (USP)



- Competition
- Possible routes to market
- Potential collaborators

At the heart of each business model is a winning value proposition, which clearly communicates the value specific technology provides. In a market-oriented product, a strong value proposition is crucial for an entrepreneurial success. CM market is characterised by complex products targeting different users and decision makers. So, Sano and related spin offs need to think of the value proposition in wider sense, as it effects different user and customer groups and their perception of value. For the complex medical technology products, the following features were identified and proven as characteristics of a strong value proposition (called 4 Cs)⁷:

- **Consistency:** built around the contextual segment, not one stakeholder. The value proposition is by definition specific to a target segment (e.g. treatment and monitoring of epileptic condition) and not to the whole market. If your solution targets more than one segment, you'll need separate value propositions for each target segment (e.g. patients with epileptic condition; neurologists treating them):
 - Definition of the target market segment to allow the alignment between what is offered and what is wanted: Segments must be homogenous (everyone in the segment must have needs and requirements similar enough to be addressed by the same offer - e.g. epilepsy patients) and distinct (characteristics and motivating needs of each segment must be different from those of other segments e.g. healthcare providers, clinicians). Strong value propositions are always built around a good understanding of the needs and specific contextual conditions of a well-defined homogenous and distinct target segment.
- **Completeness:** with your value proposition you should address the motivating needs of all targeted segments
- **Coherence:** all the elements of the value proposition reinforce each other and do not contradict, creating a combined effect.
- **Costs:** all activities are specifically and sufficiently resourced

Business Preparation

- Commercial strategy

Developing a commercial strategy involves several key steps. Sano's entrepreneurs must first conduct market research to understand customer needs, preferences, and market trends. Next, define clear business objectives and target markets. Identify competitive advantages and create a value proposition that differentiates your offerings. Determine pricing, distribution channels, and marketing tactics. Regularly evaluate and adapt the strategy based on market dynamics and customer feedback to drive business growth and profitability.

- IP Strategy

Again, several steps are required. First, identify and assess the IP assets within Sano (patents, trademarks, copyrights, or trade secrets). Secondly, establish policies and procedures to protect and manage IP assets effectively. Thirdly, conduct IP audits to evaluate potential risks and opportunities. Lastly, develop strategies for IP commercialisation, enforcement, licensing, and collaboration to

⁷ Brian D. Smith, 2018. Brand Therapy: 15 Techniques for Creating Brand Strategy in Pharma and Medtech



maximise the value and competitive advantage of the organisation's IP portfolio. Sano's strategy currently appears to be in a position to benefit from a more centralised approach.

- IP Valuation

Analyse the uniqueness and market demand for the IP asset. Secondly, evaluate its potential for commercialisation, revenue generation, and competitive advantage. Thirdly, consider the cost and effort required to develop and maintain the IP. Additionally, review the legal protection and enforceability of the IP rights. Finally, assess any potential licensing or collaboration opportunities to further enhance its value.

Risk

- Commercial Risk:

Commercial risk refers to the potential adverse events or uncertainties that can impact the financial performance, operations, or reputation of a business. It includes factors such as market volatility, changing customer preferences, intense competition, regulatory changes, supply chain disruptions, and economic downturns. Understanding and managing commercial risks is crucial for Sano to protect their profitability, sustain growth, and make informed decisions in the face of uncertain business environments. Data collection that is useful in informing risk management includes the value of the accessible market, the value of estimated sales, the degree of market penetration and the extent of territorial coverage.

- Technology Risk

The risk of Sano's products being superseded by superior technology poses a significant challenge. Rapid advancements in technology can render existing products obsolete, resulting in loss of market share and competitive disadvantage. To mitigate this risk, Sano needs to stay abreast of technological advancements, invest in research and development, foster innovation, and adapt its products or develop new ones that incorporate emerging technologies. Continuous monitoring and agility are crucial to staying ahead of the competition in a rapidly evolving technical landscape. The careful selection of low TRL products to be developed onward is required.

Sano also faces technical risks relating to the systems and equipment on which it relies for effective operation, and which are likely to be relevant to any spin-off organisation. Mitigating technology risks involves implementing robust security measures, backup and recovery plans, regular system maintenance, staying updated with technological advancements, and having contingency plans to minimise disruptions and protect sensitive information.

- IP Risk

Sano relies on maintaining the protection of its intellectual property (IP) and faces several consequent risks. Firstly, the risk of IP infringement or unauthorised use by competitors, potentially leading to loss of market share or revenue. Secondly, the risk of IP theft or misappropriation, compromising Sano's competitive advantage. Additionally, legal challenges, such as costly litigation or disputes, pose a risk. To mitigate these risks, Sano should implement robust IP protection strategies, including proactive monitoring, enforcement measures, and secure IP management practices. An awareness of each of the following must be developed.



IP Feature	Detail
Legal status - patent position	Sano's (and its spin-offs') success is vulnerable to both the actual and the perceived likelihood of its IP protection being flouted, ignored or sidestepped, and vigilance is required
Intrinsic strength of patent claims	Sano could develop a ranking system that establishes a level of risk in accordance with the likelihood that a patent may be superseded, or challenged by a comparatively minor modification
Degree of IP freedom	Sano requires an awareness of any fundamental limitation (technical, scope, territorial etc) that may restrict the value of the IP asset
Longevity of patent position	Sano must remain vigilant to the extent to which a product concept may be vulnerable to lower cost competition introduced by virtue of the expiration of protection

Business Execution

Sano can influence its commercial position by the extent to which it develops and executes a sophisticated and structured strategy. Elements to consider include:

Business Approach	Detail
Business Development	In an organisation that is predominantly technology-driven, and where the in-house expertise is mostly theoretical, speculative, academic, and engineering-heavy, the importance of having a commercially sophisticated business development team cannot be overemphasised. Responsible for the pervasive dissemination of good business practice, and the execution of all commercial initiatives, the BD team is the core of Sano's business aspirations, and its organisation, control and reporting are amongst the most important aspects of Sano's management.
Out-licensing	As discussed elsewhere in this document, a strong focus on structuring Sano's IP into licensable concepts would assist discussions with external manufacturers
In-licensing	Sano should be alert to the possibility of using its technology in conjunction with established marketplace entities that already have a reputational benefit, and which speed the transfer of technology to market. If the manufacturer is reluctant to engage more meaningfully, licensing their technology may have significant benefit.
Acquisitions	Given adequate resources, the next step beyond licensing existing technology may be to acquire the organisation responsible. Particularly an option in the case of a small niche organisation with an existing medical product that would benefit from, say, a simulation element or an AI layer.
Trade sales	Conventionally the authors of a new technology establish a company that then offers products to end-user organisations. But many of the steps involved in establishing such sales are time-consuming and costly, and more



Business Approach	Detail
	rapid success could follow from providing the products to a much more limited set of intermediaries, who then carry out the final level of business.
Collaborations	Perhaps the most beneficial of all connections to external entities could be the establishment of a long-term and mutually beneficial collaborative partnership, in which each party's strengths are combined into a more successful larger entity.

Deal Assessment

Included for completeness, deal assessment refers to the process of evaluating and analysing a business deal or opportunity to determine its feasibility, potential risks, and potential value. It involves conducting a thorough analysis of many aspects, such as financial projections, market dynamics, competition, legal and regulatory considerations, operational requirements, and strategic fit. Deal assessment helps stakeholders make informed decisions regarding whether to proceed with a deal, negotiate terms, or explore alternative options.

5.3 Fundraising

Sano and its Partners can assist researchers and founders in navigating the fundraising process. This can include providing mentorship on investor pitching, connecting researchers with potential investors, facilitating access to funding sources (such as venture capital firms, government grants, or angel investors), and offering resources for developing investment pitch decks and financial projections. Sano and its Partners can also support spin-off ventures in preparing for fundraising events, networking with investors, and negotiating investment terms.

The theme of fundraising incorporates in its concept a number of elements that should be taken into account when building a spin off culture at Sano. In particular:

- A. **Seeking private and public funding opportunities for the new entity** - the search for research funding should be preceded by thorough research aimed at identifying private and public funding opportunities suitable for a new entity. It is reasonable to consider different forms of funding for possible consideration from venture capital firms, business angels, government grants, incubators, accelerators and crowdfunding platforms. Such a procedure should consider the advantages and disadvantages of these forms of funding, informed by Sano's visions and missions. This procedure should additionally include the identification of potential investors who would be interested in Sano's innovations.
- B. **Organising the spin-off stage event for Sano innovators to meet potential investors** - the desired outcome of such an activity should be determined, in order to organise the undertaking accordingly. Working with Advanced partners such as KLSK, experienced in organising pitch events, will enable Sano to reach out to the investment community and support the delivery of the event. A spin off stage event should include networking sessions, one-on-one meetings to foster meaningful conversations and networking.



- C. **Look for industrial licensee** (established companies which would either invest in the new entity or pay for licencing for themselves). This stage includes identifying potential licensees who may benefit from Sano innovation and be interested in licensing it.

When employees aspire to create a spin-off company, securing adequate funding becomes a critical factor for their success and just by fostering entrepreneurship Sano can already play a pivotal role in assisting its employees in raising funds for their spin-off ventures. Below are relevant topics for consideration when Sano seeks to support its employees in accessing the necessary capital for their entrepreneurial pursuits.

Education and Training

Sano's employees are likely to be unfamiliar with the intricacies of fundraising for a spin-off company. Sano can provide educational resources and training programs to equip its employees with the knowledge and skills required to navigate the fundraising landscape. Workshops on business planning, financial projections, investor pitching, and valuation can empower employees to communicate their ideas effectively and attract potential investors.

Internal Funding Programs

Sano may be able to support its employees in raising funds by establishing internal funding programmes. These programmes can provide seed capital or early-stage funding for promising spin-off ventures initiated by employees. By offering such financial support, Sano demonstrates its commitment to employee entrepreneurship and creates an environment conducive to innovation and risk-taking.

Connections to External Investors

Leveraging its network and industry connections, Sano can facilitate introductions between employees and external investors. This can involve arranging networking events, investor pitch sessions, or even inviting investors to specially organised Sano events. By providing access to potential investors, Sano enhances the visibility and credibility of its employees' putative spin-off companies, increasing the likelihood of securing external funding.

Investor Mentoring and Guidance

Sano can provide mentorship and guidance from experienced investors to employees seeking external funding. Pairing employees with seasoned investors or entrepreneurs can help them refine their fundraising strategies, develop compelling investor pitches, and understand the investor's perspective. This mentorship can be instrumental in building relationships with potential investors and increasing the chances of securing funding.

Corporate Venture Capital (CVC) Support

Establishing a corporate venture capital fund or partnership would allow Sano to invest directly in its employees' spin-off companies. By becoming an investor, Sano not only provides financial support but also lends credibility and endorsement to the venture. This approach aligns Sano's interests with those of the employees and fosters a mutually beneficial relationship.

Assistance in Grant Applications



Sano can assist employees in identifying and applying for relevant grants and funding opportunities. This can involve providing guidance on grant eligibility, assisting with grant applications, and connecting employees with grant funding organisations or consultants. By supporting employees in accessing non-dilutive funding sources, Sano would alleviate some of the financial burdens associated with starting a spin-off company. The Advanced Partners can directly assist with much of this activity. Specific details on available funding opportunities have been provided in **Deliverable 6.4: Market Analysis Report** (section 3.2.2.3: *Support for the market development and technology take-up*).

Collaborative Funding Platforms

Sano can explore the possibility of creating collaborative funding platforms where employees can showcase their spin-off ventures and seek funding from a broader audience. These platforms can include crowdfunding campaigns, where employees can leverage their networks and engage with potential customers and investors who are passionate about their ideas. Such platforms can provide exposure, validation, and additional financial resources for employees' spin-off companies.

In Summary

Assisting its employees in raising funding for their spin-off companies would be a testament to Sano's commitment to employee entrepreneurship and innovation. By providing education and training, internal funding programs, connections to external investors, mentorship, corporate venture capital support, assistance in grant applications, and collaborative funding platforms, Sano can significantly enhance its employees' chances of securing the necessary capital. This support not only empowers individual entrepreneurs but also contributes to the growth and success of Sano as a whole.

5.4 Founders

Sano and its Partners can support researchers in identifying and forming strong founding teams for spin-off ventures. This may involve organising networking events, fostering collaborations between researchers with complementary skill sets, and facilitating the formation of multidisciplinary teams. Sano and its Partners can also provide guidance on team dynamics, leadership development, and the identification of key roles and responsibilities within the founding team.

Empowering employees to pursue their entrepreneurial ambitions through the creation of spin-off companies not only cultivates a culture of innovation but also serves as a strategic avenue for growth and adaptation. Below are described mechanisms through which Sano might effectively support its employees as they consider whether to create a spin-off company.

Encouraging Entrepreneurial Culture

The foundation for supporting employee spin-offs lies in cultivating an entrepreneurial culture within Sano. This can be achieved by promoting an environment that encourages risk-taking, creativity, and intrapreneurship. Recognising and rewarding innovative ideas, providing autonomy, and fostering a collaborative work environment are essential steps in nurturing an entrepreneurial mindset among Sano's team members.

Mentorship and Guidance



Establishing a mentorship program can play a pivotal role in supporting aspiring entrepreneurs. Sano can consider pairing employees interested in creating spin-offs with experienced mentors who can provide guidance, industry insights, and strategic advice. Mentors can help employees refine their business ideas, navigate potential challenges, and develop the necessary skills to succeed as entrepreneurs.

Access to Resources

Sano could consider providing a range of resources to facilitate the process of creating spin-off companies. These resources may include specific extended access to targeted research and development facilities, funding options, intellectual property assistance, legal support, and marketing expertise. By offering these resources, Sano can alleviate some of the financial and logistical burdens associated with starting a new venture.

Flexible Work Arrangements

Recognising that employees embarking on entrepreneurial journeys may need time and flexibility, Sano can adopt flexible work arrangements. This could involve reduced working hours, temporary leaves of absence, or part-time employment, allowing employees to devote sufficient attention to their spin-off ventures without completely severing ties with Sano. Flexibility can help employees balance their entrepreneurial pursuits while maintaining a positive relationship with Sano.

Investment Opportunities

Sano can explore investment opportunities in employee spin-off companies, either directly or through corporate venture capital funds. By investing in these ventures, Sano not only provides financial support but also demonstrates its commitment to fostering employee entrepreneurship. This approach can lead to mutually beneficial partnerships and promote the development of innovative solutions.

Knowledge Exchange and Collaboration

Creating avenues for knowledge exchange and collaboration between the spin-off companies and Sano can be invaluable. Regular meetings, workshops, and networking events can facilitate the sharing of ideas, expertise, and industry trends. Such collaborations can lead to synergies, potential business partnerships, and market expansion opportunities, benefiting both the spin-off companies and Sano itself.

Alumni Network

Planning ahead, establishing an alumni network specifically for former Sano employees who have launched spin-off companies can be a valuable asset for both Sano and the entrepreneurs. This network can serve as a platform for ongoing support, networking, and knowledge sharing. Alumni events, newsletters, and online forums can help maintain strong relationships and provide a sense of belonging.

In Summary

Supporting employees who wish to create spin-off companies is a testament to Sano's commitment to fostering innovation, empowering its workforce, and embracing entrepreneurial spirit. By encouraging an entrepreneurial culture, providing mentorship, access to resources, flexibility, investment opportunities, and facilitating knowledge exchange, Sano can effectively support its



employees in their entrepreneurial endeavours. These efforts not only benefit the individual entrepreneurs but also contribute to Sano's overall growth and success.

5.5 Legal Support

Sano and its Partners can offer legal support and guidance to spin-off ventures in areas such as intellectual property protection, contract negotiations, regulatory compliance, and company formation. This may involve establishing partnerships with legal experts or providing access to legal resources and templates that are relevant to early-stage startups. Sano and its Partners can help spin-offs navigate legal complexities and ensure compliance with relevant laws and regulations.

The support may include:

- legal support in determining the most optimal legal form for setting up the company;
- legal and business support to develop the best model for Sano and spin-off regarding IP - in particular IP transfer, licensing, sharing of copyrights (according to the IP Management Policy);
- legal due diligence⁸ in the development of the spin-off provides an opportunity to focus on analysing and assessing the legal aspects related to their business;
- the possibility to consult on legal aspects: Sano and its partners can provide spin-off companies with access to legal experts who can offer guidance on legal compliance, intellectual property protection, data protection, contract negotiations and other legal issues;
- legal support for the creation of a new entity, including preparation of the necessary documents for the creation of a new entity and its registration.

5.6 State Aid Consideration and Support Limitations Implications

Sano and its Partners can provide guidance and support to spin-off ventures in understanding the implications of state aid considerations and support limitations. This involves assessing whether the spin-off is eligible for state aid programs, complying with state aid regulations, and understanding any limitations or restrictions on funding or support that may apply. Sano and its Partners can help spin-offs navigate the regulatory landscape and identify alternative funding sources or support mechanisms if necessary.

When Sano carries out contract research or research services for economic operators (including spin-offs or start-ups) or in the case of collaboration with economic operators (including spin-offs or start-ups), all decisions regarding the establishment of collaboration or the acceptance of a contract will be made in accordance with the general state aid rules. The Sano will apply equal conditions for all to access its research services and contract research. When contracting out, the Sano Foundation undertakes to stipulate in the contracts that the economic operator (including spin-offs or start-ups) will become the owner of the research results and will bear the risk of failure. If the economic entity (including spin-offs or start-ups) does not require this, the ownership of the research results will

⁸ Legal due diligence involves in-depth analysis and assessment of spin-off's legal status and compliance to identify potential risks, issues or opportunities and compliance with laws and regulations.



remain with Sano. In addition, these agreements will regulate the remuneration of the Sano Foundation by an appropriate amount.

In the case of cooperation with an economic entity (including spin-offs or start-ups) for the implementation of a joint venture, Sano will conclude an agreement prior to the commencement of the activities, in which the purpose of the venture will be defined, the division of the work, the contributions to be made by each party, the principles related to the bearing of costs and financial, technological, scientific and other risks, the division of rights to the results of the joint venture, access to intellectual property rights and the principles of dissemination of the results.

When the Sano commissions services or purchases goods necessary for the performance of its tasks, the Sano Foundation undertakes to apply the necessary regulations, in particular the internal purchasing regulations and those national and European laws applicable to the specific purchase, in order to ensure openness, transparency and non-discrimination and objective criteria for the selection of contractors and to ensure the best use of the resources available to the Sano.

5.7 Sano Support for Established Spin-offs

Once spin-off ventures are established, Sano and its Partners can continue to provide support and resources to facilitate their growth and success. This can include access to Sano's network and expertise, ongoing mentorship and guidance, assistance in navigating regulatory requirements, and collaboration opportunities with Sano's research teams. Sano and its Partners can also facilitate partnerships between established spin-offs and other industry players, potential customers, or strategic partners to accelerate their development and market penetration.

It is important to emphasise that the role of Sano and Advanced Partners does not end with the creation of spin-off ventures. Understanding the challenges and barriers of the medical market facing these businesses, ongoing support and resources will continue to be provided. This commitment ensures that these ventures will continue to grow, adapting to changing market dynamics. Sano and its Advanced partners recognise the enormous value and potential in the operation of spin-offs and are committed to providing ongoing support and resources to support their development and ensure their long-term success. Sano, together with Advanced Partners, will encourage and provide comprehensive support to students, researchers and other collaborators who would like to start and maintain their own knowledge-based company. Below the roles of the partners in providing this support are listed according to their skills, competences and years of experience.

KLSK can provide support on several levels, thanks to its many years of active involvement in the life science and health market. Support may include:

- Support in terms of access to needed competences and resources in the form of mentoring, training, access to business networks, management support and access to infrastructure resources.
- Support in terms of access to collaborative networks: KLSK, as part of its activities, offers opportunities for business networking in the Life Sciences sector. By networking with other companies, research institutions, investors and business partners, start-ups and spin-offs can build relationships and find potential partners, customers or investors. This opens the door to greater



visibility, gaining knowledge and exchanging experiences with other professionals and entrepreneurs.

- Support in terms of commercialisation and technology transfer: KLSK can support start-ups and spin-offs to commercialise their innovations. They can receive support in business strategy development, marketing and branding support, business model development, target market identification.

FZJ has explored many approaches to capitalising on key developments, establishing a significant number of spin-off endeavours that have sought to bring market uptake to concepts developed from central funding. The relevant experience was shared in **Deliverable 6.1: Business Development Plan** (section 7.4.2.1: *Approaches to Exploitation*).

Table 6 describes the pre- and post- foundation support that Sano can provide spin-offs, demonstrating a continuation of support.

Table 6. Key types of support provided by Sano to Spin-offs pre- and post- foundation⁹

Category	Pre-Foundation	Post-Foundation
Financial Support	Financial support to cover patent costs, set up company, de-risk the technology and develop the business proposition, and facilitate introductions to investors	Financial support and investment to continue to cover patent costs, and invest in the technology and company development post-foundation
Facilities and Equipment	Access to facilities, equipment, and lab/office space to develop the prototypes/concepts and incubate the company pre-foundation	Continued access to facilities, equipment, lab/office space to develop the prototypes/concepts and incubate and develop the company post-foundation
Company Setup & Business Development	Company setup and business development support including help with due diligence, creating draft legal documents, patent/legal/business services, identifying experienced management teams, support with developing the value proposition and business plan	Post-foundation business development support including ongoing support for recruitment, maintaining productive relationships with the university, patent and legal support, grant writing support to access (often public) funds
Skills and capability development	Support and training to develop skills and capabilities of the founding team, including help to prepare academics for investor pitches and developing entrepreneurial skills	Support and training to develop skills and capabilities of the founding team, including help to prepare academics for investor pitches and developing entrepreneurial skills
Access to networks of investors & alumni	Facilitated access to key networks of investors and alumni	Facilitated access to key networks of investors and alumni
Ingoing Relationships with Sano		Ingoing Relationships with Sano to enable spin-offs to maintain productive links with Sano and founders remaining in Sano to engage actively with the spin-off

⁹ Adapted from: Ulrichsen, T.C. Roupakia, Z. and Kelleher, L. (2022). Busting myths and moving forward: the reality of UK university approaches to taking equity in spinouts. Policy Evidence Unit for University Commercialisation technical report. University of Cambridge, UK <https://www.ifm.eng.cam.ac.uk/research/uci-policy-unit/uci-news/uci-report-on-university-approaches-to-spinout-equity/>



6 Summary

This Deliverable provides a comprehensive overview of how Sano, a non-profit NGO engaged in scientific research and development, in the field of computational methods for personalised patient diagnosis and treatment, aims to build a spin-off culture and embrace an entrepreneurial mindset. The document defines the scope of the spin-off culture, provides relevant definitions and describes the motivation behind fostering an entrepreneurial culture at Sano, considering perspectives from the organisation's mission, its researchers and Advanced Partners, as well as Sano's environment and general society.

The document outlines various strategies for supporting an entrepreneurial mindset at Sano, including offering training, courses, informal mentoring, and acceleration and incubation programs. It also includes approaches to assessing the innovation potential, planning intellectual property protection, exploring commercialisation options, increasing technology readiness levels, and understanding applicable regulatory routes. Sano's commitment to supporting company creation and early development is highlighted, with a focus on optimal technology maturity levels for transfer, business modelling, fundraising, founder support, legal assistance, state aid considerations, and support for established spin-offs.

The spin-off culture principles at Sano emphasise the importance of cultivating an entrepreneurial mindset among researchers and stakeholders. The highlights include the needs for continuous support and training, fostering collaboration between academia and industry, and providing guidance on early-stage product development. By embracing these principles, Sano seeks to unlock the potential of state-of-the-art computational medicine research, accelerate development of user- and market-oriented solutions, and foster deployment of new products and services that make a positive impact on healthcare cost and efficiency.

Developing a spin-off culture at Sano holds immense significance in driving scientific innovations from the research phase into practical applications. By embracing an entrepreneurial mindset, Sano researchers can effectively bridge the gap between research outcomes and real-world solutions, benefiting patients and the medical community. The spin-off culture facilitates collaboration with industry partners, attracting investments, and leveraging cutting-edge research for societal benefit. Through spin-offs, Sano aims to create a dynamic ecosystem that fosters innovation-driven enterprises, strengthens the computational medicine field, and accelerates the translation of breakthroughs into tangible advancements in personalised patient diagnosis and treatment.

7 ANNEX A

7.1 Protection Options

Option	Meaning	Pros	Cons	Reading
Secret	Ideas or practise kept as an industrial secret	Cheap No public exposure of IP	No legal protection	WIPO Trade Secrets
Know-How	Tacit, valuable commercial information, which is not widely know	Can share No public exposure of IP	No legal protection	https://uk.practicallaw.thomsonreuters.com/w-013-2352
Patent	A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application.	Legal Protection	Expense IP disclosed publicly 20-year time limit on protection, need to get a return before the patent expires	World Intellectual Property Organisation (WIPO) https://www.wipo.int/patents/en/ Europe Patent Office https://www.epo.org/ UK Intellectual Property Office https://www.gov.uk/government/organisations/intellectual-property-office Patent Guide: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/463319/The_Patents_Guide_2nd_edition.pdf Patent Fact Sheets: https://www.gov.uk/government/publications/patent-fact-sheets United States Patent and Trademark Office https://www.uspto.gov/
Open Source	Allows others to use with minimal restrictions	Allows others to use Appropriate for s/w Allows community to provide fixes, improvements, and developments to code. Allows wide usage of code.	Lack of control Routes to monetarising software is less clear. More likely through services provided around the code.	Open Source https://opensource.com/resources/what-open-source Medical Device Open Hardware Projects (http://dx.doi.org/10.1136/bmjinnov-2015-000080) Using Open Source Software in Medical Devices (https://starfishmedical.com/blog/open-source-software-medical-devices/)
Creative Commons	Allows other to use with minimal restriction	Allows others to use Can include defined conditions, such as attribution	Lack of control Lack of reimbursement Not appropriate for s/w	https://creativecommons.org/
Non-Disclosure Agreement	A legal agreement between collaborators to allow the sharing of ideas.	Allows sharing of IP without loss of IP	Initial delay while NDA is put in place before collaboration	https://www.gov.uk/government/publications/non-disclosure-agreements

Consortium Agreement	Collaboration agreement that allows partners to work on a project sharing IP with clear description of background and foreground IP and how it is used before and after the project	Essential for project collaborations	Designed for research projects, different agreements may be required for exploitations	https://www.desca-agreement.eu/what-is-desca/
Publish	Disseminate through scientific literature	Puts idea into the public domain with attribution	IP not protected and cannot be patented	https://www.enago.com/academy/publish-or-patent-first/
Copyright	Copyright protects your work and stops others from using it without your permission. You get copyright protection automatically - you don't have to apply or pay a fee.	No fee No registration required Immediately protection International through the Berne Convention	Protects Literary and Artistic works	https://www.gov.uk/copyright Berne Convention: https://www.wipo.int/wipolex/en/text/283693
Trademark	A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises. Trademarks are protected by intellectual property rights.	Applies to logo and branding	Not applicable for inventions Registration required	https://www.wipo.int/trademarks/en/
Industrial Designs	In a legal sense, an industrial design constitutes the ornamental aspect of an article. An industrial design may consist of 3D features, such as the shape of an article, or two-dimensional features, such as patterns, lines or colour.		Needs registration More relevant to physical products and devices	https://www.wipo.int/designs/en/
Licensing Agreements	Permitting the use of IP owned by Sano by a third-party.	Flexibility in dividing up rights permitted to territory, portions of IP and time. Third party takes risk in developing products and services based on IP. Contractual control of IP.	Value of licences limited to IP protection. Third party benefits from IP	WIPO Successful Technology Licensing
Databases	Datasets can be protected	Protects databases Arises automatically (like copyright)	Applies to databases	https://www.dcc.ac.uk/guidance/briefing-papers/legal-watch-papers/ipr-databases
Printed Circuit Board Right	Protects layouts and components of h/w	Useful for h/w components 10-15 years Like Copyright	Not relevant to s/w	https://www.wevolver.com/article/engineers-guide-to-pcb-manufacturing-and-intellectual-property
Plant Variety	A specific variety of plant can be protected		Not relevant to Computational Medicine	https://www.gov.uk/guidance/plant-breeders-rights

7.2 Exploitation Pathways

Option	Meaning	Protection	Payment Model	Pros	Cons	Reading
Giving it away to the world	Making the ideas widely available and open for reuse by others	Open Source (s/w) Creative Commons	None, Donation, Service charges	Open for anyone to use	Loss of control No reimbursement	https://opensource.com/article/17/11/open-source-or-free-software https://www.openlogic.com/blog/proprietary-vs-open-source
Giving it to identified (so restricted) people/organisations	IP is made available to specific third parties to develop their exploitation	Licence Patent	Licensing Assigning Option	Idea is passed on for someone else to develop	Loss/share of control Share of benefits	Biotechnology From Idea to Market (Nelsen, L. 2019)
Co-developing with an entity and sharing proceeds	Collaborating with industry to bring Medical Device to market	NDA Collaboration Agreement	Licensing	Pool academic and commercial expertise	Shared benefits	Lambert Toolkit https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit The Lambert working group has created this toolkit to assist academic or research institutions and industrial partners who wish to carry out research projects together.
Licensing (for some sort of fee) to...		Licence Patent	Licensing			
Large Healthcare (h/w and/or s/w)	A company that provides h/w or s/w that may be enhanced by your IP.	Licence Patent	Licensing	Market reach and support of larger company	Locking in product with one hardware provider	Venner Shipley: Collaborating with others
Note on 'Large Software'	Analytical s/w companies are desirable allies	Licence	Sublicence	Income Prestige Connections	Possible lock-in to one software house	Ansys: https://www.ansys.com/en-gb/products/materials/granta-collaborations Dassault Systemes: https://www.3ds.com/ComSol : https://www.comsol.com/partners Materialise: https://www.materialise.com/en/inspiration/articles/factory-future-collaboration Synopsis: https://www.synopsys.com/
Small (Focused) Healthcare (h/w and/or s/w)	Working with a company who has experience of	Licence Patent	Licensing	Faster route to market, using existing company's	Sharing of control and benefits with another company	Gannons: S/w Dev IP Joint Ventures

	provisional software as a medical device.			experience and established certified practise.		
Sano Service	Provide as a service using Sano resources	Secret Publishing Patent	Free Pay per use etc.	Keep control of IP	Commitment of resources to providing services	
Separate start-up	Setting up a new spin-off company to exploit IP.	Patents	Business Plan Seek Investment to keep going until exploitation can be realised. Start-up loans and grants. Investors	Keep control and benefits	Seeking finance. Establishing certification and registration. Sharing benefits with investors. Parent organising loses skills staff to spin-off	Investopedia: Spin-Offs

7.3 Payment Models

Option	Meaning	Pros	Cons	Reading
Licence only	Sell rights to use IP to third parties	Flexibility in dividing up rights permitted to territory, portions of IP and time. Third party takes risk in developing products and services based on IP. Contractual control of IP.	Value of licences limited to IP protection. Third party benefits from IP	WIPO Successful Technology Licensing
Licence and by sales value	As above but physical component has a cost and price			
Licence and per use	Fee charge per use (per report, per patient, per hospital ...)	Profit scales with usage		
Assigning	Sell IP to third party	Immediate and upfront reward for IP No lingering responsibilities	Loss of control and subsequent exploitation of IP	Legal Zoom: IP Assignment
Options	An option to acquire rights in university IP may be encountered in several guises: as a stand-alone agreement, as a clause within an agreement (e.g. a sponsored research agreement or a material transfer agreement), or as a 'pipeline' (or 'IP framework') agreement in the context of a university spin-out company.	Immediate and upfront reward for IP	Possible restrictions on research group to further develop IP	Practical Guide to Options – PraxisAuril https://www.praxisauril.org.uk/resource/practical-guide-options