Co-funded by the Horizon 2020
Framework Programme of the European Union

H2020-WIDESPREAD-2018-01

Project

Sano

Centre for New Methods in Computational Diagnostics and Personalised Therapy

Deliverable

D6.2: IP MANAGEMENT POLICY

Deliverable Detail

Lead Beneficiary	KLSK
WP number and title	WP 6: Products, Services & Business Development
Dissemination level	Public
Delivery date	31 July 2021
Type	Report

Short Description

This document describes the IPR strategy of the Sano Centre for managing and establishing an effective and successful plan for the protection and exploitation of research results and intellectual property (IP) arising within their projects. This includes the identification of risks and challenges in the current research landscape. The overall structure of the document includes the definition of Intellectual Property assets, the mechanisms for building the IPR project portfolio, and tools used to implement the right strategy. Furthermore, the document highlights the capabilities that the Centre will need to employ and how to make them highly effective. The tremendous growth of new technology and artificial intelligence in the medical sector forces companies to take steps to prepare an applicable IPR Management strategy.

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Version Log

Issue date	Version	Author	Change description
04.11.2020	v1	Emma Hartig, Kazimierz Murzyn	Initial draft
15.02.2021	v2	Emma Hartig	Corrective actions
08.04.2021	v2.1	Keith McCormack, Emma Hartig	Structure of the document
08.06.2021	v4.3	Karolina Tkaczuk	Formatting, spelling adding input to the selected sections including 4.1

Issue date	Version	Author	Change description
09.06.2021	v4.3.	Wioletta Niwińska	Input material to 3.1.
10.06.2021	v4.3	Karolina Tkaczuk	First version of the executive summary, Introduction, input to the Section 3.3
10.06.2021	v4.3	Wioletta Niwińska	Section 5.5 and 5.7.
15.06.2021	v4.4	Emma Hartig, Katarzyna Tabor	Formatting and proofreading
28.06.2021	v4.5	Olav Zimmermann, Tanja Bratan	Quality Assurance Review
06.07.2021	v4.6	Emma Hartig, Wioletta Niwińska, Karolina Tkaczuk	Introducing changes after the review
21.07.2021	v4.7	Emma Hartig, Keith McCormack, Wioletta Niwińska, Karolina Tkaczuk, Tomasz Gubała	Further amendments to the structure and content
29.07.2021	v4.8	Karolina Tkaczuk	Final content review
29.07.2021	v4.9	Keith McCormack, Wioletta Niwińska, Karolina Tkaczuk, Katarzyna Tabor	Final comments and contributions, technical quality check
30.07.2021	v5.0	Katarzyna Tabor	Release version

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Executive Summary

This Sano IP Management Policy describes the Centre's approach to the generation and protection of intellectual property, and extends from the current early stage of Sano's development to the planned mature future position. The various activities arising from this approach will be regulated by Sano's formal internal IP Regulations, already in preparation.

The Plan's purpose is to establish the basis for the Centre's long-term management of its IP portfolio, encompassing the twin processes of the generation and management of intellectual assets, the commercial and academic exploitation of which will contribute to Sano's financial and reputational stability; some specific procedures are already in place, and others will be elaborated in a series of Sano Teaming for Excellence deliverables and in Sano's internal regulations, references to which are included in this document's sections:

Section 1 provides a general introduction to the concept and basics of Intellectual Property within the Medical Technology ('MedTech') Market, keenly relevant to Sano and its activities. This section therefore establishes the foundations on which the remainder of the document is built.

Section 2 describes the Centre's IP protection methodology, with a discussion of available forms of protection and alternative approaches to safeguarding intellectual assets.

Section 3 explains the practical approaches to IP Portfolio management, taking into account Sano's mission and goals. Particular attention is given to the IP lifecycle, as approaches to protection are influenced by the degree of an asset's technology readiness. Examples of candidate MedTech assets are examined.

Section 4 provides insights into the evaluation and exploitation of technology at each stage of development, and discusses the steps to be taken before the emergence of Sano's assets onto the market. This section also describes the concept of the Sano IP decision tree, which will form the basis for the allocation of assets to particular management pathways.

Section 5 details the internal and external metrics that are being implemented to track the success of the IP management policy in facilitating the Centre's achievement of its goals.

Section 6 briefly summarises the document.

Introduction

This deliverable discusses the approaches to Intellectual Property Rights (IPR) management at Sano. Covering the main objectives identified in the Sano Grant and Consortium Agreement, it builds on the concepts introduced in Sano's Business Development Plan (D6.1), and illustrates the fundamental issues being considered by the Sano Consortium and Stakeholders as they construct and implement the procedures for IPR management.

Importantly, it also sets out the Centre's long-term approach to establishing a robust IP portfolio. It can be achieved by describing the role of prioritisation in creating a catalogue of competitively-positioned assets that can further be exploited throughout the Sano value chain and enhancing Sano's success. Building excellence in the selection and implementation of appropriate IP protection mechanisms will maximise the potential to exploit arising opportunities and improve the overall success of the Centre's commercial and academic activities.

1. IP RIGHTS in Healthcare – Fundamentals

1.1. Healthcare Technology and the Sano Portfolio

Undeniably, "medical technology is a global growth market characterised by the fast pace of innovation."[1]. This section of the document examines the importance of cooperation between Academia and Industry and discusses the potential results of such alliances, underlining the merits of Sano's chosen approach to portfolio creation that is designed to capitalise on the accelerating growth in such complex medical technologies.

The growth in MedTech is such that the European Patent Office report for 2020 placed it in the top grouping by number of patent filings (see Figure 2 below), and such a proliferation in overt IP protection goes hand-in-hand with an equivalent increase in technology transfer[2] activity. However, notably and rightly, MedTech developers are also being significantly influenced by a wide range of bureaucratic frameworks, especially those concerning regulatory compliance, and yet further legal constraints may be imposed in particular territories limiting the commercial scope of academic institutions.

In combination, these requirements for IP protection, exploitation skill, regulatory certification and legal adherence are particularly challenging and, with the goal of streamlining its systems, Sano is carefully designing its procedures to ease the process of product development through these commercial and regulatory systems. Perhaps, because of the multitude of possible technology-transfer mechanisms, the most complex of considerations is the relationship between Sano and potential commercial partners; just some of the possible forms of collaboration between Academia and Business include:

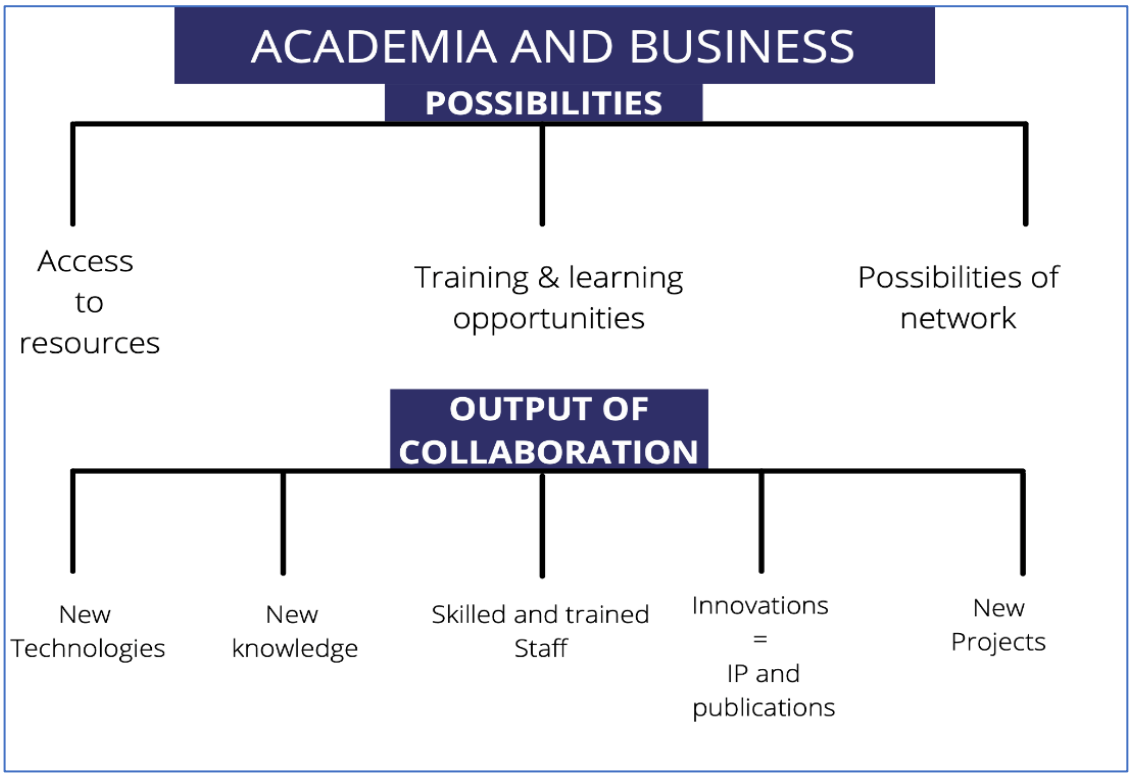
- Joint participation in (typically grant-funded) research projects [joint benefit],
- Contracted research [industry funds academia],
- Licensed technology, including software (exclusive or non-) [industry funds academia],
- Long-term co-operation [industry funds a large body of academic research],
- Favourable-terms use of commercial materials in exchange for output [mutual benefit],
- Academic spin-offs [commercial or venture funding arrangements],
- Commercial manufacture [academia buys commercial manufacturing facilities].

Perhaps most importantly, an effective IP Portfolio must be structured in such a way that complex subdivisions in assets are possible, to minimise the consequences – the reach – of any restrictive provisions and maximise their utility and applicability. Exclusivity is a particularly challenging issue as short-term benefit must be set against wider potential long-term opportunities.

A graphical illustration of the common categorisations of cooperation is shown in Figure 1.

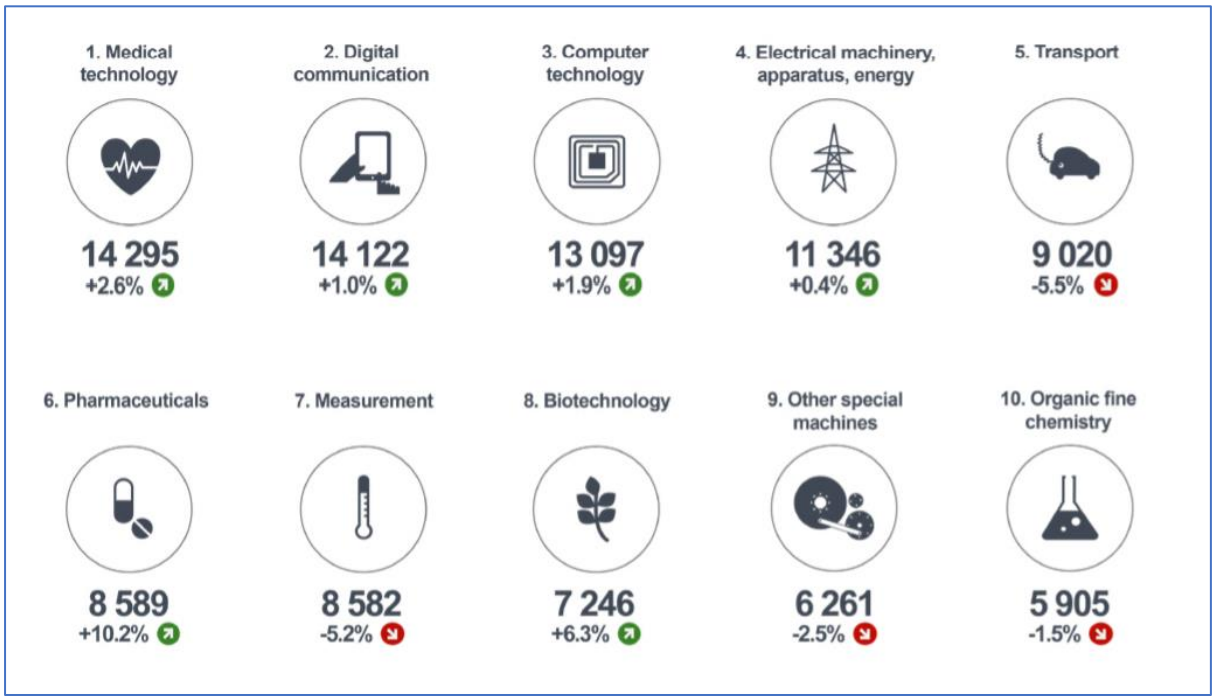
[1] https://www.luther-lawfirm.com/fileadmin/user_upload/MedTech_Studie_EN_20200525.pdf
[2] *'The process of transferring scientific findings from one organization to another for the purpose of further development and commercialization'* https://www.wipo.int/wipo_magazine/en/2006/05/article_0005.html

Figure 1. Co-operation between Academia-Business



Based on Source: Perkmann, M., Neely, A. and Walsh, K. (2011), How should firms evaluate success in university–industry alliances? A performance measurement system. R&D Management, 41: 202-216.

Figure 2. Ranking of top field of patent filing in 2020



Source: EPO – Patent Index 2020
(https://documents.epo.org/projects/babylon/eponet.nsf/0/8960BF9632AE9662C12586960035F86B/$FILE/Patent_Index_2020_statistics_at_a_glance_en.pdf)

1.2. Historical context for IP Rights

This section will consider the purposes of protecting IP, the ambitions of legislators, the current challenges of the IP system, and alternatives to the conventional, including the evolution of new IP approaches.

Intellectual property is understood as property, established by laws on intangible goods, which is the creation of human intellect. Typically, such intangible goods are characterized by four scopes:

1. Material [the definition of the particular element of IP],
2. Personal [the organizations involved],
3. Territorial [the geographical areas in which any licensing may apply],
4. Temporal [the duration of any commercial arrangement].

Where an element of IP may have multiple utilities, there may additionally be restrictions on the particular subset of uses to which it may be put.

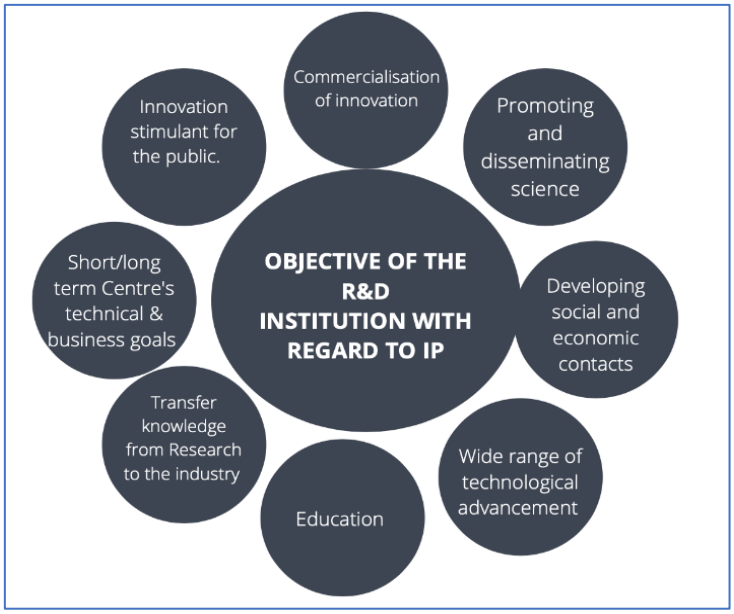
Sano's areas of activity fall into three, currently very popular, general fields of technologies:

- Medical Technology,
- Digital Health,
- Artificial Intelligence.

However, changes in categorization take place increasingly frequently, and Sano must remain alert to the possible need for redefinition. More fundamentally, there is a requirement to match the current IP legal system to the changing market needs associated with new forms of IP, and Sano's IPR management must be aligned with the current market perspective, and its requirements. The differing, fluctuating risks associated with innovation and competition make it particularly difficult to settle on a fixed approach, and it is inevitable that multiple mechanisms will be adopted, changing over time. Especially while operating in such an innovative area where the technological capabilities change almost daily enforcing legislators to create new rules that would govern the use of such tools.

It is therefore important to establish the global purposes behind the protection of IP and consider their relevance to Sano. The graphic in Figure 3 shows those purposes, further elaborated below.

Figure 3. Purposes of IP protection at Sano



1. **Commercialisation of Innovation:** Sano aims are creating highly innovative solutions that will answer practical needs of the medical sector, which implies the need for commercialization of these inventions. Also, by bringing IP to the market, Sano will build its value on the market and therefore build profitability from established assets, which will also contribute to the other efforts to make Sano a self-sustained institution.
2. **Promoting and Disseminating Science**: Sano concentrates strongly on the promotion of scientific findings and the search of new scientific solutions. Sano's success will therefore be built on establishing a reputation for scientific excellence, and evidence of excellence includes the demonstrable ownership of intellectual property established through research activity. Sano may decide to make part of the IP open to public under open-source licenses, thus the necessary steps must be taken to make sure no unintended use of that resources takes place and they are protected by a proper legal means.
3. **Developing Social and Economic Contacts:** In order to maintain currency in the Research and Development area, Sano collaborates with various entities on improving existing IP and using others' scientific knowledge, standards and created procedures to establish new products and services.
4. **Wide-Ranging Technological Advancement:** apart from creating innovative solution from the scratch Sano's process of generating innovation includes the part in which new technology production with significantly improved features – containing goods, processes or services, compared to those that were previously produced and established.
5. **Education:** Sano also aims at promoting and fostering the engagement of Academia and Business in the development of IP. Therefore, strengthening a cultural and personal awareness, aiming to promote knowledge about IP via various types of activities ultimately leading to creating the entrepreneurship spirit by providing wider public with practical tool kit will constitute one of the activity strain at Sano.
6. **Knowledge Transfer from Research to Industry:** Sano also aims at providing the possibility to share knowledge and innovation coming from one entity to be able to duplicate the work of another entity and therefor build the strong foundations of a collaboration and continuous development. That type of activities requires of course deep considerations when it comes to the intellectual property ownership and sharing that will enable fruitful and successful

collaboration between the parties. Proper legal aspects of IP management have to be in place to make sure it is possible.

7. **Short and Long-Term Technical & Business Goals**: proper protection of IP positively affects the Business Development strategy by stimulating business growth by developing a strong portfolio as well as strengthening the reputation of the Centre in terms of business acumen of the Centre.
8. **Innovation Stimulus for the Public**: IP is a trigger for asset development as well as the encouragement of innovation among the market. Sano by protecting its IP aims to add strategic value.

The IPR landscape is therefore evolving in at least two directions:

- The nature of what constitutes IP, and therefore how it might be exploited, is developing continuously as new approaches – particularly in Sano's chosen field of software for healthcare – are continuing to be introduced at an ever-faster rate,
- The available protection mechanisms and legal constraints are adjusting, albeit typically more slowly, the scope for, and limitations on, possible exploitation pathways whilst introducing new factors that potentially can disrupt existing contractual mechanisms.

Here are tabulated additional issues affecting the landscape, with elaboration of the challenge and the consequences for Sano:

Table 1. Current challenges affecting IP Management

CIRCUMSTANCE	DETAIL	ISSUES FOR SANO
IP Rights are territorial	Protection of IPR, whether by copyright or patent, can only be obtained territorially, single-step global coverage is unavailable. This has multiple consequences: • Territorial alignment between Sano and licensees may be an issue, • Pressure to extend licences to non-preferred territories may be significant • Protection of authorship rights, affecting the majority of Sano's assets, may be inadequate in many territories, • Territories with rampant abuse may be a source of reputational damage, • Licensees may be unwilling to participate in the costs of ensuring worldwide compliance.	• Healthcare is a universal marketplace, but protecting IP globally is expensive, and in some territories may be futile. • If exploitation is to be through licensed manufacture, the marketplace must be aligned with the IPR-protected territories, but this may conflict with the ambitions of the licensee, affecting negotiations. • Issues affecting decisions include: ○ Support costs, ○ Enforcement potential, ○ Local legal restrictions, ○ Reputational consequences. • Insistence on territorial restriction may be ethically unsatisfactory. • Reputational damage may attach to abuse.
IPR standards lack uniformity and transparency	There is little uniformity for the protection of intellectual property at international level: • Patents have a degree of international scope via the EPO and PTC, • Copyright has no equivalent mechanisms.	• Lack of uniformity drives a focus on key markets. • Poor initial judgement may lead to prohibitively high subsequent costs if territorial extension is required. • Familiarity with trans-national mechanisms is paramount. • Sano's likely predominant reliance on copyright is challenging given a lack of international agreement. • The argument for the maintenance of trade secrets is particularly strong, but requires skilful design, and licensee compliance.
IP protection systems are inadequate for	The growth of new technologies challenges IP Rights systems which respond sluggishly, leaving emerging IP unprotected.	AI technology has a profound impact on IP protection, especially in the case of the challenges regarding the ownership aspect and defining the "inventor". The

CIRCUMSTANCE	DETAIL	ISSUES FOR SANO
AI and emerging technologies	A clear example is the strategy for AI and the proposed AI regulation[3].	impact on Sano's Innovation and Technology Office will be significant.
A specific software protection mechanism is lacking	It is widely agreed that existing mechanisms are slow to respond and are inadequate for the protection of software. **PATENTS:** There remains fundamental disagreement as to whether software may be classified as an invention (and so be patentable), even if they implement abstract ideas. Moreover, there are incompatibilities across the practices of Patent Offices internationally. A current discussion is underway between the USA (USPTO) and Europe (EPO). **COPYRIGHT**: Much of the world's software is protected by Copyright law. **TRADE SECRET**: Secrecy, backed up with Non-Disclosure Agreements, are often effective.	**PATENTS:** Reliance on the patent system is suboptimal but may be unavoidable. Section 4.3 elaborates the differences in the approach between the US and EU. **COPYRIGHT**: Protection covers all forms of expression, in particular source code and object code, including firmware. But copyright law protects the expression of the ideas but not the idea itself. This can readily lead to misunderstandings. **TRADE SECRET**: Sano will certainly employ this approach.
Long patent registration process	The process of granting a patent is prolonged.	This may cause disaffection towards the complicated standards, therefor Sano will seek for alternatives, briefly described in Section 2.
Inadequate awareness of IPR importance	The lack of awareness and understanding of importance of IP may cause IP leaks.	For this reason, it is important that there is a common understanding of the importance of IP at each Research Centre/ Company. Sano will introduce IP awareness training to prevent development of ignorance towards IP.
Lack of IP management skills	Any lack of IP management skills lowers the ability to benefit from IP assets.	Sano will seek to establish extreme expertise in: • Asset protection mechanisms, • The multiplicity of alternative commercialisation pathways.
Limited respect for copyright	Especially piracy of software, which constitutes abuse of Distribution, Selling, Copying and Modifications.	Sano will consider all possible means to limit abuse of its rights through piracy.

1.3. Commercial significance of IPR, Categorisation

This section will underline the commercial value of IP and the need for collaboration between academia, clinical world, and business to strengthen the possibilities for the commercialisation of innovation.

The intangible resources developed as part of the innovation process are valuable because of their later use in the production of goods and services. The choice of the form of protection for IP assets and the further commercial activities conducted by the Centre are therefore important to its profit potential, driving investment in additional R&D activities.

The first and most common issue arising when defining the future potential commercial value of an asset is whether to invest in protecting it as an Intellectual Property asset, or whether to keep it secret; the advantages and disadvantages are described later in the document. Importantly, however, an invention that will ultimately be disclosed publicly through a patenting procedure must nevertheless be kept secret until that moment of publication, as otherwise the patenting process will fail.

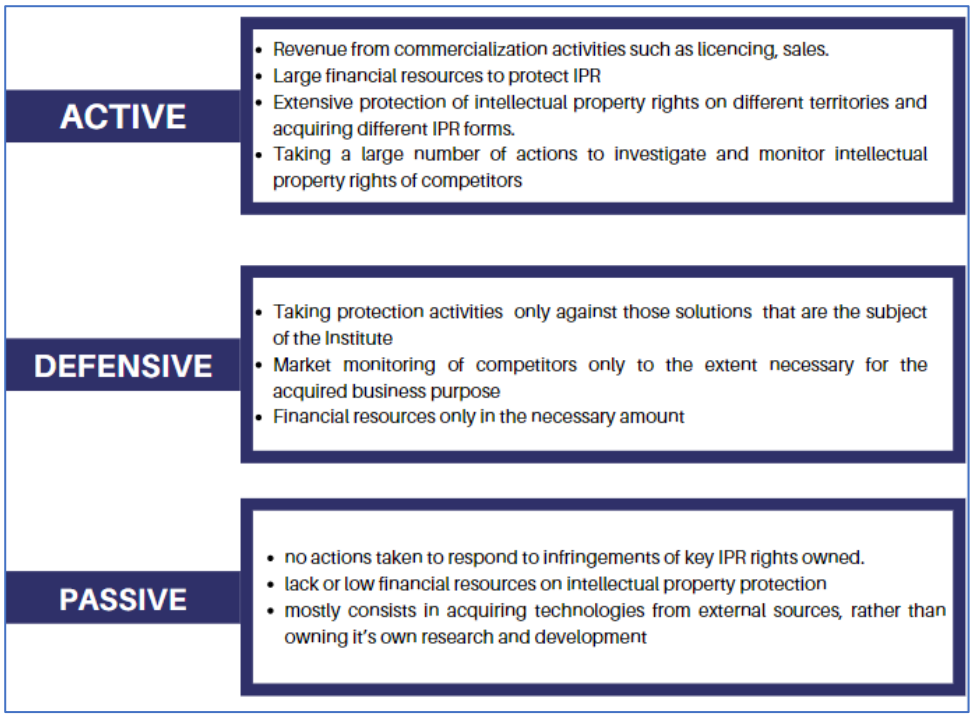
3 Proposal For A Regulation Of The European Parliament And Of The Council Laying Down Harmonised Rules On Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021PC0206&from=EN

The protection pathway to be chosen is also influenced by the desired outcome. Typically, a high level of innovation and the skillful choice of IP protection strategy will maximize consumer engagement, improving sales and translating into a higher rate of competitive growth, both regionally and globally. But popularity increases the likelihood of competition, emphasizing the need for an adequate protection strategy. The main intellectual property strategies are presented in Figure 4, but this document does not propose a single protection strategy as not only will this always be affected by circumstance but also, as a public document, it would be inappropriate to include information that may have commercial value. Nevertheless, the choice of appropriate IP strategy will follow a predictable series of steps:

- Determining the overall Sano IP Portfolio strategy,
- Characterising the structure into which intellectual assets will be compartmentalised,
- Populating the portfolio with the IP assets Sano owns,
- Identifying the portfolio development pathway that will optimise value and opportunity,
- For any new candidate asset, assessing the level of innovation and the fit with the pathway,
- Considering whether the significance of the candidate merits a revision to the overall strategy,
- Identifying the motivations for IP protection:
    - If philosophical (because of possible future value) consider the timetable,
    - If for commercial reasons (value or market access) carry out a commercial assessment,
- Assess the consequences for knock-on protection requirements of related assets,
- The process is further complicated by its circular nature – the number of IP assets and the scope of protection affects the allocation of the appropriate strategy. Additionally, the fluctuating marketplace, the existence or potential for competitive products and the need to demonstrate capability for reputational purposes each play their part. Finally, it may be that a single strategy is impossible or undesirable, particularly where multiple assets in combination may be required for appropriate exploitation.

An awareness of the three broad market positioning and development approaches and the factors that affect the choice of stance can be built from the groupings illustrated in Figure 4.

Figure 4. Possible IP Strategy pathways



The graphic was established on the base on: Dariusz Trzmielak, Szymon Byczko "Zarządzanie własnością intelektualną w przedsiębiorstwie i na uczelni", Gdańsk 2010

Importantly, Section 3 of this document discusses in detail the issues relating to Sano's construction of a Portfolio of intellectual assets based on the principles introduced here and the Section 1.4 discusses the legal structures supporting the protection of assets.

1.4. Legal structures supporting IPR – Legal Framework

This section underlines the need to meet various requirements set by several institutions, that are applicable for Sano. A brief description of H2020 requirement, which are highly relevant for Sano and complementary funding is followed by information on general standards regarding IP.

Sano must firstly respect the conditions of its two principal funders, the European Commission and the Foundation for Polish Science:

- The European Commission's H2020 Grant Agreement and the specific Consortium Agreement for the Sano project "Centre for New Methods in Computational Diagnostics and Personalised Therapy" (based on the DESCA model) together define the EC's basis for the ownership and exploitation rights for Consortium Members.
- Sano is also bound by the regulations connected with its complementary funding, provided by the Foundation for Polish Science under its International Research Agendas Programme (IRAP), which imposes additional requirements on Sano's research-related activities. General obligations stated in Competition Documentation for IRAP Plus Module define the rules for intellectual property rights resulting from executing the project. More specific guidelines for partnerships in the project give additional information on possible approaches towards IPR issues, including dissemination of results, access rights and rules for compensation for the IPR. Some of the most important rules are presented in Table 2.

Table 2. IP rules according to IRAP competition documentation and Teaming for Excellence Grant Agreement

Grant	IRAP	Teaming for Excellence
Goal	IP must be properly commercialized and bring benefits to Sano.	Protection of the results with adequate measures (incl. appropriate period of time).
General ownership rule	Any IPR resulting from the funded project are fully owned by Sano.	Results are owned by the beneficiary that generates them.
Formal requirements for agreement on IP	The potential division of intellectual property rights between the partner institutions must be included in the agreement between them, which shall specify its calculation method based on the contribution and interests of both parties.	The beneficiaries must identify and agree (in writing) on the background (data, information, or know-how) for the action (access to the background is granted according to the access rights provisions in GA).
IP developed in cooperation with other entities	Any intellectual property rights resulting from the project are allocated to the different cooperating partners in a manner which duly reflects their work packages, contributions and respective interests.	Joint ownership by several beneficiaries – if the results were generated jointly, or it is not possible to establish contribution of each beneficiary. Allocation and terms of exercise of the joint ownership must be defined in joint ownership agreement.
Ownership transfer	The IRAP implementing unit receives compensation equivalent to the market price for the intellectual property rights generated by their activities which are allocated to the participating enterprises, or to which participating enterprises are allocated access rights. Compensation received is equivalent to the market price if it enables the IRAP implementing unit concerned to enjoy the full economic benefit of those rights.	Transfer of ownership is possible for all beneficiaries, yet REA can object up to 4 years after the end of action.

These two sets of conditions act as a backbone for Sano's IP management, to be supplemented by Sano's own more specific Internal Regulations. Mindful of Sano's expected growth, additional new projects will introduce further requirements and specific rules, which will be incorporated into the structure of Sano-wide IP management activities. Moreover, Sano will follow the practices and guidelines established by the European Commission, WIPO, EPO and other offices responsible for the establishment of IP standards.

While implementing its strategies, Sano will consider Polish, European and other international legal frameworks for IP rights protection. Habitually, these IP Offices will be used as a support to search for current information and changes in legislation in each legal system. It is unfortunately but inevitably the case that there are differences between national regulatory frameworks, policies and practices, and Sano's Legal and IP Office will be responsible for the compliance of IP Management with national, regional and international regulations.

The World Intellectual Property Organization (WIPO: https://www.wipo.int/portal/en/) aims to harmonise the current approach to the strategic formulation of Intellectual Property globally. The wide range of reports and approaches published by WIPO will enable the Centre to apply standards currently practiced in most innovative countries. WIPO gives organisations access to statistical, technical and legal information and permits organisations to integrate that information into their IP Strategies.

International agreements have made it possible to create classification structures that enable the substantial amount of existing data covering IPR to be searched by potential applicants. The resulting International Classification is summarised in Table 3.

Table 3. International Classification of IPR

International Classifications	TYPE OF APPLICABLE IP	EXPLANATION	ACCESS TO NICE CLASSIFICATION
Nice	**Trademarks**	One of the points of application for protection for a trademark is the list of goods and/or services, established using the International Classification of Goods and Services, the Nice Classification.	• WIPO – https://www.wipo.int/classifications/nice/nclpub/en/fr/ • Tmclass – http://tmclass.tmdn.org/ec2/ • Similarity - http://euipo.europa.eu/sim/
Locarno	**Industrial Designs**	The Locarno classification is a system for classifying industrial designs, applied while filling in a design to identify it with a product indication (PI).	• https://www.wipo.int/classifications/locarno/locpub/en/fr/
Vienna	**Figurative elements of trademark designs**	Vienna classification is managed by the WIPO and is created for the classification of graphic elements of trademarks (graphic marks).	• https://www.wipo.int/classifications/nivilo/vienna/index.htm?lang=EN • https://euipo.europa.eu/designclass/
International Patent	**Patents and Utility models**	The main objective of the Classification for the International Patent Classification is to create an effective instrument of finding patent documents by intellectual property offices and other subjects, to simplify the examination of novelty and assessing the inventive level (including the assessment of the technical level and effects of use) of the notified inventions.	• https://www.wipo.int/classifications/ipc/ipcpub/

Table 4 lists core International IP Recourses and Offices and their Webpages, as a source of information about current IP legislation changes in different Countries.

Table 4. International IP Recourses and Offices

ACRONYM	OFFICE	WEBPAGE
OAPI	African Intellectual Property Organization	http://oapi.int
ASBU	Arab States Broadcasting Union	http://www.asbu.net/ar/
BOIP	Benelux Organization for Intellectual Property	https://www.boip.int/nl
EAPO	Eurasian Patent Organization	https://www.eapo.org/en/
EPO	European Patent Office	https://www.epo.org
EUIPO	European Union Intellectual Property Office	https://euipo.europa.eu/ohimportal/pl
USPTO	United States Patent and Trademark Office	https://www.uspto.gov
IP Australia	Australian Patent Office	https://www.ipaustralia.gov.au

1.5. Ethical Issues for IPR in Healthcare

Sano is alert to the multitude of ethical issues that can arise in biotechnological developments, and actively seeks both to establish agreed internal policies that will steer the Institute through challenges as they arise and to contribute to the international debate in emerging areas where the sometimes-conflicting interests of involved parties, including society itself, must be balanced. In particular, it recognises that, as an emerging international centre of excellence in the pursuit of innovative healthcare developments, it has a duty to act in accordance with socially appropriate codes of practice.

Recently formulated ethical challenges can typically be structured into grouped categories, as discussed in several recent publications[4,5,6,7,8,9]:

The established issues that every activity involving individual human subjects must consider include:

- Transparency of information exchange,
- Informed consent to involvement in activities, and the various categories of data usage and exposure that can range from de-identified aggregated summary analyses generating purely technical physiological or material property outputs, to the broadest of exposure within fully commercial exploitative contexts,
- Access to information that relates to individuals personally, including the appropriate release of incidental findings, and to the results of disease-related research activities that may influence the treatment of categorised patient groups,
- Access to disseminated results,
- Availability of the technological developments that represent healthcare benefits arising from individual participation,
- The equitable distribution of benefits arising from exploitation.

The research community also seeks to establish and exercise rights that can drive forward the nature and content of programmes of research:

- The fundamental right to conduct research generally,
- The right of access to data for ('significant') societal benefit,
- The right to seek (perhaps not to be granted) ultimate sanction to conduct contentious work.

At the heart are some fundamental yet debatable principles:

- Limits to the nature of research,
- Organisations seeking exclusively to protect[10] a fundamental technology,
- Authorities having the right grant such protection,
- The additional obligations on organisations granted contentious protection.

All activities within the Sano project will follow strict procedures to ensure compliance with the highest standards of research ethics. In practice this represents:

- Global compliance with standards at EU level,
- For each EC project partner, compliance with national standards,

[4] Centre for Intellectual Property Policy & Management (CIPPM): Ethics of Intellectual Property Rights: Challenges & Solutions, https://microsites.bournemouth.ac.uk/cippm/2017/03/17/ethics-of-intellectual-property-rights-challenges-solutions-2/
[5] Jorn Sonderholm (2010) Ethical Issues Surrounding Intellectual Property Rights, Philosophy Compass, 5(12), pp1107-1115, https://doi.org/10.1111/j.1747-9991.2010.00358.x
[6] School of Advanced Studies: Legal and Ethical Issues: Copyright and IP, https://port.sas.ac.uk/mod/book/view.php?id=1323&chapterid=968
[7] Is there a role for ethics in Intellectual Property? https://cronan.co.uk/is-there-a-role-for-ethics-in-intellectual-property/
[8] Sara Anne Hook (2011) Ethical Issues in IP Law Practice: Where the Rubber Meets the Rules, AIPLA Spring Meeting 2011 https://scholarworks.iupui.edu/bitstream/handle/1805/3021/Ethical%20Issues%20in%20IP%20Law%20Practice.pdf;jsessionid=FCE0DC9064265942156BF1332A903673?sequence=1
[9] Intellectual Property and Bioethics - An Overview, WIPO Publication (PDF) https://www.wipo.int/publications/en/details.jsp?id=161&plang=EN
[10] Source based on: https://www.wipo.int/edocs/pubdocs/en/intproperty/932/wipo_pub_b932ipb.pdf

- In the case that national standards disagree, compliance with the highest national standard.

The gravity of ethical issues in the development of new healthcare technologies is such that Sano will create internal guidelines, policies and procedures on ethical issues in Sano, including, amongst others a Code of Ethics and Principles of Good Scientific Practice.

The approach to ethical issues that are of particular concern to the European Commission have already been considered and reported by Sano in Deliverable 8.1 and 8.2.

2. IP Protection Mechanisms

This section provides guidance on:

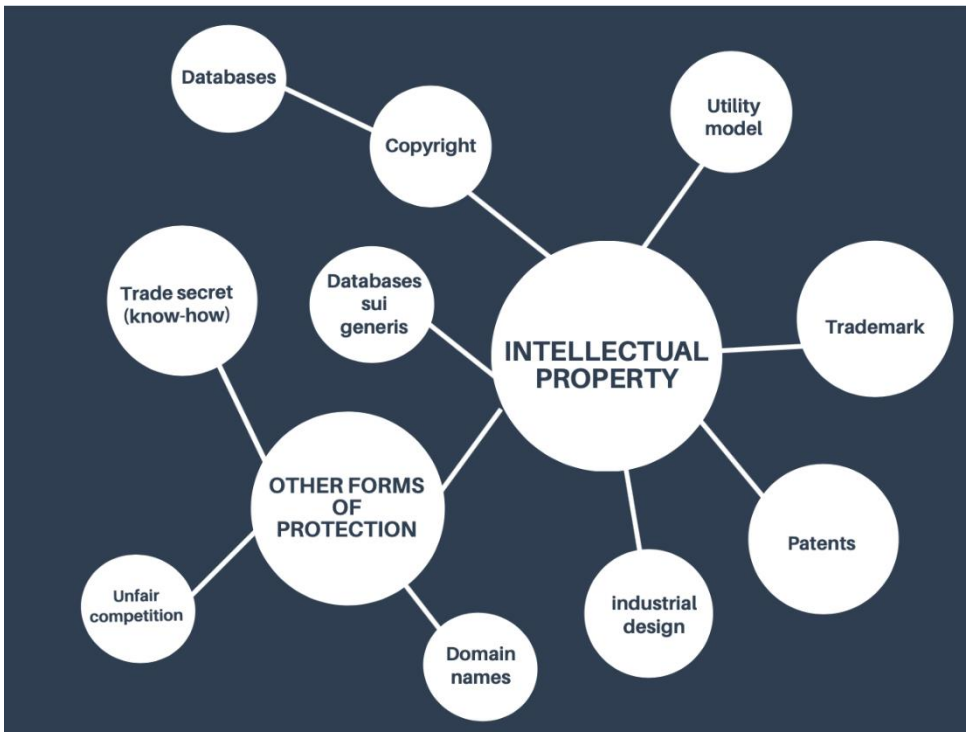
- Available IP protection mechanisms, with particular application to the MedTech market,
- The relative merits of classic and alternative mechanisms,
- The methodology to be employed and factors to be considered during implementation,
- Specific issues relating to product development and enhancement.

There are several reasons for IP developers to establish and advertise their IPR:

- Primarily, to assert exclusive rights to an asset, so enabling legal redress for infringement,
- To foster the economic contribution to social development, stimulated by the exploitation of IPR-protected intangible assets – it is widely agreed that IP has become the key factor driving the knowledge economy,
- Adequate protection of inventions and associated IP assets is a decisive step in turning ideas into economic resources with quantifiable market value,
- Sharing knowledge to promote innovation and commercialisation is central to the rapid widening of the development of technological advances.

Policymakers and public authorities actively attempt to optimise IP mechanisms such that they more effectively stimulate innovation, and their success in doing so has led to the dramatic developments in innovation witnessed in recent years. As a result of this proliferation of mechanisms, a single product or service may well be protected by multiple forms of IP protection, each of which will cover a different aspect of that product or service, and Sano is alert to this possibility. The most important candidate mechanisms are illustrated in Figure 5.

Figure 5 . IP Protection forms



2.1 Classic Mechanisms

IPRs are recognised as exclusive rights that enable the owner to decide about the possible usage of the solution. The main categories of intellectual property are *copyright* and *industrial property* that refers to trademarks, patents, utility models and industrial designs. Each of those forms enables the protection of different aspect of the asset, meaning that an asset may be protected by multiple forms. Table 5 presents the main and alternative forms of IP Protection and possible target assets that might be protected with those tools.

Table 5. Description on Classic IP protection forms

TOOL	CHARACTERISTICS	DURATION	TARGETS	REGISTRATION
PATENTS	The exclusive right granted for inventions. Patentable inventions must have the following characteristics: novelty, inventive level, industrial application capability and technical nature- **Novelty** – Not part of the state of the art. Existing knowledge cannot be patented[11]. **Inventive level** – the solution must not be obvious to a skilled person. **Industrial application capability** – the possibility to achieve a repeatable effect. Governed by territorial law.	20 years	Determined products such as devices machines tools, but also products, methods and applications.	Registration in the dedicated Office after meeting the registration requirements. To establish a patent – either solely or jointly with a partner, an application to the competent agency/Office shall be made.
TRADE-MARKS	– Protection of the Company name in different manners. – The sign must be capable of distinguishing of the goods or services produced by one entity from other entity. – Territorial law. – Trademark protection law gives the owner a monopoly in respect of the products or services classified and indicated in the application. The classification system is called the Nice Classification.	10 years, might be renewed every 10 years	We distinguish different types of trademarks such us for example[12]: Words, Generic Mark Descriptive Mark, Sound Marks, logo, colour, Pattern Mark, Position Mark Hologram Mark Multimedia Mark.	Registration in the dedicated Office after meeting the registration requirements. It may also be protected without the registration with unfair competition. Aspect to consider when registering the trademark: • The goods and services provided by Sano, • Nature of the business provided (commercial, non-commercial).
INDUSTRIAL DESIGN	– Determines the external form of the object – the appearance of the product. – The industrial design must be **new**. The industrial design might not be disclosed anywhere in the world before the date of its application for protection. – It must have an **individual character** – it must be distinctive from other previously published designs.	The right to register an industrial design can usually last up to 25 years	For example: packaging, handles, object shapes etc.	Registration in the dedicated Office after meeting the registration requirements.
COPYRIGHT	Protects the creations of human creative activity = the **result** that is determined and possible to be communicated to others. Must be **individual** in nature. Following the requirements set by the laws globally -discoveries, ideas, procedures, methods and principles of operation, mathematical concepts may not be protected with copyright protection.	Depends on the territory	Computer software, source code and object code, videos, pictures, graphical interface (layout) of the website.	As mostly there is no registration applied for Copyright, yet there is a new tool established by WIPO – called WIPO PROOF (more about it in Section 5.5).

[11] https://www.epo.org/applying/european/Guide-for-applicants/html/e/ga_c3_3_1.html
[12] https://euipo.europa.eu/ohimportal/pl/trade-mark-definition

2.2 Alternative Mechanisms

There is no single most appropriate protection pathway; each of the above forms of protection might be relevant to a particular Sano asset depending on the strategy, the nature of the asset, its suitability for exploitation either alone or in combination, and the likely contractual scenario that Sano envisages. However, there are circumstances in which these conventional approaches may be inappropriate.

When choosing the best form of protection, Sano will consider the main goal and mission of the Centre, with a special emphasis on the R&D activity. The paramount consideration in patenting is that details of the invention must be kept secret until a successful filing has been completed, otherwise the novelty requirement might be undermined.

Alternative Strategy A: The Trade Secret

Having kept the novelty secret, an alternative course of action is simply to continue to do so, a strategy that may be particularly appropriate for software solutions, where the complexity of the computational methodology may be extremely difficult to replicate. Table 6 illustrates the contrasts.

Table 6. Patent vs. Trade Secret differences

	PATENT ?	TRADE SECRET
Subject protection	Innovation that is new, non-obvious. The invention through registration becomes public, everyone may become accustomed with the subject of the patent file. The patent gives the right to exclusively use the invention in an economic and professional manner.	Protection of valuable and non-obvious information that is kept secret. The information concerns technical, technological or organisational matter. The information provides competitive advantage thus, it is kept secret.
Objective	– To increase value of the Centre, – The possibility to bring claims, – Legal confirmation of IPR protection, – Gain recognition by monetizing through licensing.	– To prevent others from getting to know the specific and details of the protected information, – The level of protection of trade secret depends on the impact made to protecting it, especially by taking certain steps to prevent them from being disclosed to the public, this includes activities such as securing the workplace, blocking access to the computer, confidentiality clause.
Costs	Cost of maintaining protection – protection fees.	No cost of protection – no protection fees.
The rights	The right to exclude others from making, selling, using, importing and thus Possible claims for non-compliance with those rights.	Unwillingness to disclose the clue of the solution.
Time	20 years	Until breach or rediscovery/ reinvention/ reimplementation
Registration	Formal application for registration.	No registration required.
Infringement	Easier to proof the infringements of rights as there is a legal evidence of being the owner of the invention.	– Harder to proof any infringements, – Possibility to make claims against the infringer with unfair competition, – The level of protection of trade secret is significantly lower than that of a patent for this solution.

Alternative Strategy B: The Utility Model

Anticipated to be less appropriate to Sano, the Utility Model refers to an innovation where the novelty lies in the form of the product, rather than its function. The attributes are contrasted in Table 7.

Table 7. Patent vs. Utility model differences

	PATENT ? .... UTILITY MODEL	
Subject protection	The patent gives the right to exclusively use the invention in an economic and professional manner. Patents include: – Products, – Devices, – Manner, – Applications.	– Applies to the specific shape of the object. – Something between industrial design and patent. – Must be of a **technical nature** and relate to the shape, construction or combination of an object – the important requirement is the **durable/ lasting form**. The utility model might not be: – substances, – mixtures, – methods, – uses.
Objective	– To increase value of the Centre, – The possibility to bring claims, – Legal confirmation of IPR protection, – In some countries a patent application can be converted into a utility model application (UPRP – Poland).	
Costs	Cost of maintaining protection – high protection fees.	Cost of maintaining protection – but are much cheaper than patent fees.
The rights	The right to exclude others from making, selling, using, importing and thus Possible claims for any non-compliance with those rights of the owner.	
Time	20 years	10 years – May be protected for short-lifetime assets
Registration	Formal registration – long granting process for patents (even 2-3 years quicker for utility models (4-6 months from the filing date).	
Infringement	Possibility to proof the infringements of rights as there is a legal evidence of being the owner of the invention.	

Alternative Strategy C: The Database

Sano will create and acquire data of value. Databases have particular forms of protection as shown in Figure 6.

Figure 6. Alternative IPR protection forms

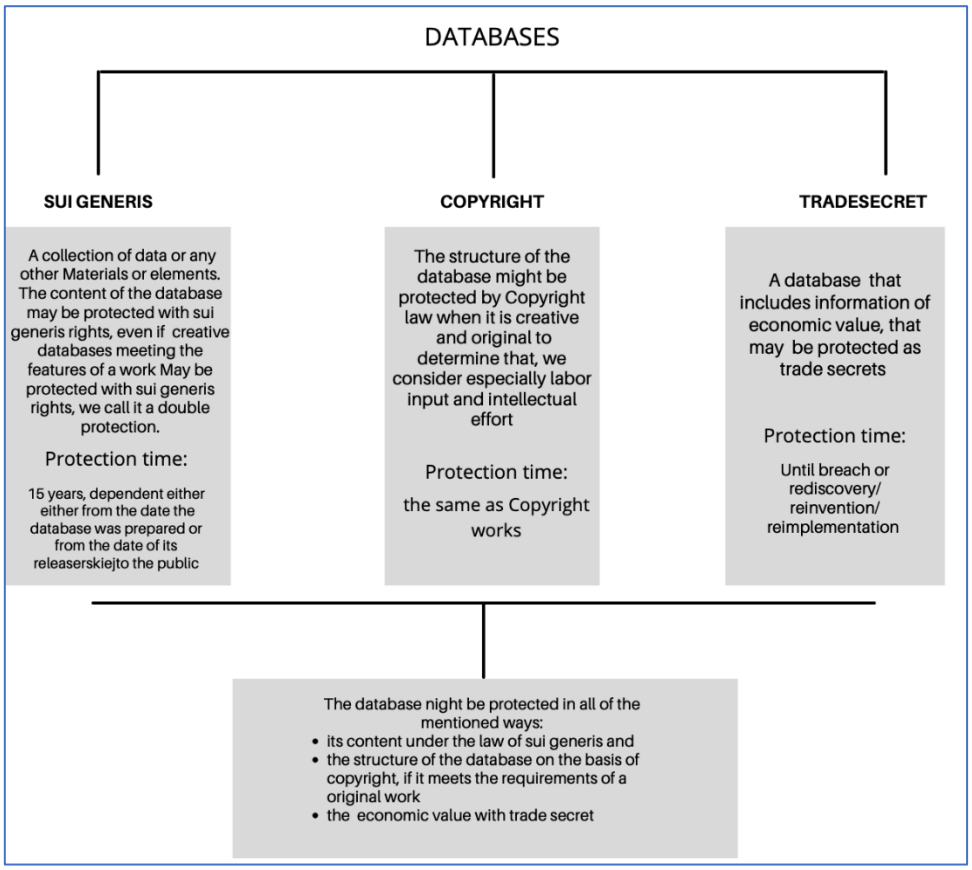
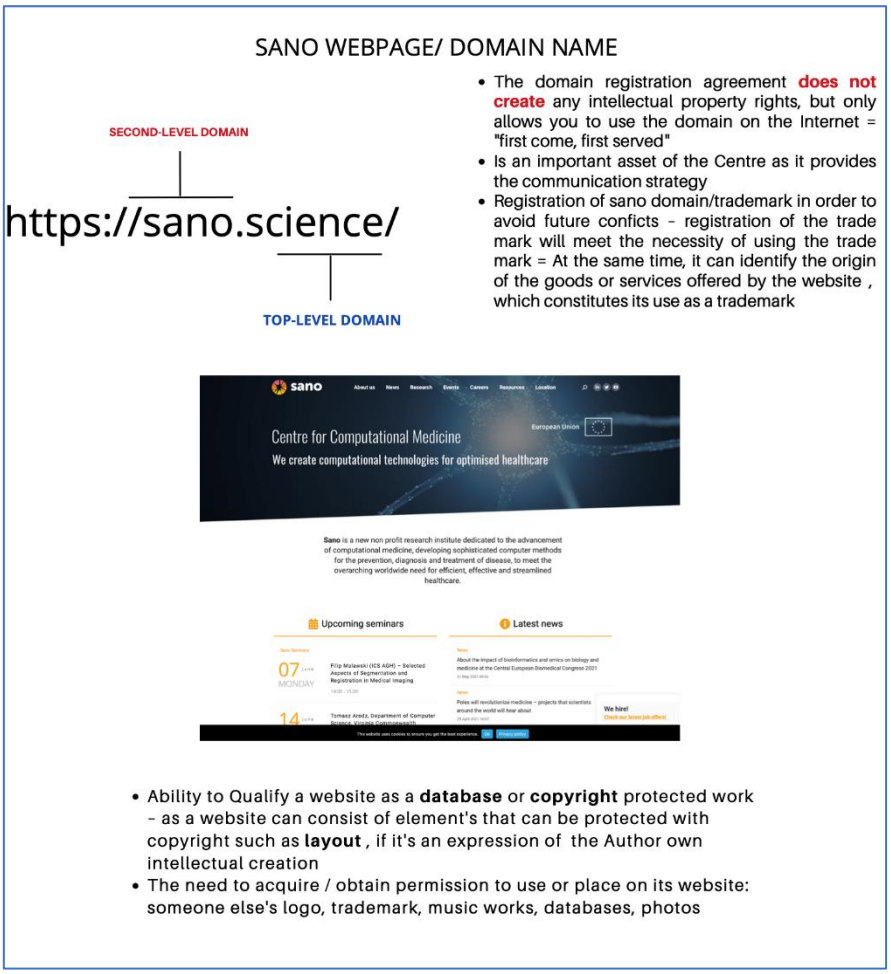


Figure 6 presents the available forms of protecting Databases, as these types of assets may be especially important to Sano, and therefore requires proper protection. The figure above expresses the general information that will be taken into account when considering the acquisition and/or protection of property rights.

Other assets that may require protection are related to the entity and domain, as for example Sano Centre domain name - this example has been shown in Figure 7.

Figure 7. Sano webpage and domain name protection



2.3 IP Protection Methodology

This section presents the factors that affect the process of acquisition of the forms of protection. Sano's IP Protection methodology will be influenced by a range of decision determinants and Sano's choices will be affected by ingrained factors, including its mission and goals, by its overall approach to the construction of a robust portfolio, and by pragmatic considerations that include the marketplace, the timetable for development fruition, and the income/investment profitability ratio. All above factors will be compared with the market environment that will determine the value and usefulness of the solution and define the IPR protection approach.

Undeniably, one of the most important factors enabling Research Centres to provide growth and compete effectively in the global market is the continuous implementation of innovative solutions. The IP Management Policy will support the Centre's mission in a way that strengthens not only the Centre's reliability but also its reputation and image, and action is required to encourage researchers actively to seek exploitation pathways to build the Centre's portfolio. Figure 8 illustrates the factors influencing the IP Management Strategy and are discussed below the figure.

Figure 8. Factors affecting the IPR Protection

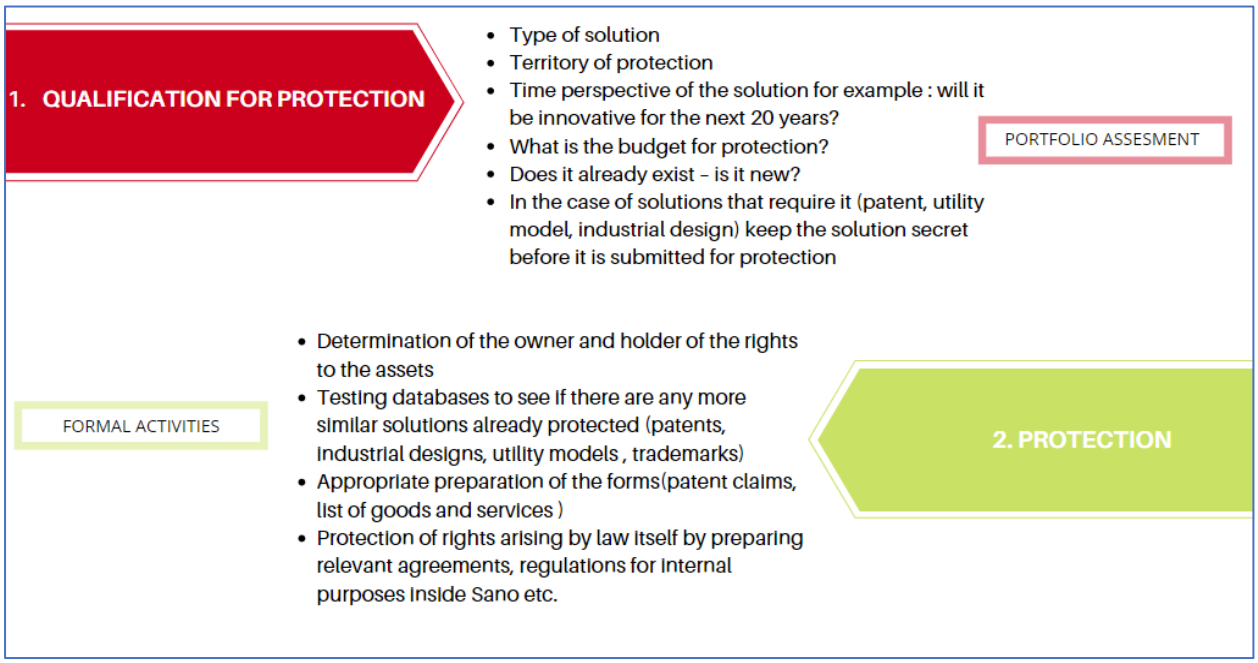
Figure 8 describes the main factors that may determine the IP Strategy of Sano. Those factors include:

1. **Industry of operation** – the field in which Sano is active, covering, among others, Digital Health and Computational Medicine,
2. **Awareness of IPR** – the awareness of IP among Sano personnel (available IP forms, confidentiality rules, etc.), which translates into developing comprehensive Strategy for IP protection,
3. **Efficient IPR tools available** – consideration, whether the available forms of IPR protection are sufficient to protect the work and Sano's assets,
4. **Estimated product life expectancy on the market** – the period of time, in which a product is being developed at Sano, and whether there is a need to protect it even if it may quickly become obsolete,
5. **Staff/organizational structure** – the efficient distribution of tasks and the usage of knowledge and skills of members of Legal and IP Office responsible for the implementation of IPR Strategy and the efficiency in updating the Strategy,
6. **Product specificity** – types of assets that Sano is developing and the possible paths of IPR protection,
7. **Financial resources** – the necessary resources allocated to the protection of Sano's IP,
8. **External support from partners** – transfer of experience, knowledge, best practices and necessary skills in the development of IPR strategy from H2020 Partners,
9. **Product development plan** – the strategy for an efficient product development from concept to market, that covers the appropriate IPR steps,
10. **The market** - perhaps the most influential of all factors, the nature, societal impact, longevity and entry mechanism for the intended product's market is fundamental to the need, nature and duration of IPR protection to be selected.

Before optimal mechanisms can be selected and the development of the portfolio put into practice a set of basic determinations must be made that assesses the potential asset, its nature, readiness,

vulnerability, and potential for income generation. With this data available a formal process can then be employed to convert the raw data into a value/protection determination that narrows the range of options. Figure 9 illustrates this process in more details.

Figure 9. IPR Methodology – prerequisites for protection qualification



2.4 Product Enhancements

This section contrasts the development of completely novel, disconnected IP with the introduction of product refinements that are sufficiently desirable to compel customers to replace or upgrade existing products, and perhaps are even sufficiently novel to win fresh IP protection by exceeding the non-obviousness threshold. The advantage of this strategy is the economic likelihood that the income/effort ratio is likely to be higher – initially – than for a completely novel concept. Over time, Sano's income portfolio (as distinct from its IP portfolio) is likely to be formed from a healthy mixture of these and other approaches to exploitation and longevity-enhancement.

However, the healthcare business is burdened with considerations that transcend simple economics, and the decision to consider product enhancement requires consideration of a multiplicity of factors, spanning the philosophical and reputational, through the practical, to the commercial as shown in Table 8.

Table 8. Enhancement Decision Matrix

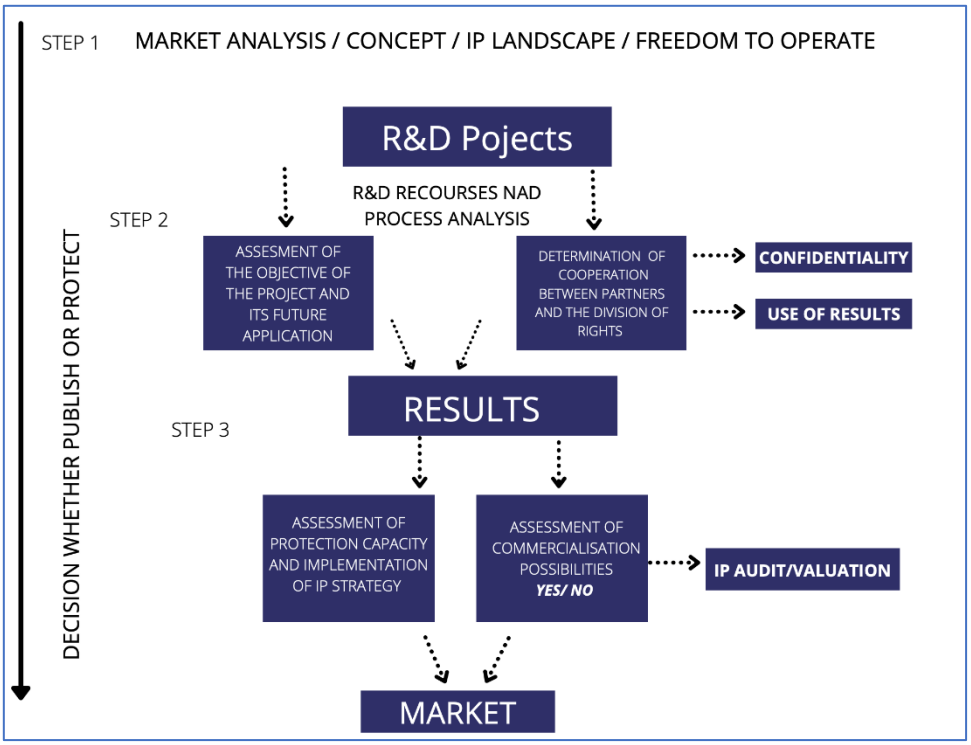
	Philosophy/Reputation	Practicality	Commerce
Issues	Is there an ethical imperative? Is Sano facing reputational damage from competitors? Will the enhancement be seen as exploitative? Does it conflict with Sano's policy on product upgrades? Does the enhancement offer genuine benefit?	Are resources available? – Human, – Organisational, – Technological, – Knowledge management and the possibility of usage of gathered information.	Is the competition sufficient to justify the work? What proportion of customers will invest in the change? Does the comprehensive market analysis adequately justify the strategy? Does the opportunity have 'hidden' commercial benefits?

When Sano achieves stable profitability, it is likely that that balance of developments will shift away from enhancements, though a strategy to transfer such assets to independent commercial entities may be preferred.

3. Sano IP Portfolio Management Process

This section describes the core of the IP Management Policy, detailing the key aspects introduced in Sections 1 and 2 regarding the commercial value and significance of a well-prepared IP methodology. The development and management of Sano's IP portfolio is an enduring process that is being introduced in these formative stages of Sano, alongside additional internal procedures. This section also elaborates the IP issues introduced in D7.2, Sano's Portfolio Management Plan, and will illustrate the interdependence of multiple activities in building the overall process of project selection, and in crafting the specific methodology for IP identification and management. The overview of the process has been presented in Figure 10.

Figure 10. IPR development methodology



3.1 Reminder of Sano's Remit, Goals, Portfolio Mix, Asset Definition

As a reminder of its operational landscape, Sano's activities encompass five domains:

- *Research,*
- *Education,*
- *Translation,*
- *Digital Healthcare, and*
- *Entrepreneurship*,

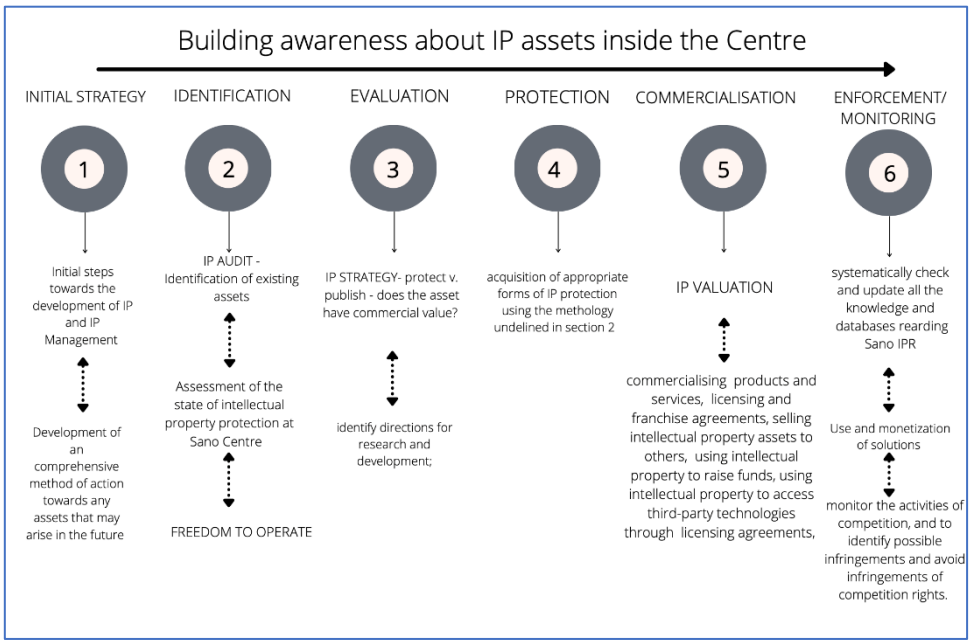
united in an endeavour to create and sustain an International Centre of Excellence in computational medicine, with direct application to the personalised clinical diagnosis and facilitate the treatment, maintaining the highest ethical and scientific standards. Sano's scientific reach includes, amongst others, artificial intelligence, modelling and simulation, data science, large-scale computing, and the design and development of decision support systems.

While achieving its objectives, Sano aims to develop many forms of IP asset, as described in Section 3.3, and will be obliged to take appropriate measures to protect its rights. Some of these assets will result from cooperation with external parties and it will therefore be necessary to introduce additional mechanisms to manage multiple complex ownership schemes, which will have to be well planned and executed to protect Sano's interests.

3.2 IP Lifecycle

The lifecycle of Sano's IP assets will vary from item to item, depending on the anticipated, and actual, research and commercial values that pertain; in each case the path will follow a trajectory from identification, through development, the 'publication/protection' decision, and on to exploitation. Sano will follow the IP lifecycle methodology shown in Figure 10, to identify, evaluate and protect the assets created within the Centre to maximise the value returned to the Centre.

Figure 11. IP Lifecycle



This section therefore establishes the methodology for handling an IP Asset, from identification, through protection and monitoring to enforcement and archiving, its aim being to establish a managed IPR environment at Sano that optimises benefit over the long term. It is clear from this that Sano staff and stakeholders must be imbued with the principles and practices that respect the absolute importance of these assets.

Later, in Section 4.2 the 'Decision Tree', non-mainstream scenarios are presented, together with a checklist of points to consider when seeking IP Protection. Here, in order to elaborate development of the IP portfolio against a background of the opportunities at each stage of the process, we cover:

IP Structure	From the earliest stages of development to the archival stage.
Measurement	Determination of progress status of protected assets.
Management	The application of the right processes at the right time.

The public nature of this deliverable means that no asset-specific detail has been provided.

3.3 Invention Maturity (TRL Development) vs. Appropriate IPR Protection Steps

Initially in this section two well-established approaches to describing the developmental pipeline for technology are examined in the Sano context:

1. The first is the Technology Development and Transfer (TDT) pipeline that considers the progress of development from the point of view of the relationships that are required to see a concept move towards yielding a positive financial return. Key to this process is the need, by stage 4, to have assigned an appropriate method of IP protection.
2. The second is the Technology Readiness Level (TRL) assessment system initially developed by NASA to allow monitoring of the technical effort required to complete a development process.

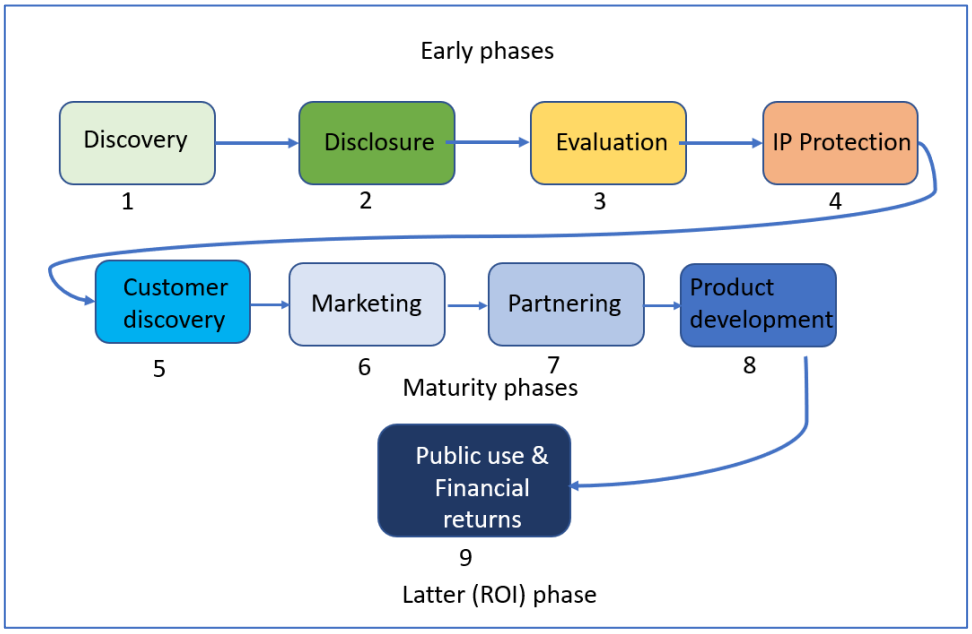
The TRL mechanism is particularly helpful to Sano, as it describes the activities typically encountered while reaching market readiness, and allows a matching of protection mechanism according to progress:

3. The section therefore next includes a presentation of the key mechanisms of protection that are available to the asset owner seeking to attach appropriate safeguards.
4. In the final step, a grid can therefore be built from the staged TRLs that examines each of the activities required and allocates the various protection mechanisms that would be appropriate at each stage, and the methodology by which the appropriate final choices might be made.

3.3.1 Technology Development and transfer stages

Figure 12 shows the sequential phases of the typical TDT process. In practice the stages may overlap and, in some instances occur in a slightly different sequence, but the practical steps of the IP protection always follow the completion of the evaluation stage. Until t that point any disclosure is prevented in case patent filing would be the best form of IP protection. Of course, the process can include a feedback loop (not shown in Figure 12) at any stage and may also result in generation of the additional income that will later be invested in further development of the product or the development of the new product by the R&D team.

Figure 12. Technology development and transfer phases



Sano's internal IP Regulations will provide detailed descriptions of the actions required by researchers developing technology at each TDT stage:

- Awareness of TDT relationships required to complete the stage,
- Identification of key information sources and contacts,
- Development strategy,
- Project-specific knowledge categorisation for possible disclosure,
- Information release guidance (conference proceedings, publications and communications),
- Structured approach to determining the optimised portfolio incorporation.

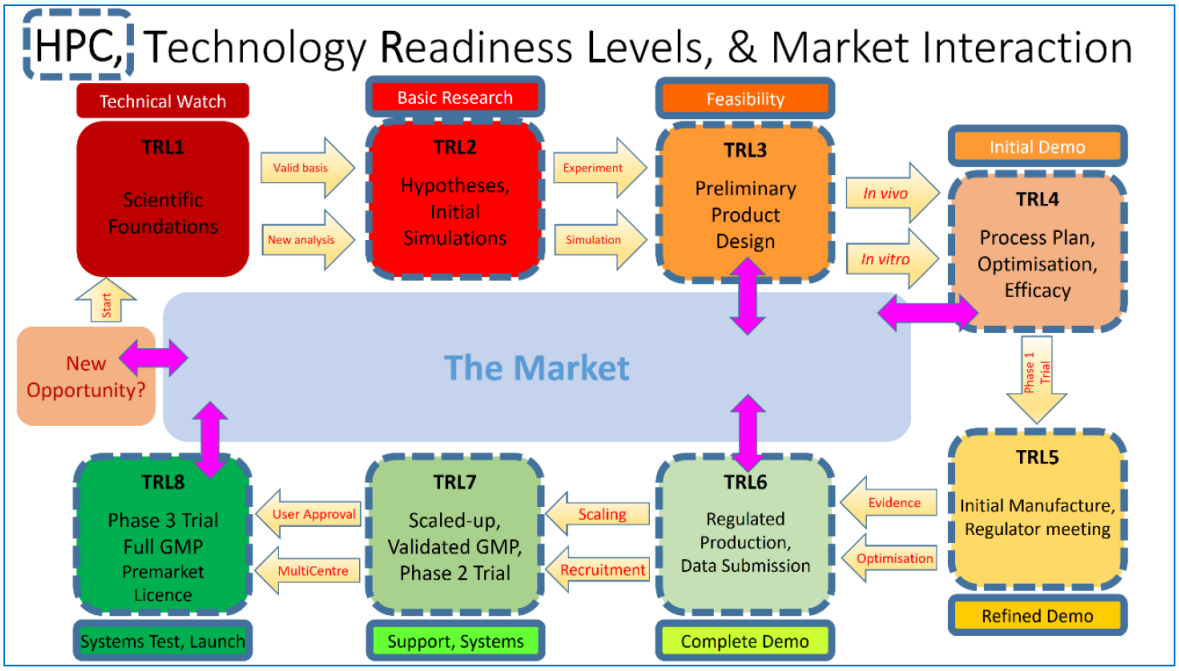
Additionally, the regulations will cover the evaluation process (Stage 3) that will be repeated throughout the development, the results of which will influence the onward process, perhaps significantly, and ultimately guide the IP protection strategy that will be employed (Stage 4).

Once the nature of protection has been determined and implemented, the development process will continue (Stages 5-9), and Sections 5.7 and 5.8 describe the measures that may be taken to increase awareness and ensure the assets fulfil their potential.

3.3.2 Technology Readiness Level – maturity assessment of the technology

In general, the Technology Readiness Level is a guide to the maturity of a technological development of the invention, and allows the owner to determine the type of protective step to be taken. Figure 13 shows the generally accepted staging process for technical developments into TR levels, where each stage represents a significant step towards commercialisation. The potential of the idea affects the means and strategy for safeguarding the asset, ranging from no protection at all or Open Source, through trade secret strategy or patent-application filing.

Figure 13. Technology Readiness Levels and the Interaction with the Market



In the domain of medical devices, including those in computational medicine, the table below illustrates the status typically held at each of the TRLs.

Table 9. Status for respective TRL levels

Stage	TRL	Status
Concept	0	Identification of unmet need
	1	Scientific Foundations: Basic principles observed
	2	Hypotheses: Technology concept formulated
	3	Preliminary Design: Experimental proof of concept (PoC)
	4	Initial Demonstration: Technology validated in lab
	5	Refined Demo & Manufacture: Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)
	6	Compete Demo: Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)
Prototype	7	Scaling and Trial: System prototype demonstration in operational environment
	8	Systems Test and Launch: System complete and qualified
Clinical	9	Marketed: Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)

The staging shown in the left column maps to the first three steps in the complete phase diagram illustrated below:

Figure 14. Technology development phases (TRL based) and key IPR protection areas

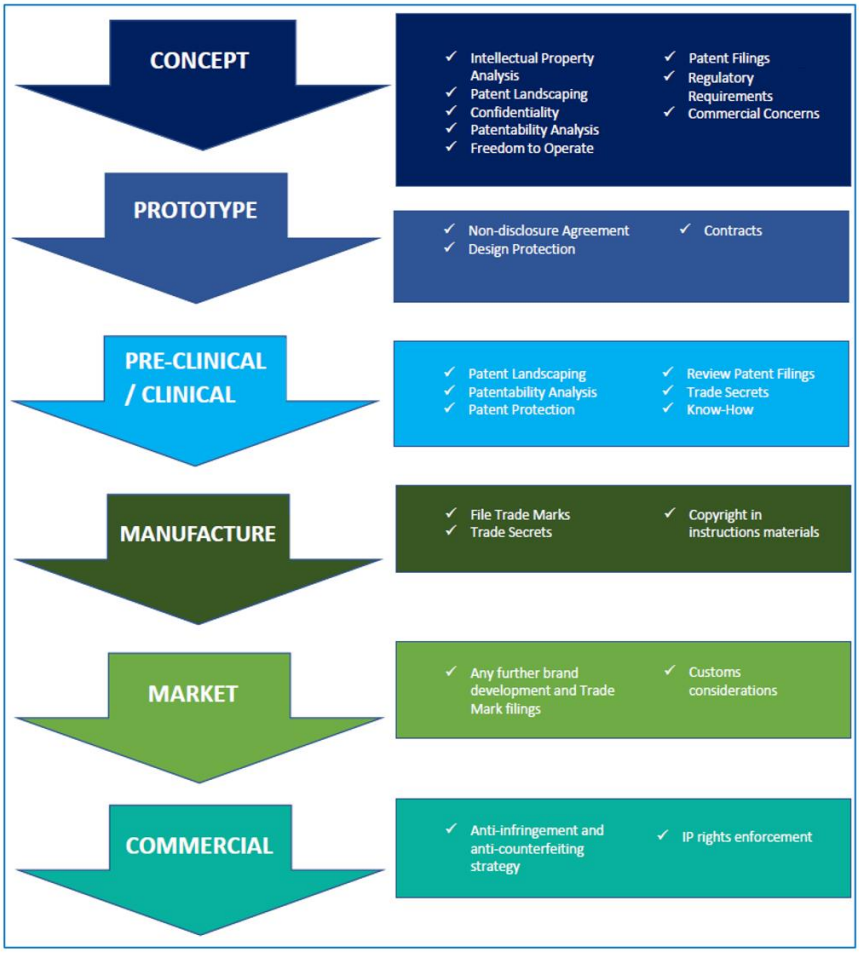


Figure based on "A practical guide to intellectual property right for medical technology companies" by Hanna More + Curley

3.3.3 Asset Characterisation

Sano is creating intellectual assets of various particular types, that will require detailed mechanisms of characterisation and logical grouping to be established. An additional challenge is that many of the assets have a comparatively general function, but they lend themselves to combination in groups or sequences that result in additional assets, which only then can be defined by their increasingly specific functionality. In essence many assets are widely capable building blocks that can be combined to form much narrower, more specific tools with dedicated clinical utility. A general approach to asset characterisation is presented in Table 10, and a more specific Sano-focused examples are given in Table 11.

Table 10. Asset type vs. IPR protection form

Asset examples	PATENT	COPYRIGHT	UTILITY MODELS	TRADEMARK	INDUSTRIAL DESIGN	CONFIDENTIAL INFORMATION
Hardware	✓					
Equipment	✓		✓			
Surgical or medical devices	✓		✓			
Innovation in a technical form	✓					
Innovation as such	✓					✓
Computer implemented inventions	✓					
Design of MEDTECH asset – appearance					✓	
Source code		✓				✓
Object code		✓				✓
GUI		✓			✓	
Names and Logos of MedTech products and services				✓		

Sano, because of the specific field of industry, may consider for protection of only specific Classes applied to specific goods and services or areas of technology and sometimes just pieces of bigger invention instead of the whole. Table 10 herein, represents the Classification available and categorised to specific forms of IP Protection. When applying for protection, the entity must classify their product, services, or the area of technology that they apply for. For this reason, it will be considered each time when applying for protection, as a guideline which classification to consider in the filling process. The aim of Table 11 below is to have a list of classes divided by IP Protection forms and matched to the field of Sano activity and proposed assets based on the Table 10. It will be constantly developed, especially during the development of goods and services or when considering the patent application.

Table 11. Proposed Sano Protection, categorised by Standard Asset Classification

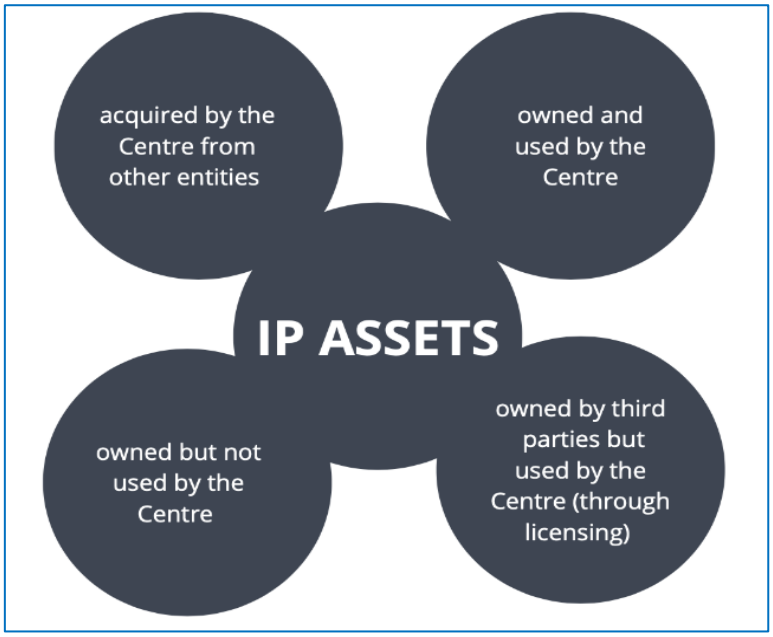
Class	Description	Sano Protection
Class 9	Includes scientific, research apparatus and instruments and, computer software; *Examples*: • Apparatus and instruments for scientific research in laboratories, • Laboratory robots, teaching robots, security surveillance robots, humanoid robots with artificial intelligence.	Trademark
Class 10	Includes surgical, medical, dental and veterinary apparatus and instruments.	Trademark
Class 14	Recording, telecommunication or data processing equipment.	Industrial Design
Class 24	Medical and laboratory equipment	Industrial Design
Class 42	Includes scientific and technological services and research and design relating thereto; industrial analysis, industrial research and industrial design services; quality control and authentication services; design and development of computer hardware and software[13]: • Software as a service (SAAS), platform as a service (PAAS); • Scientific research services for medical purposes; • The services of engineers and scientists who undertake evaluations, estimates, research and reports in the scientific and technological fields (including technological consultancy); • Computer and technology services for securing computer data and personal and financial information and for the detection of unauthorized access to data and information;	Trademark
Class A61	Medical Or Veterinary Science; Hygiene Subclass: A61b, Diagnosis; Surgery; Identification	Patent
Class G06	Computing; calculating and counting[14] • Simulators which are concerned with the mathematics of computing the existing or anticipated conditions within the real device or system; • Simulators which demonstrate, by means involving computing, the function of apparatus or of a system, if no provision exists elsewhere; • Image data processing or generation. *Important subclasses:* G06T: Image data processing or generation, in general G06N: Computer systems based on specific computational models G06F: Electric digital data processing	Patent
Class G16	Information and communication technology (ICT) specially adapted for specific application fields. *Important subclass:* G16H: Healthcare informatics; ICT for the handling or processing of medical or healthcare data	Patent

[13] https://www.wipo.int/classifications/nice/nclpub/en/fr/?classes=1&classes=2&classes=3&classes=4&classes=5&classes=6&classes=7&classes=8&classes=9&classes=10&classes=11&classes=12&classes=13&classes=14&classes=15&classes=16&classes=17&classes=18&classes=19&classes=20&classes=21&classes=22&classes=23&classes=24&classes=25&classes=26&classes=27&classes=28&classes=29&classes=30&classes=31&classes=32&classes=33&classes=34&classes=35&classes=36&classes=37&classes=38&classes=39&classes=40&classes=41&classes=42&classes=43&classes=44&classes=45&exact_search=&info_files=&lang=en&menulang=en&notion=search&op=OR&q=software&searchType=results&version=20210101

[14] https://www.wipo.int/classifications/ipc/ipcpub/?notion=scheme&version=20210101&symbol=G06Q0050220000&menulang=en&lang=en&viewmode=p&fipcpc=no&showdeleted=yes&indexes=no&headings=yes&notes=yes&direction=o2n&initial=A&cwid=none&tree=no&searchmode=smart

Figure 15 shows the potential categories of IP assets divided by the source of the IP.

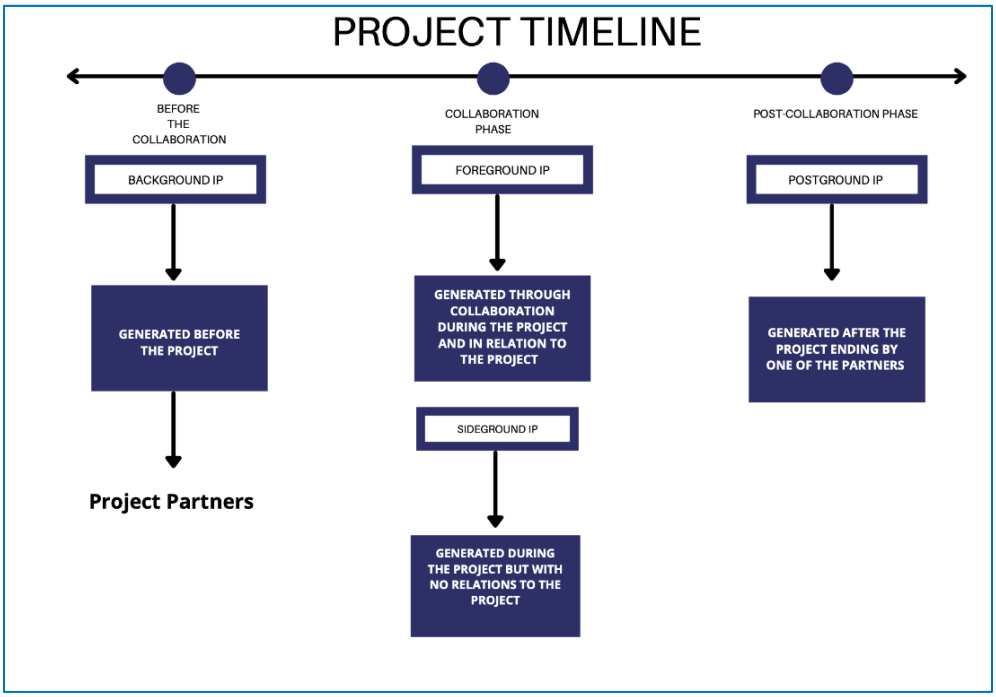
Figure 15. Categories of IP assets



The graphic was established on the base on "European IPR Helpdesk - Information brochure - Intellectual Property Audit: Discovering your business's potential"

The timing of asset development may also be a factor in determining value, utility, lifespan, and the need for protection, as shown in Figure 16.

Figure 16. Types of IP at various stages of project development



Source: http://docplayer.pl/47134505-Praktyczna-wycena-wlasnosci-intelektualnej-i-know-how-na-potrzeby-komercjalizacji-wiedzy-w-instytucjach-naukowychhtml

Contracts that involve intellectual assets are often complex, not least because they must include consideration of a multiplicity of ancillary factors:

- Asset ownership,
- Associated IP (Background, Foreground, Sideground, Postground),
- Restrictions in competing or overarching agreements (EC, IRAP),
- Access rights to those IP,
- Acceptability of restrictions, including:
    - Exclusivity,
    - Recompense,
    - Territorial, temporal and scoping limitations,
    - Sub-licensing restrictions,
    - Arrangements for modifications/corrections and upgrades,
- Liability responsibilities,
- Dispute resolution mechanisms and jurisdiction.

Sano's internal guidance documents will contain detailed discussion of contractual factors, and superset template documents illustrating the worst-case options.

3.3.4 TRL/IP Grid

Unless care is taken to assign appropriate IPR protection at each stage of product development, Sano risks incomplete value extraction from its assets. Tabulated below (Table 12) is structured guidance on the forms of protection that may be appropriate at each stage of the TRL chain of development but, in addition to an awareness of these possible mechanisms, there is the need to include consideration of the larger-scale factors influencing the investment in protection:

- Ethics,
- Risk,
- Raw value,
- Competitor-considered value,
- Lifespan,
- Likelihood of reverse engineering,
- Onward utility for use in additional and translational developments,
- External or internal-only utility,
- Indirect value as intellectual publicity.

Table 12. TRL Components and relation to IP

TRL	Category	MedTech diagnostic and devices	Data	Digital Health	Results	IP may reside in	Possible parties	Possible issues	Tools	Decision staging
0	Unmet clinical need identified	**N/A**	**?**	N/A	N/A	Topic/ concept	Source (clinical) Technology (Sano) Existing solutions	Equitable agreement Existing IP New IP	Contracts Cooperation/ Trade secret…	Basic principles and requirements estimated, basic research
1	Review of scientific knowledge base	✓	✓	✓	✓	Concept	Scientific knowledge, clinical, technology	Existing IP, New IP, Clinical, preliminary assumptions, Improved solutions	Databases, Trade secrets	Formulation of concept
2	Development of hypotheses and experimental design	✓	✓	✓	✓	Concept	Existing solutions, documentation results, technology, laboratory	Device/ solution characteristic, novelty issues, possibility of protection forms	NDA, cooperation agreements? Any IP Landscape analysis, Freedom to operate	industrial research evaluation - first attempts, proof of concept
3	Identification and characterisation of preliminary product	✓	✓	✓	✓	Function and concept	Pre-clinical, models	Validation and security, Development	NDA	Validation
4	Optimisation and demonstration of activity and efficacy	✓	✓	✓	✓	Components, test systems, analytical models / process	Non-clinical, technology	Applicability of components	Patent application when applicable	Validation, Product development
5	Advanced characterisation of product and initiation of manufacturing	✓	✓	✓	✓	Technology component/ Prototype component/ process	Non-clinical, technology	Freedom to operate, Standardization material evaluation, product liability	IP Strategy	Technology Demonstration
6	Regulated production, regulatory submission and clinical data	✓	N/A	✓	✓	Prototype	Technological components	Prototype demonstration, regulatory requirements	patent, trademark, design	Technology Demonstration
7	Scale-up, initiation of GMP process validation and Phase 2 clinical trial	✓	N/A	✓	✓	Actual Technology	commercial	Pre-commercial activities	patent, NDA regarding any collaborations, cooperation agreement	Market studies
8	Completion of GMP validation, Phase 3 clinical trial and license	✓	N/A	✓	✓	Actual Technology / System test	Commercial	Commercial activities, post market activities	Patent, NDA, cooperation agreement, licensing agreement	Successful operating of environment

The culmination of the foregoing steps to establish the developmental sequence, the expanding relationship mix, the nature of the technical work involved, and the need for a realistic but extensive valuation of the asset over its lifespan, below is an initial version of a TRL/IP grid for Sano, in which, at each TRL, the key issues affecting protection decision-making are presented. Table 12 explains the components of each TRL stage with a particular concentration on IP aspects within the area of Digital Health and MedTech. Moreover, adequate steps resulting in decision staging allow to explain the mandatory issues arising in each of the TRL components. Therefore, the table below explains the tools that might be used to protect any result outcome at each stage. At each stage, there might be an IP developed that may result in different forms of assets. Additionally, different possible parties might be involved in accordance with the adequate TRL level.

4. Market Access Readiness Assessment

There are complex challenges associated with the application of IP protection to innovations in the medical technology area, where the intention may be both to provide high-quality asset management and to facilitate the capture of external interest. Sano's research into advanced computer techniques will contribute to a fundamental transformation of the entire healthcare industry towards a system of predictive medicine, through the integration of new-generation scientific tools. Yet for its assets to realise their potential value, Sano's matching of action to circumstance must be optimised, and this implies a constantly updated awareness of asset status and development timetable.

This section explains the relationship between IPR and TRL and the impact of TRL measurement on the efficient IP Management of assets and the level of IPR readiness for exploitation purposes.

4.1 Asset Analysis – IP Value Chain and Portfolio Management

As described in Section 3, technology readiness level is an effective measure of the suitability of an asset for exploitation, and its attendant need for a particular level of IP protection. However, it is not the only consideration, as additional factors, both enabling and consequential, must be considered. Enabling factors concerning the asset include:

- Specificity of market,
- Specificity of product,
- Specificity of industry,
- Market potential,
- Potential for exploitation,
- Possible profitability,
- Economic value of IP,
- Legal issues associated with the IP.

An additional factor is the degree to which exploitation is likely.

Possible exploitation pathways for IP assets include one or more of the following:

1. Internal use for additional research purposes,
2. Collaborative licensing to a third party, with shared onward involvement,
3. Detached licensing to a third party,
4. Further development and commercialisation through spin-off creation,
5. Permanent disposal of the asset by outright sale.

In each case a means of (at least descriptively) isolating the technology will be necessary, and further consideration of formal or informal protection of the asset is required. These steps require definition and characterisation of each asset, together with an assessment of its (optimised) potential. The need, therefore, is for a formalised approach to asset valuation that takes into account both the direct and indirect costs of ultimate value realisation.

IP Valuation

An important element of Sano's income-generation strategy is the exploitation of IP assets created through its Research & Development processes, implying an appropriate awareness of the value and importance of each asset. This section underlines the purpose of conducting IP valuation at Sano and

identifies the process requirements. The practical methodology is discussed later, in Section 5. Topics covered include:

- Common mistakes to be avoided when conducting IP Valuation,
- The methods of IP valuation and the factors that influence method selection,
- Situations when IP Valuation is required,
- The particular need for IP valuation when introducing IP into the market,
- The ancillary risks to be considered.

Care is required to avoid these difficulties, though often, in doing so, high costs may be incurred:

- Incorrect market assumptions or lack of market analysis,
- Lack of competitor analysis,
- Incomplete market data,
- Incorrect market data,
- Mistaken assumptions about the life cycle of a product or service.

IP Valuation Methods

Methods available include:

Market-based	In which the driver is the market price for similar items
Cost-based	In which the value is assigned based on the cost of production
Income-based	In which the benefit to the customer is assessed

To obtain as complete a picture as possible, and so attempt to avoid the common mistakes, Sano will consider all of these valuation methods, each of which can be employed in several variants and with differing levels of risk tolerance, and Sano may partner with an entity that has expertise in the field.

A. **Market-based valuation** method is based on the assumption that two comparable assets should be traded at a similar value. Valuation by this method requires analysis of the actual sales of similar technologies that have taken place in the recent past, and to include information about market transactions that have been prematurely terminated. It is important here to obtain as much detailed information about the transactions as possible. When choosing this method, it is important to take into account the factors shown in Figure 17.

Figure 17. Market-based valuation method core factors and applicability.

Factor to consider especially cover: :	When conduct?
• Industry • Company/ Research Centre • Timing • Nature of IP asset (e. g., patent. or trademark) • Scope and status of legal protection • Validity of IP rights • Territory of IP rights • Substitutes • Profitability from use of the IP • Risks • Market size and characteristics • Channels of distribution • barriers to entry	• When there are available and comparable and up-to-date data on similar transactions made • –where the reliability of the available data is ensured

B. Cost-based valuation method is based on the costs actually expended on the development of a given property right, typically including the costs of research, advice, registration and promotion, and adding to them the production costs of the materials, equipment and labour. It included two subcategories:

- The reproduction cost method – the cost of re-creating the system, without making changes to it. It requires full knowledge of the technical data of the components,
- The replacement cost method - the cost of acquiring IP that will perform all the functions of the valued assets or the cost of producing such IP but using modern and accessible methods and materials – so the form and the appearance may differ.

When choosing this method it is important to take into account the factors in Figure 18.

Figure 18. Cost-based valuation method core factors and applicability

Factor to consider especially cover:	When conduct?
• Perspective • Growth, industry, barriers to entry, legal protection, remaining • A good economic life	• When all other methods have failed; • When the technology is at a very early stage of development ; • When the technology can be copied relatively easily ; • When technology requires no more R&D worek • An ready product on the Market

Income-based valuation method is very often used when valuing IP; this group of methods estimates the income value, the sum of the financial benefits that will be achieved through its application. Here it is important to include assessment of risk. Before choosing this method, it is important to take into account the factors shown in Figure 19.

Figure 19. Income-based valuation method core factors and applicability

Factor to consider especially cover:	When conduct?
• protection time • how forecasting is made • life cycle depending on the market and the course of the commercialisation process • discount rate • Patent procedure • the readiness of the technology to be implemented • market/industry	• can be implemented each time • when the technology is at higher stages of implementation readiness, • where reliable market data are available

The consideration-factor lists above were prepared based on these sources [15, 16, 17, 18].

4.2 Decision Tree

There's a wide number of factors that need to be considered while making significant decisions, it is usually a very complex matrix including a specific trigger that determine the next step. A huge advantage of creating a decision tree lies in the fact that it allows a decision maker to combine analytical tools and techniques, and present generated value which together show the impact of various decisions / paths on the final result, in this particular case the asset that needs to be protected or not (there are certain cases where the management takes a decision of not protecting a good per se but for example making it an open source). An example of the simplified view of the choice sequence for each potential asset is shown in Figure 20.

[15] http://brante.pl/metody-wyceny-technologii/
[16] https://aanzfta.asean.org/uploads/2020/12/IPPEA-FINAL-HANDBOOK-ON-IP-COMMERCIALISATION.pdf
[15] https://www.wipo.int/export/sites/www/sme/en/documents/pdf/ip_panorama_11_learning_points.pdf
[18] https://www.wipo.int/export/sites/www/sme/en/documents/pdf/ip_panorama_11_learning_points.pdf

Figure 20. Basic Decision Tree Structure for Sano's IP

Trigger	Choices	Factors	SubFactors	Choice	See Table…
Concept	Expose/ Protect/ Conceal/ Open-Source	Public good/ Ac'dmc repute?	⇨	Decided: Expose = Publish	Protect/ Publish
		No ethical imperative	Internal utility (Table Int/Ext)	Decided: Conceal	n/a
			Tradeable	Undecided: Protect? Conceal? OS? Decide Later?	Early Protection

Trigger	Choices	Factors	SubFactors	Choice	See Table…
(Tradeable) Need for Exposure/ Publicity	Protect now/ NDA & Decide Later	Can problem detail be omitted?	Protection takes time; is it too late?	Undecided: Where does the value lie?	Publicity; Collaboration
(Tradeable) Need to Collaborate	Protect now/ NDA & Decide Later	Collaboration without detail?	Protection takes time; is it too late?	Undecided: Must detail be revealed?	Collaboration
(Tradeable) Ready to Trade…	Protect now/ NDA	Trade without detail?	Protection takes time; is it too late?	Undecided: Must detail be revealed?	Licensing

Here we discuss an overview of the main problems that require special attention and may arise through the IP strategy creation of Sano. This section presents discussions of the factors influencing IP decisions for the key dilemmas identified in the above decision tree:

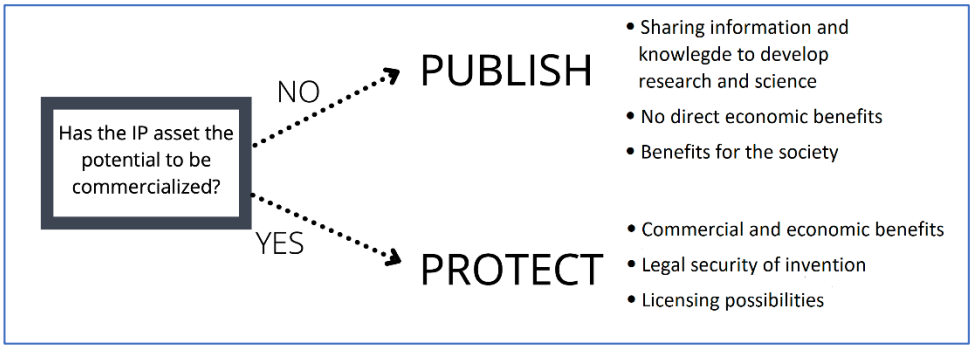
- Early protection of concept,
- The protect/publish dilemma,
- Approach to publicity,
- The collaboration decision tree,
- Licensing decision tree.

Table 13. Early protection decision tree

Early protection of concepts	• Where an item of IP is expected to be developed jointly with another party, before starting any processes Sano will conclude a non-disclosure agreement (NDA) with that entity. • All agreements will contain principles, duration of applicability, and restrictions identified separately for the in-agreement and post-agreement periods; • No confidential information will be released to any unauthorized entity; • Records of all information transfers will be maintained and retained for an agreed duration;

Table 14. Protect vs. Publish decision tree

The protect – Publish Dilemma	The dilemma between protecting and publishing new knowledge is common to academic institutions, and there are advantages to each choice, with differing effects on outcomes. Key factors influencing the decision include: • The competitive advantage purpose, • Solution status – whether the solution has the ability to be protected, • Patentability, • Protection time, • Solution category, • Solution objective.



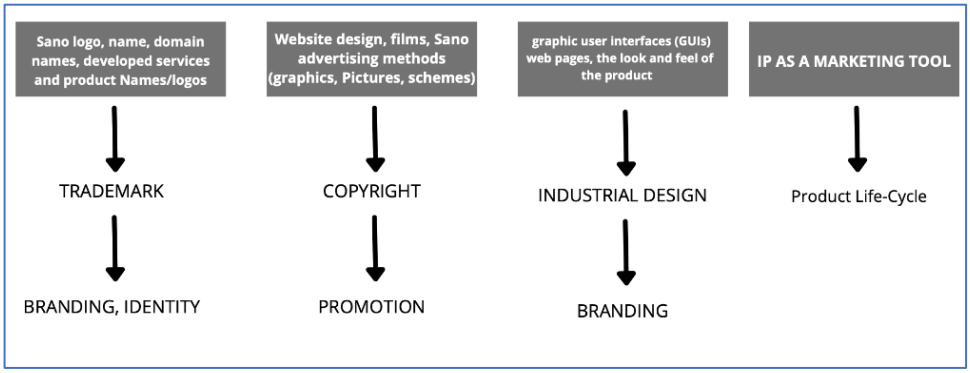
In a development environment where use is made of **open-source** materials, and where some outputs may in turn be released under such licences, there is similarly the potential for advantage and disadvantage, with the possibility of profound consequences when seeking subsequently to reach agreement with industrial partners. Sano will carefully consider each such decision, as is discussed in a later section of this document. Therefor there are pros and cons of the publishing as well as protecting. Yet Sano will recognise them to match the expected outcome to the asset. By protecting the results, Sano will have a legal proof that the assets are protected, which will be visible by granting a protection certificate. Publications may have similar value especially to the scientific and research community, as they enable to continue the process of improving and developing scientific outcomes and knowledge available. Yet it is possible to connect those two paths protect and then publish.

Table 15. Approach to publicity

Approach to publicity

The product development process is inextricably linked to IP management, as it is to marketing, and IP Rights provide a powerful mechanism to safeguard and facilitate promotional activities.

Possible interaction between marketing and IP:



Important also is the dissemination and communications strategy associated with the promotion of project outcomes, where *inter alia* the strategy will cover:

- Social media (Twitter, LinkedIn, YouTube, etc.),
- Scientific Publications, project datasheets.

There is a strong connection of this section towards the Figure 7 entitled: Sano webpage and domain name protection. It is often not paid attention to, that a Webpage may have great value and own IP assets. The value that is provided by Sano Webpage may result in the creation of significant and valuable forms of IP such as: trademark, copyright, Industrial design.

Table 16. Collaboration decision tree approach

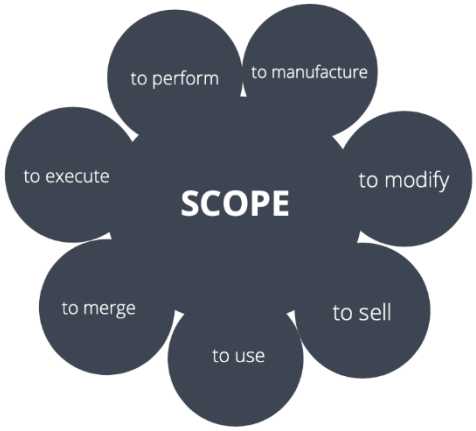
Nature of external collaborations

Sano will determine:

- The collaboration scope and purpose,
- Policies regarding the use of the output of the collaboration,
- Rules regarding collaboration partner's background IP,
- The entity owning the IP and enabling it to be commercialised:
  - by Sano,
  - by the collaboration partner, or
  - jointly by both parties.

	– To determine fair and equitable return from the Project IP assets, – Collaboration tools- Cooperation principles of services, tools, – Formalization of collaboration, – Network and collaboration structure, – Common goals for the collaboration agreement, – Rules for the financing of joint results.
Co-authorship	In the case of co-authorship, to be able to ensure transparency of the process Sano will take into account: – Type of product / service/ technology produced and the rules regarding the scope of use, – The contribution of each co-founder in the development process of the product/service/technology, – The determination of contribution among of the Co-authors Transferability/granting of licenses, – Terms that affect the negotiation conditions, – Project duration, – Confidentiality, – The ability to use the technology produced for improvement or use for other activities, – IP Lifetime.
Depth of collaboration	Collaborations will include definitions of the timetable and extent of the interaction taken between parties as well as the outcome expected.
Negotiation and termination	The negotiation process will be preceded by signing an extensive NDA. This will enable to go to discussing details. The core issues that should be worked out at the beginning are: – The possible evolution of asset ownership, – The terms of access and use to background, and sideground, as well as foreground and the consequences for postground, making changes and the emergence of dependent rights on the above-mentioned right.

Table 17. Licensing decision tree approach

Licensing and scope	**Here Sano will establish principles for both inward and outward licensing.** **Licensing – in**: Acquisition of technology/solutions from another source, **Licensing - out**: transfer of solution/technology to another entity. Conducting Due Diligence will strengthen the decision-making and will extend to valuation of the results and technology. An important step is the stipulation of scope and restrictions, as shown: 
Licence conditions	A further step is consideration of the exclusivity of the licence: – Exclusive licence, – Nonexclusive licence, – Sole licence. Moreover, the figure below expresses the key areas of a licence agreement which covers: – The moment of the licence being granted. – The time for which the licence is to be given. – Whether there are any restrictions towards the licence (is it a full or limited license). – The financial aspects of the licence. – The territorial aspects and limitations towards the license. – The time for which it is granted;

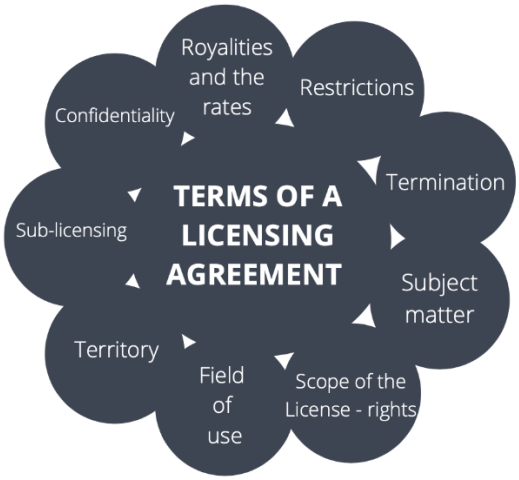
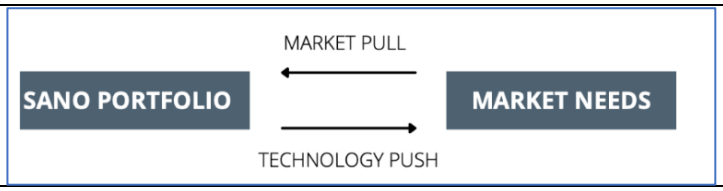
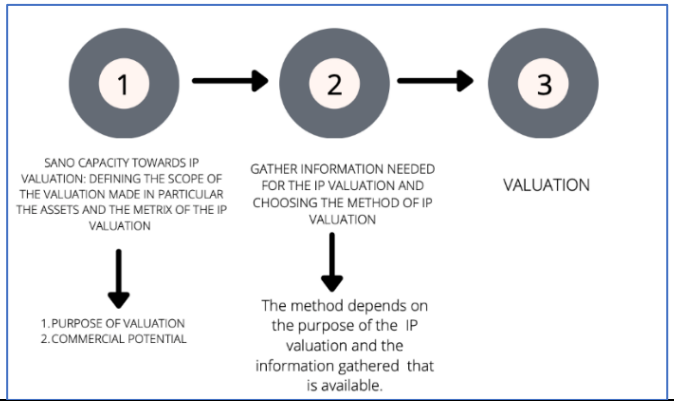
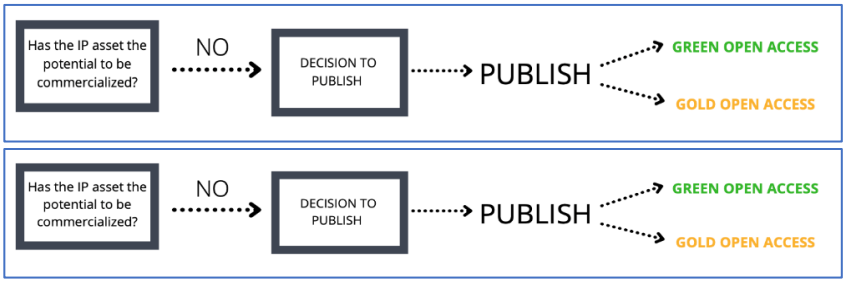
	The core aspect covering the detailed fields of exploitation.  *Source based on:* *https://www.wipo.int/edocs/mdocs/aspac/en/wipo_ttos_kul_18/wipo_ttos_kul_18_p13.pdf*
Negotiation and termination	Summarising the key conditions: – Conditions regarding termination, – The scope of the IP and the rights, – Field of use market restrictions, – Licensing type: exclusive, non-exclusive or sole, – Confidentiality clauses, – Time limits, circumstances, and territory in which the parties may terminate the license agreement, – Effect of termination terms, – Post-termination uses of licensed IPR assets, – Royalty rates.

Table 18. Internal and external decision tree approach

Internal or external development	Sano divides its IPR strategy into: – Internal Strategy o Identification of IP assets in the Centre, o IP Protection, o IP Audit, o IP Maintenance. – External Strategy o IP Enforcement, o Identification of conflicting/complementary/competitive IP, o IP Monitoring, o Collaborations, o Marketing, o Location of collaboration partners.
Business planning and evolution	Steps to consider in the business planning of IPR development process: • Internal: o Financial and budget estimation for IP, o IP awareness, o Product Life Cycle development, o Risk Management estimation, o Regulatory requirements mainly clinical trial approvals. • External: o Freedom to operate, o Business market segmentation and the relation between technology push vs. market pull. Market pull vs. Technology push key interaction:

	
Approach to valuation	Factors affecting the nature of IP valuation are detailed in Section 3.8 of this document. They have a tremendous impact on the result of such IP Valuation and therefore, a special attention should be paid to them. The approach is sketched below: 
Approach to maintenance	To ensure appropriate fulfilment of contractual commitments Sano will monitoring the IP market and implement 'Freedom to Operate' searches, to safeguard rights. In addition, steps will be taken to maintain IP Rights: – IP Audit and due Diligence = uncovering gaps regarding IPR, – Periodic searches regarding assets protected, and assets to be protected in the future, – Payment of renewal fees as a fundamental retentive action.
Open access	In appropriate cases, Sano will provide free access to scientific results, to encourage the growth of innovation in the *in silico* community, as diagrammed:  *Source based on: https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf*
AI complexities /software Complexities	**Artificial Intelligence** The European Commission will soon publish an initial framework covering the legal and ethical complexities of Artificial Intelligence. Sano, with a strong involvement in AI developments, will maintain currency (including https://digital-strategy.ec.europa.eu/en/library/proposal-regulation-laying-down-harmonised-rules-artificial-intelligence) **Patentability**: As introduced in Table 1, even now the possibility to patent software has no universal agreement. There are two main approaches, undertaken by Europe's EPO and America's USPTO, regarding the patentability of computer programs. **EPO**: – Under Article 52(2)(c) of the EPC, computer programs as such are not regarded as patentable inventions. This means that, when a computer program is regarded as an abstract idea, it is not eligible for patentability. Yet, when a Computer Program expresses *"a further technical effect, meaning a technical effect going beyond the "normal" physical interactions between the program (software) and the computer (hardware) on which it is run,"*[19], then it is eligible for patentability. The certain path,

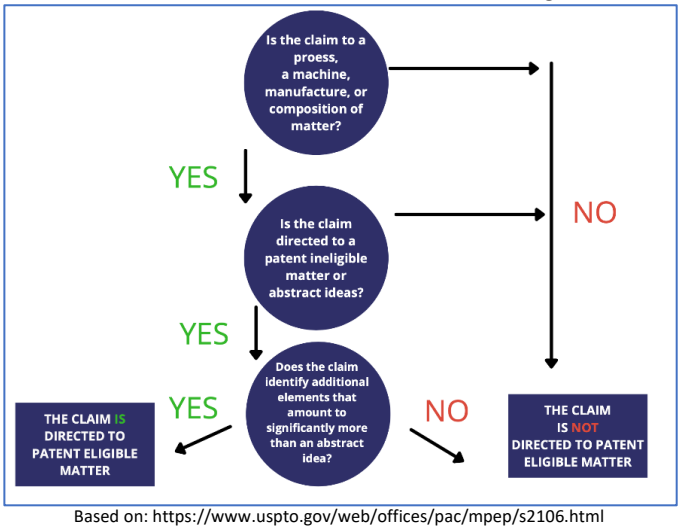
[19] https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_6.htm

that enables a detour, are computer –implemented- solutions. Therefore, Sano will pay attention to whether, the Computer Program covers: A technical effect of the solution- the clue is the further technical effect.
- Patentability requirements - PATENT ELIGIBLE MATTER.
- No abstract concepts.

Examples of granted rights in EPO using Google patents:
- EP2815372B1 - Methods and software for screening and diagnosing skin lesions and plant diseases[20],
- EP2365456B1 - Data structure, method and system for predicting medical conditions[21],
- EP2369551B1 - Imaging system and method[22].

USPTO:

For many years the USPTO has been relatively liberal in its interpretation, yet the Case of Alice v CLS Bank, in which the degree of abstraction was considered, has changed the Office's perspective, and has led to the introduction of the 'Alice Test', as diagrammed:



Based on: https://www.uspto.gov/web/offices/pac/mpep/s2106.html

Copyright:

In case of Copyright and software protection the protection is possible towards:
- "Look and feel" of the software when it covers the requirements of copyright protection;
- Source code – when it covers the requirements of Copyright protection;
- Object code – when it covers the requirements of copyright protection;
- Algorithms as such that describe the functions of a computer program, are not protected, because copyright does not protect ideas itself but only those ideas in a certain form of expression;
- Functionality of a software is not protected.

4.3 Open Source Publishing as an Element of IP Management Strategy

4.3.1 Introduction to Open Source Publishing

As a result of the fundamental transformation of software development and distribution mechanisms in recent decades, publishing software through Open Source licences is no longer a niche approach and, if appropriately executed, it can form an important element of the general IP Management Strategy for an organisation such as Sano, where software is the primary developmental focus. Publishing in that form not only improves the visibility of the Centre but also helps to improve the brand establishment.

20 https://patents.google.com/patent/EP2815372B1/en?q=computational+medicine&country=EP,PL&page=1
21 https://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=2365456B1&KC=B1&FT=D
22 https://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=2369551B1&KC=B1&FT=D

Generally, Open Source publishing is the act of making software available for public examination and, potentially, use (although restrictions may apply), based on a specific Open Source licence. Although such published code is available to anyone for inspection, it is not unprotected – the attached licence makes important provisions relating to code usage by another party: who can apply the code, if the code is modified – how the modifying party should proceed with the introduced changes, whether any field of use is acceptable, can the code be used for-profit, is any extension of the code created by a third party required to be published as well, or may stay closed, etc. A comprehensive comparison of various Open Source licences, is available at: https://opensource.org/licenses/category.

4.3.2 Benefits and Risks related to Open Sourcing

As any IP management option, Open Source publishing (OS) should be applied only after a thorough investigation of advantages and disadvantages of such a step. The following are usually considered the most important benefits of Open Source publishing:

- **Wide distribution**. Indexing by web search engines makes OS software easy to find, download and install, and therefore the uptake is generally much wider compared to closed software. This benefits the author's promotion and recognition in the target society,
- **Public scrutiny**. Due to many people inspecting and executing the code, shortcomings and errors are identified and reported more quickly, resulting in better quality software,
- **External contributions**. If the publisher enables it, external developers may contribute new functionality, fix problems and write documentation, which speeds up the process of maturing the software, and may result in crossing TRL levels faster,
- **Giving back to society**. OS publishing of a portion of an organisation's software assets, and allowing free use of it, can usually be promoted and recognised as an act of philanthropy, spreading the organisation's output back to society (especially in the case where society sponsored the development of the output in part, though e.g., public grant funding).

Wide distribution and potentially adoption of OS software may result in many beneficial outcomes, amongst which are also those relating to monetisation (see below). Others include publisher brand promotion, recognition in software developer community (which may help with future recruitment), increased citation and a larger reader base of related scientific publications (scientific OS software often requires paper citations in return for use).

Risks related to Open Source publishing include:

- **No direct sell route**. Typically, when an organisation decides to OS-publish a code, it also foregoes the possibility of selling it to other organisations. In particular any kind of exclusive ownership transfer is very difficult in such circumstances.
- **Disclosure**. OS software, by definition, is publicly available. Therefore, publishing a piece of software as OS equals disclosure, and as a result may harm/exclude some future IP protection routes for that software as an item of intellectual property. For that reason, it may be not beneficial to OS-publish software which constitutes a market advantage over a direct competitor in the exploitation field.
- **Maintenance responsibility**. While all OS software is provided *'as is',* with no warranty or formal obligation of service and maintenance, it may harm the publisher's brand if OS software published is not maintained at all. It is expected that the original author will provide at least minimal support for the community which may eventually form around the published software. Nevertheless, for some popular OS projects where the original authors had been unable to provide maintenance, members of the community took over the responsibility.

- **Customer hesitancy.** Perhaps most significantly for Sano, some commercial organisations, many of whom may be candidate customers for Sano's outputs, refuse to make use of Open Source software, choosing to rewrite any such materials that may inadvertently been utilised. Whilst a twin-licence approach (OS and commercial, see below) may offer an acceptable compromise for Sano's own outputs, the use of external OS software by Sano itself is a matter for policy consideration, as it may affect onward viability.

4.3.3 Direct Monetisation Options

OS publishing does not preclude the generation of income from the materials. Whilst it is very rare (though theoretically possible) to encounter a fee for the use of OS software – it is usually provided free-of-charge for at least some fields of application – there are other avenues by which to generate income. Two frequently used avenues are:

- Charging for consultancy services, typical for sophisticated software applied in complex settings,
- Charging for a commercial licence - the OS licence is free for non-profit use, but any application in paid commercial projects requires a paid commercial licence for the software.

From this point of view, the OS publishing approach serves as a vehicle for the widest possible distribution, thus creating the widest possible market for the monetisation effort.

4.3.4 Open Source in Marketing and Promotion

For OS software to gain wide recognition and adoption, in addition to the requirement for the published code to be of high quality and relevance to software engineers, a promotional strategy is required. Such a strategy would typically be focused on specific groups of recipients, in order to create an early-adopter community and increase the code's popularity. Without such a promotional effort, the pathway to widespread uptake will be substantially protracted.

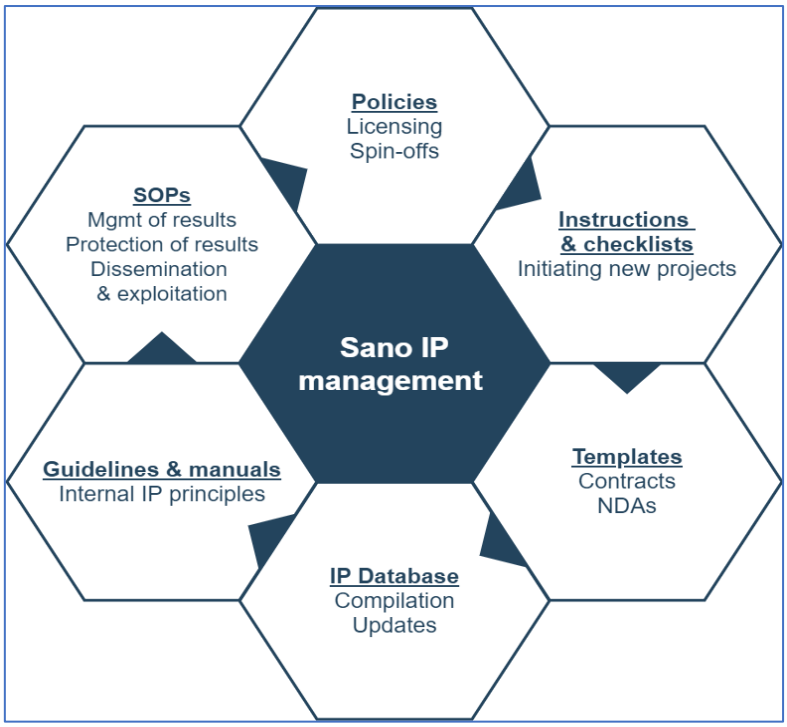
5. Implementation

5.1 Sano Principles and Policies

Managing IP in an efficient way requires the development and implementation of a comprehensive system of administration that covers all aspects of the process in a clear and accessible way. Sano is continuing to build its internal systems, and IP management is a key target for the introduction of a formalised approach. Covering the spectrum of required documentation (policies, guidelines, SOPs, instructions), the overarching goal is to provide comprehensive IP guidance to all Sano personnel.

As an important point of principle, in Sano IP is not treated as a segregated activity, rather it is embedded in the culture of interdependencies across all aspects of the Centre's functions, and this is particularly visible in procedures spanning ethics, communication and R&D in general. With the increase in Sano's cooperation with clinical, academic, and industrial partners, IP regulations are gradually being developed to ensure all formal requirements are met, and examples of documents designed to facilitate IP management are presented in Figure 21.

Figure 21. Sano IP management system – examples of resources



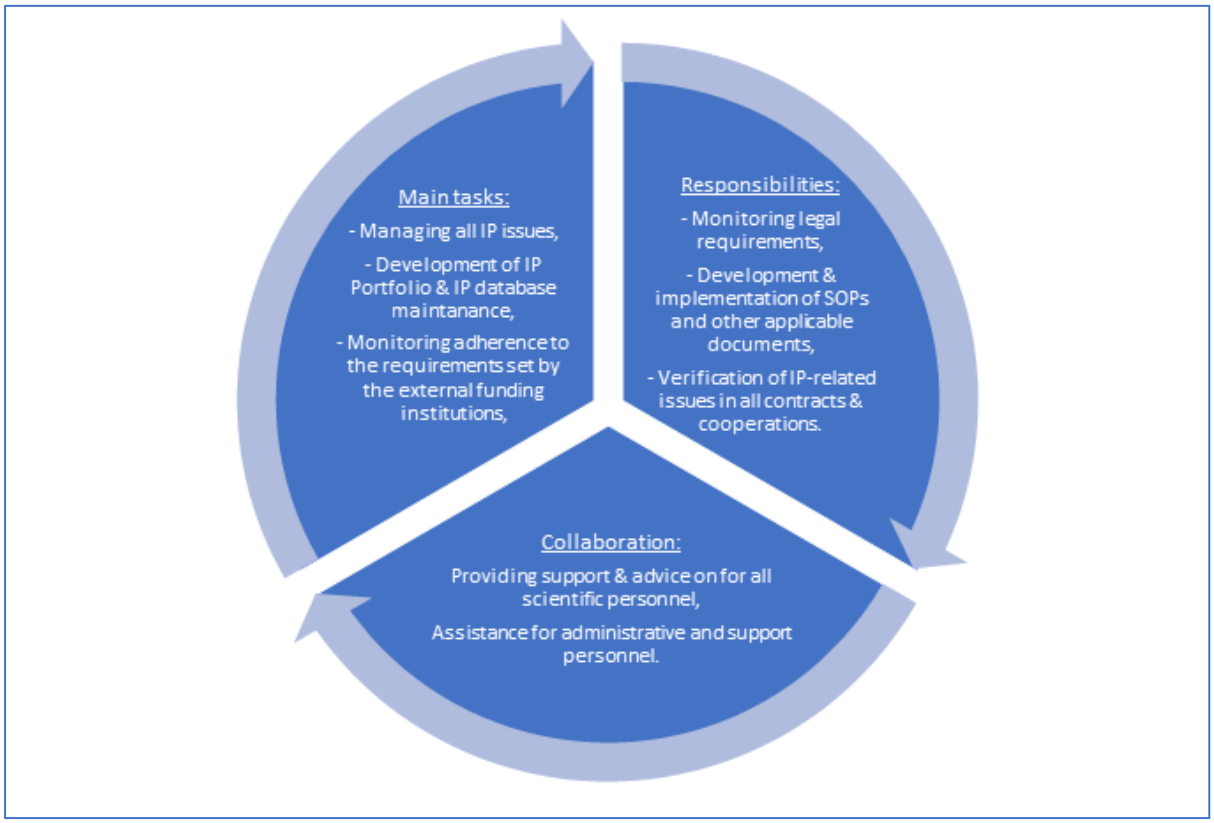
These examples serve to identify a multiplicity of IP-related issues, that must be covered by formally documented processes. Some are already developed and implemented, while others, particularly those dealing with downstream activities not yet encountered, remain to be established in the future. All will be translated into everyday operational guidance, ensuring they facilitate IP management at all levels.

5.2 Governance and Administration of the IP Management Plan

To ensure appropriate coordination of IP management in Sano dedicated structures, responsibilities for the management of Intellectual Property have been allocated. The Sano Legal and IP Office combines the knowledge and expertise of Legal Counsel with the necessary business experience and

practical approach of the Business Development Team. An overview of the Office's activities is presented in Figure 22.

Figure 22. Legal and IP Office



The main focus of the Legal and IP Office will be optimising the coordination of IP issues across the Centre with an overarching responsibility for the implementation of rules and standard operating procedures enforcement when it comes to the IP protection. The Office will also handle any infringements against a formally agreed procedure, but the emphasis will be on the minimization of such risks, through close collaboration with researchers.

5.3 Rules and Restrictions – Applicability

As described earlier, Sano's activities form a logical sequence of developments directed ultimately toward commercialisation. Beyond this linear process there is an additional factor that influences Sano's overall direction – the relative importance of any particular opportunity to Sano's development as an organisation. This adds a weighting to the prioritisation of developing, establishing and promulgating a series of messages to Sano's target communities, and the optimum content and sequence requires discussion between the marketing, business development and technical teams. Sano respects a hierarchy of influences covering commercial activities:

- **Value proposition**: identifying unmet needs through community expansion and user feedback.
- **Solution matching**: managing Sano's approach, emphasising the fit of solutions with need.
- **Value extraction**: combining marketing and legal views of the IP Portfolio, to generate wealth.
- **Emphasis on benefits**: focusing on clinical improvements – prevention, diagnosis and therapy.
- **Balance**: ensuring the mix of outcomes fulfils short-term and long-term goals.

- **Planning**: identifying opportunities from gaps between future needs and current capabilities.
- **Pro-activity**: understanding and provoking discussion of unmet needs through events.

The appropriate product structure and mix will evolve from a well-constituted management process. A tripartite combination of expertise is proposed, featuring Sano's technical management, its business development team, and its marketing team. In each case there will be contributions from the core IRAP-funded research-driven contributors, and from the H2020-funded Advanced Partners.

5.4 Inventor Rights

5.4.1 Ownership

The main legislation regulating IP rights in Poland are the Act of 4 February 1994 on Copyright and Related Rights, and the Act of 30 June 2000 on Industrial Property Law. These Acts regulate the protection of rights for creative works, related rights, inventions, utility models, industrial designs, and trademarks. Data, know-how, and business secrets are also protectable under the Act of 27 July 2001 on the protection of databases, the Act of 16 April 1993 on combating unfair competition, and the Polish civil code. A number of European and international regulations relating to IP protection are also effective in Poland.

As a general rule, copyright in a work belongs to the author, unless otherwise provided by law. Pursuant to Article 12, section 1 of the Copyright and Related Rights Act, if the Act or the employment contract does not provide otherwise, the employer, whose employee created a work as a result of the performance of duties under the employment relationship, acquires author's economic rights, within the limits resulting from the purpose of the employment contract or the consensual intention of the parties.

If an invention, utility model or industrial design is made as a result of the author's performance of his obligations under the employment relationship, the right to obtain a patent for the invention or the right of protection for the utility model, as well as the right to register the industrial design, shall be vested in the employer, unless the parties have agreed otherwise.

Sano will ensure that the copyright in works performed by employees or persons providing services to Sano belongs to Sano in all contractually appropriate circumstances.

5.4.2 Copyright

Copyright refers to both an author's *moral* right, which is non-transferrable and always remains with the author, and *economic* right, which is transferrable and expires after the lapse of a certain period of time. Copyright protection does not require the carrying out of any formalities to exist.

The Copyright Act provides an exemplary list of moral rights. Moral copyright protects a tie between an author and a work. Only a physical person can be an author. An acquirer of rights to a work must respect the moral copyright of the author and make it possible for the author to, for example, mark the work with his/her name, decide about the first dissemination of the work, and supervise the way the work is used. However, an author may undertake in a contract with an acquirer not to exercise their moral copyright.

An economic right represents the right to use the work, to manage its use throughout all fields of exploitation, and to receive remuneration for the use of the work. Economic copyright may be traded, and the owner of such a right may grant a licence to another party to use a work. Therefore, economic

copyright may be held either by the author themself or another entity (producer or publisher of a collective work, employer) or their acquirer.

Apart from moral and economic rights, the Copyrights Act grants an author a *derivative* copyright, which is the right to create and use any derivative work, created on the basis of the copyrighted work, such as a translation, sequel, modification, etc. Some entities consider works produced with machine learning to be derivative works.

5.4.3 License and Transfer of rights

An entity with the economic copyright to a work is exclusively entitled to use and dispose of the work in all fields of exploitation, including making it available for a consideration.

The owner of an economic copyright may transfer it (e.g., sell it) or authorise a different entity to use the work (a licence). If copyright is transferred only with respect to certain fields of exploitation, the author retains the rights to the work and may still dispose of it for the fields of exploitation not affected by the transfer. By disposing of economic copyrights, the seller loses the right to use the work within the scope of the transfer. The agreement for the transfer of copyright or to grant an exclusive licence must be in writing. A non-exclusive license agreement may also be concluded in a different form.

The types of contracts concluded by Sano will depend on the specific case.

5.4.4 Patents

The Polish Industrial Property Law Act, in art. 8 item. 1, provides for an inventor to own certain rights to an invention, utility model, industrial design, and integrated circuit topography - the right to obtain a patent, protection right or right in registration, as well as the right to remuneration and the right to be listed as the inventor in descriptions, registers and other documents and publications. Obtaining such rights requires taking certain formal steps, including a registration procedure, and the periodic payment of fees during the period of protection. In order to obtain such protection for an invention, utility design, trademark or industrial design, an application should be filed with the Patent Office.

The rights to which the author of an invention is entitled are regulated in detail in the Industrial Property Law Act, and some specific conditions may be determined individually. As with other forms of protection, the owner of a patent may sell or license the rights. An agreement of the assignment of rights to obtain a patent for an invention, a patent itself, a protective right to a utility design, trademark or a right under registration of an industrial design must be made in writing.

5.5 IP Registration

Below one can find a list of official sources of information on the protection of IP (and in some cases on the repositories of data thereon), they have been collected and presented in Table 19.

Table 19. Forms of protection and appropriate sources of information

FORM OF PROTECTION	DATABASES
TRADEMARKS	**Polish Patent Office** (PPO) - https://ewyszukiwarka.pue.uprp.gov.pl/search/simple-search?lng=pl **TMview** - EUIPO - https://www.tmdn.org/tmview/welcome#/tmview **eSearch plus** – EUIPO - https://euipo.europa.eu/eSearch/#advanced/trademarks **TMclass** - http://tmclass.tmdn.org/ec2/ **WIPO Madrid Monitor** - https://www3.wipo.int/madrid/monitor/en/ **Global Brand Database** - https://www3.wipo.int/branddb/en/index.jsp **TESS – USPTO -** https://tmsearch.uspto.gov/bin/gate.exe?f=login&p_lang=english&p_d=trmk

FORM OF PROTECTION	DATABASES
INDUSTRIAL DESIGN	**Urząd Patentowy RP** (Polish Patent Office) - https://ewyszukiwarka.pue.uprp.gov.pl/search/simple-search?lng=pl **DesignView** – EUIPO - https://www.tmdn.org/tmdsview-web/welcome#/dsview **eSearch plus** – EUIPO - https://euipo.europa.eu/eSearch/#advanced/designs **Hague-Express** – WIPO - https://www3.wipo.int/designdb/hague/en/
PATENTS	**Urząd Patentowy RP** (Polish Patent Office) - https://ewyszukiwarka.pue.uprp.gov.pl/search/simple-search?lng=pl **Espacenet –** EPO - https://worldwide.espacenet.com **PATENTSCOPE** – WIPO - https://patentscope.wipo.int/search/en/search.jsf **GOOGLE PATENTS** – GOOGLE - https://patents.google.com/advanced
COPYRIGHT	**WIPO PROOF** – WIPO - https://wipoproof.wipo.int/wdts/ - allows to obtain an official confirmation (digital fingerprint) of the existence of a work. This happens in the form of an electronic token.

5.6 Instruments

To protect intellectual property rights of assets generated by Sano uses various types of internal and external instruments, like for example:

- **Non-Disclosure Agreements (NDAs):** Non-disclosure agreements will be concluded internally with employees, collaborators of Sano, members of Sano bodies but also externally with advisors, third parties, contractors, partners of implemented projects. The agreements will be aimed at the protection of trade secrets and the protection of inventions before their registration at the patent office.
- **Project Agreements**: Sano, when seeking to implement a project with third parties, will conclude agreements regulating the issue of rights' ownership to works and inventions created during the implementation of these agreements with special emphasis on the background and foreground IP identification of any other dependencies that may influence the ownership division of the project's results.
- **Sano Internal IP Regulations**: Sano implements internal documents regulating the prosses of intellectual property handling and securing created at Sano for Sano specific use. Internal IP Regulations will provide descriptions of the actions required at each stage of an idea's development, and whom to inform and consult within the Sano. In addition to the regulations, detailed SOPs, guidelines and manuals will support employees in an accessible way. The expectation that Sano's processes will be subject to change obliges the constant monitoring of all documentation.
- **IP Database:** A database will be developed by Sano that will contain information on IP held by Sano, including in particular information on the sharing of particular IP with third parties. The database will also contain information on IP received from third parties and will feature in particular the restrictions on permitted use.
- **External Entities:** In order to ensure patent protection, Sano plans to cooperate with external patent agencies, which will register and maintain the currency of Sano's IP.
- **Technical Data Protection**: The storage and handling of data will be carried out in ways that as far as possible eliminate the risk of breaches of confidentiality, comply with legislation on data in the respective countries, and conform to the EU General Data Protection Regulation (GPDR). Data sets and details of innovations will be stored on secure local devices of the consortium's institutions. To avoid data loss, state-of-the-art backup systems are required.

Sano will employ the most appropriate instrument in each case.

5.7 IP Awareness Training

The effective safeguarding and exploitation of Sano's IP requires both the creation of comprehensive procedures and the sophisticated training of its personnel to ensure that the procedures are properly implemented. Special emphasis is therefore placed on the education of employees, from the induction process onward, only providing the employees of the Centre with proper awareness of the threats and opportunities may ensure the smooth introduction of all the preventive steps that will help to properly protect Sano assets from the very early phase.

IP awareness is part of the training schedule mandated by Sano and is provided primarily by Sano's Legal and IP Office. Additional highly detailed instruction for personnel managing IP on a daily basis is provided through external programmes of education. Specific guidance on IP handling within academic and industrial settings, and as part of major international projects, is provided by the Advanced Partners in the H2020 Consortium under their remit to share expertise.

Developing a culture that respects the fundamental importance of IP protection is an enduring process, which builds on appropriate attitudes instilled in core Sano personnel. The Legal and IP office remains the first contact point for researchers, who are required always to seek advice regarding the identification, protection and commercialisation of IP, and prior to any release of potentially-valuable materials.

5.8 IPR Maintenance and Review

With Sano gaining maturity and increasing the number of new collaborations, the need for continuous and well-structured IP maintenance is growing significantly. As described in previous sections of this document, Sano has a keen focus on ensuring that, as items of potential IP are generated, they automatically enter an IP-centric system that is designed to promote confidentiality, identify, register and maintain concepts of interest, and avoid the untoward release of information of potential value.

The continuously updated Sano IP database will ensure the currency and completeness of information on Sano's assets, and will be accompanied by a cyclical review of both the database contents and the maintenance procedures employed by the Legal and IP Office. The specific timetable for the revision of IP documentation is included in the general rules governing the Sano Document System, and the frequency of the Update and Verification system will be adjusted to match the rate at which concepts are added to the database.

6. Summary

Sano's Deliverable D6.2 introduces the Centre's policies on the identification, protection, curation and exploitation of its Intellectual Property, describing and contrasting the alternative means of assessing and safeguarding candidate items of IP. It also discusses the principles and practice of building a comprehensive portfolio of resources to support both academic and commercial success, whilst describing the relationship between IP and the market-readiness of the protected technology, through which the investment in IP protection is adjusted to match the maturity and market significance of the development. It concludes with a discussion of the practical steps being taken to implement appropriate IP measures within the Centre.

In Section 1 the central importance of Intellectual Property to an academic organisation is reiterated, whether the IP is exposed - to showcase academic prowess or protected - to enable exploitation. The historical context through which IP has facilitated the rapid expansion of market technology is discussed, together with an exposition of the formal legal structures that have been created to give legal substance to the principles. It concludes with a reflection on the ethical issues affecting technology in healthcare, where restricting access may have profound societal consequences.

Section 2 introduced the various ways in which exploitation of IP through commercialisation and income generation can be greatly enhanced by the application of appropriate means of protection. It explores both the traditional forms of protection and the approaches introduced more recently, with a particular focus on applicability to software, Sano's principal exploitable output.

The need for sophisticated planning, to establish an organised catalogue of IP resources that combine to support solid growth of both reputation and commercial income, is discussed in Section 3. The evolution of IP with time, particularly as technologies are advanced towards market readiness, is described, together with an introduction to the characterisation of IP in computational medicine, both to assist exploitation and to construct a logical basis for internal portfolio construction.

Section 4 examines Sano's approach to creating a value-chain of assets, supported by mechanisms for the continual reassessment of the materials in the context of a rapidly changing marketplace. A key aspect of IP management is the need for a system to support decision-making at each stage of asset development, and a decision tree is outlined in which the achievement of each goal triggers the next step in the assessment process. The factors to be considered at each decision node are tabulated in detail.

The final part of the deliverable, Section 5, discusses the practicalities of implementing the principles laid out in Sections 1 to 4, and covers governance, administration, the formalisation of Sano's set of IP rules, and the distribution of rights between involved parties. It continues with a description of the physical processes of IP protection registration, and the various legal instruments that are essential to the conclusion of agreements between parties to commercial exploitation agreements. The section concludes with a description of the routine internal processes required to maintain IP currency, and the approach to continuous staff training, both in establishing and developing awareness throughout Sano, and in equipping its legal team with the comprehensive skills required.