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WORK PACKAGE TITLE: Innovation Management, Exploitation & Business Planning

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Approvals

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1. Executive Summary

From the very outset of iReceptor Plus, efforts have been made to look at the full range of tasks under all work packages from a perspective of 'innovation' with the aim of ensuring that the services being developed will be tailored to user needs, and, at the same time, assessing business models appropriate to capture the value of these services in the future. Consortium partners have been asked to state their aims and intentions regarding the sustained provision of services after the project implementation period ends and efforts have been made to create a common understanding of the terms and notions to be employed in developing an exploitation strategy.

Developing an exploitation strategy in this setting is an intensive, ongoing process which takes place in parallel with development of the technologies to be employed in creating services. A comprehensive strategy will evolve as consortium partners can envision the possibility of taking commitments towards a joint future. Work done to identify use cases will become cardinal inputs for deliberations about a path-to-market and other aspects of the resulting business plan. The state of affairs at this stage of the project is that continued monitoring of market needs and delineating a path from use case to the technologies to be developed and employed to deliver services. This path will provide outlines for exploitation strategies.

In summary, based on a partial set of partners' objectives and a core list of use case categories the groundwork is done for mapping possible exploitation strategies. Continued efforts to build consensus amongst partners, to engage stakeholders and to identify value for product development will in the next phase make it possible to explore a limited number of options and eventually select the most beneficial exploitation path(s)

2. Deliverable description

This document describes the process for translating the R&D to maximize the impact of the project's aggregated efforts and assess the conditions for a continuation thereafter.

This deliverable reflects Task 8.1, through which the Consortium develops, implements and monitors a project-specific Innovation Management approach and plan, employing innovation/exploitation theory and process concepts applied to The iReceptor Plus business case, which is based upon increasing demands for cutting-edge therapies, such as vaccines, therapeutic antibodies, and engineered cells that rely on manipulating the adaptive immune system to fight autoimmune and infectious diseases and malignant cancers.

This report describes an ongoing process which aims to obtain a broad understanding of the importance of extending the results of applied research to a stage were these can become economically sustainable.

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3. Introduction

Innovation Management is the capability to manage an invention/idea for a new product, service, process or method up to its successful realisation[1]. It provides for a conceptual framework for all partners to work towards the final outcome of this project, namely, to demonstrate the commercial and industrial viability of a common scalable platform to integrate distributed repositories of Antibody and T-cell Receptor Sequencing Data for enabling improved personalized medicine and Immunotherapy for diseases with an immune component, including Cancer, Inflammatory and Autoimmune diseases, allergy and Infectious Disease. The conceptual framework will ensure that a focused, concise innovation pathway is followed in the project to capitalize on the market opportunities through a clear understanding of the markets that will be served, business case development, business planning and preparation for market introduction as well as mitigating non-technological barriers, such as those related to regulation especially with regard to privacy-related issues. It will assure a focused, concise innovation pathway to be followed, including preparation for the final business case and drafting of the business plan, based on and informed by a market analysis (task 8.3), an exploitation plan (task 8.4) and IPR management and technology transfer arrangements for protecting the created value (task 8.5). Likewise, the Innovation Management will include a close, interactive exchange of knowledge, data and experience gained from the use cases.

The innovation & exploitation activities will be supervised and managed by the Innovation Board, composed of an appointed representative from each industrial partner in the consortium as well as all partners that produce Foreground IP. Additional team members qualified and experienced in this domain may be nominated by the core partners interested in the exploitation and business planning for project outcomes. The Innovation Management will manage the different groups - specific partners and designated experts from these partners - to work together towards the introduction of the new products and services. It also includes a close, interactive exchange of knowledge, data and experience among the partners. The Innovation Manager, a member of the Project Executive, will be the Chairperson of the Innovation Board.

As stated on the European Commission's Horizon 2020 website, "Horizon 2020 is the financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe's global competitiveness.[2]" In this respect, the EU recognizes that more emphasis needs to be placed on funding research and innovation that will eventually lead to commercial opportunities both within and beyond the borders of the EU. Within this context, the EU funded Research & Innovation Actions, such as the iReceptor Plus project, are specifically aimed at bringing new technologies closer to market readiness level, with the expectation that they will be duly commercialised after completion of the project. In the implementation of such projects, it is no longer sufficient to simply develop new technologies; rather, the eventual

[1] European Commission (2004), *Innovation Management and the Knowledge-Driven Economy*, Luxembourg: Directorate General for Enterprise.
[2] https://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020

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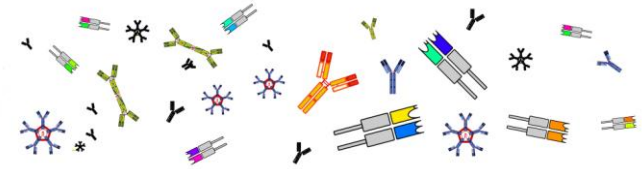

exploitation and business potential must be considered and planned as part of the project activities. To achieve this, the development of a project-specific Innovation Management approach and plan are required. These can be built based on innovation/exploitation theory and process concepts.

In this deliverable (D8.3), the project specific innovation approach and the corresponding innovation management process, which will facilitate further deliverables of WP8 and eventually lead to the development of the final business plan, will be described in more detail.

4. Problem Statement

Knowledge is a driving force for economic development. The countries with the highest levels of economic development, such as Switzerland, Japan and the Scandinavian countries, are also those with the highest Knowledge Economy Index.[3] Within these knowledge-driven economies, innovation plays an important role, allowing for organisations to differentiate themselves in an ever increasingly competitive market. However, creating an environment that fosters and capitalises upon innovation still presents problems for many. In particular, **the ability to bring together the right players that will facilitate the innovation, and subsequently the introduction of a new product/process on the market, remains one of the biggest challenges**, thus necessitating Innovation Management.

The following sections will address this challenge along with the following questions:

- What are the steps that we as a consortium need to take to be able to sell the technology to the relevant stakeholders?
- Whom do we need to achieve this?

5. Collaboration

a. Personnel/organisation

With the iReceptor Plus project being a Research & Innovation Action that addresses the complete research-development-innovation cycle, applying novel technology as well as "scaling-up" and "scaling-out" of the platform, the consortium has been built with this in mind. To achieve the ambitious objectives necessitates a multi-disciplinary collaboration combining experts in key enabling technologies. Therefore, the consortium is composed of four complementary sets of partners to include all required skills, expertise and experience:

Academic researchers: accelerate research discovery, give visibility to their research and results

[3] World Bank Institute (2007), *Building knowledge economies – Advanced strategies for development*, Washington DC.

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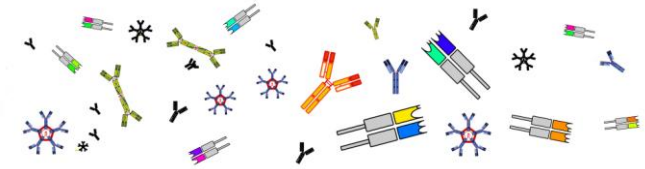

Biopharma companies: look for patterns (i.e. biomarkers) to be exploited in personalized medicine
Clinicians: refine predictions of treatment outcome
Cancer therapy, therapeutic antibodies, vaccine development: more statistical power, bigger sample sizes, streamlined bioinformatic pipelines.
Project Management partner, for overseeing the progress and outcomes of the project (Agora)

The fact that the consortium covers almost the entire research-development-innovation cycle was a strategic decision, as these are the parties needed to drive the innovation process. Moreover, this allows for the technology to be developed and tested in near to operational environments. As a result, the technology development is expected to reach at least a high TRL, if not already a commercially viable product.

b. Project management

An important aspect to successful innovation is effective project management, which is necessary to maintain focus, facilitate progress, and make crucial decisions to be able to achieve the ultimate goal. In general, a project manager should therefore be in place to be responsible for ensuring effective coordination and communication, understanding and managing the innovation process, and understanding and guiding the actors involved. Moreover, project management should oversee all phases of the innovation process, from the idea stage to eventual implementation.

In iReceptor Plus, the project management is the responsibility of the Project Executive that consists of the Coordinator as the chair of the committee (Prof. Yaari from Bar Ilan), a Scientific Manager (Prof. Felix Breden from SFU), a Technical Manager (Mr. Brian Corrie from SFU), an Innovation Manager (Mr. Tobias Hinz from Ascora) and an Administrative Manager (Mr. Simon van Dam from Interteam).

With regards to the Innovation Management, the supervision and management of all innovation & exploitation activities are done by the Innovation Board, consisting of appointed representatives from each industrial partner in the consortium as well as all partners that produce Foreground IP. Tobias Hinz as the Innovation Manager will be the chair of the Innovation Board, and is responsible for planning, coordinating and supervising all tasks related to Innovation Management, including exploitation and business planning. He will be assisted by Simon van Dam (Interteam) and his team.

c. Internal communication

Innovation relies on effective communication, both externally to the outside world and, perhaps more importantly, internally within the consortium. Developments within the consortium therefore need to be shared in an easily accessible and transparent manner to facilitate effective

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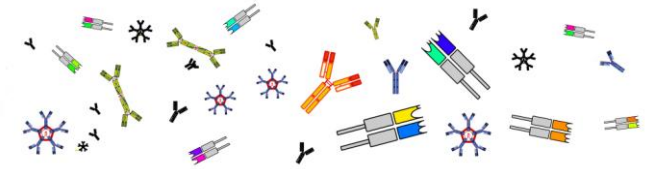

collaboration. Within the iReceptor Plus project, a number of different communication strategies have been employed to ensure that information is readily shared among partners. In addition to email and phone calls, these include the use of an extranet and the organisation of dedicated meetings. The extranet, based upon OwnCloud, is a secured internet platform that hosts regular updates on the project development, meeting documents (agendas, minutes, and presentations), manuscripts in progress, and project reports. The platform also includes a content management system, to allow partners to upload content themselves. Meetings can be held remotely by making use of virtual tools, such as Skype and conference call services. However, the most effective means of communication is via face-to-face meetings, which allow for dynamic and interactive exchange of information. In addition to the regular annual project meetings, smaller working group meetings are also held at least once a year, usually dedicated to specific topics.

d. External communication and social media

As mentioned, the key to Innovation Management is bringing the right players together to facilitate the innovation process and ultimately bring the technology to the market. In the previous section, it was highlighted that internal communication within the consortium is critical for driving the innovation process, but the success of the innovation strongly relies on effective communication and engagement with a broader audience. Moreover, this external communication should go two-ways: to create awareness and inform different stakeholders about technology that is being developed and also to gauge their needs as well as response and receptiveness to the technology. To achieve this, different communication tools and channels are used, including:

A Project website creates the project identity and is used to generate awareness and disseminate information to various target audiences, including opinion leaders, the scientific community, regulators, healthcare providers, industry, owners & providers of data (repositories), the media and the general public. This is the main information resource for the project.

Social media platforms provide a direct link to specific audiences, in particular opinion leaders, the scientific community and the media. Given the immediacy of posts on such platforms, they allow for regular updates and insights into the developments that are happening within the iReceptor Plus project, but also generate buzz and discussions about related subjects.

A Stakeholders forum has been established via a LinkedIn group, to engage key players including technology providers for healthcare solutions, owners & providers of data (repositories), biopharmaceutical companies, providers of genomics-based diagnostics, IT healthcare platforms, providers of scalable large data platforms (including SMEs), healthcare providers and opinion leaders. The goal is to reach out to vulnerable populations and explaining what can be gained from our efforts, and how the Platform can be designed to maximize their benefit and, in doing so, gain valuable insight into the possible threats and opportunities for the iReceptor Plus

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technology. Moreover, it is also hoped that some members of this forum may fulfil the role of ambassador, and champion the iReceptor Plus technology to others.

6. Market Intelligence

The objective of any innovation development is to ultimately be able to sell the outcome, whether it be a product, process or service. To achieve this, it is important to have a comprehensive understanding of the commercial landscape, including potential competitors/competing technologies, current trends in the market, and the potential barriers to a successful launch of the products/process on the market. In gaining such intelligence, it is also expected that potential customers and market uptake strategies will be identified. Below are some early results of this process.

7. Customer Relationship Management (CRM)

In addition to understanding the competitive landscape of iReceptor Plus-like applications, it is also necessary to identify the potential customers for the iReceptor Plus technology. Although the iReceptor Plus consortium consists of several partners who could be launching customers, they will only capture a fraction of the potential market for the technology. The Consortium works already in close cooperation with both AIRR-C and TABS (trade association with ~1800 members, 1/2 industrial) and these communities contain many potential customers for the iReceptor Plus technology. Thus, there will be the need to build and manage a possible client base.

As mentioned earlier, the challenge with Innovation Management and bringing a new technology to the market is to bring together the right players. Perhaps an even more pertinent question is who the right players are. In general, the right players are those that see the value in and/or will benefit from the technology. However, they should also be in a position to adopt the technology, or influence others to do so. Ultimately, the right people will be those that will be champions for the technology.

A part of the Innovation and Customer Relationship Management process is to identify and build relationships with these potential champions. This will be done by evaluating which companies/industries are expected to benefit most from the technology, and who within these companies would be best to approach. It is anticipated that the motivation for these companies to adopt the technology will be related to current pain points and/or incentives, putting them in a position where they are ready to make a change. The individuals to approach within companies will likely be those that feel these pain points the most.

To understand what the pain points are, industry players will be invited to engage in conversations and participate in workshops/events about integrating distributed repositories of Antibody and T-cell Receptor Sequencing Data for enabling improved personalized Cancer,

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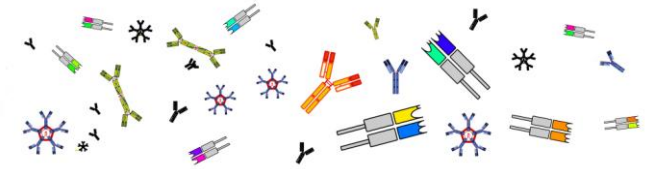

Autoimmune, and Infectious Disease Immunotherapy as a part of the Stakeholders Forum. These discussions will be used to gauge the level of interest but also scepticism in the technology, to understand what information or data is needed to alleviate any concerns or doubts about the technology, to identify the triggers that will pique someone's interest in the technology and to ascertain how the technology can best cater to their needs. Acquiring such insights will help to define strategies on how to approach the companies that are most likely to adopt the technology, thereby maximising the impact of the technology on the market.

8. Business Creation

a. Developing the business cases

The iReceptor Plus business case is based upon increasing demands for cutting-edge therapies, such as vaccines, therapeutic antibodies, and engineered cells that rely on manipulating the adaptive immune system to fight autoimmune and infectious diseases and malignant cancers. For example, anti-cancer therapeutic antibodies have increased the 3-year survival rate from advanced melanoma dramatically, from 12% to 60%. Such advances depend partly on applying next-generation sequencing to characterizing the vast and highly diverse population of receptors that the body employs during an immune response. These AIRR-seq data are of huge potential value to biomedicine.

The iReceptor Plus business case will demonstrate the expected impact of the technology, in terms of enhanced market opportunities for the industrial partners of iReceptor Plus and thus growth and jobs in Europe (and Canada and the USA), in the short to medium term. It will describe the targeted markets, in terms of targeted sectors, estimated size in Europe and globally and user, customer and consumer needs; it will also demonstrate that the solutions will match the market and user needs in a cost-effective manner and describe the expected market position and competitive advantage.

Given that the iReceptor Plus consortium consists of partners from most stages of the research-development-innovation cycle, the business cases will be considered at each level, as well as for a range of clinical applications.

b. Roadmap after the duration of the project

By the end of the iReceptor Plus project, it is expected that the **innovation will be brought to an industrial validation level through pilot testing in clinical settings**, thereby achieving a Technology Readiness Level (TRL) of 7. For the technology to reach TRL9, and eventual commercialisation, it must be incorporated into a commercial setting and prepared for full scale

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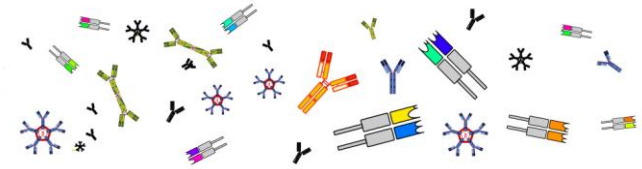

deployment. The steps and timeline necessary to achieve this will be outlined in a roadmap that will consider the following aspects:

Demonstration activities may be needed to confirm that the technology works in its final form and under real operating conditions. Currently, the technology is already able to integrate big data sets, but the demo activities are aimed at showing that the technology will meet all the desired security, quality and performance specifications and with all required advanced features, such single cell analysis. Such activities are also intended to further build trust with potential clients, which may facilitate a smoother transition to the market.

Regulatory compliance of the iReceptor Plus technology is critical for commercial implementation and is currently being addressed within the project, in particular GPDR.

Additional financing will most likely be needed to be able bring the technology to commercial maturity and the early stages of market introduction. This will be used to support the activities related to the above-mentioned steps, which are critical for commercial launch of the technology. While at this stage, no capital investments are anticipated, it may become necessary prior to commercialisation. A lack of available financing is often a barrier for launching new innovations on the market, with the funding gap typically referred to as the 'Valley of Death'. Possible sources of financing include both public funding, such as (EU) subsidies, or private equity that may be derived from internal investments or venture capital. The Roadmap for achieving TRL9 that the project will prepare will include a detailed overview of the funding needed to bring the technology to market.

Commercial agreements will need to be put in place, in order to bring the iReceptor Plus technology to the market. As the iReceptor Plus consortium covers almost all of the supply chain, there have already been a number of discussions on the types of agreements that will need to be established. These may include license agreements as well as other agreements. The terms of these agreements are also under discussion, and it is intended that by the end of the project, that these will be at a stage where they can be agreed upon by all relevant parties.

c. Business plan

The iReceptor Plus business plan will combine information from the various inputs mentioned in this document and be used to develop a strategy for commercialisation. It will involve all partners and reflect their common as well as proprietary interests in achieving the outcome of a sustainable and successful service. The business plan will address a number of key issues that relate both to the "products" and/or "services" that will be offered as well as the "markets" that will be served for each level and how they will be served. Given the fact that the Consortium includes partners that cover most stages of the research-development-innovation cycle, the definitions of "products" and "markets" differ for many partners. Similarly, for each product, the

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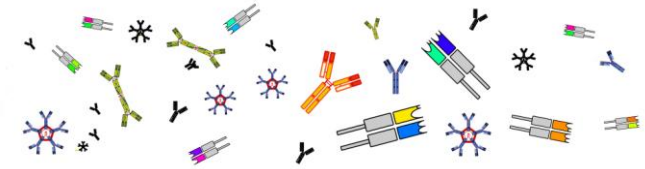

markets to be served must be defined including the end users of the particular product and which "needs" will be met.

This process will also include market assessment actions and the definition of a business model and a business plan. Specific objectives are:

- **Market assessment:** Assess the economic impact of iReceptor Platform (tools, products and services): (a) socio-economic characterization of target markets; (b) estimation of the production side cost; (c) assessment of the demand-side benefits;
- **Definition of a business model:** the kind of services that are being proposed in the framework of this proposal may be offered under different business models (e.g. advertising, subscription, pay per use, etc.). The business model (or business models) that should be used to support the service distribution represents a critical aspect that must be carefully evaluated.
- **Business plan:** once selected a line of action for the business model to apply a business plan will be prepared.

Barriers to Commercialisation

In undertaking any venture, it can be expected that there will be certain barriers or hindrances when launching a new technology on the market. Understanding the nature of these barriers can mitigate their impact and/or spur development of alternative strategies for bringing the technology to the market.

d. Regulatory aspects

Legal and ethical issues as core aspects for successful eHealth implementation – both as potential barriers, but also as strong facilitators when providing a trustworthy, reliable framework for complex ICT-enabled healthcare delivery processes. They must be addressed as part of the innovation process to enable a sustainable implementation and successful, compliant usage of the eHealth applications to be developed.

The outcome of this process will be to assure that the data platform and iReceptor Plus platform are fully compliant with all legal, regulatory, certification and ethics requirements at the EU, national and international level.

9. Knowledge Management

Innovation is based on the Knowledge that has been generated both prior to (Background IP) and during the iReceptor Plus project (Results = Foreground IP). It is important to ensure that these

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aspects are identified and documented, so that the generated IP can be appropriately protected and an effective exploitation strategy can be implemented.

a. Background Knowledge/IP

The iReceptor Plus project is a Horizon 2020 Innovation Action that builds upon existing IP that has been brought by the partners to the project. While the main Background IP is associated with the preliminary research on the integration of large-scale genomic data with extensive health data, the partners also contribute specific know-how and expertise that is used to further develop the technology within the project.

In the Consortium Agreement, Attachment 1 lists the Background that the partners have identified and agreed on for the project. In this same attachment, they have also stated if access to specific Background is subject to legal restrictions or limits. While each partner can propose to modify their own Background upon written notice to the other partners, approval of the General Assembly is required should a partner wish to modify or withdraw its Background.
While the Background IP is clearly the foundation upon which the iReceptor Plus project is based, it is anticipated that the Results (Foreground IP) will form the basis of the exploitable IP. Therefore, identifying and maintaining this Foreground IP is the more critical aspect in the Innovation Management process.

b. (Foreground) IPR management

Within the iReceptor Plus project, the Results (Foreground IP) form the basis for the technology that will eventually be brought to market. Effective management of the generated IP is necessary to facilitate the exploitation and commercialisation of the results.
IPR management involves several steps:

Maintaining overviews of all the Results from the iReceptor Plus project. This includes both tangible outcomes, such as product prototypes, as well as intangible results, such as know-how and processes. Each partner will be asked to provide periodic updates on the Results they have developed.

Protection of IP may elicit a competitive advantage when launching the iReceptor Plus technology on the market. Thus, possible strategies for seeking this protection, such as filing patents or maintaining trade secrets, will be assessed. Recommendations for the appropriate IP protection strategy will be made by the iReceptor Plus Innovation Manager, subject to the considerations and decisions of the owners of the Results.

Identifying partners involved in generating the Results plays a crucial role with regards to exploitation and commercialisation. Partners who jointly own Results need to agree on the allocation of ownership and the terms under which each partner may exploit the results, which

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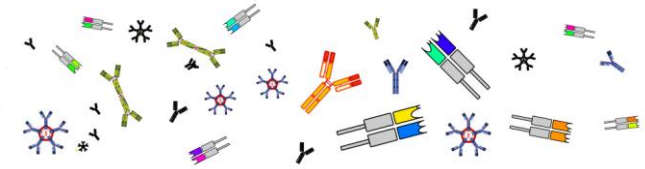

should be explicitly outlined in a joint ownership agreement. Failure to do so may result in unnecessary delays in bringing the technology to the market. When the partners are asked for updates about their Results, they will also be asked if other partners contributed to the development of these Results.

Technology transfer agreements may facilitate other technology developers to access the technology developed within iReceptor Plus. Such agreements often take the form of licensing, where the licensor legally grants the licensee the right to use the technology under specified conditions for a certain fee (royalties). To be able to establish technology transfer agreements, all the above-mentioned aspects need to be in place.

c. Patent mapping and analysis

When managing the IP that is generated during the project, it is also important to map and analyse the patents that address similar innovations, as this can be used to:

- Assess the novelty of the Results and whether they are in conflict or infringe upon other inventions/patents that have already been filed
- Determine the 'freedom to operate', which not only considers whether it is possible to bring the technology to the market, but also the geographic locations where there is the opportunity to do so
- Identify potential acquisition targets and/or the opportunities for subsequent innovations

Nowadays, it is relatively easy to access patent databases, such as ESPACENET, either directly or via search engines such as Freepatentsonline.com and Google Patents. The mapping process involves taking the patents from related inventions and comparing these with the IP from iReceptor Plus. The assessment will pay particular attention to the claims, field of use, geographic regions etc., to understand whether these patents impose any restrictions/limitations on the freedom to operate for the iReceptor Plus partners. As part of the Innovation Board functionality, they will monitor ongoing patent searches performed by legal experts within the consortium and keep the partners informed in real time of any potentially competing patents.

10. Innovation Management in Progress

While this deliverable outlines the Innovation Management within the iReceptor Plus project, this is a process that has been ongoing since the project began. Several meetings with the Innovation Board have been held in the first year of the project, to outline the strategy and discuss the inputs for developing the business plan.

- Innovation Board Meeting during the Kick-Off Meeting 12- 14 January 2019, Eilat, Israel (M1)
- Monthly conference calls from the Innovation Board Meeting to monitor progress of WP8
- Innovation Board Meeting, 21-22 November 2019, Haifa, Israel (Month 11)

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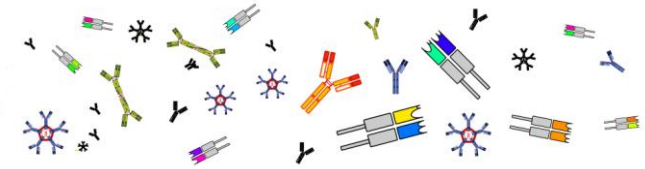

Moreover, the outcomes of these meetings have already been used as part of preparation of several specific deliverables:

- D8.1: Initial exploitation strategy and business planning (Submitted M6)
- D8.4: Intermediate exploitation strategy and business planning (Due M24)
- D8.5: Roadmap for achieving TRL 9 (Due M48)
- D8.6: Final exploitation strategy and business planning (Due M48)

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