

DELIVERABLE D8.1.

TITLE: Initial exploitation strategy and business planning

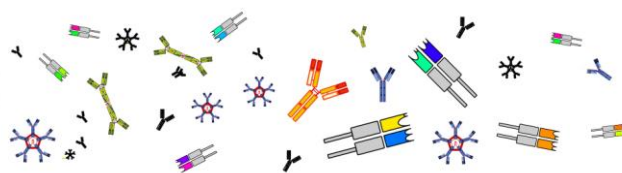
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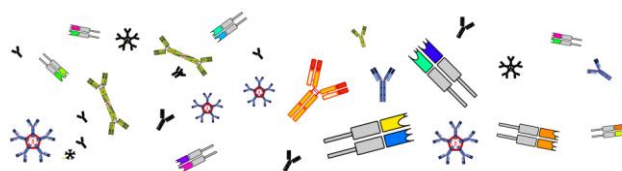


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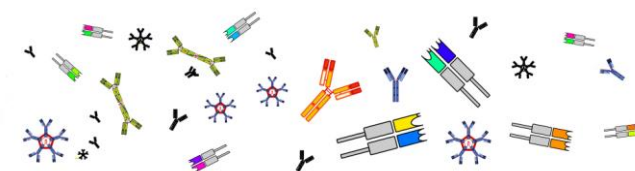


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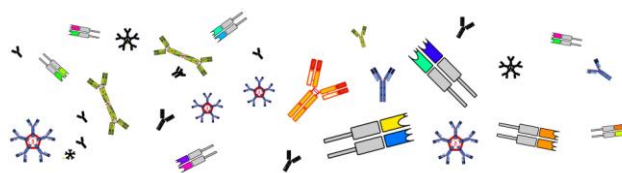
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1. Executive Summary

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. Of the twenty eight partners in the Consortium, eight are research and technology development partners and at this stage the project’s centre of gravity is clearly at the technology front, the lab.

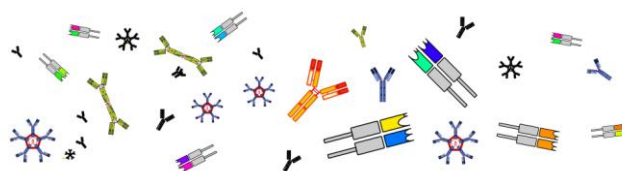
Developing an exploitation strategy in this setting is an intensive, ongoing process which takes place in parallel with development of the technologies to be employed in creating services. A comprehensive strategy will evolve as consortium partners can envision the possibility of taking commitments towards a joint future. Work done to identify use cases will become cardinal inputs for deliberations about a path-to-market and others 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 and 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 summarizes the work done towards mapping a path for the consortium to follow in order to maximize the impact of the project’s aggregated efforts and assess the conditions for a continuation thereafter. The findings presented here are derived from extensive discussions amongst partners in the Use Case Working Group, preliminary statements of partners’ objectives in response to a questionnaire and insights from use cases as compiled by Work Package 1. 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 where these can become economically sustainable.





3. Introduction

The iReceptor Plus project is a joint effort by research institutes, technology and commercial entities and health care providers, to develop a services platform based on integrated distributed repositories of AIRR-seq data (Adaptive Immune Receptor Repertoire data, antibody/B-cell and T-cell receptor sequences). The iReceptor Plus platform will have at its core a community of scientists implementing the vision of a Data Commons as developed by the Adaptive Immune Receptor Repertoire (AIRR) Community. In developing the service platform this core group of immuno-geneticists and bio-informaticists will cooperate with experts in legal, ethical, intellectual property rights and business development.

iReceptor Plus will be designed as a network of federated repositories (an AIRR Data Commons) that facilitates data queries and advanced analyses through a web portal. Non-AIRR-seq data – both clinical and biological – will be included for wider scope analysis of the immune system. An additional aim is to lower the barrier for the non-specialist to access and analyze large AIRR-seq data sets, amongst others, by employing appropriate User Interface/User Experience (UI/UX) features.

Platform services will be developed based on an assessment of their need and the value created for identified categories of users, and the platform as a whole, will be embedded in a business development context to enable sustainability after the EU round of financing terminates.

The iReceptor Plus consortium is fully committed to work towards sustainability and maximum possible exploitation of the project results. This means, among others, continued operation and maintenance of the platform after the project has finished having legal and regulatory arrangements in place for access to additional repositories not yet linked to iReceptor Plus and for the multiple use of data and IPR issues according to the Open Data principle and any R&D that still may be required.

The exploitation will start with an initial business planning through employing a so-called business model canvas approach, with strategies and ideas for each commercial partner. The business plan will cover the additional costs to be incurred after the project, potential market size in M€ for each device and service, expected stage of development at the end, protection of the results, further collaborations, a SWOT analysis, potential customers, possible barriers and corresponding contingency measures and indicators for monitoring the progress of the plan. Ultimately, the business plan will present how the final project outcomes will become translated into viable, sustainable business ventures, thereby positively impact on jobs and growth. This deliverable, as stated, will focus on the process in order to get to meaningful results to be presented in **D8.4 Intermediate exploitation strategy and business planning** (M24) and **D8.6: Final exploitation strategy and business planning** (M48). An initial canvas is presented below.



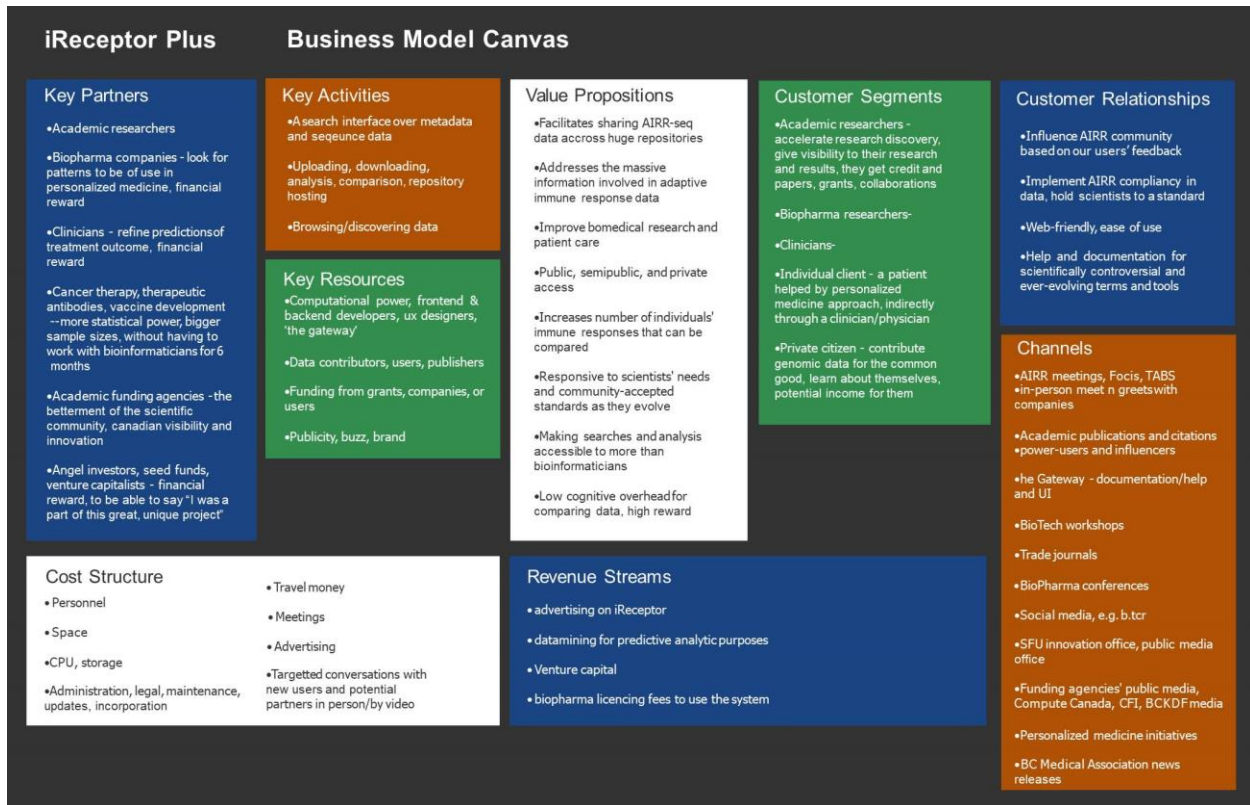
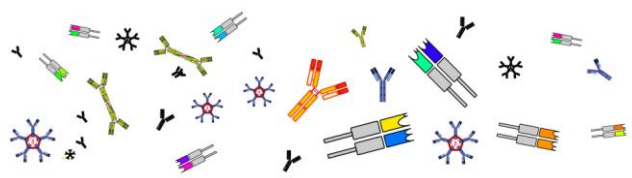


Figure 1 - iReceptor+ Initial Business Model Canvas

4. Partners' strategies

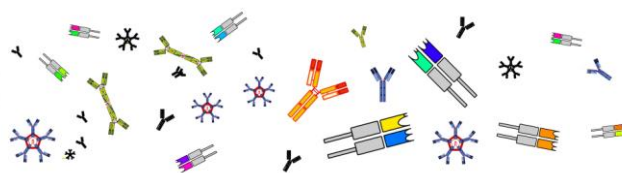
The first and critical element of deciding on an exploitation strategy is of course the objectives of partners of the Consortium, in particular those in principle willing to make commitments beyond the current EU financed stage. A questionnaire designed for initial, quantitative information about partners' business objectives was designed and distributed amongst all 28 partners. The provisional, non-binding character of the inquiry was stressed. The following is a summary of responses from the six replies received:

1. Interested in become part of a legal entity for joint exploitation of results after the end of the project:
50% (3 out of 6); 2 respondents on condition.
2. Having the intention and some kind of plan to exploit results individually:
66% (4 out of 6)
3. Willing, in principle, to commit financial resources after the end of the project:
50% (3 out of 6)
4. Willing to contribute non-financial resources after the end of the project:
100% (6 out of 6).

The responses are decidedly in favour of some kind of involvement after the end of the project, which at this stage is a positive sign. Of course, the non-respondents, the vast majority of



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partners, constitute too important a group to take the above results as indicative of the consortium as a whole at face value.

The response to the questionnaire produced a range of opportunities for exploitation of interest to partners. Following is a selection of the most prevalent opportunities mentioned:

- Development of specialized software
- Maintaining a hardware configuration with advanced host storage and computational capabilities, especially for systems based on federated sets of repositories
- Biomarker and potential drug discovery.

Clearly, both the extent of willingness to embark on a joint future as well as the sphere of interest of partners will impact the exploitation strategy. The main point at this stage is the early adoption of an approach that, inherent in the project, constitutes an obligation to at least assess the possibility of an economically viable future of the project.

5. Value and services

The potential for value creation of the proposed iReceptor Plus platform is chiefly that it makes it possible for researchers around the world to share and analyse huge immunological datasets taken from individuals including those whose health has been compromised, that have been sequenced and stored in databanks in several countries.

The platform under construction envisions a broad range of users of AIRR-seq data in a wide span of user domains, such as:

- scientific research
- clinical research
- clinical/hospital use
- use within the biopharma sector
- use within AIRR-seq data processing and analysis service providers to the clinical, hospital, biopharma sectors, and
- use within infrastructure service providers that provide “cloud” (computation, storage) services to the clinical, hospital, and biopharma sectors.

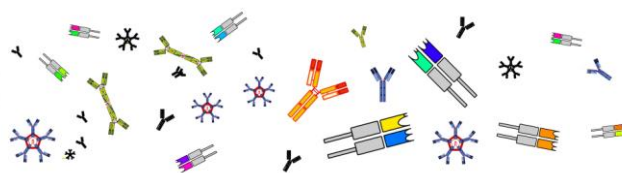
In particular, the iReceptor Plus project will benefit:

- Drug and vaccine design
- New therapeutic approaches
- Biomarkers for diagnosis and prognosis

From the start of the project much effort has gone into thinking about defining the inherent value in the data and the tools into defined uses (use cases). For such a task to succeed a very keen user orientation is required to give answers to questions such as:

- Where exactly are the values created – at which stages of the process?
- What form shall those values take – what do the products look like?





- To whom are these products important?
- Are these of the “nice to have” or “prepared to pay for” kind?

The process described is ongoing and the very fact that these issues were explicitly part of identifying use cases has great importance for the actual planning and development of the platform, its data ecology and repertoire of tools.

Until now some 20 use cases have been compiled, mostly from or through the agency of consortium partners. The use cases relate to research as well as clinical and commercial enterprises in character. Much useful information is obtained from these use cases and a number of them will be followed up for further analysis in order to fully understand the implication of the value that lies at their core. The use cases identified up to now can functionally be grouped under one of five categories:

- **Discovery:** finding AIRR-seq data that meet specific search criteria.
- **Analysis:** performing complex analyses on AIRR-seq data that are either computationally complex or that produce ancillary data that needs to be maintained and used in downstream analyses.
- **Comparison:** comparing two or more AIRR-seq data sets, ranging from relatively simple statistics about the data sets to extremely sophisticated and computationally expensive comparative analyses.
- **Statistics:** performing statistical analysis of AIRR-seq data at either the repertoire metadata or the rearrangement level.
- **Tool Integration:** users wanting to integrate analysis tools into the iReceptor Plus platform to expand on the analysis capabilities.

A description of the use cases compiled up to this point appears as Appendix B.

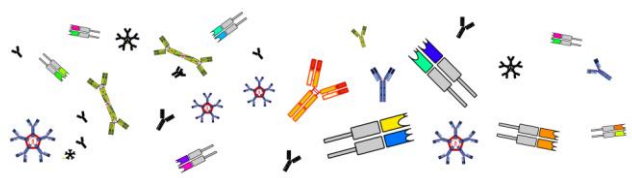
At its core, the iReceptor Plus Platform under construction will have a community-driven character as envisioned by the AIRR Community for its Data Commons, based on open access, community approved minimal standards for depositing and publishing AIRR-seq data.

A number of comparable data portals, in particular serving cancer research exist (e.g. cbioportal.org, cancer.sanger.ac.uk) offering data and assorted tools, free of charge. However, none of these integrate the specific data type that is the core of iReceptor Plus, i.e. antibody/B-cell and T-cell receptor data (AIRR-seq data).

In its current form access to the AIRR repository platform is free, and by using open software the research community can extend and adapt the tools and technologies that can be employed. The value inherent in the platform as development and investment is under way will increase and the discussion on how best to capture this value for contained development now is only in its opening stages, will become of critical importance.

Parallel to these efforts preparations are under way to make a more detailed, quantitative assessments of the markets for the type of services as described in the use cases.





6. Stakeholders

Maximizing the impact of the project, in a wider sense, and unlocking the inherent value of the platform can only be achieved by engaging with as many stakeholders as possible. The project includes setting up an international Stakeholders Forum to support the dissemination activities. Representatives of health-care providers, industries, scientists, regulatory bodies, end-users will be invited for updates and feedback and to establish channels of communication. Additional stakeholders for such a forum include technology providers for healthcare solutions, owners & providers of data (repositories), biopharmaceutical companies, and providers of genomics-based diagnostics, IT healthcare platforms, end-user associations and NGOs involved in, for instance, healthcare or data protection. Individuals, whose health is compromised and can benefit from or contribute to AIRR-seq data, form a third tier of participants in a stakeholder's forum.

Apart from disseminating the workings and findings of the project, interactions with participants contribute to our understanding of the wider environment, a sort of reality test. Insights gained from stakeholders therefore are an important determinant in deciding on an exploitation strategy.

7. Exploitation path

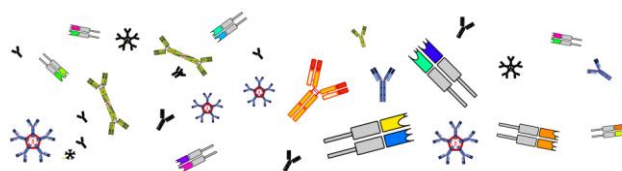
As stated above, formulating an exploitation strategy for an undertaking of this type that conforms to the objectives of a relatively large number of partners in a consortium is complicated and time consuming. At this stage of the project the main task is a consensus about getting the research and development activities operating towards a set of products, in a particular direction. The willingness has been demonstrated by the replies partners gave to explicit questions. The direction that exploitation will take is also an ongoing process, driven by the value as defined by use cases. Eventually the products to be developed and the technologies employed will be decided. All of this is to happen on a timeline commensurate with the project as a whole.

iReceptor Plus partners with their core capabilities, comparative advantages and networks of contacts are well placed to successfully carry out the exploitation strategy that they will decide on in the next stage. Apart from the range of products to be developed for the different types of customers part of the exploitation activities will be focused ensuring the sustainability of the outcomes of the project including a leadership role in the international AIRR Community aimed at developing standards for sharing and analysing AIRR-seq data, which will then be implemented by iReceptor Plus.

iReceptor Plus intends to assist the AIRR Community to implement and deploy distributed "turnkey" repositories, to enable the secure sharing and analysis of AIRR-seq data. Whether or not there is going to be a follow-up beyond the current EU funded phase, exploitation activities will result in the integration and incorporation of iReceptor Plus technologies and tools by the industrial partners in the consortium for the benefit of their own proprietary products.

Any exploitation strategy includes continued operation and maintenance of the iReceptor Plus platform after the project has finished to ensure its sustainability, legal and regulatory





arrangements for access to additional repositories not yet linked to iReceptor Plus as well as providing legal and regulatory arrangements for the multiple use of data and IPR issues according to the Open Data principle and any R&D that still may be required. Sustainability could be achieved either by hosting and operating the platform through one of the members of the consortium or through setting up a new “iReceptor Plus” entity that will be engaged in hosting and operating the platform. The various options will be explored and presented in ***D8.4 Intermediate exploitation strategy and business planning (M24)***.

8. Planning for Business

Alongside the work being done in mapping the exploitation strategy steps are being taken to put in place data gathering procedures for product development. This in addition to the qualitative information that will be the result of a canvas mapping of each product category. The data to be collected will primarily serve the preparation of a business plan for after the project. Use cases indicated above will evolve into products to be developed and markets to be assessed. Resources committed will provide a basis for cost planning and product pricing. The development and production platform, beyond the trial phase, will yield insight into the scale of investment necessary for a commercial or semi-commercial launch.

In the course of the process described the need for specific, smaller scale economic feasibility checks may arise as decision support for larger aspects of the project. The data gathered will support doing such analysis.

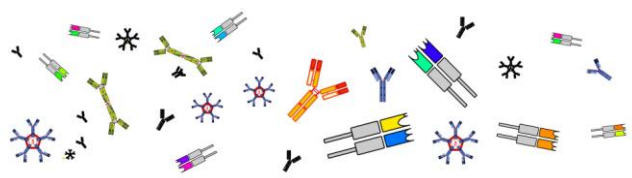
Supporting market analyses will be necessary as well as SWOT analysis, potential customers, possible barriers and contingency measures. As in any such undertaking there is uncertainty about the operating environment on various levels and many assumptions will have to be made. At all stages the assumptions that need to be made will be the result of open consultation in the team and stated clearly and transparently. Once the outlines of the type of joint future the consortium has in mind is clear and an exploitation strategy is mapped out and being implemented, a business plan can be prepared resulting in clear statements about the feasibility of the venture. Such a plan is best developed in a flexible format and updated as required.

Following is an outline of the business case environment.

A comprehensive exploitation strategy and business planning process is being put in place to produce services to serve a wide range of customers. The services are the result of research and development employing tools and technologies developed and demonstrated during the project. The iReceptor Plus business case is based on the assumption of an increasing demand 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.

The core business case and the exploitation plan aims at increasing revenues for each industrial partner from ***products or services*** developed in the project. AIRR-seq data, for example, have been shown to be much more effective at monitoring MRD (minimal residual disease), and the





US FDA has approved the use of AIRR-seq data in clinics for this purpose. It is expected that more clinical uses of AIRR-seq data will be discovered in the next few years, and iReceptor Plus will be the platform of choice for securely managing these data. The block chain approach, enabling an auditing and traceability layer that complements the security layers to the platform, greatly facilitates the future exploitation of iReceptor Plus' cyberinfrastructure.

The **potential value** for users/customers can be categorized as follows:

- **Academic researchers:** accelerate research discovery, give visibility to their research and results
- **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 bioinformatics pipelines.

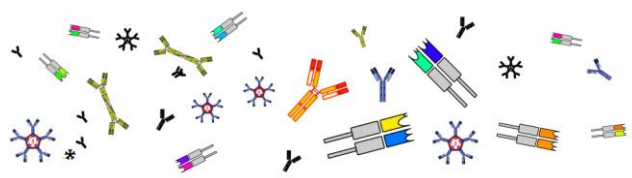
Products & services: For preparing a business case and business plan, it is important to define the “product” that will be delivered through the project. A “product” is defined in marketing literature (Kotler, 1984) as “*anything that can be offered to a market of attention, acquisition, use or consumption that might satisfy a want or a need*” and as a “*bundle of capabilities to be representing a shape taken solution for the specific benefits sought by the customer*”. Applied to iReceptor Plus, the products and services are:

1. The iReceptor Plus project is to build 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
2. A layered security model to the existing iReceptor platform that will allow data stewards to protect data and control access based on privacy and security constraints
3. An analysis platform that makes it simple to integrate existing AIRR-seq data analysis tools into an easy-to-use, web-based analysis platform for large, federated data sets.

Once the product or service is defined, the pricing of the product can be addressed as well as the estimated or perceived price/performance ratio compared to the competition. As for the competition, the business planning will try to map competitors of similar solutions. It is expected that there will be some direct competitors, i.e. competitors with similar product offerings, as iReceptor Plus will provide solutions that are beyond the current state of the art. However, substitute competition – other solutions are available to provide similar core functions – is even more expected and to be more precise, iReceptor Plus will provide substitute competition to existing immunotherapy solutions.

Pricing: The iReceptor Plus platform creates value at considerable investments and development cost under the working assumption that some market segments will be willing to pay for premium





value services. The full range of services will be subjected to an assessment of pricing methods appropriate. These include:

- **Profit-maximizing or market-based pricing**
- **Cost-recovery pricing**
- **Marginal-cost pricing**
- **No-charge pricing**

Since most primary data are made available free of charge and the fact that the initial stages of the iReceptor Plus platform is being financed by public funds at no cost and no claims to surplus revenues, many or most basic services, involving un-processed data, will be priced at marginal costs or less. Profit maximising for data collected with public funds is not considered under the terms of the project. A most likely approach seems to be a combination of the methods described, used in a discriminatory fashion depending on the type of user and the use to which the product is being put.

Different prices may then apply for academic users, government users and commercial users. "Use for research" or "Use for public reporting" is usually considered differently to "use for commercial gain". In accordance with the principles of the Open Research Data Pilot, federation services available through iReceptor Plus Platform will be free of charge for research and public reporting purposes, but cost-recovery fees may be charged for premium products, regarding processed or derived data, or when used for commercial purposes.

Not even considering the regulatory and legal aspects of the venture under consideration, work on the business plan entails collecting, analysing and processing data and estimates from a wide range of sources, making assumptions that must be fair and realistic and taking into account inherent uncertainty about most aspects of the environment. These challenges shall be faced in the next phase

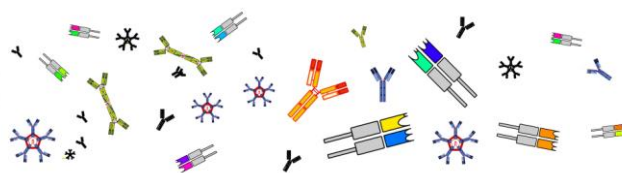
Competition: The entity or entities that will introduce the iReceptor Plus services may very well be the first to market. This, however, does not imply an absence of competition and will have implications for the marketing and sales aspects of the business plan.

In its very essence, competition is based on the classical economic notion that (almost) all goods and services are scarce. More particular, the means (read: budget) to acquire goods and services for any consumer and organization are scarce, i.e. limited. This is called the budget line or constraint: the consumer has limited means to spend. By contrast, desires and needs are virtually infinite which forces the consumer to prioritize and decide.

Theory holds that for a given budget, a consumer will choose the mix of products and services that maximises his or her desires and needs.

Applied to any business case, competition means the availability of alternatives from which any given consumer can choose. If the price of a product exceeds the consumer's perception of its value in terms of needs and desires, he or she will look for alternatives. Therefore, the first form





of competition is called “**desire competition**”. If iReceptor Plus services are overpriced, then researchers or clinical institutions will not purchase it, despite all its advantages.

Competitive Strategies: It is common knowledge that timing is a major issue in the commercialisation of novel products. Professional literature mentions four broad strategies applied to companies introducing novel knowledge-intensive products. These strategies are the first-to-market or leading strategy; the second-to-market or fast follower strategy; the cost minimization of late-to-market strategy; and the market-segmentation or specialist strategy. Given the novelty of iReceptor Plus, the companies introducing iReceptor Plus will be the first-to-market and they will apply a first-to-market strategy. The other three strategies will not be discussed as they are not relevant for our case.

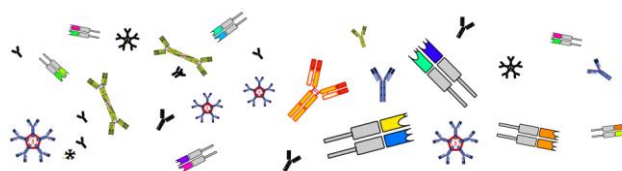
The **first-to-market** or **leader** strategy aims to get the product before the competition. It provides the advantages of a temporary monopoly in exploiting a new technology during the period preceding the adaptation of the new technology by the competitors. Such a strategy normally requires a strong commitment to applied research and development, in order to achieve a position of technological leadership. Richard Foster (in: Shankly and Ryan 1984, p.103-104) identified the so-called five realities of technologically based economic competition, concerning technological leaders:

1. Technological leaders that are successful in staying on top never lose sight of the reality that all products and processes have performance limits. As a technology approaches these limits, it becomes more expensive to make subsequent performance improvements. As a result, the leader looks for new and better technology.
2. Technological leaders do not underestimate their competition, regardless of how small that competition may be at the present time.
3. Technology leadership requires that an enterprise aggressively pursues and invests in potentially superior new technologies.
4. This aggressiveness should come early on because the process by which one technology replaces another starts slowly and then explodes, usually in an unpredictable way.
5. Knowledge-intensive enterprises that maintain leadership positions have close collaboration between the chief executive officer and the chief technical officer. This arrangement helps to ensure that technical programs are responsive to business strategies and vice versa.

9. iReceptor Plus IP Status

It is possible that by the end of the project, iReceptor Plus may not yet have reached TRL9 and therefore not ready to offer marketable products. The exploitation strategy will assess the project’s IP status at various stages. The value of the IP of iReceptor Plus consists of Background, Foreground (a.k.a. Results) and future work to reach TRL9. The quantitative values of each of





these three elements are still subject to negotiation, though this process will be concluded before M24. However, the current status of the IPR and the process to manage the generated IP in general and joint IP in particular, will be described below. The quantitative value of the IP will be negotiated among the partners in the next year and it will be included in the intermediate business plan for M24.

Task 8.5: Roadmap for achieving TRL 9: A roadmap for taking iReceptor Plus to TRL9 will be prepared. It will describe the steps and timelines for bringing the results to commercialisation, which may include further demonstration/validation of the technology, establishing production processes and procedures, achieving regulatory compliance, implementing a quality management system, and protecting (new) IP.

The effort that each of the partners will invest will be included in the total value of the IP and used to determine the percentage of ownership that each partner will have in IP. However, it will only be possible to provide reliable estimates of effort required by each of the relevant partners, towards the end of the project.

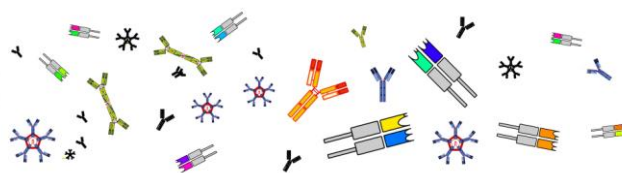
Managing Joint Foreground IP: One of the critical yet more challenging aspects of the iReceptor Plus project is in the management of the joint foreground IP. Some of the partners that contribute to the generation of the IP are also potential beneficiaries, which is expected to have implications for the conditions of use/exploitation of the results as well as any financial compensation from license agreement(s). Moreover, it is anticipated that depending on the relationship between the partners, specific agreements may need to be established, to clarify the role of each partner in the ownership and exploitation of the results.

Although many examples of joint IP ownership and exploitation agreements can be found online, the European Commission has no "official" templates for preparing such agreements. As each Innovation Action will have very different results, and correspondingly business models, it makes sense that each joint ownership and exploitation agreement needs to be individually tailored on a project basis. Having said that, the IPR Helpdesk did refer to their case study regarding the "Allocation of shares of jointly developed results", which highlights different examples as to how the jointly owned IP can be divided. In addition, their fact sheet on "IP joint ownership" provides information as to the content of such joint ownership agreements, and includes a short checklist of the main aspects that should be addressed. When preparing the agreement, it is essential to first:

1. Define the parties and their relationships
2. Identify the joint results very precisely, so that the objective of the contract is fully clear to everyone involved
3. Identify the key terms in a definition section, maintaining consistency with the terminology used in the GA and CA, in order to avoid confusion

Once this is completed, the IPR Helpdesk checklist can then be used as a basis for the development of the agreement, where the following is addressed:





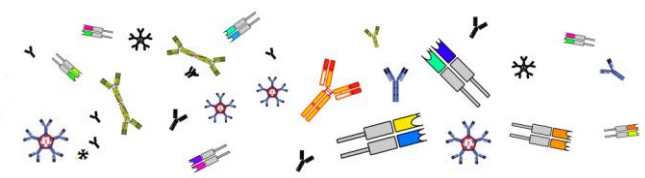
1. Allocation of shares, indicating whether the will be shares will be divided equally or proportionately based on the amount of work carried out by each partner (for example)
2. Conditions of direct use (by the co-owners themselves) of the joint results, such as whether prior notice or approval is required from the other co-owners and/or if financial compensation is required
3. Conditions of indirect use/exploitation of the joint results (e.g. by a third party, such as a licensee), and whether prior notice or approval is required from the other co-owners and/or if financial compensation (e.g. royalties) is required to be paid to all co-owners
4. Conditions for non-commercial use (direct or indirect), and whether it is subject to the same rules, or whether the co-owners prefer to differentiate between commercial and non-commercial use
5. Conditions for splitting the market among the various co-owners, such as an agreement that each co-owner would exploit the results in a specific area only (thematically and/or territorially)
6. IP protection of the joint results: who is responsible to file for protection? How are protection decisions made? How are protection-related costs split amongst the joint owners? What happens if one of the co-owners refuses to pay for protection or renewal fees?
7. IP monitoring and enforcement: which co-owner is responsible to monitor the market, check for potential infringement, and enforce the joint IPR? How are split costs enforced?
8. Conditions regarding dissemination of the results and maintaining confidentiality
9. Governing law and jurisdiction for the agreement
10. Duration of the agreement and signatures

While this framework provides a basis for the content of the joint ownership agreement, any final agreement should be reviewed by a lawyer.

Terms of use of the Foreground IP: In order to establish the joint IP ownership and exploitation agreement(s), it is necessary to indicate the terms of use and/or exploitation of the project results. While it is difficult to explicitly define these terms so early in the project, it is anticipated that the following will need to be addressed in the term sheet that will be negotiated and presented in M24.

IP ownership: Each party is responsible for the application and maintenance of its own intellectual property. In case joint IP is created, the ownership will be determined according to the relevant contribution of each partner. Use of the relevant background IP during the course of the project is allowed by the IP owners for no charge, for the implementation of the project, while it is planned that after the project implementation period, the IP will be used for purposes of commercialization by the industrial partners according to the agreements reached.





Royalties and License Fees: To be negotiated

Exclusivity: To be negotiated

Patent Expenses: covered by licensor

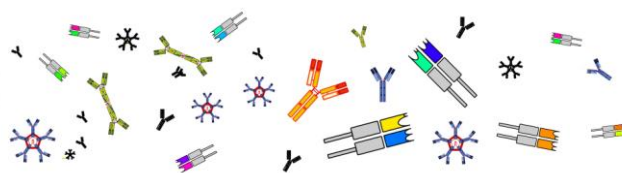
Sub-licensing: To be negotiated

10. Summary and tasks ahead

Having compiled a partial set of partners' objectives and a core list of use case categories the groundwork is done for mapping possible exploitation strategies. The partners are decidedly in favour of some kind of involvement after the end of the project. This is a satisfactory stage, merely 6 months after kick-off, for a Consortium of this size and variety. 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). In parallel the business planning process will make a quantitative assessment of market potential and revenue model so that towards the end of the project phase clear, quantitative statements can be made about the continued sustainability of the iReceptor Plus platform in a post -EU funding era.



This project is funded by the European Union's H2020 Research and Innovation Programme under Grant Agreement No. 825821 and Canadian Institutes of Health Research (CIHR)



Appendix A

QUESTIONNAIRE

EXPLOITATION STRATEGY AND BUSINESS PLANNING

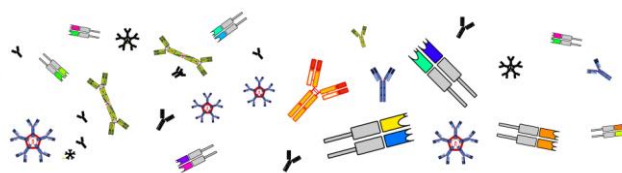
Important note: The answers in this form are not binding for future decisions. They are only intended to capture the general opinion and thoughts of the consortium on topics that usually arise in the course of a project.

General Information	
Organisation Name	
Persons from organisation involved in WP8 (used for mailing list)	

Individual Exploitation	
What are your organisation's plans to individually exploit the results of iReceptor Plus as a whole in terms of business opportunities?	
What are your organisation's plans for the individual exploitation of partial results of iReceptor Plus for your own business?	

Commitment After End of Project





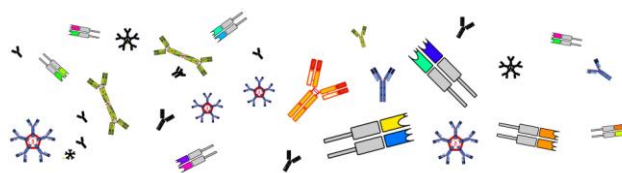
<p>What financial resources can your organisation contribute to the operation of project outcomes after the end of the project?</p>	
<p>What non-financial resources can your organisation contribute to the operation of project outcomes after the end of the project?</p>	
<p>Would your organisation be interested in becoming part of a (commercial or non-commercial) legal entity for jointly exploiting and developing the results after the end of the project?</p>	

<p>IPR</p>	
<p>What IPR limitations result from your organisation's contributions to the iReceptor Plus Project for the envisioned business product?</p>	<p>No IPR limitations identified.</p>
<p>Will your organisation allow other partners to use the own results free of charge for the further exploitation of iReceptor Plus?</p>	<p>Our role in the project does not include the generation of results.</p>

Business Opportunities



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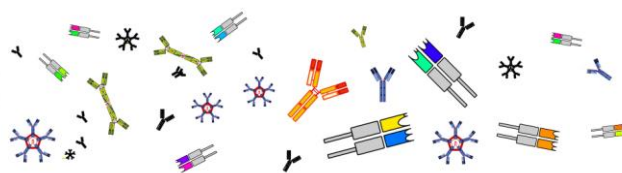


What business opportunities does your organisation foresee for iReceptor Plus? How can the results of the project be used?

- a) As a clinical stage drug development company (pharma/biotech) will use the TCR repertoire diversity to know the T cell exhaustion of a given patient or cohort to then use this TCR diversity level as surrogate marker for cancer immunotherapy enabling patient stratification, monitor drug efficacy or patient prognosis.
- b) As a cancer research center or drug discovery company looking for drug candidates to reverse this dysfunctional state and reinvigorate immune responses.



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Appendix B

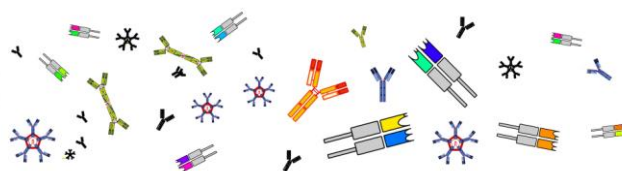
Use cases overview

The table below provides a list of the use cases, divided by category, that have been acquired thus far.

Use case purposes

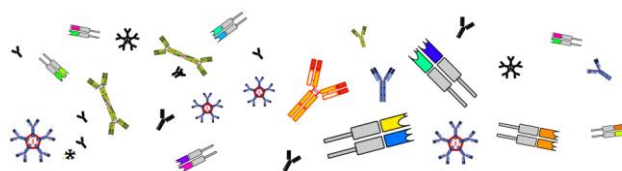
Analysis Use Cases
AN-01: For a given filtration of the data according to the associate metadata (e.g., all samples coming from PBMCs of MS patients using UMI library preparation protocol), a researcher would like to perform a series of exploratory data analyses (EDA). The idea is to have quick analyses that will return the user graphs and tables and not force him/her to download all the data and run these analyses locally.
AN-02: Researchers want to perform a non-exact (fuzzy) search for a given sequence feature (e.g. CDR3) and find all of the AIRR-seq data (and its associated MiAIRR metadata) that meets that search criteria.
AN-03: As a data steward responsible for the content of an institutional iR+ repository, I want to clone public data sets from other iR+ repositories, to avoid bottlenecks in computational resources, achieve load balancing and keep queries that contain confidential information "in house".
AN-04: As a researcher I would like to have a simple way to perform allele inference on datasets present in iR+ to be able to create aggregate statistics about allele frequencies.
AN-05: As a researcher developing machine learning algorithms, I want to find AIRR-seq data sets with specific characteristics, so that I can train/test/validate my machine learning algorithm with the AIRR-seq data sets.
AN-06: As a computational immunologist, I would like to leverage the data stored in the iReceptor database to perform large-scale machine learning driven pattern detection in the effort to identify patterns that predict immune status.





Comparison Use Cases
<p>CO-01: Researchers want to find the overlap between two data sets (typically partitioned at the “sample” metadata level). The overlap is determined by searching AIRR-seq features by either comparing identical sequence features (e.g. CDR3) at the nucleotide or amino acid level or by fuzzy matches that allow some variations in the sequence feature comparison.</p>
<p>CO-02: As a researcher studying autoimmune and inflammatory diseases, I want to find AIRR-seq data sets from other similar studies with a focus on TCR data, so that I can compare features in my data to features from other AIDs AIRR-seq data sets.</p>
<p>CO-03: We would like to understand how unique these BCRs are to this gut disorder, i.e. whether they are found in other AIRR-seq data sets. This analysis will help understanding the pathogenesis of celiac disease, and ultimately this endeavor has the potential to develop diagnostic tests based on BCR repertoire interrogation.</p>
<p>CO-04: As a researcher studying the TCR repertoire in different vaccination settings I would like to compare the “bystander” (i.e. not antigen-specific) T helper cell response of immunized mice in the context of immunizations to understand the effect of various adjuvant systems.</p>
<p>CO-05: Given a researcher or company possesses an Ig sequencing dataset from an immunization trial, it might be useful to know which antibody possesses features (in this case mutations) that are not common in other datasets</p>
<p>CO-06: As a researcher, I would like to find the same (or similar) antibodies in different datasets to compare antibody reactivity.</p>
<p>CO-07: As a researcher using VDJSerVer to analyze my data, I want to find AIRR-seq data sets from other similar studies, so that I can perform comparative analysis between my data and the queried AIRR-seq data.</p>
<p>CO-08: As a clinical stage drug development company (pharma/biotech) I will use the TCR repertoire diversity to know the T cell exhaustion of a given patient or cohort to then use this TCR diversity level as surrogate marker for cancer immunotherapy enabling patient stratification, monitor drug efficacy or patient prognosis.</p>
<p>CO-09: A researcher I would like to compare their own TCR data with iReceptor+ data from similar studies. The purpose could be to analyze clinical prognosis, diagnosis, and treatment of various cancers.</p>





CO-10: As a cancer research center or drug discovery company looking for drug candidates I will use comparisons of the TCR repertoire diversity to identify T cell exhaustion and reinvigorate immune responses.

Discovery Use Cases

DI-01: As a researcher/clinician/etc. who is unaware of the blessings of AIRR-seq I want to use a meta-search engine to discover AIRR-seq data sets within iR+.

DI-02: As a researcher I want to find data sets with similar subject-sample-processing profiles (i.e. metadata) within the iR+ framework to perform a case-control study against datasets of my own.

Statistics Use Cases

SI-01: As a researcher studying the antigen specificity of B cells* in the context of an infectious disease** I would like to query for paired chains, retrieve paired chain data and perform basic statistics on chain pairing (e.g. enrichment or depletion of specific combinations vs. a neutral model). Alternatives: * T cells; ** malignancy / autoimmune condition

Tool Integration Use Cases

IN-01: As a bioinformatician developing new analysis tools, I want to acquire AIRR-seq data sets, so that I can implement my method, test it on a variety of different data sets, and deploy it to the iReceptor+ platform so other users can use the analysis method.

Source: WP1 report “END USER EXPERIENCE & USE CASE DEMONSTRATION”



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