Coordinated Research Infrastructures Building Enduring Life-science services
- CORBEL -

Deliverable D8.3
Industry Collaboration Best Practice Guide

WP8 – Accelerating Innovation

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Executive Summary

The aim of this deliverable is to bring together in a single document best practice guideline for a wide range of aspects relevant to industry collaboration and thereby to provide a convenient source of information and guidelines for staff in public biomedical science research institutes and infrastructures to help them with all aspects of setting up and maintaining effective industry collaborations.

Project objectives

With this deliverable, the project has reached/this deliverable has contributed to the following objectives:

a) To provide practical assistance with engaging with industry and setting up collaborations which will help to accelerate innovation in the biomedical sciences.
b) As a product of the CORBEL Innovation Help Desk, to make available guidelines, templates, advice and literature sources which can help to promote effective and timely industry collaboration.
c) To share innovation best practices from the CORBEL work package 8 programme and the experience available from the research infrastructures.

Detailed report on the deliverable

Background

In the course of the WP8 programme various deliverables, milestones and products have materialized featuring research collaboration and exploring different models. In addition, the activities of the Innovation Help Desk, the CORBEL Open Call initiative, workshops and meetings around competitive and pre-competitive research cooperation and guideline documents posted on the CORBEL website have all contributed to a mosaic of knowledge and advice in the field. Much of this relates to collaboration with industry. This all forms the background to the current deliverable which aims to provide a single reference work based on inputs from a number of people involved in the WP8 programme and to combine expertise on all relevant aspects.

Description of Work

A team was formed to contribute inputs to a common document framework, posted as a Google Doc. The scope of contents was agreed, tasks assigned to the team members and a target length for the complete document was proposed. A shared objective was to provide a comprehensive set of guidelines drawn from the work of the WP8 programme to date, past experiences of all involved, best practices from the network of RIs and institutes and sources available from the literature.

After the first draft became available a small sub-group spent some time harmonising style, format and contents. Inevitably, since a number of authors contributed, there remain some differences, but it is hoped that the final product is readable and provides sufficient detail on the main aspects without being over-prescriptive.

1. Introduction

This guide to public-private collaboration best practices in biomedical science brings together a range of relevant aspects which have featured in the CORBEL programme since its inception in 2015 and are continuing themes in the performance of work package 8, "Accelerating Innovation". As a deliverable from the WP 8 activity this is therefore designed to crystallize a substantial body of knowledge and experience which has accumulated in the field of biomedical science collaboration, through the work of the CORBEL WP8 Innovation Help Desk and in the form of articles on the CORBEL web site and milestones and deliverables. In addition, a workshop held in Ljubljana in December 2018, which featured lectures on a wide range of aspects as well as a novel exercise in setting up public-private research collaborations, provided a forum for testing out many features.

Producing this guide was a combined effort by staff from several research infrastructures (RIs) involved in all of the main activities of work package 8. They have tried to capture as much of the learnings as possible and to cover a broad spectrum of possible industry collaboration models, both pre-competitive and competitive, and applying both to SMEs and big pharma companies. Scientific, commercial and legal aspects are all treated, as well as the personal aspects of networking, communication, negotiation and building trust.

Inevitably, an undertaking such as this will not succeed in giving equally comprehensive coverage to every aspect of relevance. Furthermore, the various contributions will differ in terms of author's style and emphasis, which may make the reading experience less than perfect. The intention nonetheless has been to provide a comprehensive guide including references to sources of further help, for use by practitioners in the field. The authors hope the guide will be a sustainable product of value after CORBEL.

2. Objectives and Types of Collaboration

Public-private collaborations comprise a broad spectrum of objectives, where the objectives of the respective partners are based on differing incentives to collaborate.[1],[2] A complete list of all objectives and types of collaborations cannot be listed exhaustively. However, for collaborations involving academic institutions and industry partners the most important reasons for entering a collaboration are:

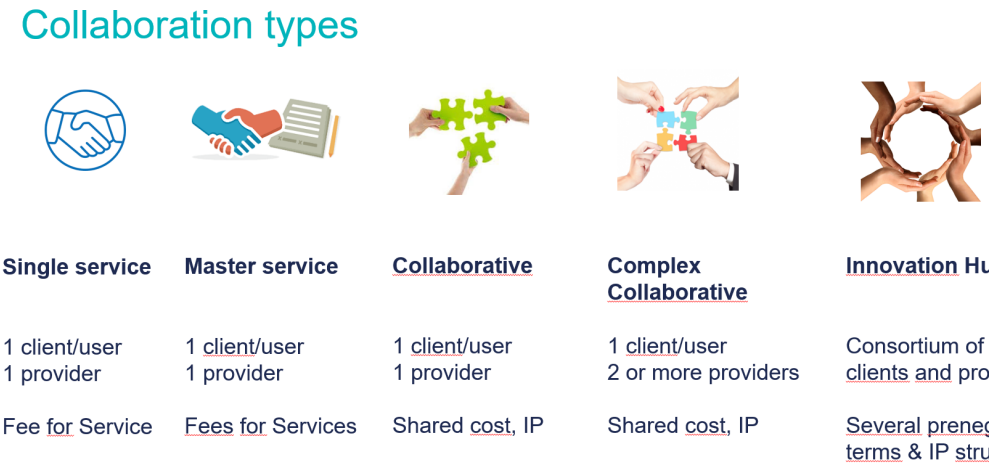
- Complementing competences, knowledge and technologies to advance research and development

[1] "Challenges for pharmaceutical industry: new partnerships for ...." (Accessed 12 Mar. 2019.) https://royalsocietypublishing.org/doi/abs/10.1098/rsta.2010.0377

[2] "(PDF) Industry-academia collaborations for biomarkers - ResearchGate." (Accessed 12 Mar. 2019.) https://www.researchgate.net/publication/283444447_Industry-academia_collaborations_for_biomarkers

- Obtaining access to resources that are available only from specific partners (e.g. clinical research)
- Broadening the scope of the innovation process
- Exploiting existing intellectual property (IP) through inclusion of specific competences
- Attaining critical mass to address complex projects

The type of collaboration is usually chosen according to purpose and extent of the complementary information or resources that are needed to fulfil the purpose of a cooperation. Generally, collaborations may be bilateral or multilateral. The figure and bullet points below illustrate examples of bilateral and multilateral collaborations and how complexity increases when the scope and number of partners increase. **(ReF)**



- Sharing/distributing labour - dividing a problem among several partners to facilitate or speed up progress. The work can be divided into similar or identical pieces of work. Partners can cooperate that have similar competences or operate sequentially to achieve the goal. An example is distributed computing, in which a large computational problem is broken into smaller tasks that are distributed over several partners working in parallel. The individual results are assembled/integrated after each task has completed its work. Although not frequently encountered in academic/industry partnerships, the parallel distributed workload model is increasingly found in computation-intensive research (e.g. Protein-Folding@Home[3], SETI@Home[4], drug discovery platforms).
- Dividing labour among specialists. Here the work is divided among the partners according to their specific capabilities or resources, like in an assembly line. After each specialist has completed its task, the final result is assembled. This is frequently encountered in scientific cooperation as well as in academic/industrial partnerships. Multilateral projects of this type of collaboration usually require clear leadership and coordination towards the finished result and

[3] Folding@home – Fighting disease with a worldwide distributed super .... (Accessed 5 Mar. 2019.) https://foldingathome.org/
[4] "SETI@home." (Accessed 5 Mar. 2019.) https://setiathome.berkeley.edu/

control of the timing of the individual contributions. While such a collaboration allows generating results that cannot be obtained otherwise, the delivery of the result depends critically on the performance of each partner, since redundant capacities are usually not included (due to unavailability of similar competences, lack of budget and insufficient reward (publication) for two partners working on the same problem)

- Strategies of cooperation in Open Innovation. This is a vast and highly diverse range of cooperation models that has been described in a previous paper.5 These are variations of the two models described above.

Precompetitive Collaborations

A collaboration between potential future competitors to work on the early stages of an industry-wide problem is called precompetitive. These types of collaborations can often include academic as well as industry partners.[6] The outputs can be aimed at the development of standards and tools, generation of data, product development, etc. Both the outputs and participation can be open or restricted. Detailed descriptions and examples have been published before[7], but relevant example are discovery-enabling consortia (e.g. Human Genome Project[8]) or public-private consortia for knowledge creation (e.g. Innovative Medicines Initiative[9]).

Examples of Successful Open Innovation Models

We briefly summarize here examples that have been discussed in a previous paper:
Eli Lilly has applied Open Innovation concepts in their early drug discovery programme which has benefited both the company and the large network of partners[10],[11] An impressive move towards Open Science and Innovation was made by Nestlé who set up a public-private partnership with its Nestlé Health Sciences institution that utilizes a broad spectrum of instruments to gather innovative concepts for its research and development.[12]

[5] "CORBEL Concept paper on new business models related to Open ...." 4 Sep. 2018 (Accessed 7 Mar. 2019), https://zenodo.org/record/1408808
[6] "Lowering industry firewalls: pre-competitive informatics initiatives in ...." (Accessed 12 Mar. 2019) https://www.semanticscholar.org/paper/Lowering-industry-firewalls%3A-pre-competitive-in-Barnes-Harland/133b66a6de5e02d83544b8913b2216e442a4bf40
[7] "TYPES OF PRECOMPETITIVE COLLABORATIONS ... - NCBI - NIH." (Accessed 4 Mar. 2019) https://www.ncbi.nlm.nih.gov/books/NBK210028/
[8] "An Overview of the Human Genome Project - National Human ...." (Accessed 7 Mar. 2019) https://www.genome.gov/12011238/an-overview-of-the-human-genome-project/
[9] "Innovative Medicines Initiative." (Accessed 7 Mar. 2019) http://www.imi.europa.eu/
[10] "Open innovation in SMEs—An intermediated network model ...." (Accessed 11 Mar. 2019) https://www.sciencedirect.com/science/article/pii/S0048733309002248
[11] "development of an open innovation model for r&d collaboration ...." 28 Apr. 2016, (Accessed 11 Mar. 2019) https://www.researchgate.net/publication/301719807_DEVELOPMENT_OF_AN_OPEN_INNOVATION_MODEL_FOR_RD_COLLABORATION_BETWEEN_LARGE_FIRMS_AND_SMALL-MEDIUM_ENTERPRISES_SMES_IN_MANUFACTURING_INDUSTRIES
[12] "HENRi Nestle: HENRi@Nestlé | Open Innovation Startup Programs ...." (Accessed 11 Mar. 2019) https://henri.nestle.com/

3. Roles and Perspectives

A well-functioning public-private partnership (PPP) is built on a firm basis where there is clarity about 'who is doing what,' with a fair distribution of roles and expected benefits among the partners. Key during the development of the relationships and setting up of the PPP is to align and manage the expectations that each partner has towards the other(s). This section will review the possible roles that could/should be fulfilled during the different phases of the PPP lifecycle and how the perspectives of each partner can vary per project type.

Roles and Responsibilities

Different expertise and commitment are required during the various phases of the PPP lifecycle, which can be divided into the following:

- Exploration phase
- Building phase
- Execution phase
- Termination phase

The following Table lists the possible roles and their key duties associated in running a successful collaboration.

Role	**Key duties**	**Phase**			
		1	**2**	**3**	**4**
Client	Identify key needs and priorities, timely communication to service provider if scope changes.	X	X	X	X
Funder	Secure project funding, ensure effective invoicing, implement policy with transparent eligibility criteria for granting new projects		X	X	

Service provider	Deliver according to expectations as outlined in the Project Agreement, timely communication to client in case milestones will not be met or if new opportunities arise.		X	X	X
Project Team Leader (PTL)	Overlook the overall Project Progress according to Project Plan and take actions according to good project management practice adhering to Project Agreement conditions.		X	X	X
Team members	Fulfil tasks as outlined in the Project Plan.			X	X
Academic scientist/KOL/clinician	Provide scientific leadership to define scope and support the formation of a strategic agenda.	X	X	X	
Industry specialist/ scientist	Provide technical leadership to define scope and support the formation of an operational agenda.	X	X	X	
Project (portfolio) manager	In case of one project, this task is often fulfilled by the PTL. In case of complex projects this can be a supportive role next to the PTL. In case of a research program, the manager can be single point of contact for multiple PTLs and manage the overall portfolio (avoid redundancies of tasks)			X	X

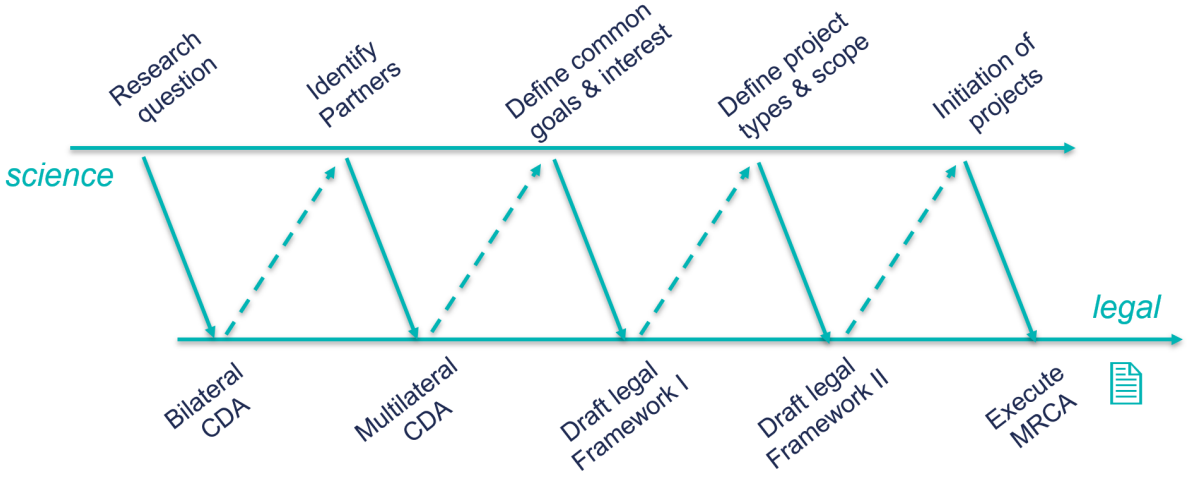
QA/QC manager	Ensure that all Project Tasks are performed in an ethical and legal compliant manner			X	
Academic business developer	Central coordination contacts during the exploration and building phase. Design of business plan and collaboration framework. Identify new opportunities.	X	X		
Academic alliance manager		X	X		
TTO legal counsel	Represent the public institution to define the legal terms of the collaboration. Advice on (implications for) the operational framework.		X	X	
Industry legal counsel	Represent the private company to define the legal terms of the collaboration. Advice on (implications for) the operational framework.		X	X	
(Industry) Procurement officer	Assist in purchase planning and execution of the Project Agreement, e.g. determine specifications of the Project deliverables, financing/invoicing, price negotiation, contract administration.			X	
Negotiator	Explain pros and cons of different scenarios, collaboration types during building phase. Manage conflicts in the execution phase.		X	X	

Administrator	Track and report progress to all partners			X	X
Facilitator	Act on the rate limiting steps in the overall process (Project and Program), single point of contact	X	X	X	X

Legal and Scientific Tandems

During the formation of a PPP, there are two important workstreams that work in tandem to drive the process. The first is driven by the experts that define content, scope and overall aim of the collaboration. Academic expert scientists are often approached as (clinical) key opinion leaders in their field to provide senior leadership *en-route* to a well-designed Collaboration Framework. The industry expert brings in complementary technical expertise to enable an efficient process to achieve the overall Project aim.

Parallel to the development of the scientific and strategic agenda, the second workstream tandem that needs to act in concert is formed by the legal counsels from the institutional (often TTO) and industry partner. They are tasked with shaping the legal and operational framework that will form the backbone of the collaboration. This can result in a Project Agreement or a Master Research Collaboration Agreement (MRCA) that can enable the execution of multiple contracts under one umbrella.



The diagram outlines a possible sequence of events that can be followed for the parallel scientific and legal tracks. During the building phase the partners will explore:

- What are common goals and interest?
- Who takes decisions?
- How does the decision-making process look?

- Who pays?
- Who is responsible for overlooking and steering the long-term strategy?
- Who manages the portfolio? And how?
- Who takes care of legal matters?
- Who takes care of project management?
- How and how often to communicate?

A trusted third party that can act as an independent facilitator can be of high value. A technology transfer office (TTO) often represents one of the partners itself and may not be accepted as an independent party. Research infrastructures, such as EATRIS can fulfil such a role. There are many research management partners[13][14] that offer services to facilitate the formation of (public-private) consortia and can act as "Independent Enabler" in the formation and management of, for instance, IMI consortia.

Specific Role for Research Infrastructures?

European (distributed) Research Infrastructures can fulfil several roles in PPPs.

- Service provider
- Facilitate access to Academic expert scientists and (clinical) key opinion leaders.
- Provide access to QA/QC expertise
- Independent negotiator and facilitator. Creating trust from an objective role and act as a sounding board for each partner to reflect and reach consensus
- Administrator – as a single point of contact
- Bringing multiple stakeholders together
- Source missing components and develop workarounds when technical challenges arise

Examples:

- *BBMRI*[15] - Provide ELSI support to academia, small and medium enterprises. Provides support in collating sufficient numbers of human biological samples and data, as well as quality-related counselling.
- *EATRIS*[16][17] - Set up tailored public-private collaborative research to develop translational tools in milestone-driven, pre-competitive and competitive research.[18][19]

[13] "SYNAPSE | Research Management Partners." https://synapse-managers.com/
[14] "Lygature." https://www.lygature.org/
[15] "ELSI: Ethical, Legal, and Social Issues in Biobanking | BBMRI-ERIC." http://www.bbmri-eric.eu/services/common-service-elsi/
[16] "Unique hub collaboration - Imaging method development in ... - eatris." 4 Jun. 2018, https://eatris.eu/insights/unique-hub-collaboration-imaging-method-development-inflammatory-diseases/
[17] "Matchmaking - EATRIS." https://eatris.eu/solutions/matchmaking/
[18] "A continuum in translational research - NeurATRIS." http://www.neuratris.com/index.php/en/neuratris-offer/a-continuum-in-translational-research
[19] "How to collaborate - NeurATRIS." http://neuratris.com/index.php/en/neuratris-offer/how-to-collaborate

- *ELIXIR*[20] - Engage with ICT enterprises to promote open source software and sharing of data and promote the exchange of personnel.
- *Euro-BioImaging*[21] - Bring together the commercial vendors of scanners with the scientific community that pushes technical boundaries to define future specifications of equipment.

A workshop that explored the roles of Research Infrastructures in the innovation process was held in Brussels on June 20, 2017[22]. Representatives of the Research Infrastructures, industry, IMI and the European Commission explored the innovation potential through providing Open Access to resources and competences. Some specific issues arising from Open Innovation, e.g. the handling of intellectual property, data handling, costs and efficiency, as well as quality and reproducibility were thoroughly discussed.

Perspectives & Managing Expectations

In a successful PPP there is a mutual understanding of what drives the other partner. The classical view of public vs. private partners is that the academic researcher 'goes for the publication' and the company 'goes for the patent'. However, the one does not exclude the other. In order to realize both ambitions it is important to find common ground, identify the activities where the partners need each other and come to an agreement on the terms how each partner protects its own interest (e.g. often focused on publication and IP rights).
Aligning expectations is key, for which a good foundation can be laid during the building phase. The key to success is to recognize and appreciate the different drivers and motives as early as possible during the collaboration to create the right mindset. Relevant factors are:

- *Size and development stage of the organization*. Large enterprises (pharmaceutical industry) have different dynamics vs. small and medium enterprises regarding decision making, strategy and risk-averse behaviour to maintain their reputation.
- *Nature of the collaboration*: Research service projects are more straightforward and often follow a more linear path than joint collaborative projects and long-term strategic initiatives where thematic partnerships will generate knowledge as part of an 'extended department' of the company.
- *Project size and complexity*. A larger number of partners brings in more complexity to align legal representatives in setting up a larger consortium. Technically demanding projects requires

[20] "Industry support | ELIXIR - ELIXIR Europe." https://www.elixir-europe.org/industry
[21] "Euro-BioImaging Industry Board | Euro-BioImaging." http://www.eurobioimaging.eu/content-page/euro-bioimaging-industry-board
[22] "Innovation by Open Access Meeting | CORBEL Project – Coordinated ...." 20 Jun. 2017, (Accessed 12 Mar. 2019) https://www.corbel-project.eu/innovation-by-open-access-meeting.html

collaboration between different stakeholders representing different disciplines.

	Type	Key success factors	Rate limiting factors
	**Single Service**	Matching expertise	Finding the right partner Check: freedom to operate
	**Master Service**	Robust platform Client orientation	Successful pilot
	**Collaborative**	Trust Track record	Due diligence Audit(s)
	**Complex Collaborative**	Aligning expectations early Project champion Single point of contact	Project complexity Lack of technical expertise Lack of PM capacity/experience
	**Collaboration Hub**	Critical mass Long term commitment True collaborative spirit Facilitator/negotiator Administrator	Legal & operational design Slow decision making (private) Priorities, capacity planning (public)

Incremental complexity

Getting to know each other and understanding what drives the other partner(s), before and during collaboration can be very helpful to align expectations. There are some useful resources (blogs) on internet that can support the academic researcher in getting a better understanding of the non-scientific and more process-oriented aspects of (pharma) industry R&D.[23,24] In some cases academic partners perceive industry collaborations as a limitation of their academic freedom.[25]

In Summary: Characteristics of a Well-Functioning PPP

- Excitement about the science and the joint mission
- The role of the Project Champion(s)
- Quality and excellence
- Clear organization with defined roles & responsibilities
- (Robust but flexible) legal framework 'fit-for-purpose'
- Expectations managed well from both ends
- 1+1= 3
- Trust and good chemistry among the partners (will be the result)

Examples of what could go wrong:

- Overpromising/unrealistic timelines, too slack timelines
- Overall aim of the project is unclear/ changing over time
- Poor communication

[23] "In the Pipeline | Derek Lowe's commentary on drug ... - Science." 28 Feb. 2019, http://blogs.sciencemag.org/pipeline/
[24] "Cafepharma." http://www.cafepharma.com/
[25] "Collaboration between academics and industry in clinical trials: cross ...." 3 Oct. 2018, https://www.bmj.com/content/363/bmj.k3654

- Unclear governance
- Milestones are not met, deliverables not delivered in time
- Lack of effective fallback/troubleshooting mechanisms
- Too high expectations of funding, under budgeting of critical parts
- Slow decision making within one of the partners
- Conflict between patenting vs publication process
- Losing momentum, loss of marketability, novelty

4. Identifying Potential Partners and Networking

Identifying the right partners to complement a consortium can be a daunting task, as a partner with complementary competencies could very well be outside your own network or expertise and might speak another 'language' in the sense that their technical background can be vastly different from your own. The following three steps form the ideal pathway to identify and interact with prospective partners in setting up a research collaboration:

1. Determine the right partner profile
2. Create a proposition that fits your target audience
3. Reach out to prospective partners

Determine What Competences You Need from a Partner

The first step in identifying partners for collaboration is to clearly identify which competences the right partners need to have for the collaboration to be fruitful. Roughly speaking, these competences can be found in either academia or industry. The incentives to join a collaboration can be vastly different between academia and industry and will therefore determine whether a prospective partner can be a good fit. In general (but exceptions are common), academia is interested in funding to conduct research that will lead to scientific publications, whereas industry is incentivized by revenue, although this can come in more indirect route such as patents, access to technology, or exposure (possibly via publications). Some service providers already have various academic collaborations and might be more open than others to collaborate again. Biotech and pharmaceutical companies with open innovation programs will generally also be more fitting for partnering with academia.

Creating a Proposition

When creating a proposition, it is important to strive for a specific description of the project and the needed competences, while keeping it concise. In short, it should explain the scientific plan, what you want out of the collaboration, and in what ways a partner can benefit. Besides scientific publications, incentives to collaborate can be related to in/out-licencing or access to IP, funding, access to data, or jointly developing novel tools where this is not possible by individual groups.

The proposition should be understandable for the prospective partners, tapping into their goals and incentives. Do specify the positives, especially why the project is unique, competitive, and strives for high quality research. Don't disclose confidential information without a signed confidentiality agreement (CDA/NDA), and try not to include assumptions regarding the incentives of prospective partners. Besides the scientific scope of the project, also state clearly what *you* have to offer: this could be novel results, data, access to cohorts, IP or know-how, skills and personal or specific facilities.

Reaching Out and Interacting with Prospective Partners

The obvious first step to get in contact with prospective partners is to look into your own network and send around an email with a brief proposition to request contact to engage their network. It can be helpful to look through your LinkedIn connections as there may be contacts that could be helpful at this stage. Besides search engines like Google and Pubmed, it might be worthwhile to use lens.org (patent searches), LinkedIn, or commercial databases that might be available through your technology transfer office.

Relevant avenues to meet prospective partners can be scientific conferences, industry events with a scientific scope, industry partnering events (academic discounts often apply), or local events at a university campus or biotech cluster. Generally, attendees will be open to chatting with people they have not met before and are usually willing to refer you to any of their contacts that would be suitable for a collaboration.

When looking for industry partners, biotech umbrella organisations (Sweden BIO[26], Flanders BIO[27]) or parks & clusters (Leiden Bioscience Park[28],Barcelona Biomedical Research Park[29]) are great starting points and have communication officers that will direct you to potential companies that could fit the profile.

Academic institutes are connected in various European research infrastructures based on specific expertise. The general goal of RIs is facilitating collaboration and are therefore a great point of entry for potential contacts. For European RIs and their main focus, see the list below:

- BBMRI (http://www.bbmri-eric.eu/) - biobanks & samples
- EATRIS (https://eatris.eu/) - translational Medicine
- ECRIN (https://www.ecrin.org/) - investigator-initiated clinical trials
- ELIXIR (https://www.elixir-europe.org/) - computational biology

5. Funding Aspects

For most academic researchers public funding is their primary (and often sole) source of income to fund their research. The process to secure funding is largely dictated by grant writing with pre-set application

[26] "SwedenBIO." (Accessed 6 Mar. 2019) https://swedenbio.se/
[27] "Flanders.bio." (Accessed 6 Mar. 2019) https://www.flanders.bio/
[28] "Leiden Bio Science Park." (Accessed 6 Mar. 2019) https://leidenbiosciencepark.nl/
[29] "Barcelona Biomedical Research Park." (Accessed 6 Mar. 2019) http://www.prbb.org/

process and deadlines, where the funding supports project-based, explorative research (PhD/post-doc programs) and is bound to time (e.g. 4-years project life cycles). Private funded research is more output driven and tailored to maximise chances of successful delivery of a product or specific research outcome. More effort is put into the project design to de-risking as many aspects upfront, where resources are provided more on an as needed basis.

Academic vs Industry Rates

The fast technological developments in (biomedical) research often make it unfeasible for academic institutions to create a 'standard catalogue' of services with pre-set prices, like commercial contract research organisations have in place. Public research institutions are also bound to legislation to prevent market-disturbing activities. Nevertheless, a distinction can be made between 'academic CRO-type' services (that could ultimately result in an academic spin-off enterprise) and more exploratory, joint collaborative research activities when setting prices.

A common misconception is that collaboration with industry generates revenue to fund new academic research, or 'hobby projects' beyond the anticipated collaboration. This 'scope creep' poses risks to the relationship and can lead to distraction of the overall project(s) aim of the collaboration. In general, it is recommended to charge realistic prices that (at least) cover the actual costs (including materials, personnel, depreciation and overhead and, in some cases, a market-relevant profit margin), but to be aware of the value of academic expertise and ensure that this expertise is reflected in the price. The researcher can check with the institution what rigorous process is in place to work with an academic business developer, supported by its technology transfer and legal offices.

Private Funding

Small and medium enterprises will have investors behind them and various (seed) funding[30] rounds that can impact the dynamics of a collaboration (for instance Series A, B, C funding).[31] They often want to move fast with limited resources where limited amounts of funding are available to support academic research. Larger enterprises are becoming more and more interested in developing long term partnerships and often have organised supporting capacity in academic alliance offices with academic liaison management. Many bigger industries advertise their R&D interests (e.g. need for specific assets, expertise, research tools) on their website that generates licensing and collaborative research opportunities. Partnering meetings are organised to explore these opportunities more in depth (e.g. BIO,[32] Bio Fit,[33] BIO Europe[34] or NLS Days[35]). For mature research programs that have prototypes (at

[30] "Seed money - Wikipedia." https://en.wikipedia.org/wiki/Seed_money
[31] "Series A, B, C Funding: How It Works ...." 8 Feb. 2019, https://www.investopedia.com/articles/personal-finance/102015/series-b-c-funding-what-it-all-means-and-how-it-works.asp
[32] "Biotechnology Innovation Organization." https://www.bio.org/
[33] "BioFIT - academia-industry collaborations in Life Sciences." https://www.biofit-event.com/
[34] "BIO-Europe - EBD Group - KNect365." https://ebdgroup.knect365.com/bioeurope/
[35] "NLSDays." https://www.nlsdays.com/

least technology readiness level TRL 4 or 5)[36] closer to market, venture capital investment[37] may be considered, although this requires professional business planning and expertise.

Public Funding

The biggest source of funding for public-private funded research is the European Innovative Medicines Initiative[38]. Here they work to improve health by speeding up the development of innovative medicines, focusing on areas where there is an unmet medical or social, public health need. The >5.3bn EUR budget enables collaboration between the key players involved in healthcare research, including universities, the pharmaceutical and other industries, small and medium-sized enterprises, patient organisations, and medicines regulators. Their IMI1 and IMI2 programs follow a specific legislation and agenda[39] with calls for proposals.[40]

Patients are getting better organised to set public research agendas and crowdsourcing, angel investments and philanthropy provide new opportunities to fund public-private research. Charities such as the Bill & Melinda Gates foundation[41] invest in programs to combat infectious diseases in areas of poverty, the Michael J Fox foundation[42] provides research funds to find cures for Parkinson's Disease and National funded programs, such as Cancer Research UK[43] are key drivers of cancer research. In this respect, the recent example of the Dementia consortium supported by LifeArc[44] is an interesting development where a major pharmaceutical company (MSD) is directly funding a public-private initiative to fund dementia research.

Other Means of Value Creation

Much attention goes to the total amount of funding associated with the Project Agreement. Although the price tag associated with an agreement can influence the level of prestige and indicator of the potential impact the project can have in the research field, in itself it is not more than an expression of the resources that will be devoted to the project (e.g. direct costs for research materials, personnel and depreciation costs for the use of equipment and facilities.

Apart from the project value, there are many more aspects that can be considered to create value in a PPP, depicted in the following (non-exhaustive) list:

- Generation and sharing of knowledge

[36] "TRL Scale - Innovation Seeds." http://www.innovationseeds.eu/virtual_library/knowledge/tlr_scale.kl
[37] "Venture Capital - Investopedia." 16 Feb. 2019, https://www.investopedia.com/terms/v/venturecapital.asp
[38] "Innovative Medicines Initiative." http://www.imi.europa.eu/
[39] "Strategic Research Agenda | IMI Innovative Medicines Initiative." http://www.imi.europa.eu/about-imi/strategic-research-agenda
[40] "Apply for funding | IMI Innovative Medicines Initiative." http://www.imi.europa.eu/apply-funding
[41] "Bill & Melinda Gates Foundation." https://www.gatesfoundation.org/
[42] "The Michael J. Fox Foundation for ...." https://www.michaeljfox.org/
[43] "Cancer Research UK." https://www.cancerresearchuk.org/
[44] "Dementia Consortium: Home." https://www.dementiaconsortium.org/

- Access to company expertise
- Access to high-end, high-throughput core facilities
- Access to consumables and materials (subject to terms of MTA)
- Joint publications (with higher impact)
- Expanded professional network
- Enhanced quality and reproducibility of research outcomes
- More attractive terms to obtain licenses (non-exclusive or exclusive)
- Generation of joint IP, generating future income from issued licenses
- Personnel exchange (e.g. PhD, Post-Doc, technicians)
- More opportunities for co-funding (Company Letters of Support for grant applications**)**

6. Setting Up Discussions, Roles and Best Practices

There are numerous articles giving guidance and tips how to engage with industry.[45],[46],[47] In this section an outline is given of some key features based on experience from the research infrastructures and CORBEL.

Appreciate Industry Objectives

As starting point for a dialogue, it is good to first explore what resources and expertise the parties bring to the table and what objectives are likely to be served. Experience shows that academic institutes and their networks usually avail of extensive research capabilities. Sometimes the sheer breadth can be daunting for industry, particularly small or medium enterprises (SMEs). **SMEs** have narrow fields of activity and generally come with very specific needs for their product pipelines. Cost and timing are also major concerns. These factors make matchmaking with SMEs a rather precise activity and one requiring a high degree of objectivity. Finding exactly the right match of skills and needs, cheaply and quickly, is demanding and may not fit the academic parties' objectives well. In contrast, when a match is identified, particularly from trawling an extensive research infrastructure (RI) network, this can be extremely effective.

Initial discussions should therefore focus on the objectives and perceptions of the industry parties. What is required, why is it that academia may offer a solution and what are the constraints in cost and timing? Additionally, who will fund the research, the SME and/or a subsidy provider?

[45] See for example: "The Value of Academic-Industry Partnerships – BIO." https://www.bio.org/articles/value-academic-industry-partnerships

[46] "Academic engagement and commercialisation: A ... - Science Direct." (Accessed 11 Mar. 2019) https://www.sciencedirect.com/science/article/pii/S0048733312002235

[47] "Targeting Academic Engagement in Open Innovation ... - Springer Link." (Accessed 11 Mar. 2019) https://link.springer.com/article/10.1007/s13132-015-0254-7

Engaging with Larger Companies

If the potential partner is a large pharmaceutical company the scope will be broader than for an SME. Big pharma companies often have "shopping lists" of where their interests lie and where not. For example, which medical conditions they are working on and which not. These can help in identifying common interests and should always be asked for.

With larger companies there may be benefit in exploring the possibility for a **framework or master research agreement.** This sets out the general terms for research collaboration between the company and one or more academic institutes. Once agreed it can be invoked for future research proposals as and when they arise. Achieving such agreements may take time as they set out a framework which everyone should feel comfortable with, and they may involve several parties (multilateral agreements). However, master research agreements can save considerable time later in the relationship, and as trust grows, they can be very useful and efficient vehicles.

Take Time and Create Trust

Whether dealing with large or small companies, making good agreements takes time. The number of aspects to be considered is wide and to come together the parties must generally develop good working relationships between the people involved. The various roles (see below) can be a complicating factor, and there are phases in the preparation and actual negotiation which cannot be rushed.

Roles

Setting up a multilateral collaboration can involve scientific, commercial and legal disciplines from the various parties to the ultimate agreement. There may also be facilitators not being party to the agreements (e.g. funding bodies and research infrastructure coordinators). Drawing up a blueprint for the discussion and negotiation process will mean involving everyone but not all at the same time. While there is no single perfect solution some points deserve attention:

- From the academic side a focal point to lead the process and a small core team are recommended
- A similar team from the industry partner(s) is indicated
- There should be a contact person for each of the parties to the ultimate agreement, with authority to comment on the process and provide inputs
- It is good practice to report or minute each stage of the discussions and to ensure that everyone is made aware of progress
- TTOs and legal counsels should be consulted throughout but it is not necessary for everyone to be present throughout. See in this regard the best practice agenda example below.

Non-disclosure Agreements (NDAs)

In setting up discussions consideration should be given to signing non-disclosure (secrecy) agreements. These provide protection for confidential disclosures from any or all of the parties and can therefore make the scope of discussion more relevant.
It is recommended that NDAs should be two-way (or multiple for more than 2 parties), and that the **scope** of information to be disclosed (for the **purpose** of exploring a possible collaboration) should be carefully defined. The duration for confidentiality should in general be finite, e.g. several years, and academic parties will not normally be allowed to accept financial penalties for non-compliance.

An Example of a Best Practice Agenda

As a general principle, the discussion process is served by agendas which in the early stages concentrate on the **scientific content,** then move on to address important issues for conduct of the project, treatment of results, **exploitation and commercial features,** and finally address all **legal** aspects for an agreement. Although there is no unique formula for this, most people arrive from experience at this kind of prioritizing.
An example from a workshop produced the following recommendation for prioritizing an early

AN AGENDA SUGGESTION

Green=high priority, Yellow=medium, Red=preferably postpone till later

O Applicable law and arbitration for the collaboration
O Actions to follow from the meeting
O Objectives of the parties
O Division of budget among the parties
O Scope and activities
O Software requirements to access the data
O Timing
    To reach agreement and kick off the project
    To complete the project
O Contact persons for the various parties
    Technical/scientific
    Legal
O Type of collaboration
O Intellectual property matters
O Requirements of the subsidy provider
O Liabilities
O Confidentiality and publication issues
O Access to data and materials

7. Negotiation

Securing a good, sustainable collaboration will normally require some degree of negotiation, depending on the nature of the collaboration and the issues to be addressed. There are some useful general guides to negotiation[48],[49],[50] and in this section we will focus on some best practices applicable in particular to negotiating multilateral research collaborations.

The Negotiating Team

Rather than leaving events to unfold haphazardly, it is important to formulate a plan for the negotiations and to nominate a team. Teaming up is always better than doing things on one's own. If possible, enlist the help of experienced negotiators from within the organization.

The team should comprise the roles and expertise required. This may be some combination of scientific, financial and legal skills. It should also be clear from the outset which parties are represented by whom—particularly if a multilateral collaboration is involved—and what the formal mandates are.

Research infrastructures may have various degrees of involvement, depending on their business models and which entities will be party to the agreement. An RI may be instrumental in setting up a research proposal involving constituent institutes which will themselves be the parties to an agreement with one or more industry parties. In such cases, if the RI is involved in negotiations it must coordinate closely with the individual institutes taking part as these will be the ultimate parties to the agreement.

In other situations, an RI may have certain criteria applying to the collaboration while other aspects are left to the industry partners or become the subject of negotiations at the individual institute level. This could apply to business models involving access to data or facilities managed by a hub.

It is recommended that the negotiating team agree who will take the lead (which may rotate from session to session) and who will back up.

It is good practice to exchange information in advance on the team members and their backgrounds.

Preparation

Good negotiation follows from good preparation. Successful negotiating teams spend much time before the negotiations discussing internally what they know of the other party, what its likely objectives are and what information is available through publications, patents, websites and, if appropriate, previous personal contacts. In a public research institute this homework could include checking if there are previous agreements between the industry party and the institute, perhaps involving other groups. A technology transfer office or legal department should have this on record.

[48] "Getting to Yes - Wikipedia." (Accessed 11 Mar. 2019) https://en.wikipedia.org/wiki/Getting_to_Yes

[49] "Negotiation Guidance Notes - European Commission - Europa EU." (Accessed 11 Mar. 2019) http://ec.europa.eu/assets/eac/msca/funded-projects/how-to-manage/funded-projects/how-to-manage/irses/irses_negotiation_guidelines.pdf

[50] "Good Negotiating Practice - CORBEL Project." (Accessed 11 Mar. 2019) https://www.corbel-project.eu/fileadmin/corbel/media/docs/Innovation_Office/CORBEL_Good_Negotiating_Practice_21.11.2016.pdf

In addition, homework should include analysis of one's own position and objectives from the negotiations.

Planning the Negotiations

For the negotiating process there are a number of best practices which will improve the chances of success.

- Agree an agenda, venue, timing, who will participate. An open attitude and clarity are important to avoid surprises and engender trust.
- Start by exploring the parties' objectives and possible mutual interests. Look for common ground and complementarity of skills and resources. Exploring the science is often a good way to break the ice and establish friendship and trust.
- Do not be in a hurry to settle individual points. Explore the wider picture and try to establish as much information as possible. Ask for clarification if required.
- Make sure there are good housekeeping arrangements, coffee breaks etc. If the meeting is held on one's own premises, provide a pleasant meeting room and facilities.
- Call time outs if needed. Breaks provide opportunities to discuss among the team members or refer points into your own organisation.
- Prepare a written summary of what has been agreed, if anything, and what matters are referred till later. Have both parties sign off on this so that progress is suitable documented.
- It is often good to make agreement subject to approval in your hierarchy. This can either be checked by consultation during a time out or taken home after the meeting. It is important that this be a formal piece of due diligence, to be expedited promptly, not a delaying tactic.
- Good agreements take time. Be prepared for several rounds/meetings.
- Focus on issues not people.
- If possible, take time to establish friendly relations. Negotiation is the starting point for a research collaboration which can be of long duration and be dependent for its success on friendly working relationships.

Agendas and Priorities

Negotiation is a process often involving successive meetings or rounds. It will seldom be possible to tackle all the issues simultaneously so preparing meeting agendas and prioritizing the sequence of items to be addressed at each stage is very important for success.
It is generally recommended to address scientific matters and programme content in early exchanges, while postponing legal issues ("boilerplate") till later in the process. Other matters such as commercial issues, communication, governance, intellectual property, confidentiality, data sharing and publication can be introduced at an intermediate stage.

It should be noted that the legal issues are essential and should be addressed by or with the help of the legal counsels, but preferably not at an early stage when they might dominate and become obstacles to agreement.

8. Agreements and Important Elements

The backbone of each collaboration is a good legal framework enabling smooth execution and achievement of collaborative goals to the satisfaction of each collaborator. However, the road through the legal maze is not always easy and it requires close cooperation of scientists and legal experts.
There are several agreements to be identified on a pathway to collaboration but before doing so it might be useful to reiterate what a contract generally stands for. A contract is an agreement reached between (two or more) parties, based on which parties agree on certain terms governing their relationship in a particular situation (license, service, assignment etc.) and commit to perform certain obligations. Therefore, a valid contract is legally binding which in other words means that it gives parties legal right to enforce it by demanding fulfilment of the obligations agreed. Contracts are usually bilateral and involve two parties having obligations towards one another but can also be multilateral where several parties are involved which is specific for research collaborations.

Confidentiality & Non-Disclosure Agreements

At an early stage of setting up discussions between potential collaborators confidential/ non-disclosure (secrecy) agreements are a standard vehicle for providing protection for confidential disclosures and enable sharing. A confidentiality agreement template can be found here.[51]
Confidentiality agreements have fairly standard content and are usually simple and fast in execution, however there are some important features and issues worth mentioning. When considering choosing a "1-way"/unilateral (protecting only one party as a discloser) or a "mutual" confidentiality agreement (protecting all parties), it is recommended to choose mutual confidentiality agreement because it protects all parties equally while not taking away from the protection of the main discloser.
The definition of confidential information (description of what information is to be kept confidential) should not be set up as too broad because it can become impractical to abide by the contract but not too narrow either so that important confidential information is not left out. Attention should be made when defining of the scope of the confidential disclosure and the use receiving party can make of while exploring a possible collaboration (agreed purpose). It is recommended to carefully define such by specifying and restricting it according to each situation.
The duration of the secrecy is often an issue. In general, the longer a party is under the obligation for secrecy the more inconvenient it may become and the greater is the risk of accidental disclosure in breach of the agreement. For academic institutions a long duration is unlikely to be required, but industry parties may require longer periods of non-disclosure. Many situations result in a 3 to 5 years of

[51] "Innovation Helpdesk : Templates | CORBEL Project – Coordinated ...." (Accessed 12 Mar. 2019) https://www.corbel-project.eu/innovation-helpdesk/templates.html

secrecy obligation often counted from the expiration or termination date of the agreement and therefore there is no need to have the duration of the confidentiality agreement set to a longer time than needed for the exchange of confidential information because confidentiality obligations survive the term of the confidentiality agreement. However, for industry parties it might be important to have longer periods of secrecy agreed such as 7 or 10 years or even indefinitely (not recommended).

Material Transfer Agreements

In the area of research, it is common that the parties exchange tangible materials, therefore either at an early stage of investigation, or to explore a possible side-line to ongoing research, it may be desirable to transfer materials (substances, cell lines, biological materials, mouse models etc.) between the parties. Material Transfer Agreements (MTAs) cover issues relating to the transfer and use of the materials, among which the ownership and rights to the materials and any inventions resulting from their use.[52] Some of the important aspects to define in the MTAs is to clearly define the materials transferred, establish limitations on how recipient can use transferred materials (only employees working directly on the research, only for authorized purpose and not for any commercial or other purpose) and define ownership of results and access rights to improvements and modifications of the material, ownership of IP developed by recipient while using material, return of materials after use or agreed disposal procedures and use/publication of results.

License and Assignment

In the context of the research collaborations, often involving various intellectual property rights (IPR), two legal instruments are worth mentioning- license and assignment. License and assignment of IPR can be executed by way of the self-standing license or assignment agreement or through assignment or license clauses contained in the other agreements.[53],[54]

IP assignment is similar to sale and it entails permanent transfer of ownership of IP from one party (assignor) to another party (assignee). Consequently, the assignee becomes the new owner of the transferred IP assets and can no longer use such transferred assets after the transfer has taken place or otherwise such use would be considered as an infringement of the IP assigned. Assignments are useful tools for commercialization when the IP owner does not have enough capabilities (financial, HR, marketing) to commercialize developed intellectual asset or where owner would like to realize immediate cash flow from an IP asset.

On the other hand, an IP license is comparable to a rental because it does not imply permanent transfer of the IP in question but a grant of right to exploit certain IP assets within the certain limits which are set

[52] "Innovation Helpdesk : Templates | CORBEL Project – Coordinated ...." (Accessed 12 Mar. 2019) https://www.corbel-project.eu/innovation-helpdesk/templates.html

[53] "Your Guide to IP Commercialisation - IPR Helpdesk." (Accessed 12 Mar. 2019) https://iprhelpdesk.eu/sites/default/files/documents/EU-IPR-Guide-Commercialisation-EN.pdf

[54] "European IPR Helpdesk - Your Guide to IP and Contracts." (Accessed 12 Mar. 2019) https://iprhelpdesk.eu/sites/default/files/2018-12/european-ipr-helpdesk-your-guide-to-ip-and-contracts.pdf

in time (concrete licensing period in years or until IPR expires), territory (specific country, several countries, EU-wide or worldwide) and level of exclusivity (exclusive, non-exclusive, sole or cross license). A license is given by the IP owner (licensor) to a third party (licensee) in exchange for a monetary compensation (usually lump sum or royalties) or in exchange for another right (cross- license).
Licensing can be seen as a means of turning a possible competitor into a partner as licensor retains ownership of its IP and receives income (royalty) in return without need to deal with or invest in production, marketing and distribution. The choice of license type will therefore depend on the business strategy, target market conditions and the capabilities of the licensee.
IP assets are often transferred to the spin-off company by a way of assignment while technology transfer agreements (i.e. for production of products involving exploitation of given technology) often take shape of a license where licensee produces such products. However, both – transfer of assets to spin-offs and technology transfer agreements can take shape of license and assignment.

Collaboration Agreement

A Collaboration Agreement can be concluded between parties for one, specific project. In that case, we are talking about a project-based collaboration agreement that facilitates one concrete project and provides for the full details and legal framework supporting such project.[55]
However, a more common type of collaboration agreement is a framework type of agreement with a legal structure suitable for execution of multiple, different projects under the pre-negotiated set of clauses. This helps save time as the parties have previously agreed on all the main features (such as intellectual property, publication, liability, etc.) that will generally be applicable to all specific projects to be executed under such framework Collaboration Agreement. In that way, only specifics of each project such as project plan with budget, contributions, deliverables and timeframe for performance need to be agreed upon between the parties which steers the process and enables execution of more projects in a shorter time. Specific projects are therefore executed by way of separate project agreements concluded under the Collaboration Agreement. Such are therefore an integral part of the Collaboration Agreement and can be executed as appendices to it. Although agreements for setting up collaborations are almost inevitably a tailor-made process, there are guidelines to help identify some of the collaboration agreement main components. For further details and example clauses consult *CORBEL Collaboration Agreement Template Tool with Commentary*.[56]

Use of Templates and Model Agreements

Although there is no universal template that can accommodate every particular situation, templates available can serve as a good starting point and save some time in preparation. However, great caution

[55] "Innovation Helpdesk : Templates | CORBEL Project – Coordinated ...." (Accessed 12 Mar. 2019) https://www.corbel-project.eu/innovation-helpdesk/templates.html
[56] "Innovation Helpdesk : Templates | CORBEL Project – Coordinated ...." (Accessed 12 Mar. 2019) https://www.corbel-project.eu/innovation-helpdesk/templates.html

should be exercised when using pre-existing templates as such need to be adjusted to the particular circumstances of each individual project and applicable laws so professional assistance of the legal experts is strongly advised.
Some of the model agreements or template tools currently available are:

DESCA model agreement[57]

The Development of a Simplified Consortium Agreement (DESCA) is the most widespread and supported model of the consortium agreement in the 7th Framework Programme which offers a reliable frame of reference for project consortia. The signature of a consortium agreement between the partners of a research project is mandatory for almost every Horizon 2020 project so DESCA seeks to balance the interests of all participant categories such as large and small firms, universities and public research institutes. The modular structure of DESCA, with various options and alternative modules and clauses, provides maximum flexibility setting out rights and obligations during a temporary partnership for the purposes of carrying out a specific project in EU-funded programmes. DESCA 2020 version 1.2.4 is current version and was last updated in October 2017.

Corbel templates

Corbel Innovation Helpdesk[58] offers guidelines on the main aspects to consider when setting up collaborations. It is not an exhaustive treatment but attempt to introduce the overall context and the features, which need to be addressed. There are number of useful sources of information on agreements, in particular templates and template tools on Material Transfer Agreements, Confidentiality Agreements and Collaboration Agreements which can be consulted.

Lambert Toolkit[59]

The Lambert Toolkit resulted from the efforts of the Lambert Working Group on Intellectual Property (2004), which brought together key stakeholders representing universities and business to produce a small set of model collaborative research agreements for voluntary use by industry and universities who wish to carry out research projects together. These agreements set out a range of approaches to the ownership and exploitation of IP and are not sector specific, allowing for flexible use. However, Lambert toolkit, including the model agreements, is designed to be used only when the agreements are governed by English law. To use a different legal system legal advice and necessary adjustments are needed.

[57] "DESCA." (Accessed 11 Mar. 2019) http://www.desca-2020.eu/
[58] "Innovation Helpdesk | CORBEL Project – Coordinated Research ...." (Accessed 11 Mar. 2019) https://www.corbel-project.eu/innovation-helpdesk.html
[59] "University and business collaboration agreements: Lambert ... - Gov.uk." 6 Oct. 2016, (Accessed 11 Mar. 2019) https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit

9. IPR and Licenses

Intellectual property issues arise in research collaborations with industry and must be addressed taking account of the rights and obligations of all parties. Although on occasions an academic party may be accustomed to operating without intellectual property, in general institutes will have the policy to establish IP protection and to realize a return on their research investments through licensing.
For industry partners IP is generally essential for their business models, usually in the form of patent coverage to secure a monopoly in exploitation of products or services.
IP is therefore an important feature to be addressed during planning and negotiation.

Categories of Intellectual Property

The main categories of intellectual property are summarized in the table. It is good practice to be aware of all of them, although an academic research institute will generally encounter mainly copyright (think of publications, software code etc.) and patents.

	DURATION	**COST INDICATION**	**REGISTRATION REQUIRED?**	**HOW TO APPLY FOR**
COPYRIGHT	LIFE OF CREATOR + 70 YEARS	FREE	NO	AUTOMATIC
TRADE MARKS	10 YEARS, RENEWABLE	MODEST	YES, PER COUNTRY OR REGION	SIMPLE: ONESELF COMPLEX: TRADEMARK ATTORNEY
PATENTS	20 YEARS	HIGH	YES, NORMALLY PER COUNTRY	PATENT ATTORNEY

Patents form the most powerful category of IP protection and are often key to commercial exploitation of research.

Important Points to Consider

In the planning phase discuss with the industry partner(s) and all the academic parties what IP can be expected from the project (“Foreground”) and what exists already (“Background”). It is good practice to agree beforehand how IP will be handled, in particular patentable inventions.

A key question is: which party will file patents?
Rights to patentable inventions are determined by the **inventors**. Inventors may be employed by one or more of the parties, including possibly the industry partner(s), if involved in the conduct of research. Care must be taken to identify correctly all the inventors and their respective contributions. Failure to do so (or inclusion of inventors whose intellectual contribution to the invention could be challenged) can have negative consequences if the invention would be challenged or if disputes arise.
The party or parties in whose names a patent application is filed are called the **applicants**. Applicants may be individual inventors or their employers if entitled to rights through the employment contract. In the event of different inventors an application could be made jointly by all the parties. This has as disadvantage that decisions must be agreed at every stage by all the parties, which can be cumbersome and time-consuming.
An alternative often worth considering is for a single party to file in its name, taking responsibility for the process, with an **IP ownership agreement** between all the parties to determine their rights and obligations.
In any event, aspects such as licensing rights and royalties should be agreed, as well as who will pay the patenting costs (which can mount up considerably). The patent process may also involve many decisions relating to filing and defence of the application, all requiring liaison between the parties. The governance of this process should be agreed beforehand. Academic parties should ensure that they retain a license to perform further **research** in the field.
The **background intellectual property** consists of pre-existing IP such as patents, know-how and copyright, belonging to any of the parties in the proposed research collaboration and necessary for carrying out the research and/or commercializing the results. All the background must be documented (for example in an Appendix to the collaboration agreement) and appropriate rights granted. It is good practice to start gathering information at an early stage. Background IP is often forgotten or incomplete.

When to File for Patents?

Best practice for academic researchers is inevitably to agree with industry partners that results will be published in the open literature, with minimum delay. Industry partners may want a delay to allow patents to be filed. The filing process itself, which should always be charged to experienced firms of patent attorneys, can be very fast but filing too early may not be optimal as later results can improve the application. This is always a dilemma, but the time delay to allow patent filing should always be agreed in advance, to safeguard the publication duty of academia and allow PhD students to plan the timing of their dissertation defence. In certain cases, part of the thesis may be held secret for a time but a good general agreement on publication procedures is preferred.

Features of Licensing

The grant of rights to use intellectual property is known as licensing and is a versatile tool in research collaboration.[60],[61]

Typical terms to remember include:

- Licensing-in and licensing-out
- Licensee and licensor
- Exclusive and non-exclusive licenses. An exclusive license grants rights ONLY to the (single) licensee. There is a form of license which grants rights to both a single licensee and the licensor (who retains rights). This is often called a SOLE license. To avoid confusion, it is always good practice to **describe the situation exactly** rather than relying on definitions which may not be clear to all.

Licences can be geared to suit situations:

- Scope definition
- Geographical territory
- Duration
- Exclusive or non-exclusive
- Right to grant sub-licences or not
- Rights to improvements or not

Define the Scope

The scope of the license is an extremely important variable which should be defined with care. Scope can be the type of activity (research, commercial exploitation) and the product or service (industry segment, scope of application, type of product).

License Fees

In certain situations, the grant of a license may be free. More frequently, a fee is charged to reflect the effort invested to enable application of the technology. If a fee is to be paid it can be

- Lump sum, one off or in instalments
- A royalty as percentage of turnover (preferably) or profit (more difficult)
- Milestone payments for achievement of certain requirements on the path to commercialization (e.g. upscaling, regulatory approval)
- Option premiums.

[60] "Successful Technology Licensing - WIPO." (Accessed 13 Mar. 2019) https://www.wipo.int/edocs/pubdocs/en/licensing/903/wipo_pub_903.pdf

[61] "Your Guide to IP Commercialisation - IPR Helpdesk." (Accessed 13 Mar. 2019) https://iprhelpdesk.eu/sites/default/files/documents/EU-IPR-Guide-Commercialisation-EN.pdf

License fees depend on a number of factors and should be decided case-by-case. There are literature guides to give ballpark figures for various industry segments.62 Experienced consultants can give help, though fees may be involved.
Certain professional organizations (e.g. the Licensing Executives Society, LES, and the Association of Science and Technology Professionals, ASTP) carry out royalty surveys available to their members. Becoming a member may be a useful option to gain access to these resources. As an industry partner normally bears all the risk of commercialization, this will be reflected in the license fee percentage.

10. Competitive and Pre-competitive Multilateral Collaborations and Expert Centres

Generally, bilateral collaborations are comparatively simple to handle, since the complexity of interactions between the partners is low. Moreover, negotiation of agreements depends only on the abilities of two partners, therefore we give some specific suggestions dealing with multilateral partners here. It should be noted that the initial statements about multilateral collaborations include academic and industrial partners equally, specifics for industry are mentioned separately.

Simplifying Multilateral Corporations by Hierarchical Structuring

Since the number of bilateral interactions (Ni) with partners of equal standing increases with the number of partners (Np) as Ni = (Np)!/(2*(Np-2)! (for 6 partners this would already mean 15 bilateral interactions, whenever multilateral interactions are included too, this number increases to 56) it is evident that the complexity must be reduced by dividing the partnership into lead and accessory partners (which is not derogatory, but a simple need). It is recommended that only one partner takes the lead in defining the goal, the strategy and the project planning, management and governance. Certainly, 'accessory' partners will contribute to the overall project according to their competences, tasks and resources, but eventually the lead partner is responsible to carry the project through to success. Experience shows that distributing leadership over too many partners results in problems that result in failure. This is true for purely academic, mixed academic/industry and industry projects.
The partner taking the lead is usually the one who designs the project, but in industry co-operations it may also be the industry partner with the highest commitment (e.g. financial contribution, interest in developing/marketing a product/service, etc.). In the latter case it is often advisable to have a small governance board that takes responsibility both of the innovative and the exploitation sides of the project. This hierarchical organisation of a multilateral project facilitates greatly to manage contracts (cooperation contract, MTA, DTA, etc.) by setting up quasi-bilateral contracts between the lead partner and the accessory partners, by which process the multi-laterality of the overall project becomes subordinate to the bilateral commitment between lead and accessory partner. There are often

[62] "Setting Values and Royalty Rates for Medical and Life Science ...." (Accessed 11 Mar. 2019) http://www.mbbp.com/news/setting-values-and-royalty-rates

situations in which truly multilateral situations at the contract level cannot be avoided (e.g. in case of EU-funded projects) but usually these contracts are on very general terms, and specific agreements for data and material exchange need to be negotiated separately.

Using Publicly Generated Resources, Maintaining Privacy, Guaranteeing Quality - the Expert Centre Model

A very specific problem arises whenever academic partners bring into a cooperation with industry resources that have been generated through public funding, be it grants from funding organizations, public funds from governments or charities, or the healthcare system: Such resources cannot be exclusively used for competitive research and development by industry, meaning that in a direct cooperation industry will never have legal access to such resources for competitive research. A second problem arises from the data protection issues incurred with research on human subjects: (clinical) patient data that are often indispensable for the research purpose cannot be shared outside the (clinical) environment in which they have been created, and data protection goes even further, forbidding sharing of such data with other physicians (specializing) than the one which is responsible for treating the patient (i.e. with whom the patient has concluded the 'treatment contract'). The latter problem can be solved, but for cooperation outside the treatment context, patient data and samples are not available any more, unless there is direct cooperation with a clinician/physician that takes care of all the ethical and legal prerequisites. An additional factor is the increasing demand for high-quality samples and data that cannot be met by individual cop-operations of this kind.
Since the situation above is a major obstacle in this type of research, a model had to be found that circumvents all these obstacles in a ethically and legally compliant way.[63],[64] This model, termed Expert Centres separates the research using human biological samples and data in a pre-competitive part, which eventually is 'not for profit' and a competitive part. In the Expert Centre model, industry approaches the Expert Centre with a specific research question. The Expert Centre either performs the requested research for an appropriate fee, or develops the project together with the industrial partner, with appropriate industrial funding. In either case, the Expert Centre guarantees to the industrial partner delivery of high-quality data and results, while maintaining ethical and legal prerequisites towards the donor (patient). The data delivered are anonymized and do not allow re-identification of the donor. These data can be used exclusively for a pre-specified grace period by the industrial partner to perform its research & development. After the grace period, the Expert Centre transfers the data generated to the public domain in an appropriate way, thus avoiding the problem of generating private resources with public money.

[63] "BBMRI-ERIC as a resource for pharmaceutical and life science ... - NCBI." (Accessed 11 Mar. 2019) https://www.ncbi.nlm.nih.gov/pubmed/25407005
[64] "CORBEL News | Issue 2 - CORBEL Project." (Accessed 11 Mar. 2019) https://www.corbel-project.eu/nl-issues/corbel-news-issue-2.html

For specific types of research (e.g. Genome sequencing), the Expert Centre model needs adaptations to accommodate specific needs, e.g. regarding data protection and related issues.

11. Project Planning, Budgeting and Governance

Planning and budgeting a project determines success and failure before the project has even started and should be performed in parallel and not in succession. It is necessary during the planning phase to find the right balance between too little and too much detail: on the one hand it can kill a project if crucial elements are not sufficiently well understood, underequipped with resources and whenever financial and time budgets are insufficient; on the other hand, R&D projects usually contain a high degree of uncertainty about the amount of resources to be allocated, intermediate delivery timelines may not hold more often than expected, and the budget may be unrealistic for some crucial elements, therefore project planning should allow for some flexibility. In general, project planning and budgeting should be done concertedly before the project starts and leave some manoeuvring space for governance and troubleshooting. The latter is often overlooked in situations where the budget is tight.

Project planning in research-centred project is often left to an academic lead, who has to fit the project into a budget that is set by the industry partner. However, in such a case, joint planning and budgeting may provide some understanding on both sides for the constraints either side experiences, and eventually in higher flexibility and better collaboration from the beginning. Such transparent project planning, management and governance is often the key for successful and extended cooperation from which both sides benefit most.

Initially, the necessary key resources and an estimation of time for the most important steps should be matched against the available budget, to check feasibility. This is usually an implicit step; however, it can be decided already at that stage whether it makes sense to continue planning, or not.

The next step would be to set up the major elements sequentially, to identify critical points in the project, that will need additional time and budget buffers, or require fallback strategies. Parallel tasks should be checked for the availability of sufficient resources. In case of insufficient resources, sequentialization, and its side-effects (increased project duration, tasks waiting to begin) need to be considered. Already at that point, critical milestones should be identified that can decide about failure or success. If no suitable fallback strategies can be proposed to overcome failure to reach a milestone, and the risk for this is not negligible, it is probably better to abandon the project in this form.

During this stage, a budget draft must become mature, leaving some margin for governance and troubleshooting in the last refinement stage.

The next step would be to prepare the project plan for governance, by adding sufficient detail to allow performance monitoring, alternative/fallback strategies, resolving bottlenecks and communication issues, and the budget finalized. Setting up timelines, e.g. in the form of a Gantt chart can be helpful and lead to realistic estimation of the sequential succession of the elements of a project and the necessary time buffers, if done with some attention to detail. In case of limited resources, they may also be helpful in allocating workload most effectively.

Although the steps mentioned above are obvious (and are laid down in most project management techniques), reality shows often time delays and budget overruns beyond reason which might be avoided by realistic planning.
Explicit governance mechanisms are not always a prerequisite, especially for small, short, bilateral projects, but are certainly essential for large, multilateral and complex projects. In larger projects it is sometimes preferred to employ the services of a project management agency to monitor project progress, support reporting and other organisational work. This may be a resource-effective way of dealing with work that is not the core expertise of the project partners, and some of these agencies deliver superb work. However, in the stages of planning and budgeting, and later decision-making, their work is accessory at best.

12. Monitoring Progress and Impacts

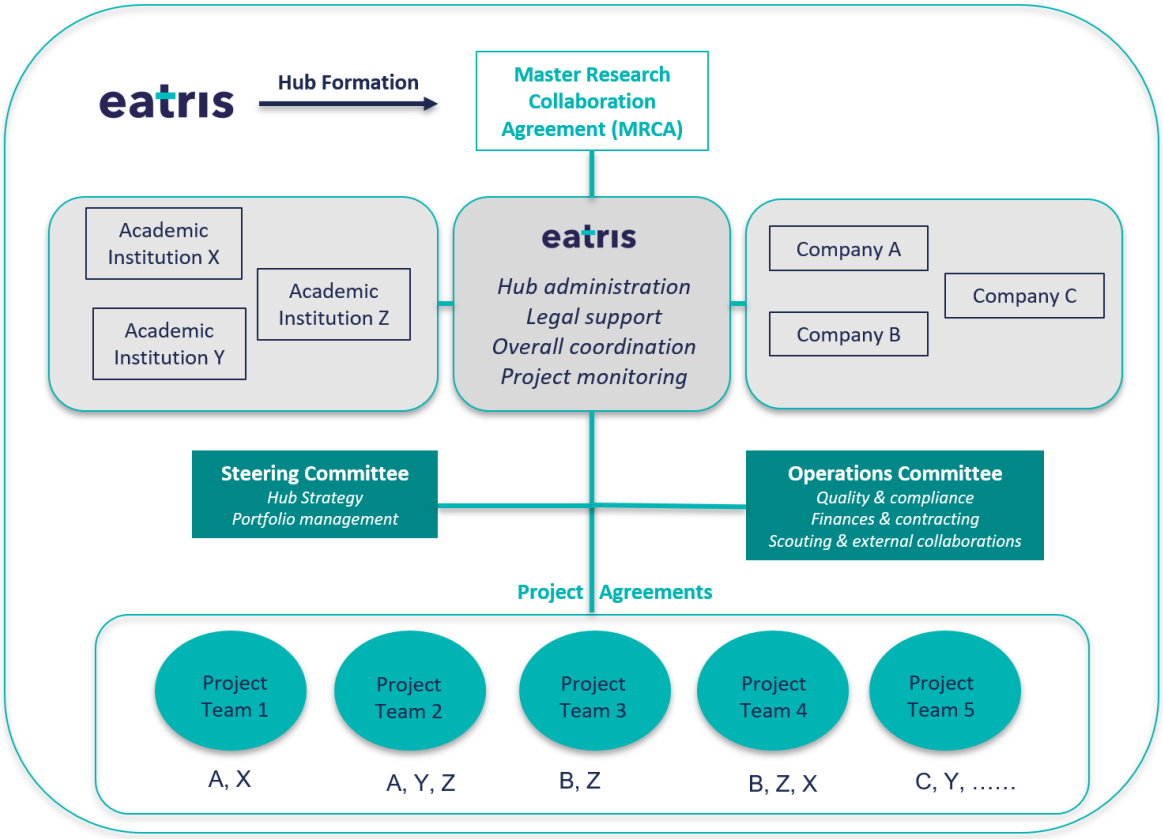
Once the roles and responsibilities are clearly defined and the legal and operational framework for the collaboration is established, good progress can be made only if the project or program is managed properly from all sides. Many resources and training courses are available to incorporate project management and best practice,[65,66] all the way up to professionally and certified management systems, which are beyond scope of this guide. This section highlights some key aspects and potential pitfalls, concerning governance, decision making, communication and reporting that drive public private collaboration.

Governance & Decision Making

In good collaboration where there is trust among partners, it is good practice to take pivotal decisions in a joint manner, despite different insights and drivers that each individual organisation may be bring to the table. For instance, the more risk-averse nature of industry partners may require more stringent quality criteria for a deliverable to be considered suitable for moving to the next stage in development. Agreement about the role of each partner to reach the deliverable with pre-agreed go/no-go criteria is key to prevent disappointment and avoid risk of project delay due to subjective definition of the project deliverable(s). Open communication about adjusting criteria in case of new insights should be safeguarded.
One example of a public private collaboration[67] with clear governance structure is an international multi-site Innovation Hub that has been created by EATRIS. This Hub is aimed at the implementation of new clinical imaging tools and deliver several projects per year with enhanced speed and throughput towards innovative imaging methods for inflammatory diseases. The imaging hub aims to achieve these

[65] "PMI | Project Management Institute." (Accessed 3 Mar. 2019) https://www.pmi.org/
[66] "PRINCE2 Certification Courses | Online Project Management Training ...." (Accessed 3 Mar. 2019) https://www.prince2.com/eur
[67] "Unique hub collaboration - Imaging method development in ... - eatris." 4 Jun. 2018, https://eatris.eu/insights/unique-hub-collaboration-imaging-method-development-inflammatory-diseases/

goals by optimising existing technology for drug development and translating emerging probes towards the clinic. The initiative creates a scientific bridge between industry clinical imaging scientists and five leading European imaging and experimental medicine research institutes within the EATRIS network. To enable experts in the alliance to fully focus on the scientific and technical challenges, EATRIS acts as portfolio manager, playing a key role in developing and administering the legal framework and operations, for optimal speed and efficiency. EATRIS will facilitate initiation of both independent and collaborative transnational projects under a master framework, with up-front auditing and quality agreements. In such a novel collaboration format, working from concept to project execution, the wealth of knowledge around drug development of the private partner can be combined with the clinical and technical expertise from public institutions having highly specialised experimental medicine capacity, all supported with dedicated coordination staff within the EATRIS central support office.

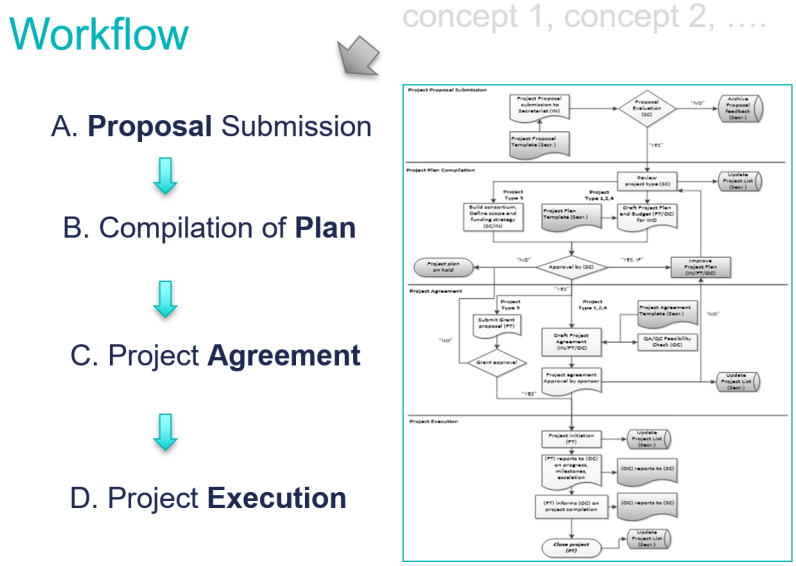


A master legal framework with predefined legal conditions at start provides a 'basket of options' to support different project types (open precompetitive, investigator initiated, industry sponsored or externally funded). Upfront negotiation of the terms of these various project types (IPR and publication) allows the discussion to focus on the science and projects during the collaboration. The simplified the legal and operational workflow (under a single overall legal umbrella framework) allows faster initiation and extension of projects and brings in flexibility by having various collaboration types supported.

The steering committee oversees the project portfolio and makes an inventory of the required and available capacity and research expertise. It also defines the elements of the due diligence required prior to initiation of the project between public and private partner.
In the case of bigger portfolios common issues affecting multiple projects can be addressed by an operations committee. These can involve quality assurance and compliance in projects, financial aspects and ensuring alignment with external collaborators.
The secretariat provides legal support towards execution of newly established Project Agreements in a harmonised manner. It facilitates communication among the partners (project teams) and maintains an overview of the project portfolio.

Operational Workflow

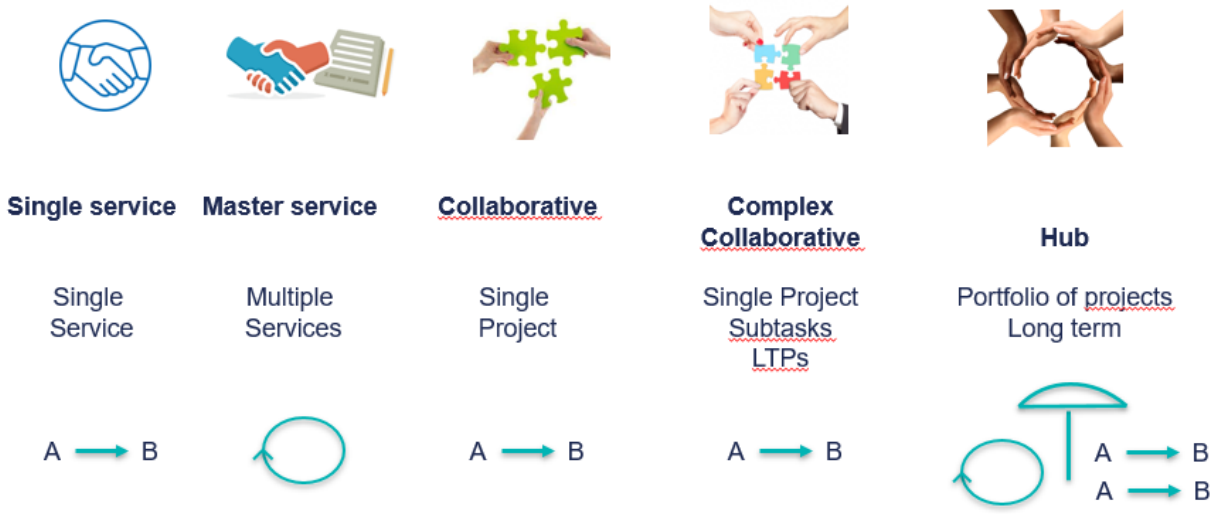
Both in preparing and running public-private collaborations it is key to have a common understanding among the partners on where you are in the process. It helps to define common language describing the main steps in the process to work from a concept to a fully executed project. This could be as simple as 1. Concept; 2. Proposal; 3. Plan; 4. Draft Agreement; 5. Project start. Depending on the size and complexity of the collaboration and the governance structure created to run it, a more detailed workflow can be worked out and managed by the administrator. See Figure.



Projects vs Programs

Collaborations may be different in nature in terms of their longevity and sustainability. Often, project results give rise to new ideas and new interactions (in particular when multiple partners are involved) and may lead to the initiation of new projects. Managing the relationships in an efficient way requires a good management of the portfolio of activities. In this regard it is good to discriminate between projects

and programs. Projects are defined by a specific set of activities that have a clear start and a clear end (from A to B) with a certain amount of resources. Programs can be comprised of multiple projects, complemented by other activities (such as expert meetings, portfolio management activities, functioning as a think tank) and may not be characterised by a clear start and end point. The latter offers more flexibility to a public private collaboration, in particular involving multiple partners, but should be managed as well (both in terms of roles as in allocation of resources). One example of flexibility in running a program (such as described in the Innovation Hub above) vs. a project is that, it can accommodate different projects types, allowing for instance pre-competitive and competitive projects to co-exists in a collaboration framework.



13. Exploitation and Follow Up

The translation of research results in the biomedical sciences into societal and economic value is a major objective which features strongly in public funding of research programmes and accompanying policies. Future exploitation is often a requirement which receives, however, mixed emphasis among academics. There remain wide differences of opinion with regard to the best approaches to innovation and value creation.

The biomedical science field features arguably the longest lead times to market, the highest costs and the greatest commercialization uncertainty of any research activity. In addition to the inherently difficult innovation pipeline for medical products, problems with poor reproducibility of results are responsible for vast losses of time and money.

These challenges are prompting new innovation approaches such as risk-sharing ventures, pools and pre-competitive hubs with access to data and resources, in addition to classical exploitation and commercialisation models.

Technology Transfer Through Licensing or Start Ups

In the classical approaches results, usually in the form of IP/patent rights, are licensed to an established industry party or a start-up company.[68] Teaming up with an established industrial company **early** in an academic research project is not often a high priority but on balance it is to be preferred. While there is some risk that the match will turn out to be non-optimal, the early approach allows the company to take over or share the patenting costs from the start, to identify potential products to develop and to prepare its approach to market. If an academic centre files for patents in its own name its ability to continue to bear the costs (which increase strongly upon entering the national phase at 30 months after the initial filing) is probably limited. Thirty months is not long if an industry partner has to be found and signed up.

The alternative is to form a start-up company. While this is a high-risk approach because of the difficulty to secure sufficient starting capital, the likely absence of an experienced entrepreneur to manage the venture and the "valley of death" funding problem, some companies nevertheless survive and go on to flourish. For the academic party, a university or academic medical centre, the start-up route bears obvious risks and may require a separate 'holding' to manage a shareholding participation. Institutes with long experience in such ventures are nonetheless able to manage the risks adequately. Concentrating the commercialization activity in a separate entity like a start-up company can be an advantage as this is often attractive to a take-over party later in the development chain.

A special problem may arise if a scientist wishes to divide his or her time between an academic career and involvement in the start-up. It is then essential to make agreements on the allocation of time to protect the core tasks of the institute (teaching and research) and to keep working times manageable.

Other Approaches: Expanding the Innovation Pool

New approaches to exploitation are appearing and may offer perspective if the classical models fail.[69] Here follows a short summary of some interesting approaches.

- Academic-industry precompetitive consortia enable extensive sharing of data and resources in an open resource environment. The European BMS RIs are in some cases adopting this type of model including experiments such as the Expert Centres.
- Investors are adopting risk-spreading venture capital approaches in which several R&D projects are performed simultaneously under a common corporate umbrella, thereby lowering risk. Some entities have been set up to "fish" in research circles and identify and adopt suitable research projects for development.

[68] "Academic Entrepreneurs: Organizational Change ... - Semantic Scholar." 11 Dec. 2007, (Accessed 11 Mar. 2019) https://pdfs.semanticscholar.org/3f4f/63ec856e7d2edcc7696133ac64d1dd2566c8.pdf

[69] "Partnering with the professor | Nature Biotechnology." 10 Oct. 2012, (Accessed 11 Mar. 2019) https://www.nature.com/articles/nbt.2385

- Patent pools are another example of risk-sharing, in this case to minimize the risks of orphaned or low-quality early stage patent filings.
- Crowdfunding (on line) has gained in popularity as a source of project funding for R&D.

14. Use Cases

A selection of actual examples of industry collaboration is provided below. The examples have been anonymized since in some cases the information has not yet been released to the public.
The examples are certainly not exhaustive of the many possible avenues to and types of collaboration, but they illustrate from actual experience various features and learning points which - in addition to a measure of good luck - arise from application of best practices.

- As part of an open call intended to introduce industry to the resources available from a number of biomedical research infrastructures (RIs), an invitation was sent to a sizeable number of European SMEs and umbrella organizations to participate in short public-private research projects in several areas. Funding was available in kind and for travel expenses to make this attractive. The initial response was disappointing. Probably the time horizon for submission of proposals was too short for SMEs and their requirements were too specific for the broad RI scope on offer. As the deadline for proposals approached two possible matches did materialize. One of these arose from contacts with an RI going back several years. At the time of writing a research proposal tailored to the SMEs needs is in preparation.
- At a major Biomed partnering event a small, early stage SME sought academic resources to help its development pipeline for a pharmaceutical product. The company was interested to start a clinical trial but needed urgently a key opinion leader in the neurosciences field to provide understanding of the therapeutic mechanism which until then had had only an empirical basis. Exploring the networks of two RIs generated a list of potential KOL candidates, including one geographically close to the SME. A tailor-made research collaboration ensued.
- A master research agreement between a big pharma company and a consortium of biomedical academic expertise centres took several years to conclude but laid the basis for several successful projects. An RI helped facilitate the collaboration although not itself a party to the agreement. The long lead time, while in itself somewhat disappointing, was conducive to building trust and good personal relationships. The pharma company now has a reliable access track to a wide range of academic skills and resources.
- An industry consultant informed a medium stage SME active in the field of oncology about a biomedical RI as a potentially useful source of external research capacity to complement their resources. This triggered the company to explore opportunities beyond their field of interest and expertise to increase their business opportunities and potential impact in other disease areas. The company requested expertise to assess the validity of their target for the treatment of Alzheimer's Disease targeted by novel therapeutics. Relevant expertise was matched by the RI and a preclinical program was designed to the satisfaction of the SME. Once the program was

close to start it turned out that a key diagnostic component for the assay readout was only available under certain terms requiring a third-party license, which was not granted in time. The project was still performed under less optimal conditions and results were inconclusive.

- An academic expert key opinion leader in Europe with years of industry collaboration experience had just finished a preclinical study for an Asian Pharma company. The project concerned the evaluation of a novel therapeutic candidate in a small animal model requiring specific expertise and infrastructure with promising results. The company was interested to continue the exploration under the same challenging technical conditions in a large animal model. This model was not available, so the RI was contacted to seek for additional opportunities. Three research sites in three different countries were identified. Separate explorative TCs were held between the groups and the company. Selection of the preferred institute was followed by a site visit to inspect the facilities, discuss study details and develop the relationship. A joint research plan was generated to be performed by two research sites collaborating closely with the company and the study was completed in time according to predefined specifications.
- A National Coordinator representing an RI met a Biotech start-up at a partnering event in Northern Europe and pointed the company at the possibilities that RI can offer for them to expand their research capabilities. The company contacted the central coordination and support unit with a research request to identify sites that have very specific bioanalytical research capability. One institution was identified in Eastern Europe. After exploring the technical requirements and confirming the institution's track record, the company and institution agreed on the steps to work out a collaboration. The RI facilitated these interactions which, after a pilot experiment, turned into a permanent collaboration that was laid down contractually in a service agreement where costs are covered on a 'fee for services' basis and joint publication of results is allowed after agreement by the company.
- A rather systematic model of instigating tight academic-industry co-operations is regularly initiated by a national funding organization. Competence centres are established around an academic core that consists of researchers from several universities and other research institutions. The industry partners are initially brought into these competence centres by the researchers. From these partnerships, the competence centre is founded as a firm that operates with equal contributions from industry and funding, as well as own income. After an initiating period of maximally 8 years, the firm becomes independent of the original funding and is continued as a research company, relying entirely on self-generated income. A recently founded competence centre providing integrated biomarker research methodology added to its networking capacity by becoming an Expert Centre acknowledged by BBMRI-ERIC. The advantage of the combination of the competence centre and the Expert Centre concepts is that such a public-private partnership starts with a large network of industry and academic contacts, as well as a strong link to a Research Infrastructure. These assets allow covering a broad spectrum of research and development topics while guaranteeing high quality and access to valuable resources over a large consolidation period after the establishment of the firm. Both

sides benefit from the competence centre – academia can conduct projects for which there are only limited funding instruments available and can strengthen its contacts with industry. Industry gets access to a large research network, competence and resources.

Next steps

The guide will be made available on the CORBEL Innovation web portal and attention given in the CORBEL newsletter and through other vehicles. Its use, as a ready guide for practitioners in the field, will be promoted through the CORBEL network and contact with the RIs. If there should be interest in training possibilities, workshops can be organized, like the one held in Ljubljana in December 2019.

Appendix

References to sources (as links) of information and guidance:

- EU IPR help desk - http://www.iprhelpdesk.eu/
- IMI - https://www.imi.europa.eu/
- EPO - https://www.epo.org/
- ASTP-Proton - https://www.astp-proton.eu/
- AUTM - https://autm.net/
- LES - https://www.lesi.org/
- DESCA agreements - http://www.desca-2020.eu/
- Lambert agreements - https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit#history
- WIPO - https://www.wipo.int/portal/en/index.html

References

These have been taken up in the body of the report.

Delivery and schedule

The delivery is delayed:
The original planned delivery date of 31st December 2018 was extended to 31st March 2019 to allow time for learnings from a best practices workshop held in December 2018 to be incorporated.

Adjustments made

None