

IXA valorisation guide for medical technology



A practical handbook for healthcare professionals and researchers
at VU University Medical Center Amsterdam and Academic Medical
Center

Contents

This valorisation guide was compiled by IXA. The text is based on the knowledge and experiences of researchers, healthcare professionals and the IXA team. We wish to thank the healthcare professionals, researchers and our colleagues for their contributions to this guide.

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Pontes Medical is a valorisation approach for medical technology of VUmc, AMC and UMC Utrecht



IXA is the valorisation centre of:



Amsterdam Medical
Center of the Amsterdam
University of Applied Sciences

UNIVERSITY OF AMSTERDAM



VU University
Medical Center
Amsterdam

Innovation in medical technology	4
<i>An introduction</i>	
Where it all begins	8
<i>A clever idea, or the identification of a clinical need</i>	
The Pontes Medical approach	10
<i>Bridging the gap in medical product development</i>	
Navigating the innovation funnel	13
<i>A focused process from opportunity to market introduction</i>	
Collaboration with industry	20
<i>The key to successful innovation</i>	
Routes to the market	27
<i>A manageable approach of complex matter</i>	
A complex playing field	30
<i>The multiple stakeholders in medical technology innovation</i>	
Rules and regulations	34
<i>A plethora of rules and regulations for medical devices</i>	
How can we help you?	38

Appendices

1	Overview of different contracts	40
2	Overview of funding	43
3	Overview of patent aspects	45

Innovation in medical technology

What is valorisation? And why is it important?

The term 'valorisation' is generally used to denote the creation of societal impact and economical value from scientific knowledge. In healthcare this implies, for a large part, the development of innovative products that contribute to better healthcare, the ultimate value resting with the patient.

Better healthcare can take a number of different forms, such as innovations that enhance the quality, lead to more affordable care or contribute to patient safety. However, to have an impact, innovative concepts must be substantiated in actual products which are implemented in healthcare.

With their user-friendly measurement instrument for the quantification of spasticity, Jules Becher and Jaap Harlaar aim to revolutionise therapy in children with spasticity. Becher explains that the cause of spastic muscles can be of neurophysiological or biomechanical origin, each requiring specific therapy. By employing three different sensors the new device can pinpoint the precise cause of spastic muscle so that the most effective therapeutic approach can be applied.

"Developing a product of clinical value takes time"

According to Harlaar the development of the new device has until now taken approximately three years. "From the onset we had a clear concept of the device, but to translate that into a product of clinical value sure takes some time. It has to be convenient to apply, affordable, and comprehensible, to name the most important aspects." Becher and Harlaar realised their instrument would not find its way into clinical practice until the underlying knowledge had become commonplace. That is why they organised two European Consensus Meetings among physicians and scientists working in paediatric and adult neurorehabilitation, underpinning the diagnostic relevance of their device. The enthusiastic feedback confirmed they are on the right track.

In this brochure you will discover how to pursue new ideas and to develop your innovations into effective solutions and new products for healthcare. We hope to provide you with insight and understanding of innovation in medical technology and offer you helpful tools and assistance.

The relevance of medical technology innovation

The focus of this brochure is on innovation in medical technology used to diagnose, prevent, monitor, and treat patients. This refers to a broad range of medical devices such as diagnostic devices, surgical tools, imaging equipment, and e-health solutions.

Thanks to innovation in medical technology many people now live healthier, longer, and lead more active and independent lives than ever before. At the same time the productivity and efficiency of healthcare systems has been improved, which is crucial for providing sustainable and affordable health-care for a growing and ageing population.



Definition of "medical device" according to European Union Medical Devices Directive

'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- ▶ *diagnosis, prevention, monitoring, treatment or alleviation of disease*
- ▶ *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- ▶ *investigation, replacement or modification of the anatomy or of a physiological process,*
- ▶ *control of conception and which does not achieve its principal intended action in or on*
- ▶ *the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.*

A challenging field

The economic feasibility of new concepts and products in general is an important prerequisite for successful innovation. In medical technology the viability of innovations strongly depends on additional aspects. Healthcare innovations are subject to ethical, social and technological criteria. In addition the industry comprises many different types of stakeholders with differing needs to be taken into account, rendering this field both complex and challenging.

The IXA team is experienced in this particularly challenging field of innovation and thanks to the Pontes Medical approach we have been able to assist healthcare professionals and researchers to successfully develop and implement innovative ideas in medical technology.

By sharing our insights and information in this brochure we hope to clarify the complex matter of innovation in medical technology. Most of all we hope to encourage you to identify innovation opportunities, develop and pursue your own innovative ideas, or identify in what clinical situations innovation could create substantial value.

For whom is this guide?

This guide is for healthcare professionals and researchers at AMC and VUmc looking for practical innovation guidelines for the development of medical technology. Whether you are taking your first steps along this path or are already experienced in the field, it will help you make the most out of your knowledge whether as a healthcare professional exploiting hands-on practical experience or as a researcher employing your scientific results. The IXA team of business developers and legal experts will be more than happy to provide the necessary support.

If you would like to know how we can help, please give us a call at +31 (0)20 566 50 56 (IXA AMC) or +31 (0)20 598 99 05 (IXA VU-VUmc), send an e-mail to info@ixa.nl.

Where it all begins

A clever idea, or the identification of a clinical need

The starting point for successful innovation may be less complex than you think.

The concept of innovation is often thought to start with an ‘invention’: the brilliant insight that leads to new technologies, provides solutions to persistent problems and opens up promising business opportunities.

From our experience we know that the onset of most innovation projects is far less imaginative. The mere identification of a bottleneck in your daily work, a flaw in existing procedures or a problem never recognised before can be the starting point for successful innovation. In much the same sense the outcome of a research project does not have to be a ready-to-use invention in order for the results to provide opportunities to innovate. Innovative ideas may also arise simply from keeping an open eye for new trends in medicine and technology.



Whenever an idea, a problem, a clinical need or perhaps a potential solution pops up, an important thing to do is talk about it to a business developers at IXA.

No matter how premature or vague your concept is the sooner we hear about it, the better we can assist you with the next steps.

We apply a process, the so called Pontes Medical approach, to pass through the steps from discovery to delivery of medical devices that improve healthcare. In the following pages we will demonstrate how this approach can help you develop your idea, your invention or your research outcome into a proven, globally available, innovative medical device. The ultimate objective is to improve healthcare centered around the patient.

About three years ago orthopaedic surgeon Olivier Temmerman approached the Physics and Medical Technology (FMT) department of VUmc. He had an idea to improve the surgical chisel for removing old cementing layers during hip prosthesis revisions. It was ‘a real pearl’ according to Micha Paalman, head of the development group at FMT. “Olivier had worked out his idea quite well. We don’t see that very often.”

‘A ‘pearl’ of an idea provides unexpected business opportunities ’

Temmerman adds that although he is not the typical do-it-yourself guy he enjoys developing improvements in his working situation. “Orthopaedics also is a rather technically oriented field of medicine, that might help too.” FMT assisted Temmerman in the manufacturing of a prototype. The IXA business developer arranged for the Dutch company Van Straten Medical to assist in further development. It’s a good match, says Paalman: “The company has a strong orthopaedics portfolio.”

Temmerman is excited about the joint development although he is not very fond of handling the formal and legal aspects. “But that’s all in the game. To be honest, I hadn’t given my business case much thought, nor had I realised that there might be a substantial market for my chisel. It’s a good thing IXA, through its Pontes Medical approach, provides a framework for assessing stuff like that. I’d never been able to do this all by myself.”

The Pontes Medical approach

Bridging the gap in medical product development

Our mission as IXA is to work closely with healthcare professionals to turn innovation opportunities into new products, to validate them, and to bring them to the market. We strongly believe in a commercial approach for achieving healthcare product innovation.

The Pontes Medical approach has been successfully developed and applied by AMC, VUmc, and University Medical Center Utrecht. This methodology is IXA's proven instrument for medical technology valorisation projects at AMC and VUmc and has led to the successful market introduction of many new

products. It is employed by IXA business developers located at the VUmc and AMC hospitals to effectively explore the potential of new medical technology ideas in close cooperation with specialists, researchers and healthcare professionals.

Building the bridge

As the Latin name implies, the Pontes Medical approach lays the foundation for a proverbial bridge between specialists, researchers and healthcare professionals on the one hand and industries and investors on the other. Its characteristics are:

- ▶ market-pull perspective
- ▶ the formation of an optimal knowledge mix
- ▶ co-creation
- ▶ co-investment

The idea had been lingering for years. When Armand Girbes decided to finally pursue it, he almost instantly got a publication in the New England Journal of Medicine. The electrolarynx, which is known for its use after laryngectomy, produces vibrations that allow the intubated user to speak. As professor of intensive care medicine, Girbes understands the increasing relevance of this: "Where in earlier days we would sedate most IC patients, we now prefer to keep them awake. For intubated patients this often leads to stress since they cannot speak and thus have limited capabilities to express themselves."

'An electrolarynx for use in IC-units'

Over the last few years Girbes and coworkers have performed more research showing that the electrolarynx really improves this. He now wants to make the voice generator part of the standard equipment surrounding an IC-unit. This does however require some adjustments, in particular making it more user-friendly for IC-nurses. IXA teamed him up with the Dutch medical technology firm Relitech and now a prototype is being developed and the market explored. Girbes appreciates these efforts: "Not only do I lack experience in this field, I simply do not have the time needed to make this innovation a success. It's good to have experienced people assisting me here."



In all product development the transition from an idea to a prototype is one of the most difficult and critical phases. In this so-called Valley of Death, resources may be scarce, organisational roles not well defined and objectives often unclear. The approach we use aims to bridge the Valley of Death by appointing champions, finding the right business partners and employing a dedicated formal development process that is specifically tuned to the needs of medical technology transfer.

Establishing feasibility

At the heart of the approach lies the establishment of feasibility for all relevant criteria:

- ▶ **Clinical:** Is there a clinical need? Is the product clinically effective?
- ▶ **Economical:** Is the market size sufficient? Is there an effective business model?
- ▶ **Technical:** Can the concept be realised technically and in a user friendly fashion?
- ▶ **Organisational:** Which companies are willing to cooperate and co-create? Can satisfactory collaboration agreements be reached covering, amongst others, investments and Intellectual Property?

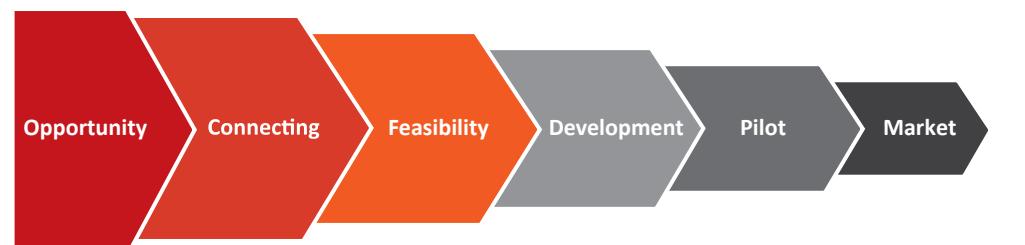
The process that addresses all these issues in the right timeframe and with the right partners is known as the *Pontes Medical innovation funnel*. It is explained in the following pages.

Projects that successfully run all the way through the funnel have the best outlook on becoming successful innovations. The ultimate value of these innovations lies with the patients, contributing to more effective and efficient healthcare. At the same time successful innovation results in a boost to both the participating companies (profit), the inventors (royalties) and the care providers (better healthcare, visible valorisation, new research funding, publications and royalties).

Navigating the innovation funnel

A focused process from opportunity to market introduction

The Pontes Medical innovation funnel structures the valorisation process into well-defined phases with clear Go/No Go moments in a focused process from opportunity to roll-out.



• Problem scouting	• Articulation of demand	• Business case	• User research	• Making a null series	• Determine the distribution
• Idea generation	• Stakeholder analysis	• Commercialisation strategy	• Marketing plan	• Clinical effectiveness testing	• Out-licensing / founding a company
• Screening	• Novelty search, IP strategy	• Reimbursement development	• Health technology assessment	• Drafting a technical file	• Acquiring certification
	• Intended use and requirements, brainstorm session	• Market research, literature & patent search	• Formation of business cluster		• Setting up production
	• Partner search	• Proof of Concept			• Implementation

The phases of the innovation funnel explained

Opportunity phase

The fundamental approach of Pontes Medical method is demand-driven and needs-based. From the outset the development of a new product has to meet a clinical need.

It must therefore be established that the proposed innovation will actually lead to an improvement in healthcare. In addition, in this phase the opportunity is broadly classified along such lines as:

- ▶ Is it a medical device?
- ▶ Does it offer a solution for an unsolved problem?
- ▶ Is it an improvement of the diagnosis or the treatment of patients?
- ▶ Is it interesting from a commercial point of view?
- ▶ Do you need external partners?

The IXA business developers assess these aspects together with the healthcare professional or researcher responsible for the idea, clinical need or invention. The wide IXA business network combined with the dedicated Pontes Medical network of experienced healthcare and industry professionals provides a sound base for this assessment. It is crucial that healthcare professionals commit to further development in this phase. At this stage the so-called *invention disclosure form*, describing the invention or idea, is drafted.

This phase leads to a go or no-go decision by both the healthcare professionals and the IXA business developers.

Connecting phase

This is the phase where medical experience, technical expertise and entrepreneurial skills come together in a team consisting of specialists, healthcare professionals, developers, scientists, manufacturers and business representatives. The IXA Business developers identify the required knowledge and technology, approach the right people and involve them in the project.

To be able to do this effectively they maintain a strong network of Dutch Small and Medium Enterprises (SMEs) in medical technology. Long experience has shown that these companies are very interested in cooperating with knowledge institutes and university hospitals to commercialize new products.

Often brainstorm sessions are organised with the experts to get a better idea of the possible technical solutions answering a clinical need, or to identify

how an invention may be turned into a product. In some cases these may already lead to experimental tests.

At this stage the invention disclosure form is agreed upon. Confidentiality agreements are made between parties. Although in this phase there is uncertainty as to the final direction of the development, orientation does take place. The development team, type of collaboration and Intellectual Property (IP) requirements start to take shape. In appendix 1 different types of agreements are explained.

Finally, in this phase market research is performed to establish:

- ▶ the needs and desires of (potential) customers
- ▶ what the predominant market trends are
- ▶ an analysis of all stakeholders (to define product requirements in a later phase)
- ▶ who the main competitors are
- ▶ which comparable products and/or services are already available
- ▶ the differences in price and performance of these competing products

The end results of this phase will be a collaboration agreement, or having a more clear idea on the opportunity and perhaps even some ideas on the potential technical solution.

Feasibility phase

In this phase the formal cooperation with one or more companies or other external parties starts. The IXA business developers have extensive experience in setting up collaboration agreements for this. A *functional prototype* will be developed jointly to provide *proof of concept*. This defines the intended use and user and creates a clear technical and medical focus. If external funding is required for this phase, then several possibilities may be explored, such as grants or investment funds. The business developers at IXA can choose the right type of financing and assist in the application process. Also, IXA can provide Proof of Concept (PoC) or PreSeed funding which offers researchers from the Amsterdam knowledge institutes as well as external entrepreneurs an opportunity to carry out technical and/or commercial feasibility studies on their concepts, inventions or ideas.

In this phase, if appropriate, protection for Intellectual Property (IP) is applied for, for example filing patent applications, or availing of copyright protection. A prototype is often required for patent application in medical technology. So in the first phases, we rely on the confidentiality of all team members. The aspects involved in patenting are described in appendix 3.

It is also important to decide on future revenues. According to Dutch law all inventions by employees of a knowledge institute are the property of their employer, in this case, AMC or VUmc. However, hospitals and universities have regulations which grant a share of future revenues from the exploitation of IP rights to the inventors.

More details on these regulations can be found at www.ixa.nl/en/for-scientists/patents/ipvalorisation-regulations.

Last but not least in this phase the project team decides on the most appropriate business model. IXA has multiple tools to assist in this process. Added to this are a regulatory strategy and an R&D strategy.



The feasibility phase results in the testing of some functional prototypes for clinical feasibility, a regulatory strategy as well as a research & development and business strategy. We take a moment to make the go or no-go decision based on technical and economic feasibility.

Development phase

In the development phase the concept is further developed into a prototype (often called a 'demonstrator') that can be used in pilot studies to determine the clinical usability. A user-friendly design is crucial for the acceptance and implementation of the product. User research therefore often forms part of this development phase, and external parties with expertise in product design are regularly involved in the project.

Also product and user requirements are listed. In the development phase a so called 'technical file' is built, describing the components of the product and the risks involved in using the product, to comply with regulations for the use of medical devices.

These are exciting times for Dave Koolbergen, congenital cardiac surgeon at AMC. With his company Haermonics he hopes to bring a new technology to market for postoperative pericardial flushing. It was developed upon his observation that after heart surgery often the removal of accumulated blood and clots can be achieved by flushing the pericardial space with a warm saline solution. Koolbergen's continuous postoperative pericardial flushing (CPPF) can save lives by achieving a strong reduction in postoperative bleeding and bleeding related complications, such as a life-threatening acute cardiac tamponade.

'Improve draining after heart surgery can save lives'

Koolbergen is a veteran innovator - the CPPF method is not his first invention. In this case he decided, with helpful guidance by the IXA business developers, to bring his idea to market with Haermonics as a spin-off company. "Not only was this a business decision, for me it's important to keep control of the realisation of my idea. I have not really considered finding a company to assist in further development." He does admit that being Chief Medical Officer for Haermonics is quite a new experience. "It's a lot of work which now and then interferes with my duties as cardiac surgeon. On the other hand there's also lots of synergy, in running clinical trials and heading research projects."

Pilot phase

In this phase the product is almost fully developed. A small testing series is produced for validation research, sometimes performed in cooperation with clinicians in several other hospitals. This will not only establish clinical relevance or technical reliability but also yield user feedback to be incorporated in the final version of the product.

In the meantime the manufacturing is geared up for the production of the first series, a distribution network is set up and a marketing strategy is established to introduce the product to its potential end users. The party selling the product, be it a start-up company or an existing company, will have to agree on a licence with the IP owner(s), often the universities. Negotiating this licence is one of the expertises of the IXA business developers.

In appendix 1 a license is explained.

Sometimes, if relevant, the European conformity (CE) marking can already be applied for in this phase. However this can also be performed in the next step of the process. An introduction to applicable regulations can be found in on page 34.

An important regulatory aspect in this phase is that clinical research with medical devices falling within the scope of the *Wet Mensgebonden Onderzoek* (WMO) must be reviewed by an accredited "Medisch Ethische Toetsingscommissie" (METC) based on the Medical Research Involving Human Subjects Act. Furthermore the devices used for the clinical tests have to be admitted to the hospital; all medical equipment has to be registered to minimise the risk to employees and patients.

The result of this phase is a report with findings of the clinical evaluation. We also look at the validation of the business case and implementation hurdles that need to be taken.

Market phase

To commercialise a device there are basically two routes: the first route is that a licence is agreed upon between VUmc/AMC and the company. The second route, which depends on the idea, invention or research results at hand, may be founding a company for further development and/or commercialising of know-how and/or intellectual property rights. Together with the business developers at IXA you evaluate the pros and cons of this route. At this point the role of VUmc or AMC often gets smaller in the project, as the business partner is responsible for the production, CE approval and market introduction.

In this final phase the new product is launched on the market by the business partner. Its implementation will often be promoted by presenting the validation results at scientific conferences and executing the marketing strategy.

Manufacturing and distribution will become operational in this phase and after sales service will be developed. The clinical use of the product by the customers will be evaluated. Depending on the success, the product could be further developed into a second version. Also plans can be developed to expand into new markets, either through the extension of production and sales or through licensing the technology to international partners.

Implementation of medical technology in mainstream healthcare is complex. Since the healthcare industry consists of many different stakeholders this often leads to contradicting needs regarding innovations. Moreover the adoption of innovations is influenced by strict regulations, and can be hampered by the need to alter the behaviour and practices of clinicians and healthcare organizations. Generally speaking, the healthcare market is fragmented, conservative and focused on proven technology. By following the Pontes Medical method we aim to identify clinical, regulatory, technical, financial, and implementation hurdles and to successfully counter them.

Collaboration with industry

The key to successful innovation

Turning an idea or a scientific result into a practical solution always requires co-creation between several different parties with different expertise, skills and facilities. Our approach is strongly dependent on collaboration with industry companies, in particular small and medium-sized enterprises (SME's).

Co-creation

The essence of co-creation is that all participants commit and contribute equally to the initiative and its result. Distinctive aspects of co-creation are dialogue, common ground, enthusiasm, vigour, and focus on results.

At the Academic Medical Centre Arthur Kievit has developed a method for diagnosing prosthetic loosening of Total Knee Replacements (TKR) in a direct manner. The orthopaedic surgeon in training designed a device that enables the application of a constant force to the knee while recording a CT-scan. With the use of dedicated software the condition of the bone-prosthesis interface can subsequently be evaluated. Kievit's method improves the diagnosis of TKR loosening which is currently costly, time consuming and has a risk of a false positive result. He realised that this also implied a business opportunity, which he explored during AMC's Graduate Course 'Entrepreneurship in the Life Sciences'. His case stood out and yielded him participation at a training day of IXA Pontes Medical, where he won a development award.

'Extensive media coverage and a positive impact on my academic development'

He now hopes to demonstrate the clinical relevance in a study in seven hospitals, funded by a valorisation grant from NGI/ZonMW, the Netherlands Organisation for Health Research and Development. With the establishment of his spin-off firm Comforthod, Kievit hopes to pursue other projects as well: "I like to bridging the gap between clinic and business", he says. 'Providing a solution for everyday clinical problems is satisfying in itself, but turning it into business means you're really giving it relevance.'

Making co-creation a success requires equivalency, reciprocity, openness, trust and integrity. IXA caters for these conditions by bringing together the right partners and providing a creative, safeguarded and open environment for exchange of information and development of novel ideas for mutual benefit.

This ensures that both the university and the business partner invest in terms of time, knowledge and money, and that they both benefit from this. The business community brings expertise in design, manufacturing and distribution, and can offer support to end users. The university or the hospital provides the starting idea and the medical expertise, and can facilitate an environment of trust.



The benefits of successful business collaboration

There are multiple benefits to both partners in a successful business match, establishing a fruitful co-creation process. To name a few important ones:

For healthcare institutes and universities:

- ▶ Creating societal impact
- ▶ Creation of business opportunities
- ▶ Contribution to economic development
- ▶ Training and employment opportunities for students
- ▶ Enhancement of university's reputation and innovative image
- ▶ Access to new technologies
- ▶ Initiate new clinical and scientific research
- ▶ Source of revenue

For companies:

- ▶ Access to clinicians and their needs
- ▶ New or improved products and/or processes
- ▶ Clinical and scientific research
- ▶ Improved competitiveness
- ▶ Access to new knowledge and leading edge technologies
- ▶ Product testing with independent credibility in testing
- ▶ Connection with key opinion leaders
- ▶ Launching customers

There are a number of issues to be addressed in this public-private collaboration structure. Academic research must maintain its independence and not in any way be biased by other interests. Fundamental and applied research

themes need to be in balance. Freedom to publish and for PhD applicants to defend their theses must be safeguarded. Confidentiality agreements and embargo periods to enable patenting before publication should not interfere with the academic research process. These are challenges for which university technology transfer offices like IXA exist to provide solutions.

Finding the right partner

Connecting the medical and business communities is not always straightforward. To help you find the right business partner the IXA business developers maintain a tried-and-tested approach in which five stages are identified, all with their essential steps:

Stage 1 Partnership Identification

- Establish the purpose
- Obtain general knowledge of the capabilities of potential partners
- Consider pre-existent relationships

Stage 2 Make contact

- ▶ Contact potential partners
- ▶ Identify prospective partners
- ▶ Establish Confidentiality Disclosure Agreements if required

Stage 3 Partner assessment and selection

- ▶ Objectively assess the strategic interests of the prospective partners
- ▶ Analyse actual versus professed capabilities of prospective partners
- ▶ Determine and organise the appropriate mix of partners
- ▶ Choose the partners

Stage 4 Partnership negotiation

- ▶ Define the partnership
- ▶ Define and agree on the partnership's documented purpose or mission/vision
- ▶ Determine the specific common goals/objectives for the particular effort
- ▶ Define the organisational structure of the partnership
- ▶ Define the management and administration of the partnership with clearly defined responsibilities
- ▶ Agree on the plan
- ▶ Specify the milestones
- ▶ Identify the measures/indicators for success
- ▶ Specify the interim and/or final deliverables

Stage 5 Agreement signing

- ▶ Preparation and signing of collaboration agreement and/or intellectual property agreement

Negotiating an agreement

Negotiating an agreement that suits the interests of all parties involved can be particularly challenging. Especially when commercial parties are involved, it is key to prepare thoroughly for discussions and negotiations. IXA business developers assist you during these negotiations and safeguard the institute's and the researcher's interests. They strive towards a deal that is reasonable for all parties concerned (the researcher, his/her research group, the institute AND the business partner), taking into account not only the financial aspects, but also the mission of the university, which is to bring the technology to the benefit of the patient/society

IXA has solid experience in closing collaboration and consortium agreements as well as other types of contracts. We make sure the financial aspects, intellectual property (IP) aspects and other legal aspects of the contract are fully compliant with the hospital and university policies and guidelines.

The following contracts are most often negotiated and agreed upon. More information on the details of each agreement can be found in appendix 1.

- ▶ Collaboration Agreement
- ▶ Research Collaborations
- ▶ Confidentiality Disclosure Agreement (CDA)
- ▶ Licensing agreement

Responsibilities of the different partners

Different parties bring in different type of expertise. Figure 3 visualises type of expertise the different parties bring, and what they are responsible for.





Apply existing eye-tracking technology for the development of a state-of-the-art digital instrument for orthoptic strabismus measurements. This clever idea by physicist Bob van Dijk is now nearly a reality with Laméris Ootech, a Dutch supplier of orthoptic practice equipment. In his office at VUmc Van Dijk proudly demonstrates his almost perfectly functioning prototype. "A few minor tweaks, a slick design and it's ready for use".

'A few minor tweaks, a slick design and it's ready for use'

According to orthoptist Jacqueline Krijnen, closely involved with the development, the new instrument offers a major step forward in strabismus measurement. Currently a variety of simple handheld devices are used, their relative inaccuracy being the most important factor for the high rate of repeated surgeries in strabismus correction. Krijnen expects the new instrument to significantly improve the surgery results, especially with children who lack the peace and focus required for accurate measurement using the current devices. For Krijnen and Van Dijk the secret to success lies in the close cooperation between technician, clinician and the company involved. For them the contribution of the IXA business developers in initiating and guiding this cooperation has been crucial. Van Dijk: "I'm an inventor, not an entrepreneur or marketeer." Krijnen: "I really enjoyed the cooperation. I can't wait to see Bob's idea becoming clinically relevant."

Routes to the market

A manageable approach of complex matter

There are multiple strategies to bring an innovation to market. In the complex healthcare environment it is important to distinguish the most relevant parties and determine how to convince them of the value of your innovation. In the development process the IXA business developers will have already involved both the health stakeholders and the market stakeholders, and where needed the regulatory stakeholders. In the implementation phase the focus on these groups will be strengthened.

Further on in this brochure we will focus more in depth on these stakeholders. Here we present a manageable approach for the implementation of your innovation by distinguishing four *routes to market*. The IXA business developers can assist you following the route that will increase your chances of successfully bringing your innovation to market.

The consumer route

This route is applicable if the innovation can be sold directly to consumers. This is usually the case with innovations focusing on wellness, health management, or devices for convenience and comfort. This route will also become increasingly important for medical technology innovations of which the clinical or economic benefits are not being recognised by health insurance companies and therefore not reimbursed. Patients and healthcare providers can independently choose to purchase these technologies. It does however imply that there are no other stakeholders that can support the financing, promotion and distribution of the product.

The provider route

This is the route to be taken if the innovation provides immediate benefit to healthcare providers. For example because it enhances the efficiency of care, creates a competitive advantage or underpins a desired corporate image. To arouse the providers' interest it is important to demonstrate that the innovation meets their needs and provides financial benefits. In other cases, healthcare providers can be interested in implementing new technologies in so-called 'diagnosis-related groups', to save spending within this reimbursed group.

The insurer route

Here it is important that the innovation provides a cost-effective alternative for existing care, enhances health benefits or provides other advantages to health insurers. If insurance companies are interested, they can provide financial means to aid further development or implementation of the innovation.

The government route

This applies to innovations that lead to new healthcare that is not yet provided for or not yet reimbursed. These innovations could for instance change the nature of healthcare or provide new care that was previously non-existent. To be able to put your innovation successful in the market, it is important that it wins its place within the financing and funding of healthcare.

Iwan Dobbe is bringing the benefits of modern 3D image analysis and printing technology to the clinic. As a researcher at the Biomedical Engineering and Physics department at AMC he devised a method for the design and production of a patient-specific plate for the alignment of bone segments. It requires a single CT scan, preoperative 3D planning, and 3D printing of a titanium positioning and fixation plate. As a result surgeons are able to accurately position bone segments while avoiding the use of intraoperative navigation equipment for the complicated task of 3D repositioning.

'More effective surgery through improved alignment of bone segments'

The IXA business developers provided Dobbe with valuable support, amongst others regarding the decision whether or not to apply for a patent.

"Assessing the financial viability of the patenting process is quite hard to figure out for yourself", he says. Patenting seemed worth it, even though Dobbe's patient-specific plate is more expensive than plates currently used. "We expect that health insurance companies will be persuaded to compensate when we demonstrate the cost reduction of the overall procedure." To this end Dobbe recently started a validation project among 50 patients. He expects the outcome to be satisfying: "Faster surgical procedures, less malalignment associated problems and overall more effective revalidation. That's what we want to bring to the clinic."



A complex playing field

The multiple stakeholders in medical technology innovation

Many different stakeholders are involved in the development, validation and implementation of medical devices. To start from an idea and then take your innovation all the way to market success requires that all these key stakeholders are timely involved and that all their wishes and requirements are taken into account.

The Pontes Medical approach allows for this in all the distinctive phases of its innovation funnel. This chapter aims to provide a clear and practical overview of this complex playing field.

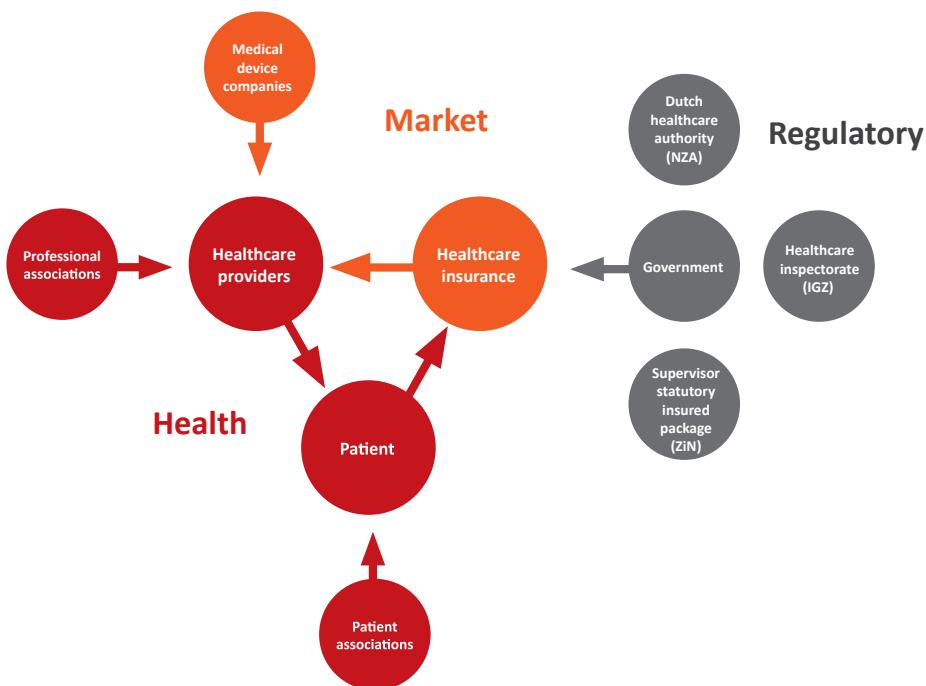


Figure 4 shows the different stakeholders and role in usage and development of medical devices. Central is the triangle between the prime stakeholders: **patients** (paying insurance fees and receiving care), **healthcare providers** (providing the care) and **health insurance companies** (purchasing the care). Surrounding these are interest groups such as associations of patients and healthcare professionals. Last but not least the governmental regulatory bodies are main players in the field, providing regulations and ensuring affordability.

Health stakeholders

Patients and healthcare providers all want the best care but changing methods and using new technologies can be met with apprehension, which can profoundly hamper the introduction of new medical technology. Involving patients and healthcare professionals in the early stages of definition and development of new devices will increase the likelihood of successful implementation.

Market stakeholders

This involves on one side the manufacturers, suppliers, vendors and distributors involved in the supply chain. On the other side it includes providers and health insurance companies respectively buying and reimbursing medical technology.

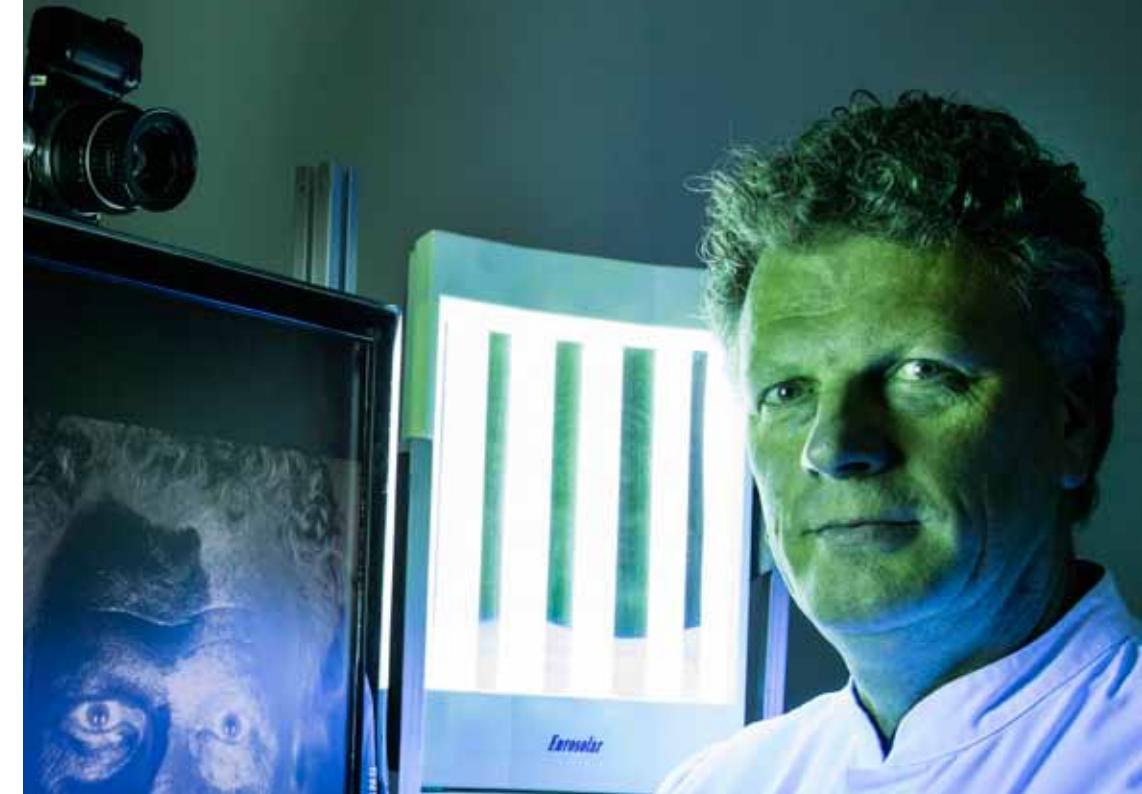
The underlying driver for implementation is providing the best possible care for the lowest possible price. Insurance companies will be interested in new medical technology if it reduces costs and improves quality, efficiency and/or safety. There should be always a balance between added benefit and extra costs; a less advanced but cheaper device performing equivalent to existing devices can be acceptable. A health technology assessment can be an important tool in market acceptance, determining the cost-efficiency versus clinical benefits.

It is important to note that innovation in medical devices should not be pursued from a technology perspective only. Technological feasibility does *not* necessarily imply a solution to a clinical problem. New medical technology should therefore be developed from a market-pull perspective. This enables entry into successful innovation routes and increases the chances of actual implementation.

Regulatory stakeholders

Regulatory stakeholders are of crucial importance to bring new medical technology to market. In the Netherlands the government has established three regulatory bodies in healthcare that are relevant to the long-term implementation of medical innovations:

- ▶ The National Health Care Institute (Zorginstituut Nederland, ZiN) determines and advises on the healthcare included in the basic health insurance package. ZiN also determines the patient's yearly budget for different types of healthcare.
- ▶ The Dutch Healthcare Authority (Nederlandse Zorgautoriteit, NZa) protects the interests of citizens with regard to accessibility, affordability, and quality of health care in the Netherlands. The NZa sets the tariffs and the treatment descriptions in the health care market and regulates healthcare providers and health insurers.
- ▶ The Health Care Inspectorate (Inspectie voor de Gezondheidszorg, IGZ) enforces the quality of health services, prevention measures and medical products, to ensure that healthcare providers offer only 'responsible' care. IGZ designates Notified Bodies who observe that manufacturers introducing a medical device to the market meet all legal requirements. In addition, IGZ takes action in the event of a breach of these requirements and evaluates notifications about malfunctioning and quality issues of medical devices. Clinical investigations involving (new) medical devices are also supervised over compliance with this legislation by IGZ, and require almost always notification to IGZ.



By request of the dermatologists at VUmc, Ruud Verdaasdonk has developed a 'UV-mirror'. It enables people to see whether UV-light has damaged their skin and helps them to assess their sunscreen application skills. "The mirror is a very effective instrument for education and prevention purposes", says Verdaasdonk, who is not only professor of Biophotonics and Medical Imaging but also heads the department of Physics and Medical Technology at VUmc. He developed the mirror by tweaking an existing digital camera and combining this with a safe UV light source. Showing the camera image on a regular flat screen computer monitor effectively results in a digital UV-mirror.

'My advice: find a business partner as soon as possible'

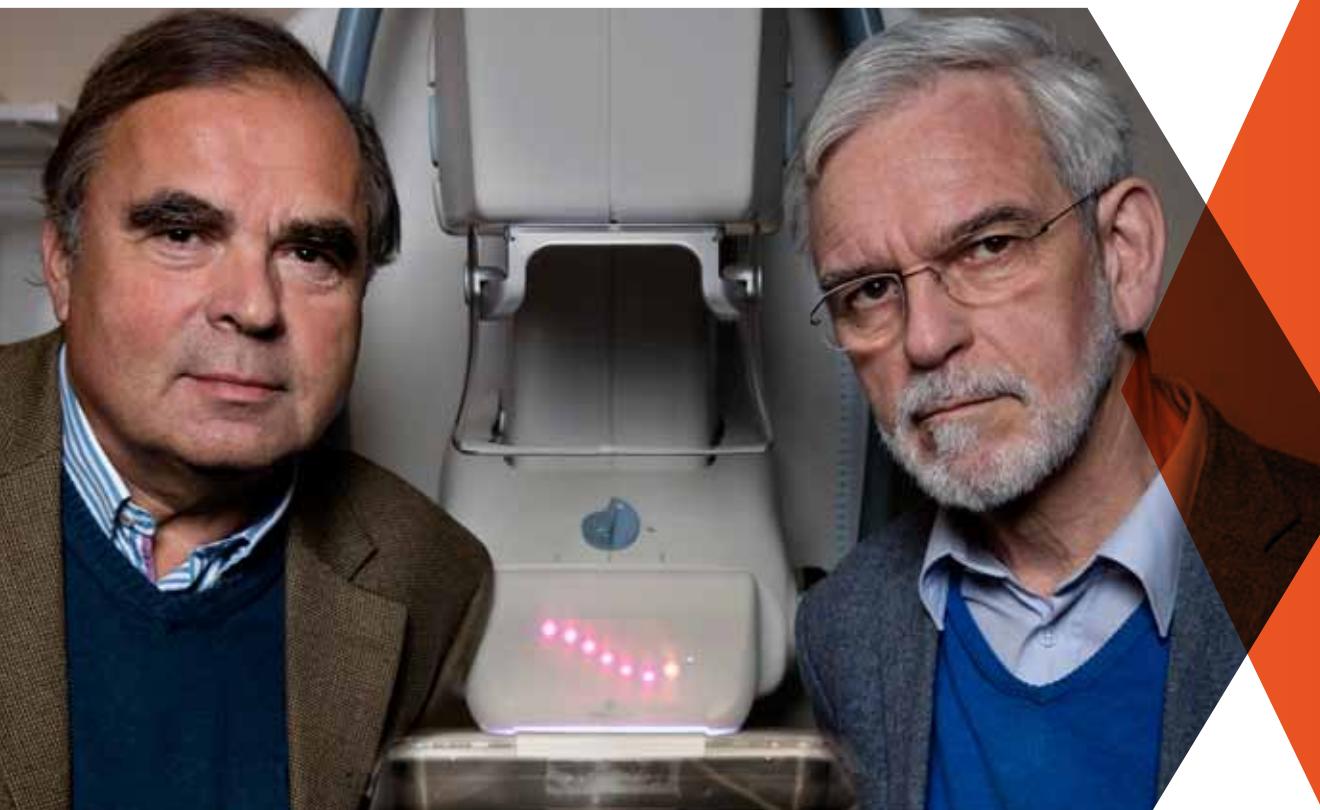
The set-up already generated lots of attention at public awareness events to which the VUmc hospital contributed. This spawned the idea to develop an integrated system for general use, for instance at beaches and in drugstores and pharmacies. Verdaasdonk is now pursuing product development in co-operation with an SME company. "Find a business partner as soon as possible, make a satisfying Intellectual Property agreement, and license the technology. That's the fastest way to make your idea a reality", is his advice.

Rules and regulations

A plethora of rules and regulations for medical devices

In bringing medical technology to market many rules and regulations apply. The main legislation is imposed by the European Union, other legislation is drafted nationally, and adding to this hospitals have their own regulations. Some legislation applies in the development phase and other, like the requirement for CE marking, is effective when the product is used by or sold to third parties.

The IXA business developers will guide you in navigating through the daunting regulatory environment of medical technology innovation. It would be difficult to try to inform you of all details here, we therefore provide you with a general introduction to medical devices legislation.



Medical Device Regulation

Dutch regulations regarding medical devices are governed by the European regulations. Currently the European Medical Device Regulation (MDR) is being implemented, integrating all previously existing directives (in particular the Medical Device Directive; the Active Implantable Medical Device Directive; and the In Vitro Diagnostic Medical Device Directive). The MDR will come into effect late 2019 or early 2020, regulating medical devices ranging from home-use items such as sticking plasters, pregnancy tests and contact lenses, to X-ray machines, pacemakers, breast implants, hip replacements and HIV blood tests.

When Ard den Heeten, professor of Radiology teamed up with his AMC colleague Kees Grimbergen, professor of Medical Technology, a new approach to mammography was born. It has been developed upon Grimbergen's observation of a serious flaw in the current mammogram procedure: the establishment of a standard force of the so-called "paddle" compressing the breasts. "Applying the same force throughout means that the experience greatly varies among differently proportioned women", says Grimbergen. "The smaller their breasts, the larger the exerted pressure. Not force, but pressure should be the relevant parameter here." Den Heeten explains that the varying pressure among patients also implies that mammograms currently are not obtained under comparable, standard conditions. "This impedes comparative scientific research."

'Less pain, more scientific value'

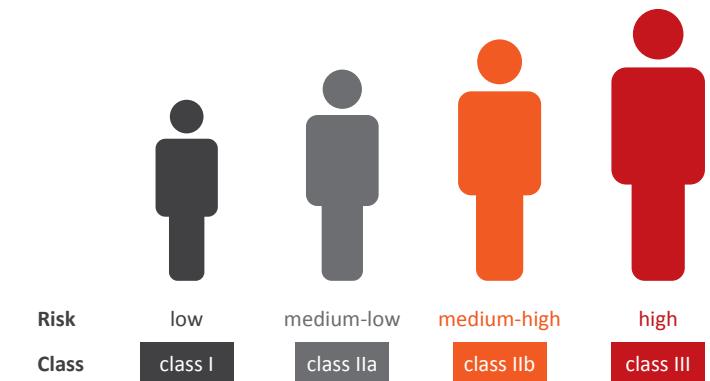
The new Sensitive Sigma Paddle, developed by the two professors and co-workers, changes all that. It features capacitive sensors measuring the breast's contact surface, so that a 75 mmHg compression pressure can be maintained for breasts of all sizes. Its "retrofit" design fits with all major mammography apparatus and to ensure brand independent, maximum availability, AMC spin-off company Sigmascreening was founded. Clinical studies in ten hospitals are now underway, the first device has been sold, and - if all goes well - within a few years the new minimal force mammography will be widely available.

Medical Device classification

Medical devices in the European Union are divided in four classes, ranging from low risk to high risk. The classification depends on rules that involve the medical device's duration of body contact, invasive character, use of an energy source, effect on the central circulation or nervous system, diagnostic impact, or incorporation of a medicinal product.

To obtain market access (i.e. a CE mark) a decision from the relevant authorities is required, which depends on compliance with the regulations. The higher the risk, the more requirements with regard to safety, performance and clinical evaluation, see below figure for the four different risk classifications. For lower risk devices, clinical evaluation may depend on the literature or existing data; for higher risk devices clinical investigations are required.

Risk classification of medical device



AMC clinical physiologist Peter Sterk's idea to explore the use of e-nose technology for diagnosis of lung disease has really payed off. His brand-new 'SpiroNose' breath analyser will shortly become available for hospitals and general practices. Sterk is confident about the clinical validation studies that are now underway: "The SpiroNose will be a formidable addition to the diagnosis of asthma, COPD, lung cancer and other pulmonary diseases. It offers a fast and reliable first assessment, even without testing blood or sputum. Since we integrated it with common spirometry, it comes without any additional effort for the patient." With the aid of IXA the SpiroNose was developed in cooperation with the Dutch specialist e-nose firm Comon Invent.

'Fast and reliable diagnosis of lung disease with the SpiroNose'

With multiple sensors it profiles a few thousand molecules in the patient's exhaled air. These data are then analysed in real-time by comparing them with thousands of other profiles stored online in a 'BreathCloud', employing Artificial Intelligence based self-learning algorithms. Although he did not foresee all this at the onset of his research, Sterk was more than happy to put a lot of effort in developing the SpiroNose. "That's how it goes: an idea leads to a research project for which an instrumental set-up is needed. In fact there you already have the germination of a new product. Because if the research leads to clinically relevant results, of course you then want to make the set-up available for as much doctors as possible!"



How can we help you?

At IXA we can support you with the valorisation of your scientific knowledge in various ways. These include:

- ▶ Working together to develop your valorisation case, from idea to product or service.
- ▶ Examining other possibilities to utilise scientific knowledge or technology.
- ▶ Carrying out joint network, stakeholder, and market analyses and project plans, preparing budgets and collaboration agreements, conducting negotiations on your behalf, and establishing partnerships or consortia.
- ▶ Brainstorming with you on how to incorporate all of this into your research group or faculty.

Do you want to know exactly how we can be of assistance and how to obtain such assistance? Give us a call at +31 (0)20 566 50 56 (IXA AMC) or +31 (0)20 598 99 05 (IXA VU-VUmc) or send an e-mail to info@ixa.nl.

Appendix 1

Overview of different contracts

Research collaboration and Contract research

A large part of the academic research takes place in the context of a research consortium in which companies, universities, research institutes and/or societal organisations participate. Examples are public private partnerships (PPPs) or EU-funded collaborations through the Framework Programmes. In such collaborative endeavours, the costs of research are only partially covered by the funding instruments (subsidies, research grants). The participants each invest ('match') from their own resources.

That is why at the start of such a collaboration, it is very important to formalise agreements on property and exploitation rights that may stem from the research results. The work performed in collaboration with the external parties may result in the development of knowledge and/or intellectual property rights. IXA negotiate on behalf of their institutes and researchers an agreement which reflects a fair arrangement with respect to the research that is performed and the compensation that is paid for it. The legal counsels can assist you in this process. They will where needed liaise with the legal counsel of the external party and guide you through the clauses of the agreement.

Contract research: a form of collaboration with the private sector in which research facilities are made available. This may be the case, for example, in clinical trials (patient-based research) for a pharmaceutical company.

Confidentiality Agreement

Open discussions are key to any successful collaboration. To protect the rights of each partner, it is strongly advised to sign a confidentiality agreement before the discussions start. Then information can be exchanged freely to determine whether a formal collaboration is indeed possible and useful. If this is the case, the next step is to draw up a collaboration agreement.

Confidentiality agreements are also referred to as non-disclosure agreements (NDA) or confidential disclosure agreements (CDA).

License agreement and Joint Ownership agreement

In essence, license agreements cover the rights to third parties or spin-off companies to use certain know-how or intellectual property rights.

If it is clear that an IXA Institute owns certain intellectual property rights, such as patents or copyrights, a license can be granted to another party to use the intellectual property for commercial purposes. In return, the licensee pays a compensation to the licensor, for example through royalty payments or a lump sum amount. License contracts will have to be drafted for every specific case. IXA can assist you in such drafting and in establishing the market value of the license.

If the IXA partner is not the sole owner, and/or the intellectual property rights are developed within a collaboration with other parties, it may be appropriate to agree on a joint ownership arrangement in which the rights of both parties are secured.

For example, the other owners can transfer his rights to one party in return for compensation, or all partners point out one single party (the lead) which has the task to explore commercialisation.

Please be aware that arrangements concerning licensing and the ownership of intellectual property may be part of a collaboration, or consortium agreement in some cases. IXA can help you in the negotiation process with other parties and help draw the appropriate contracts.

General information on concluding contracts

A contract is an agreement between two (or more) parties, regardless of its form. An e-mail correspondence can qualify as a binding contract, as long as an 'offer' made by one party is 'accepted' by the other party.

As a general guideline, the following subjects should be included in each contract:

- ▶ Main obligation of Parties (milestones and timing);
- ▶ Financials;
- ▶ Intellectual Property Rights;
- ▶ Liability;
- ▶ Confidentiality;
- ▶ Warranties;
- ▶ Publication and Research Rights;
- ▶ Term and early Termination;
- ▶ Choice of Law.

Appendix 2

Overview of funding

Research and development funding

There are different funding opportunities for the development of new medical devices. Below you can find a list of funding agencies.

Stichting Technologie Wetenschappen (STW)Technology (www.stw.nl)

Foundation STW realises the transfer of knowledge between the technical sciences and users. It is funded through government and NWO, with co-financing from industry. STW offers funding for technological research, valorisation projects and collaborative public-private partnerships.

RVO (www.rvo.nl)

Netherlands Enterprise Agency (Rijksdienst voor Ondernemend Nederland) encourages entrepreneurs in sustainable, agrarian, innovative and international business. The agency provides access to funding for entrepreneurs and researchers, as well as tax credit for R&D activities (WBSO).

IXA financing of valorisation (www.ixa.nl)

Proof-of-concept (POC) funding to carry out technical feasibility studies on their concept, invention or idea. A Pre-Seed loan allows start-ups to create and further build a business.

Funding is available to employees of AMC, HvA, UvA, VU, VUmc and NKI for studies conducted by the research institutes, but also for companies validating a premature idea collaborating with the affiliated Amsterdam knowledge institutes.

ZONmw Doelmatigheid (www.zonmw.nl)

ZonMw DoelmatigheidsOnderzoek funds research into the cost-effectiveness and clinical impact of new diagnostic procedures and new treatments.

Two types of research are funded:

- ▶ The efficacy of novel interventions.
- ▶ Comparing costs of existing interventions.

EU Framework Programmes

(www.ec.europa.eu/programmes/horizon2020)

Currently called Horizon 2020, the EU Research and Innovation programme with nearly €80 billion of funding available over 7 years (2014 to 2020).

EFRO – Kansen voor West II (www.kansenvoorwest2.nl)

EFRO funding aims to improve the financing of innovative technological developments, and to further commercialisation of production and sale of new product-market combinations.

Health Insurance Innovation Funds

Health Insurance companies often have Venture Funds to invest in technologies that will increase healthcare productivity by reducing healthcare costs while improving patient health.

For up to date information on funding opportunities, check with your IXA business developer and the agency websites.

Appendix 3

Overview of patent aspects

Bringing a new invention to market is normally a costly and risky process, and will not occur if a company cannot be certain that others will not be able to copy the innovation and compete against them. A patent allows a company the time to recoup the costs associated with design, development and marketing of the innovation.

Therefore, as an inventor interested in seeing your innovation be brought into the public domain it is essential that it is given the proper protection. A successfully filed patent can represent a great deal of financial and social value.

A patent

A patent is a form of intellectual property. It consists of a set of exclusive rights granted by a sovereign state to an applicant for a limited period of time in exchange for the public disclosure of an invention. It is important to realise that a patent right is not a right which allows the applicant to perform the invention, but a right to deny a third party from copying the invention.

What are the criteria for a patent?

In Europe, as well as in most other territories outside Europe, patentability is determined by novelty, industrial applicability, and inventive step:

- ▶ **Novelty:** An invention is novel if nothing identical previously existed.
How does your invention differ from what already exists?

► **Industrial applicability:** An invention is useful if it produces an effect, if the effect is the one claimed, and if the effect is desired by society, at least in principle. This criterion is considered met if an invention has at least one possible industrial use.

► **Inventive step:** Inventive step measures the degree to which an invention differs from the totality of previous knowledge, and the degree to which an invention could not have been anticipated from that knowledge. At the time it was conceived, why might your invention not have been obvious to people reasonably skilled in the field? Are there ways in which it might be an evolutionary step? What is the difference between the proposed invention and what has previously existed?

What is an invention?

Inventions include new processes, products, apparatus, compositions of matter, living organisms, or improvements to existing technology in those categories.

A process is a method of producing a useful result. A process can be an improvement on an existing system, a combination of old systems in a novel manner, or a new use of a known process. A machine is an apparatus that performs a function and produces a definite result or effect. It can range from a simple device to a complicated combination of many parts. A manufacture is an article that is produced and is useful. Compositions of matter include chemical compounds, mixtures such as drugs and, more recently, living matter.

Abstract ideas, principles, and phenomena of nature cannot be patented.

Procedure for a patent application

A patent procedure usually begins by submitting a Dutch, European or international (PCT) patent application. Within the first 12 months – the priority year – from submitting the first patent application, a new application may be submitted for another country or region on the basis of the first patent application.

Evaluating patent applications basically, two systems exist:

► The examination system allows the patent granting authority to verify whether the application intrinsically complies with several requirements such as novelty, inventive step and industrial applicability. To this purpose the patent granting authority carries out the so-called searches to determine the state of the art.

► In a so-called registration system, the patent granting authority will only verify whether the application meets the legal procedural requirements. Usually the patent granting authority does carry out searches although the outcome does not directly influence the patent granting decision.

In the Netherlands a registration system prevails. Europe and the United States apply the examination system.

The timeline is below:

Time scale (years)	Activity
0	Patent application filed in NL; any modifications of the invention must be done within 12 months of filing. This period is crucial for adding value to the patent. If details of the invention are published or in any way made public before filing, the opportunity to patent is lost.
1	Potentially updated application filed; at this stage more data can be added to the invention; PCT system
1 - 5	Patent Application published with results of novelty search

Time scale (years)	Activity
2 - 4	Patent Examiner report received, the patent lawyer working with the TTO Project Manager, the inventor(s) and the examiner negotiate and agree the Patent claims
5 - 7	Patent is granted or refused individually in each of the designated countries
4 - 20	Patent renewal fees payable annually

So always remember: **Patenting before publishing!**
Publishing and applying for patent protection are not mutually exclusive: they can be done simultaneously under the proper circumstances.

However, from the moment of a public disclosure or publication is made, patent rights are lost. Therefore, inventors are urged to use discretion, take advantage of Confidential Disclosure Agreements available from this office, and file invention disclosures with the University well in advance of presentations or publications.

Inventorship/ownership

It is important to note that, as an employee of the University or Medical Centre, you are obligated to report any discovery of interest to your manager or to IXA. Discoveries made by employees of universities and their medical centres are the legal property of the employer as follows from the Dutch Patent Act. Through internal regulations, also persons other than employees who are involved in research are bound by the same rules, such as interns and external PhD candidates.

The Universities do acknowledge the inventorship of the researchers and have developed a reward policy, laid down in the respective IP Regulations of the institute. The board of directors of the VUmc and AMC have given IXA the exclusive right and mandate to decide to apply for patents on behalf of the institute and to initiate and coordinate actions to exploit them. IXA administers the intellectual property and arranges the licenses for external partners, always in close cooperation with the researcher/inventor.

Who is an inventor?

An inventor is anyone who makes an intellectual (or original) contribution to the invention. Those who translate the concept into practice are not considered co-inventors unless they add to the original concept of the invention although, with the agreement of the inventor(s), they may share in financial benefits of the invention as laid down in the respective IP Regulations of the institute.

Initiate the patenting/licensing process

Filling in the IXA Invention Disclosure Form is the start of the patenting process. We are happy to consult with inventors before or after they complete this form. Once you submit a completed form and other requested information, we will initiate efforts to locate interested companies. These efforts may include personal contacts, mailings and presentations at trade shows. However, full participation is needed from the inventor, both in meeting with potential sponsors and licensees and in helping the patent attorney prepare and prosecute any patent applications. If you initiate the process, you should be prepared to get involved.

Publish and applying for a patent

An important element of patent law is that it is not possible to receive patent protection once details of an innovation are in the public domain. Thus publishing an article about a new product that is not yet patented, for instance, will automatically disqualify you from ever being able to protect it.

IP/Valorisation Regulations

The IP regulations of each Institute describe the rules pertaining to knowledge valorisation. Rules with respect to protection and commercialisation of knowledge and intellectual property rights. If research results in an idea/invention or some other form of commercially exploitable knowledge it must be reported to IXA. Then IXA can evaluate and decide whether to protect it through, for example, a patent filing. Subsequently the knowledge can be exploited, for instance through out-licensing to the commercial sector or by starting a spin-off company.

The IP regulations also provide clarity over the rights of the various relevant parties/stakeholders to the knowledge/invention and the potential future revenue resulting from it. In addition, the policy and rules for participation in a spin-off company are described in the IP Regulations.

In general the net income from exploitation of IP rights is divided as follows:

- ▶ 1/3 share: the inventor/ participant(s)
- ▶ 1/3 share: faculty(s)/Division(s)
- ▶ 1/3 share patent fund/ central budget

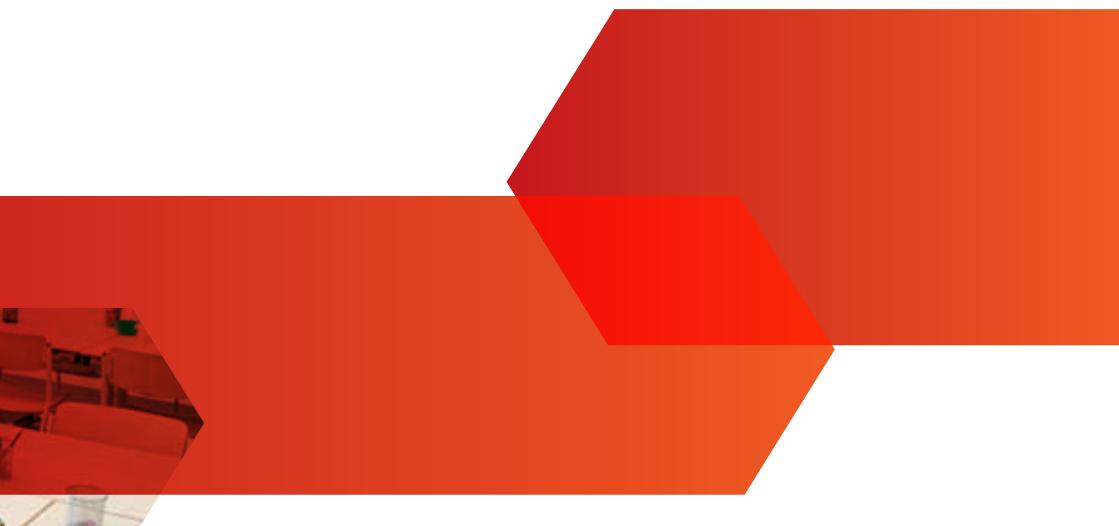
The ultimate goal of the IP Regulation is to valorise knowledge coming out of the University or Medical Centre by making it available for society through products and services. In this process of knowledge valorisation IXA can provide guidance.

More details on IP regulations per institute can be found at:
www.ixa.nl/en/for-scientists/patents/ipvalorisation-regulations.

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