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A cluster initiative:

Advanced Materials and Pharmaceutical TEChnologies (AMPTEC)

2 Mers Seas Zeeën
INTERREG IV A
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Sandrine Rousseau
Vice President for Research and Higher Education of Conseil Régional Nord Pas de Calais.

The European and regional levels of government are much closer in reality than they might appear at first sight, in particular when it comes to innovation. European programmes provide unique funding opportunities for research, development and innovation projects. In France, economic development falls within the competence of regions. The Nord Pas de Calais region is also the managing authority for the European funds allocated to the region, namely the European Regional Development Fund (ERDF) and the Interreg Programmes. That is why it seemed natural for me to sign this editorial for a publication about the dissemination of results of two previously-funded Interreg projects.

Territorial development is a common goal of the European Union and its member states' regions, taking shape in the concept of "Euro-regions". Cross-border cooperation brings together European regions from different EU countries and erases geographical frontiers in order to foster united consistent areas of scientific excellence and innovation while overcoming hurdles that are peculiar to the area about a specific topic.

Interreg projects serve the growth of territorial capital through the building of networks and the support of cooperative efforts by regions across European borders. Cluster initiatives also do this. The two converge here when Europe decides to fund geographical concentrations of excellence on a dedicated subject such as Advanced Materials and Pharmaceutical TEChnologies.

I fully support this publication, which makes the results of scientific projects funded by the Interreg programmes accessible to the citizen. Showing the citizens what Europe can do for them on a local scale and how it can contribute to the concrete improvement in the quality of their daily life is the best way to foster euro-regional citizenship. And when the fallout can benefit a much larger community of citizens from Europe and even beyond, as is the case with projects regarding the healthcare sector, it brings us closer to reaching our common goal, as set forth in the Lisbon Strategy: to become the most successful, most competitive and most knowledge-based economic area in the world.
Could we ask for more?

Sandrine Rousseau

Introduction

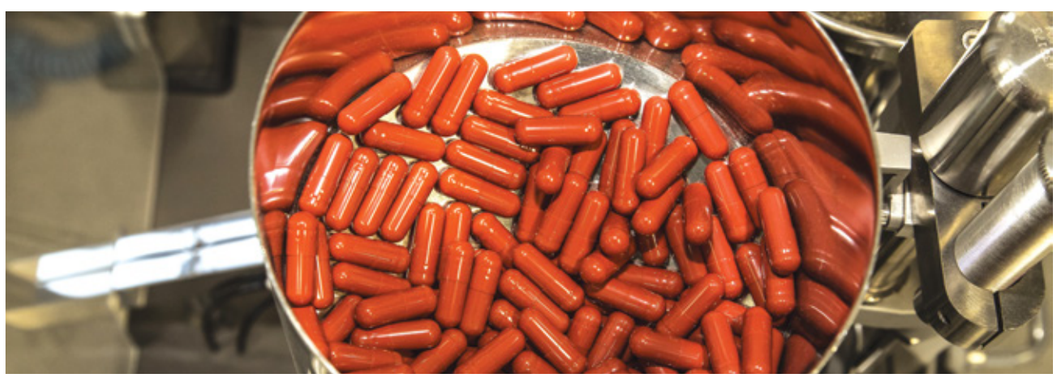
The pharmaceutical sector accounts for a total of 13 billion euros of R&D spending in the four Member States taking part in the Interreg 2 Seas Programme (Belgium, France, Netherlands, United Kingdom). It represents a market of 53 billion euros and 216,000 employees. On top of that, these four countries have a total of 40,000 students in pharmacy and 1250 hospitals. The Lille CHRU is a benchmark university hospital for primary care, teaching, innovation and research, a centre of excellence and a reference in northern Europe.

In this sector particularly, Europe has to face the fierce competition of big federated countries such as the United States of America and China. Contrary to these countries, Europe is divided into multiple nations, which represents a great source of diversity and cultural wealth but can easily become a hurdle to overcome when R&D efforts are scattered and when no common innovation strategy is defined.

Fortunately, areas of expertise and excellence exist along with specific cross-border funding schemes to break down frontiers and foster innovation. Currently, the 2 Seas area concentrates internationally recognized researchers in materials science, pharmaceutical technologies and medical devices, willing to carry out innovative projects together by joining forces and pooling their respective skills and technologies.

"AMPTEC", which stands for Advanced Materials and Pharmaceutical TEChnologies, is a cluster uniting the "IDEA" (Improving Drug Efficacy and Availability) and "Multi-DES" (Multifunctional Drug Eluting Stent) projects. It aims to consolidate and valorize their results while making them accessible to citizens.

The partners have built a unique trans-disciplinary network in the 2 Seas cross-border area in order to establish a centre of excellence that will promote the excellence of research, innovation and training in advanced materials and pharmaceutical technologies and attract companies for the development of new products, improved healthcare and higher education. This consortium, a product of European cross-border cooperation, already is and will remain a key player in furthering research, innovation and economic development in the field and positively impacting the life of European citizens.



The AMPTEC partnership, meeting in Villeneuve d'Ascq (France), May 16th 2014

CHAPITRE 1

Promoting the excellence of research, innovation and training in AMPTEC in the 2 Seas area

A cluster initiative focused on Advanced Materials and Pharmaceutical TEChnologies

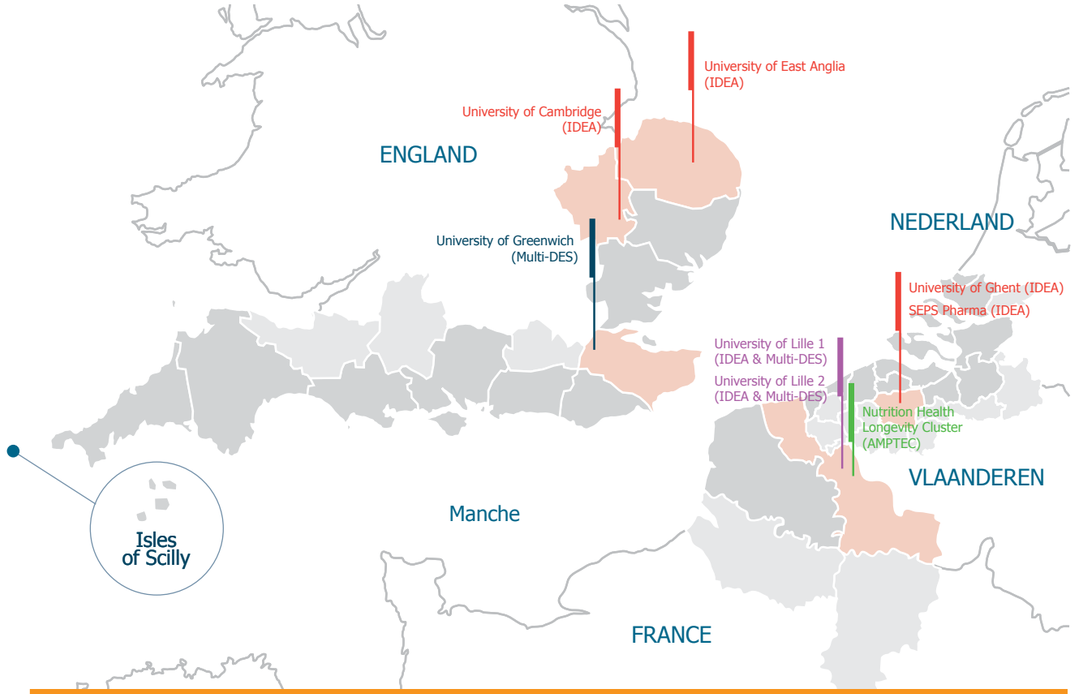
People and places. An overview of AMPTEC

"It's the geography, stupid!" Bill Clinton's famous catchphrase about the economy can easily be diverted here to best explain what gave birth to the two Interreg 2 Seas projects, IDEA (Improving Drug Efficacy and Delivery) and Multi-DES (Multifunctional Drug Eluting Stent), and what enabled their merging in the AMPTEC (Advanced Materials and Pharmaceutical TEChnologies) cluster.

These projects originate from the good fortune and opportunity of BOTH the **presence in the 2 Seas area** (see map) **of some of the world-leading researchers** in the challenging fields of materials sciences, pharmaceutics, continuous processing technologies and medical devices **AND the existence of the Interreg 2 Seas Programme "supporting innovation, research and cooperation** between universities, knowledge institutes and businesses" (priority 1-c of the Operational Programme 2007-2013).

"*The members of AMPTEC belonging to the 2 Seas area have both a shared vision of the work to be done and tailored scientific skills to complete the project successfully. It is remarkable that such skills are grouped in the same geographical area; such a project could certainly not be carried out elsewhere*", says Jean Doucet, co-founder of Novitom and associated partner of the AMPTEC cluster.

The AMPTEC consortium is composed of partners forming a multidisciplinary group with strong expertise in areas such as chemistry, pharmacy, biomaterials and biological sciences. It includes the Universities of Lille 1 and Lille 2, Cambridge, Ghent, Greenwich, East Anglia, the Nutrition Health



The AMPTEC cluster on a map

Longevity Cluster (NHL) and the Flemish SME SEPS Pharma. Several associated partners also wished to support the project: Novitom, Cristal Therapeutics, Up-Tex Cluster, Ashford & St Peter's Hospitals NHS and University College London.

Combining skills to overcome common hurdles and boost innovation: synergies between the two projects and theme of the cluster

The design of effective medicines and medical devices has been the central focus of the IDEA and Multi-DES projects. Two main themes are at the heart of both projects: the theme of material, "**advanced material**" and the theme of **bioavailability** of the active molecule, the latter being the common hurdle to be overcome by the "advanced materials" concerned. Explanations follow.

Even if they are not often thought of this way, medicines are "**advanced pharmaceutical materials**", in the sense that they are "an assembly of active pharmaceutical ingredients and excipients helping to preserve them before use and activate them where and when needed", explains Professor Marc Descamps, coordinator of IDEA. Like materials, all medicines have their own physicochemical properties which can interfere with the delivery of the active principle.

Stability and solubility are two of these properties. For a drug, "stability" refers to the capability to preserve its properties in terms of efficacy, non-toxicity, and purity until the declared expiration date. "Solubility" refers to the capacity of a chemical substance to dissolve. The degree to which a drug or other substance becomes available to the biological target after administration is called "**bioavailability**". The extent of absorption of a drug varies dramatically according to the method of administration (intravenous, oral, transmucosal, percutaneous, pulmonary, etc.). Most drugs are administered orally from the solid state. The more soluble a drug is in the body, the better its bioavailability.

Consequently, **the aim of the IDEA project was to be able to optimize the resulting concentration of a drug at its site of action**. This required overcoming major hurdles, such as poor drug solubility in water, limited permeability through biological membranes and rapid elimination out of the body. "*A medicine's stability and capacity for dissolving are two contradictory properties. We are trying to reconcile them by looking for new formulations for potentially very active pharmaceutical compounds which are unfortunately insoluble in the body in their usual crystalline forms". By manipulating the physical state of this "therapeutic material", we can make the active molecule more soluble and more available for the body in good conditions of stability, release…*" The highly interdisciplinary consortium of world-wide leading researchers in the field allowed new insights on how to better formulate a drug, for example by mixing it with appropriate compounds and using innovative preparation procedures.

The knowledge and experience obtained in this highly challenging field were extremely valuable for **the Multi-DES project, which aimed at the development of novel drug treatments minimizing the risks associated with stent implantation**. The life of patients suffering from severe heart diseases can be saved by implanting hollow metal cylinders into damaged blood vessels. These metal cylinders, also called "stents", mechanically ensure that the blood vessels stay open and provide sufficient blood flow to and from the heart tissue.

Unfortunately, the presence of these metal constructs in the human body also suffers drawbacks, namely a significant risk of uncontrolled growth of new cells causing in-stent restenosis (leading to re-closure of the blood vessels) and the formation of blood clots, which might cause serious harm in other parts of the human body (e.g., the brain). To minimize these risks, drug substances with anti-proliferative or anti-thrombotic actions can be delivered locally by embedding them in biocompatible polymeric matrices. These "**Drug-Eluting Stents (DES) are advanced implantable devices for cardiovascular applications**.

However, this type of advanced drug delivery is highly challenging and numerous obstacles need to be overcome. **Importantly, the skills, know-how and experience created by the IDEA project can effectively facilitate solving such problems and advance science in the Multi-DES project. For these reasons the two Interreg projects are highly complementary**.

It is now clear that both projects meet around the theme of **bioavailability of pharmaceutical materials**: one project aiming at improving drug solubility and bioavailability (IDEA) and the other providing the active molecules locally through a controlled re-

Multi-DES	
Title	Multifunctional Drug Eluting Stent (DES)
Total Budget	€ 869 449
ERDF	50%
Timeframe	2009/06/01 - 2013/03/31
Lead Partner	University of Greenwich
Consortium	Universities of Lille 1 and Lille 2

IDEA	
Title	Improving Drug Efficacy and Availability
Total Budget	€ 2 670 477
ERDF	50%
Timeframe	2009/06/01 - 2013/06/30
Lead Partner	University of Lille 1
Consortium	Universities of Lille 2, Cambridge, Ghent, East Anglia and the Flemish SME SEPS Pharma

AMPTEC	
Title	**Advanced Materials and Pharmaceutical TEChnologies**
Total Budget	€ 299 865 (phase 1), € 300 000 (phase 2 pending approval)
ERDF funding	100%
Timeframe	2014/01/01 - 2014/09/30 (phase 1) 2014/10/01 - 2015/06/30 (phase 2)
Lead Partner	University of Lille 1
Formal Partners	Universities of Lille 2, Cambridge, Ghent, Greenwich, East Anglia, Nutrition Health Longevity Cluster (NHL) and the Flemish SME SEPS Pharma
Associated Partners	Novitom, Cristal Therapeutics, Up-Tex Cluster, Ashford & St Peter's Hospitals NHS and University College London

lease, where they are needed: at the site of action (Multi-DES). The synergy between the two projects comes from yet another factor: **the pooling of technologies and capabilities**. Some polymer platforms (families of large molecules with versatile properties, adapted to the specific needs of the respective applications) used in Multi-DES for the local release of active molecules via a medical device could be used as excipients for medicinal products. Conversely, the innovative technologies developed by the IDEA project are extremely valuable to further optimize the advanced local drug delivery systems discovered by the Multi-DES project.

The Multi-DES project developed a new multifunctional drug eluting stent to treat cardiovascular diseases and improve the lives of patients. The IDEA project established a platform for the development of innovative drug dosage forms with better stability, efficiency and bioavailability. **The added value of the two projects when combined within the new cluster is the unique capability for the development of new pharmaceutical drug products and medical devices by using novel formulations and analytical techniques. Both projects have mobilized world-leading researchers, willing to join forces, maintain a partnership over time and pool their respective skills in materials sciences, pharmaceutics, continuous processing technologies and medical devices to establish this new cluster.**

Prof. M. Descamps (coordinator of IDEA), Prof. F. Affouard (coordinator of AMPTEC) and Dr D. Douroumis (coordinator of Multi-DES)

The cluster initiative: bringing cross-border research and innovation closer to the citizen and capitalizing for the future

"*This new cluster will help us to improve our research capabilities but most importantly to build a Research Centre of Excellence within the cross-border area*" explains Doctor Dionysios Douroumis, Coordinator of Multi-DES. All the partners have complementary skills that they can pool to tackle issues with water insoluble drugs which have, as explained earlier in this publication, a central role in the development of effective medical devices and medications.

The word cluster usually refers to the bringing together on a specific territory of three different types of activity: research, innovation and training. This definition perfectly fits the AMPTEC cluster which gathers, through all its partners, researchers, students and companies and aims at becoming a centre of excellence in the 2 Seas area in the field of advanced materials and pharmaceutical technologies. As Doctor Dionysios Douroumis points out, "*the Centre will help SMEs to develop commercial products, increase the employability of students and produce highly skilled researchers*".

Clusters are key strategic players in terms of geographical economics. "*The prevalence of clusters reveals important insights about the microeconomics of competition and the role of location in competitive advantage*," according to Michael E. Porter, famous strategic management Professor at the Harvard Business School[1]. The critical mass and excellence in a specific field can give a territory a key position and a decisive competitive advantage over other places, or even a world supremacy in the field.

"*Clearly, the joining of the forces of the IDEA and Multi-DES projects via the creation of the Interreg cluster AMPTEC offers the unique opportunity to unite clinicians, physicists, chemists, pharmacists, pharmacologists, mathematicians, materials scientists and biologists in the 2 Seas area to advance science and discover therapeutic innovations.* ***The new consortium provides the required critical mass to become a world-wide leading hub in this field of life and health sciences***", states Professor Juergen Siepmann (Director of the INSERM research group "Controlled Drug Delivery Systems and Biomaterials", who is directly at the interface of IDEA and Multi-DES, being involved in both projects).

1. "Location, Competition and Economic Development: Local Clusters in a Global Economy", Michael E. Porter, Economic Development Quarterly 14, no. 1, February 2000: 15-34.

The cluster aims at consolidating and disseminating the competency, expertise and the state-of-the-art research capacities of the cluster members of the IDEA and Multi-DES projects.
The partners have built a unique trans-disciplinary network in the cross-border area with expertise in material synthesis, advanced characterization and development of pharmaceutical/medical products. **Thus the ambition of the cluster is to consolidate the IDEA and Multi-DES partnership in order to make the 2 Seas area an attractive area for companies developing new products to improve healthcare and education**. In addition, the cluster will capitalize on the state-of-the-art equipment and expertise involving a highly diversified range of modern instrumentation in physicochemical characterization and process manufacturing to meet new challenges in pharmaceutical and medical development.

There is currently an enormous need for the development of new solid-state pharmaceutical products with improved bioavailability, efficacy, safety, and chemical and physical stability. In addition, new materials should be biodegradable, haemocompatible, non-toxic and their physical states fully characterized. It is also important to introduce new products by using novel technologies such as nanoparticles (tiny particles, invisible to the eye), solid dispersions (very fine dispersions of a drug within an ingredient), cocrystals (crystals made of two different types of molecule) and implantable devices (dosage forms, which are inserted into the human body by surgery).

"*The initiative of funding clusters to disseminate the results of previously funded projects refers to a triple helix model of innovation that we completely endorse*", says Julie Lefebvre, project manager for the Nutrition Health Longevity Cluster. According to this scheme, innovation is fostered by universities, companies and the government. Here, AMPTEC will increase cross-border collaboration between Universities and SMEs under the support of European and regional governments through the Interreg 2 Seas Programme. "*This initiative even involves a fourth helix by encouraging researchers and companies to make the results of their projects and their innovations accessible to the citizens, enabling them to understand the impact of European-funded research and innovation on their daily life*", she adds.
In fact, during the lifetime of the IDEA and Multi-DES projects, **the partners have produced significant outcomes in drug formulations, medical implants and clinical trials, as well as student training and employability**. The final aim of the AMPTEC cluster is to disseminate the results obtained and enlarge the impact to the public, research community and the crossborder area. The present publication contributes to this goal.
For this purpose the cluster partners will organize a conference in Lille with the participation of eminent scientists, under/postgraduate students, industry leaders and local authorities to communicate the scientific outcomes of the IDEA and Multi-DES projects. Furthermore, the partners will also organize training activities which will be introduced in chapter 3.

Overall, **the cluster will help the cross-border area to develop a competitive and dynamic knowledge-based economy and to unlock business potential, particularly that of SMEs**.

AMPTEC meeting, in Villeneuve d'Ascq (France), May 16th 2014

In addition to the dissemination roadmap, AMPTEC partners will conduct **a research case study in "Advanced Technologies on Manufacturing of Solid Dispersions and Cocrystals"**. This important study will be used as a platform to demonstrate the combined expertise in state-of-the-art research and development of the cluster. The in vivo and ex vivo efficiency of the drug eluting stents developed will be further evaluated. Thanks to IDEA project, some new polymer platforms will be used and tested on the stents.

CHAPITRE 2

When scientific cross-border collaboration…

Results and impact of the IDEA and Multi-DES projects

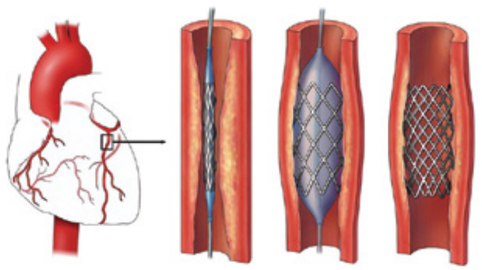
… moves research and innovation forward

Developing a Multifunctional Drug Eluting Stent (Multi-DES)

Atherosclerosis is the most common form of vascular disease and a leading cause of death and disability in the developed world, especially in France, the United Kingdom, Belgium and the Netherlands - "the 2 Seas area". It is a disease process in which fatty substances (plaques) are deposited on the inner lining of blood vessels.

To treat atherosclerosis, patients undergo coronary stent implantation after balloon angioplasty. **Drug-eluting stents (DES) are expandable slotted metal tubes acting as a scaffold to provide structural support to blood vessels and deliver biologically active agents directly to the target site to prevent restenosis** (re-closure of blood vessels). Drug-eluting stents (DES) revolutionised the field of interventional cardiology and provided a significant innovation for preventing coronary artery restenosis.

Yet, this innovation remains to be refined. A few years ago, the US Food and Drug Administration (FDA) agency expressed concerns due to the growing number of thrombogenic incidents of DES that led to increased death rates and myocardial infarction. The lack of clinical efficacy of commercial stents has shown ineffective action in preventing restenosis in several cases.



Coronary artery: insertion of a stent into a coronary artery

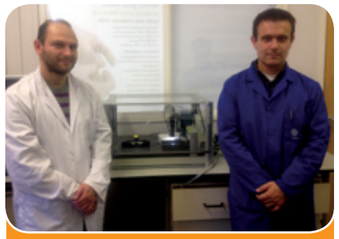
There is a **very clear need to improve the bioavailability** and efficacy of the drugs provided by stents. The Multi-DES project proposed **the development of a new drug eluting stent for the treatment of cardiovascular diseases**. This was a collaborative project between the Universities of Greenwich, Lille 1 and Lille 2.

The partners developed a new vascular stent with a coating, which allows the adsorption of one or more active substances and subsequent release over several months. The new stent is coated with a biocompatible and biodegradable polymer loaded with two different drugs in order to reduce the post-operative risk related to stent implantation simultaneously (restenosis, thrombosis, inflammation or infections).

The drug-polymer formulations are **applied with a novel coating technology known as ink-jetting** (University of Greenwich) **or by an innovative surface modification process based upon a layer-by-layer system (LbL)** (grafting or cross-linking) (University of Lille 1). Ink-jet printing is a type of computer printing that creates a digital image by ejecting small droplets of drug/polymer solutions on stent surfaces with high accuracy.

The newly-designed stents were clinically assessed in the laboratory facilities at the University of Lille 2, and **the preliminary results were very impressive**. The Intra Stent Restenosis (IRS) index was better than the two commercial stents that were used as controls. In addition, the ink-jet technology produced uniform and completely coated stents with accurate drug amounts. The selection of the appropriate drug/polymer combinations allowed the drug to be tailored at various release patterns.

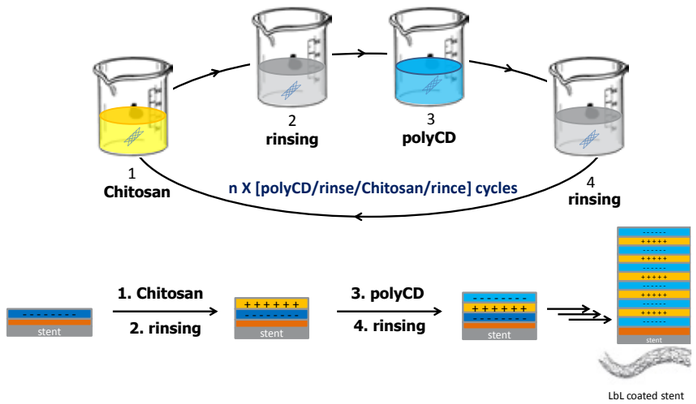
The coated polymeric materials used for development of the Multi-DES have now been fully evaluated in terms of cytotoxicity, biocompatibility and haemocompatibility. The in vitro results showed excellent performance suggesting that polymers are safe to be used for stent coating.
At present a DES loaded with two different active molecules has not been developed for the market, due to the lack of appropriate technology. In this case, the selected polymers can provide a breakthrough carrier system by simultaneously loading at least two different drugs that could act synergistically. Furthermore, the ink-jet technology provides accurate, reproducible, scalable coating with negligible drug loss.



The Greenwich team in front of the ink-jetting machine

The Multi-DES project has enabled the development of two active stents; one for a slow release of the active molecule (2-3 weeks); the other for a quick release (1-5 days). It was demonstrated that the quick release stent could significantly reduce the risk of recurrence during the first days.

Similarly, it was shown that statins, widely used to decrease LDL cholesterol, had a beneficial effect on restenosis (recurrence) when the latter was used locally. Such statins would replace cytotoxic and cytostatic drugs currently used in drug eluting stent.
Finally, the partners have developed **a new biocompatible and bioresorbable polymer platform to prevent the risk of inflammation** due to the long presence of non-degradable polymer after implantation of current drug eluting stents. This new bioresorbable polymer could prevent the risk of late acute thrombosis, a major problem with the current drug eluting stents.



Biodegradable multilayer coating of a stent by "layer-by-layer" deposition for the sustained release of anti-restenosis drugs

Partner	Area of expertise
University of Greenwich	Preparation of the PLGA Stent by ink-jetting
University of Lille 1	Preparation of the Multilayer Stent
University of Lille 2	In vitro and in vivo evaluation of the DES

Improving Drug Efficacy and Availability

The vast majority (80%) of drugs are supplied as solid products (tablets, capsules). Due to the poor solubility of many novel drug candidates in water (70% of new drugs), the absorption of these compounds into the bloodstream is often low after oral administration. These characteristics limit their use in pharmaceutical practice as the drug concentrations in the blood are too low to provide a therapeutic effect after oral administration of the compounds to a patient. Newly synthesized drugs for cancer therapy are particularly concerned by this hurdle.

"*When you swallow a pill, you expect the active molecules it contains to be released in the organism to play their therapeutic role. So obviously, you expect the tablet to dissolve. If the medicine is "a stone", we can easily understand that the body will reject it as it was swallowed with no positive action whatsoever",* explains Professor Marc Descamps. *"However active the molecules are from a therapeutic standpoint, they will not reach their target and will be completely useless. Countless of these "stones" remain in the drawers of pharmaceutical industries where they are waiting for alternative "formulations" to release all their healing power*", he adds.

While this problem could perhaps be partially solved by injecting these molecules directly into the bloodstream, it is evident that this is not the preferred route of administration for patients (linked to the pain observed during injection) or for the pharmaceutical industry (linked to the higher costs associated with the manufacturing and transport of sterile injectables). Hence research in the pharmaceutical industry as well as by academic teams focuses on **strategies to design pharmaceutical dosage forms for oral administration which ensure a high bioavailability of poorly water soluble drugs by enhancing the dissolution properties** in the gastro-intestinal tract. Moreover, the pharmaceutical industry is continuously searching for new approaches which could possibly offer unseen advantages and/or reduce the manufacturing costs of the dosage forms. Optimizing formulation also requires controlling and predicting the solid state properties during manufacture and storage as they are major issues in the development of new pharmaceutical products as well.

IDEA Closing Conference in Villeneuve d'Ascq (France), June 21st 2013

That was the simple idea behind "IDEA": improving the formulation of the drugs for a better solubility and bioavailability of the active molecule. The IDEA project developed within the 2 Seas area an original research activity programme with technical applications to the design of new solid state pharmaceuticals, with a view to **facilitating the development of both new and existing drugs with improved bioavailability, efficacy, chemical and physical stability, safety and predictability.**

At first, partners implemented **a state-of-the-art trans-disciplinary** (physics, chemistry and pharmacy) **technological platform** dedicated to material synthesis, advanced characterisation, and formulation of pharmaceutical materials using a collective, rich and complementary know-how and equipment base. Then, and thanks to this platform, they succeeded in **discovering rational ways to develop new physical forms of drugs which increase their solubility** and thus, their therapeutic efficacy while improving their long-term stability. The main results have been obtained for Active Pharmaceutical Ingredients (API) and excipients which enter into the final composition of medicines.

The structural organizations and molecular mobility of several active pharmaceutical ingredients have been analysed in detail. This established the best ways to obtain the most efficient therapeutic physical forms (nanocrystalline, crystalline, amorphous). On the basis of these results, new formulation routes associating Active Pharmaceutical Ingredients and excipients have been defined and optimized.

To improve the dissolution characteristics of poorly water-soluble drugs (thus formulating an immediate-release dosage form and enhancing the bioavailability of these compounds after oral administration), **different manufacturing techniques** (hot-melt extrusion, coacervation) **were evaluated and several formulations** (polyol-based as well as polymer-based formulation platform) **were examined** for their ability to enhance the dissolution properties of poorly water-soluble drugs. A drug is always an association of an Active Pharmaceutical Ingredient (API) with an excipient whose role is to facilitate body assimilation and conservation of the drug. **Hot-melt extrusion** is the intense mixing of different compounds under high shear at elevated temperature. It forces active ingredients to be molecularly dispersed in an excipient to provide easy dissolution in water and stability during conservation. **Coacervation** includes several technologies which aim to specifically design nano or microparticles which control drug release in the body. The new forms were mainly based on nanoparticle technologies, amorphous drug forms and molecular complexations.

These preliminary results were very promising and they could only have been obtained through close collaboration of the consortium's members (physicists, chemists, pharmacists) who possess a very broad expertise to understand the issues of the chemico-physical state of medicines in a very wide context.

The participation of a pharmaceutical company (SEPS Pharma) in the project provided **fast and efficient validation** of the most innovative developments. "*The role of SEPS Pharma was to look for applicability of the research within this cluster and validate academic research with practical examples. SEPS Pharma was also able to improve its scientific excellence*" explains Jody Voorspoels, Chief Scientific Officer of SEPS Pharma.

Partner	Area of expertise
University of Lille 1	Physical analysis of pharmaceutical solid forms and use of high energy milling to transform the physical state of drugs. Molecular simulation of drugs in the solid state. Teaching master and PhD students how to use these specific techniques.
University of Lille 2	Development of controlled drug delivery systems and biomaterials. Development of innovative strategies using novel types of advanced drug delivery systems and biomaterials allowing for accurate control of the resulting drug release kinetics.
University of Cambridge	Preparation and characterization of co-crystal systems with improved pharmaceutical performance. Development of strategies for drug formulation and characterization to enable generic methods of drug formulation to be developed for the general use of the pharmaceutical industry.
University of Ghent	Preparation of novel drug products with appropriate excipients for optimized drug release and long-term stability. Determination of the in vitro drug release kinetics of the novel pharmaceutical dosage forms using pharmacopoeial methods.
University of East Anglia	Development of hot melt extruded solid dispersions for enhanced delivery of poorly soluble low molecular drugs and peptides, with a strong emphasis on using novel nanocharacterisation methods to understand the microstructures of extruded solid dispersions
SEPS PHARMA	Drug development services encompassing preclinical development, preformulation development, formulation development, analytical development, dosage form development, scaling-up and clinical trial manufacturing of small molecules and biopharmaceuticals for oral, pulmonary, nasal and parenteral delivery.

In terms of scientific achievements, the IDEA partnership **led to optimized protocols and polymeric matrices and to prototypes of new drug products** thanks to the possible upscaling phase at SEPS Pharma. Results were also disseminated through publications in leading scientific journals.

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scientific publications have been released thanks to the 2 projects.

… fuels economic development

The IDEA and Multi-DES projects along with the AMPTEC Cluster brought together complementary scientific know-how and equipment to implement a new activity which meets the urgent demands of advanced drug delivery systems and approaches. This innovation-driven research programme has important outcomes for the economic development of the 2 Seas area.

It will lead to **valuable economic fall-outs, some of which are still pending, relating to the attractivity of the 2 Seas area for industries and students, increased competitiveness for SMEs and future business opportunities.**

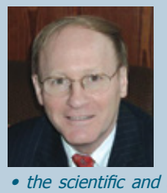
Yves Gonnissen, Chief Executive Officer of SEPS Pharma, highlights the importance of this research and development project for the company: "*SEPS Pharma is a company dedicated to the formulation of new drugs. The development of new drugs today is very challenging, time consuming and a costly process.* ***This process can only be successful by an intensive multidisciplinary collaboration****. Collaboration with top universities increases the chance of success in our work, but also a higher external visibility supports the business development of the company. The company is now known to students of the universities we are collaborating with. This way we are able to apply a more international hiring policy than before.*"

The Chief Scientific Officer of the company, Jody Voorspoels, continues: "*As an SME it is crucial to be on the edge of technology and innovation. IDEA was key in supporting innovation at SEPS in collaboration with top academic institutes. Currently we have a better understanding of the behaviour of solid dispersions and the analytical tools to support this type of formulation. Today we are still collaborating concerning evaluation of these formulations, but also in modelling the in-vivo behaviour of our drug delivery systems*".

The projects provide **a unique opportunity to position the region as an international leader in the solid state pharmaceutical field**, establishing the 2 Seas area as an attractive choice for companies developing new drug products. In addition, it has already attracted and supported new SME companies in the pharmaceutical area for whom the consortium supplies world-leading technology for the development of novel drugs. Today, such biotechnological companies are dramatically lacking in the region.

As a result of the IDEA and Multi-DES projects, new innovative drug products and stents are currently being developed. Partners are only at the stage of discussion with companies, but the potential developments seem promising. Unfortunately, it is impossible to give more information as these negotiations are highly strategic and confidential. The commercialization of the new stents will not be within the next five years; the time required to manufacture industrial prototypes and to respect all stages of the CE marking process. As for the potential new drug products, it could take longer, given the required safety and efficacy standards and duration of human clinical trials.

Now, the cluster aims to provide support and expertise to local SMEs by establishing strong collaborations in Research and Development which eventually will lead to the materialization of innovative research and business ideas.



Jean Doucet,
co-founder of Novitom, a start-up based in Grenoble and specialising in imaging techniques explains why he chose to support the AMPTEC cluster as an associated partner.

"Novitom decided to join the AMPTEC cluster for three reasons:
• the scientific and technical subject on solid forms which is consistent with our characterization activities;
• the internationally recognized expertise of the teams involved in the two projects;
• the relational aspects of trust with the members of the network.

Participating in the AMPTEC cluster gives us the opportunity to expand our business to the pharmaceutical field. The objective of Novitom through the AMPTEC cluster is to develop new tools for 3D imaging and characterization of solid drugs that can go further than existing tools.
To that end, Novitom needs the support and expertise of the network specialists who understand the needs in the pharmaceutical field. The analysis protocols to be implemented will then benefit all pharmaceutical companies".

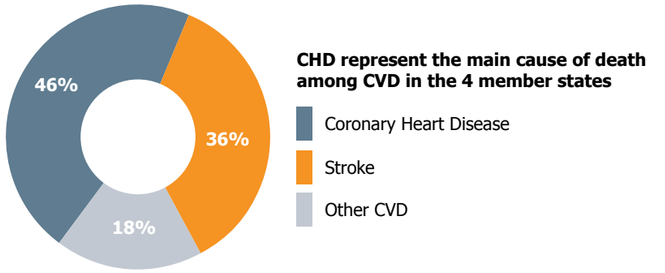
… improves the quality of life of patients and citizens

"*The purpose of the Interreg 2 Seas Programme is to strengthen the collaboration by bringing together groups within the cross border area but also* ***to improve people's quality of life within this area and we are very proud to contribute to this goal***", says Doctor Dionysios Douroumis.

Advances in life and health sciences have a tremendous impact on the life of European citizens. In the last century, the life expectancy has significantly increased, the spreading and the consequences of serious infectious diseases were limited, drug treatments substantially improved (e.g. using antibiotics) and the quality of life in the disease state could be increased in many cases. This progress is likely to continue, but major challenges have to be faced, such as cancer, neurodegenerative diseases, including Alzheimer's disease, and various other harmful disorders. **Only a highly interdisciplinary cooperation across national borders at the cutting edge of knowledge can allow such progress to continue**. The aim of the AMPTEC cluster is to facilitate and contribute to such therapeutic innovations in the specific field of advanced materials and pharmaceutical technologies.

The IDEA project could lead to the optimization of large numbers of drugs and the commercialization of new molecules which have been revealed as potentially very effective in treating a disease but are currently unusable because they cannot be administered or commercialized in proper conditions. "*The IDEA project brought us a better insight in new formulation techniques to increase the solubility of drugs. In this way, new drugs can be formulated with a higher bioavailability and thus a better efficacy.* ***As a result, patients need to take fewer or smaller tablets. Also, these drugs would otherwise not have been developed and can now find their way to the patient***", underlines Jody Voorspoels CSO of SEPS Pharma.

As for the impact of Multi-DES, in the countries that are represented in the 2 Seas area (Belgium, France, the Netherlands and the United Kingdom), more than 140,000 citizens die annually from coronary heart disease (CHD). The four member states totalize almost 21% of deaths originating from CHD in the European Union. Among the causes of death related to cardiovascular diseases (CVD) in the four member states, 46% are due to CHD turning it into the main identified cause of death of CVD[2].



Annually, over 45,000 angioplasties are carried out in the United Kingdom and 46,000 in France. Unfortunately, some complications are observed: thrombosis occurs in 5% of cases with significant inflammation, but the major problem is restenosis involved in 30% of cases. **It is essential to sensitize the general public to cardiovascular diseases and their clinical consequences** so that they understand the importance of research and development in this field. Under the Interreg MuliDES project, a public "cardiovascular day" was held in Lille on April 13th, 2012.

The impact of the recently designed stents could be beneficial for the quality of patients' life. The project partners anticipate that a marketed Multi-DES stent will reduce the administration of other drugs, minimize side effects, and most importantly will treat the two major issues related to stent implantation and decrease mortality. The development of a safer stent with new more effective drugs and biocompatible/biodegradable polymers will fulfill patients' expectations for the treatment of coronary diseases.

All citizens are concerned by the impact of the projects. Not only can patients be involved directly, but entire families can be affected by the disease of one relative. These projects contribute to the effort to cure patients and to improve living conditions for all those who might be affected by diseases.

In addition, students of the 2 Seas area and beyond are other citizens whose lives can be affected by the development of these projects, as they are strongly committed to improving the quality of training in their dedicated field.

Such an apparatus allows the advanced physico-chemical characterization of novel materials and pharmaceutical dosage forms

2. Latest available year, European Cardiovascular Disease Statistics, 2012 Edition

CHAPITRE 3

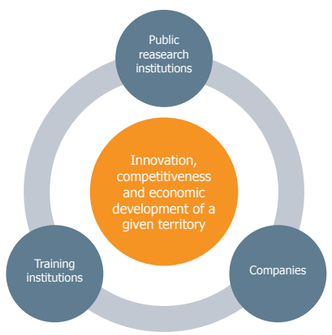
The higher education challenge

Adapting training to transfer knowledge, fit the needs of the industry and perpetuate the excellence of the region

The three-part mission of clusters: research, innovation and training

To get deeper into the notion of "cluster", let us remember that this term was conceptualized by Michael E. Porter. In "Clusters and the New Economics of Competition" (1998), he defines clusters as follows:

"*Clusters are* ***geographic concentrations of interconnected companies and institutions in a particular field****. Clusters encompass an array of linked industries and other entities important to competition" […]. Many clusters include governmental and other institutions – such as universities, standards-setting agencies, think tanks, vocational training providers, and trade associations – that provide* ***specialized training, education, information, research, and technical support***".



Clusters gather the three pillars of innovation.

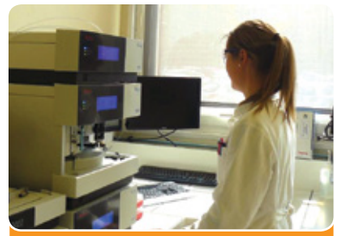
The role of "other" institutions is often underestimated in clusters because we naturally picture innovation as being mostly fostered by companies. Yet, very often, as is the case with universities, **some of these institutions provide two decisive pillars of innovation: training and academic research.** "*We must not forget that the young scientists we train today will be the leading researchers of tomorrow. Neglecting advanced education in our day will have fatal consequences in the future*", points out Juergen Siepmann, Professor at the University of Lille 2. In technical curricula, this brings the decisive advantage of fuelling the training of students, who can be future researchers or future businessmen with the latest developments of science.

Additionally, **clusters encompass a notion of geographical proximity** between the three types of actors of innovation of a specific field. This proximity enables **industry partners to contribute to the teaching** of applied sciences in universities and also permits **lifelong training of professionals** with the latest scientific knowledge. When clusters materialize in the form of a distinct organization such as the Nutrition Health Longevity Cluster or a dedicated consortium as in the case of AMPTEC, they intervene as facilitators to establish and maintain this link among the entities. This way, training (referring both to university education and lifelong training within companies) can always be adapted to the evolving needs of the industry. **This high-level training is a critical success factor to maintain competitive advantage over time. One of the strongest added-value features of the AMPTEC cluster is to incorporate training in its strategic goals.**

There is a current awareness in industry of research and training reorientation so as to incorporate an understanding of the solid state of drugs.

IDEA training school in Norwich (United Kingdom), April 8th 2011

For this reason, three training schools will be organized as part of AMPTEC activities. Notably, training schools had already proven to be of high added-value in the IDEA project.



A session of practicals during the training schools

The IDEA training schools summed up in a few figures:

- Students trained on this project so far:
- 2 PhD students & 2 postdocs (Lille 1)
- 3 PhD and 2 Master students (Cambridge)
- 5 PhD and 3 Master students (Lille 2)
- 2 PhD and 1 Erasmus student (Ghent)
- 2 PhD students and 1 postdoc (East Anglia)
- 1 PhD and 4 Master students (SEPS Pharma)
- "Training Days" at partner sites (Lille, Ghent, Cambridge, Norwich)

The training included lectures and Master courses and training seminars at industrial sites such as BASF in Switzerland, AstraZeneca in Sweden, and Sanofi during its 2012 Biopharmacy symposium.

Tailored programs to address shortcomings for students and industry: a look back on the IDEA training schools

"*As part of the IDEA project, we created in the area a training centre for a new trade dedicated to the optimization of the solid-state drug manufacturing processes",* says Professor Marc Descamps. *This (by nature trans-disciplinary) type of training, perfectly fitting the needs of pharmaceutical firms in order to overcome the major bottlenecks of drug development, did not exist before the IDEA project. It is a great source of pride for us*, he adds.

Workshops and training days have been successfully held, improved and

Aurélien Mahieu, who presented his thesis for a doctorate in physics last year and benefited from the IDEA project, gives us his opinion about the IDEA training schools and the project in general.
"*When I joined the IDEA project, it was just a way to write my thesis. After a few weeks of work, I finally realized where I really was. For a PhD student, the IDEA project is much more than a classical PhD contract, it's an international human adventure.*

All IDEA members need to meet very often and share their knowledge to solve some problems through, in particular, training schools. The IDEA project is composed of academic and industry leaders from different specialities such as Physics, Chemistry and Pharmacy. As a consequence, when you are part of such a project, it is essential to open your mind to the others and be able to listen and directly propose simple answers to some current scientific questions. These training schools are a mixture between high quality training from professionals and friendly meetings between partners. After the end of my contract, I sent lots of emails to share ideas for future work or just to set a time to have a drink and chat about the world".

An-Katrien Vynckier, PhD Student at SEPS Pharma:
"*To me, as a PhD Student, the IDEA training programme was a good opportunity to present my work to world-leading researchers in the pharmaceutical solid state field and to discuss ideas in a collaborative atmosphere. The trans-disciplinary training brought me a thorough understanding of the fundamental physics and chemistry behind phenomena regularly encountered during pharmaceutical manufacturing. As a result of the facilitated collaboration I also enjoyed the possibility to cooperate across borders with some members of the partnership*".

jointly organized by all partners of the consortium. This involved practical demonstrations, lectures, poster presentations and industrial exhibitions. It targeted the members of the IDEA consortium (students from partner universities), but also external participants, including the pharmaceutical industry (personnel undertaking continuing professional development) and researchers in academia.

The training days also significantly increased the mutual awareness of the consortium partners on the activities of the associated laboratories. **The educational offer of the IDEA consortium has become increasingly comprehensive and known by the scientific community in academia and industry**.

On top of the IDEA training schools, it should be noted that **the IDEA network itself served as food for thought for the establishment of university courses dedicated to the new skills developed by the network**. For example, Universities of Lille 1, Lille 2 and Ghent are currently collaborating on a training project for joint Master "DECOD: DEvelopment, Characterization and Optimization of solid forms of Drugs". This project should develop strategies for new Master courses in the future. Proposals to Marie-Curie Network and Industrial Doctorates should also be submitted in the fall of 2014.

Sticking with a winning formula: the AMPTEC training schools

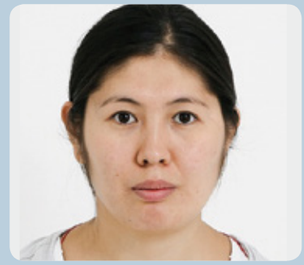
Capitalizing on the success of the IDEA training schools, the AMPTEC partners decided to **maintain the concept of training schools in the cluster as a good practice of collaboration in their field**.
The combined expertise of the AMPTEC cluster members offers an opportunity for specialised training in physics, chemistry and pharmacy that meets the needs of local industry.
Consequently, the partners will organize training activities for highly qualified specialists from pharmaceutical and agrochemicals companies and academic research institutions in the 2 Seas area. **Three training schools will be organized in the United Kingdom, France and Belgium** and will involve taught lectures and laboratory training in advanced characterization and formulation techniques. The training school in France was granted support by the French CNRS (National Centre for Scientific Research).

The three training schools are complementary and based on each organizing partner's core competencies in order to make a coherent whole and a complete training course. Currently, it covers the entire chain of development, from the fundamentals of material science and pharmaceutical formulation (France, Val Joly in June) to the production of nanoparticles, continuous processing, clinical trial manufacturing and scale-up (Belgium, Ghent in September), including drug delivery and novel characterization approaches (United Kingdom, Greenwich in July). The programmes are built to include as few redundancies as possible in order to enable most students from partner universities to participate in all three of them.

"*This type of training provides students with the fundamentals of materials science underlying the research in pharmaceutical formulation*" says Professor Frédéric Affouard, scientific coordinator of the AMPTEC cluster. The training focuses on the different materials used in the field of pharmacy and food, their physical states, and their specific modes of preparation and transformation induced by the typical constraints imposed by industrial processes. Students also gain a thorough understanding of specific experimental methods suitable for the physical characterization of these materials. The teaching is illustrated by examples encountered in the pharmaceutical and food sectors. "*It is a trans-disciplinary education at the interface between materials science and pharmacy*", he adds.

Overall, **these novel trans-channel and transnational training events will help to reduce the striking fragmentation of the educational systems in this EU region**. Furthermore, the cluster will help the cross-border area to develop a competitive and dynamic knowledge-based economy.

As a result of AMPTEC, mini-colloquia about "Physics of pharmaceutical amorphous solids" will take place at the "Condensed Matter" Conference in Paris in August 2014. This conference is jointly organised by the Condensed Matter Divisions of the French Physical Society (SFP) and of the European Physical Society (EPS).



Cholpon Rustem from the University of East Anglia was looking forward to participating to the French training school in Val Joly in June. *"I'm a first-year PhD student with a chemistry background. My PhD project is on oral nutrient delivery. The training school gives me a unique opportunity to not only gain more in-depth knowledge on advanced formulation and characterisation, but also exchange research ideas with other students and researchers and build up my own research network for my future work. This will be extremely beneficial for my on-going PhD and future post-PhD career".*

IDEA training school in Cambridge (United Kingdom), April 7th 2011

CHAPITRE 4

The European adventure

Looking back… Looking forward!

Good practices of cross-border collaboration

The Partners of the IDEA and Multi-DES projects reflect on the projects' origins and share with us their impressions about European cross-border collaboration, the added-value of the Interreg 2 Seas Programme and good tips for projects to succeed.

There are several ways of coming up with a proposal of European project. Almost all roads can lead to it. **However, there are good practices that must be kept in mind when trying to set up such projects**.

A collaborative research project is a recipe made up of three main ingredients: a theme (overcoming a scientific challenge), a consortium (finding the right partners) and a funding scheme (with eligibility conditions that fit the project and the consortium). The first two ingredients can be incorporated simultaneously or sequentially, whichever one comes first. For instance, a lead partner can have an idea for a project and then look for the right partners with complementary skills, or have an established relationship of trust with a potential partner and define a common interest research subject. However, the search for the funding scheme must always come in the end. It shouldn't be the starting point. Sometimes, to meet the eligibility conditions, consortia have to be completed with a partner from a specific country but in that case, partners should be very careful that this partner can be trusted and will carry out the work.

Doctor Nicolas Blanchemain explains how the Multi-DES project emerged. *I have been working with the team of Professor Martel (University of Lille 1) for more than 10 years on the functionalisation of medical devices to improve their therapeutic properties. We work specifically on polymer matrices for the local release of active molecules. I met Doctor Douroumis (University of Greenwich) at a meeting organized by Professor Siepmann in Lille (June 2009). The aim of the meeting was to explore possible collaboration within the field of drug eluting stents. In the meeting of we presented our scientific findings (published in international peer reviewed journals) on "Coating of Drug Eluting Stents" and "Functionalisation of vascular prostheses with cyclodextrins" respectively. It was then decided to combine our expertise and develop a new DES using cyclodextrins as the drug delivery system on a stent surface. We decided to submit an 'Interreg IV A 2 Seas' research project because of the programme's relevance to our research field.* ***This kind of collaboration will promote knowledge exchange between the North of France and South of England and more specifically within the cross border area through the Interreg program*** *(production, commercialisation and clinical trials of the new DES*).

Doctor Dionysios Douroumis continues: "*the funding of the Multi-DES project by the Interreg 2 Seas Programme allowed* ***the collaboration for the first time between one British and two French Universities in the area of medical devices***. *The collaboration was successful and all partners have enjoyed working together for the last two years.* ***We established strong personal and scientific bonds and now we seek to apply for new research projects that will sustain our research***. *This was a great journey for all partners and we managed to overcome the difficulties over the project's lifetime*".

In both projects, the partners demonstrated excellent collaboration and worked hard towards the project's objectives and deliverables. All partners showed responsibility and a professional attitude.

The main lessons learned are about the importance of the partners' full cooperation, involvement and mutual understanding during the project's lifetime. Partners should think out of the box and in a creative manner when difficulties arise. All partners found scientific and cultural exchanges between the cross-border regions very enriching and international exposure highly valuable. "*IDEA was for SEPS Pharma an excellent tool for building an international network with academic institutes that are specialized in the field of formulation science. It gives us international exposure and access to other programs.* ***It was really a stepping stone to other European programmes and collaborations***", says Yves Gonnissen, CEO of SEPS Pharma.

To be continued… when cooperation leads to more cooperation

Partners of IDEA and Multi-DES come out of these projects mindful of the merits of cross-border collaboration and future research and innovation projects.

"*I believe Interreg programmes address a crucial challenge in Europe: overcoming the multiple national borders, which are separating scientists*", says Professor Juergen Siepmann (who grew up in Germany and moved to France). "*In contrast to our main competitors (such as the USA and China), Europe is divided into multiple nations. This significantly hampers innovative research. We can very strongly recommend applying for this highly efficient tool overcoming frontiers, basing projects on sound approaches and considering the potential present in the respective cooperation areas*".

IDEA meeting in Ghent (Belgium), January 31st 2011

For Interreg programmes, the theme of projects should be chosen to face a common regional problem and solve it through cross-border cooperation. As Doctor Nicolas Blanchemain explains, "*the greatest added value of the Interreg 2 Seas Programme is the pooling of regional knowledge to carry out a research project on a common problem. I am really proud of having managed within our research team my first cross-border/European project. I'll be even more proud when this new medical device, the product of our partnership, is operated by a company. I recommend joining these cross-border projects to my colleagues.* ***This is an opportunity not only to develop new projects, but especially to respond to a regional problem****. It is also the opportunity to meet new research teams working on the same theme. The pooling of the scientific skills of cross-border regions will meet the expectations of the citizens*".

Beyond scientific achievements, the cluster is proud of bringing together a group of world-class leaders and establishing a research centre with state-of-the-art equipment. AMPTEC's scientific roadmap is now written, for the continuation of the cluster programme and even beyond…

With the help of the novel characterisation methods, partners have accumulated better understanding of in vitro and in vivo behaviour of pharmaceutical materials and products across the IDEA and Multi-DES teams. "***The future generation of medicine should be designed to suit each individual patient's need. We would like to work towards the realisation of the 'medicines by design' concept*** *by employing novel processing methods, such as electrospinning and 3-D printing, to produce formulations that are engineered with high sophistication at nanoscale*", says Doctor Sheng Qi from the University of East Anglia. The novel processing methods will allow the preparation of formulations with a detailed nanostructure, which can endow the formulation with special functions, such as targeted and controlled release of the drug. These formulations have great potential to be used for targeted delivery and combination therapy. "***We believe that the creation of 'medicines by design' can only be achieved by cross-disciplinary collaborations*** *and the Cluster Programme is the best way to bring the scientists with expertise in pharmaceutical characterisation, processing and biomaterials from IDEA and Multi-DES together*".

A few questions about AMPTEC to Gilles Pargneaux, Member of European Parliament (MEP)

• What are the benefits of taking part in cross-border projects?
As a member of the environment and health committee in the European Parliament, I've had the opportunity to meet several researchers involved in territorial cooperation. They all say that being exposed to different research cultures benefits their work. When you compete on a global level, building EU commonalities with other European researchers stimulates innovation. I believe the trans-disciplinary dimension of the AMPTEC project is a catalyst to translating state-of-the-art research into marketable solutions. It is very important for the economic development of my region - Nord-Pas de Calais - and for the English and Belgian partners involved.

• What are the opportunities for researchers at the EU level?
With an increased budget of 79 billion euros, European opportunities for funding research have increased under the new research framework Horizon 2020. We want to develop cooperation across Europe, and have introduced the concept of Knowledge and Innovation Communities. This is a way to reinforce the cluster approach already developed by cross-border cooperation programmes. It is instrumental for innovation. One of the new KICs will address the issue of innovation for healthy living and active ageing. I sincerely hope that first-rate research institutes already involved in cross-border cooperation will be able to take part in the Knowledge and Innovation Communities. Whether in advanced materials or pharmaceutical technologies, I believe our regions are well-equipped to take part in EU-funded projects and compete on the global level.

• How can innovation contribute to the EU health objectives?
Promoting good health is an integral part of Europe 2020, the EU's 10-year economic growth strategy. Innovation can help make the healthcare sector more sustainable and find new cures for health conditions. And the healthcare sector has an important role to play in improving skills and creating jobs, as it employs 1 in 10 of the most qualified workers in the EU. Our goal on the EU level is to make Europe a world leader in developing innovative ways to promote active and healthy ageing. That is why I strongly support all EU health research projects, like AMPTEC, that are related to this objective.

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This cluster is led by the University of Lille 1. The cluster partnership also gathers the University of Cambridge, the University of East Anglia, the University of Ghent, the University of Greenwich, the University of Lille 2, the Nutrition Health Longevity Cluster and SEPS Pharma.

For further information about the AMPTEC cluster: amptec.univ-lille1.fr

The Interreg 2 Seas Programme launched the "cluster" initiative to enable two or more 2 Seas approved projects per cluster to come together to work on a given theme in order to capitalise their results. "AMPTEC", which stands for Advanced Materials and Pharmaceutical TECnologies, is a cluster uniting the "IDEA" (Improving Drug Efficacy and Availability) and "Multi-DES" (Multifunctional Drug Eluting Stent) projects. This publication is entirely funded by the Interreg 2 Seas Programme in order to consolidate, valorise and disseminate the results of IDEA and Multi-DES and make them accessible to the citizens of the 2 Seas area.

For further information on the 2 Seas Programme, please visit our website :

www.interreg4a-2mers.eu

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The Interreg 2 Seas Programme is an EU funding programme which promotes crossborder co-operation between partners from France, England, Belgium (Flanders) and The Netherlands. It aims to develop the competitiveness and the sustainable growth potential of maritime and non-maritime issues through the establishment and development of cross border partnerships.