Workshop

Accelerating EU-US business collaboration in health/e-health Research & Innovation: Opportunities, Barriers and Best Practices

Friday, June 20th, 2014, Boston, MA

Venue: Atlantic Wharf, Waterfront District

Public workshop report

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CONTEXT

The **workshop "Accelerating EU-US Business Collaboration in Health/e-Health Research and Innovation: Opportunities, Barriers and Best Practices"**, held in Boston, Massachusetts, on Friday June 20th, 2014, was part of the **BILAT USA 2.0 project** which aims to enhance and develop Science, Technology and Innovation (STI) partnerships between the European Union (EU) and the United States of America (US). The workshop was built towards the specific objective of **supporting transatlantic cooperation between innovation actors,** with a specific focus on the health/e-health field.

The results of the workshop will be analyzed to provide **inputs and recommendations to US and European policy makers at an EU-US Innovation Conference** (planned to take place in January 2015); it will aim to illustrate **how to overcome the identified barriers**, and **what changes could be made** to consider the innovation dimension in the next EU-US STI Cooperation Agreement in order to support EU-US businesses collaboration, including in Health Research and Development.

This workshop was organized in **4 sessions**: the **opening**, **presentations on the opportunities** for transatlantic research technological development and innovation (RTDI) business cooperation, **panel presentations** with showcases on transatlantic business collaboration in RTDI and examples of support through clusters and other facilitators, and finally **roundtable discussions** with experts.

The contributions to the different parts of the workshop are summarized in this report following the agenda of the day.

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Session 1 – Opening

The workshop organizers, represented through Svetlana Klessova, Director of inno TSD, welcomed the audience to the workshop which was organized in the framework of the BILAT USA 2.0 European project. She was joined by **Laurent Bochereau, Head of Unit "Health - Strategy" of the European Commission's Health Directorate** who welcomed the initiative of organizing such a workshop and thanked the audience for their interest in the activity.

Presentations then began with a **general scene setting**, and presentation of the input report previously carried out by the BILAT USA 2.0 team, on **barriers and drivers to transatlantic RTDI business collaboration**. **Industrial feedback from the US** and a **European innovation agency** also opened the workshop.

Input presentation

Scene Setting: BILAT USA 2.0 project goal, aim of the workshop (15 min)

Ms. Svetlana KLESSOVA, Director, inno TSD, France

Svetlana Klessova is the **Director of inno TSD**, a consulting firm based in France with expertise in the field of Science, Technology and Innovation (STI) policies and European RDI projects, and a partner of the BILAT USA 2.0 project.

Ms. Klessova welcomed the audience and **introduced the BILAT USA 2.0 project and the workshop.** The **BILAT USA 2.0 project** aims to enhance and develop STI partnerships between the European Union and the United States of America and is funded by the Seventh Framework Programme of the European Union for the funding of research and technological development (FP7). She explained the **main goals of the workshop:** promoting relevant funding opportunities, identifying ***barriers*** to EU-US business RDI collaboration, highlighting existing support and ***best practices*** in this field, identifying missing elements and ***possible solutions***, and thereby being able to provide ***recommendations*** to EU and US policy makers after the workshop to enhance this cooperation. She also recalled the **context of the workshop**, occurring in view of a future **policy brief** for EU and US policy makers on how to address the main barriers and how to enhance US-EU collaboration, before policy discussions will be engaged at an ***EU-US Innovation Conference*** dedicated to exchange information on how to integrate the "innovation" dimension into the new **EU-US S&T Agreement**.

The speaker then presented the **input report** which was prepared prior to the workshop and identified **three main stages in RDI collaboration**:

1, **Collaboration team identification,** where the global lack of awareness on international RDI collaboration advantages and requirements, the ignorance of partners' search tools and methods, and businesses' lack of involvement in international networks hinders collaboration

2. **Collaboration project set-up**, where lack of knowledge on funding opportunities, the lack of opportunities to access funding schemes, potential legal and jurisdictional barriers and difficulties with defining common Intellectual Property Rights (IPR) provisions hinders collaboration

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3. **Collaboration project implementation**, where differences in regulatory or customer requirements for different markets, and barriers linked to the administrative burden of public financing hinder collaboration.

Other horizontal barriers were also addressed in the input paper. These are mainly traditional barriers associated with distance and linguistic and cultural differences. Finally, Svetlana Klessova presented the **agenda of the day**.

Transatlantic business driven collaborative health research: drivers, barriers and open issues (20 min)

Mr. Richard SATCHER, Sr. Business Manager, RTI International, USA

Richard Satcher, as Senior Business Manager at **RTI International**, a world leading research institute headquartered in the U.S. and also part of the BILAT USA 2.0 project and workshop organization team, completed the introduction of the event.

He started with a presentation of **typical drivers** to EU-US business' RDI collaboration, such as the increasing emergence of global challenges faced in Health, Energy, Food, etc., the rising R&D costs for companies, the rise of research mobility that enhance network building, and the growing efforts of political dialog on transatlantic harmonization in RDI regulations. Mr. Satcher also expanded on the **barriers** identified by Svetlana Klessova. For example, he showed that most partner search tools are EU or US-centric and focused mostly on precompetitive partnerships, where partners agree to share intellectual property in an effort to advance the scientific field so that all can benefit from new ideas.

Industrial feedback from US

Transatlantic Research, Technological Development and Innovation (RTDI) cooperation of companies: sharing ideas (15 min)

Mr. O. Sinan TUMER, Sr. Director, SAP Co-Innovation Lab, USA

Sinan Tumer as a Senior Director in the **SAP Co-Innovation Lab located in the USA**, a local center of a global network designed to facilitate project-based co-innovation within the SAP (world leading provider of business software) ecosystem, was invited to **bring an industrial point of view** into this introduction.

He began by giving the audience some background on the **innovation cycle**, from research to the market, reminding that "innovation happens when inventions are transferred to market" and that an **innovation gap** or "valley of death" exists between applied research and product development. He advocated for a **co-innovation ecosystem** to reduce this barrier. Thereafter, he developed the functioning of **co-innovation public private partnerships**, and the respective roles of governments (in setting up an innovation-friendly environment), universities (which work on basic and applied research, but should not work in an "Ivory Tower") and industrial companies and SMEs, reminding that innovation mostly comes from SMEs and start-ups. He then focused on the role of **Public Procurement of Innovation (PPI)** in Europe and the USA to stimulate the commercialization of research.

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Next, the subject of **transatlantic cooperation** was addressed with the following important facts and figures:

- The U.S. and EU account for **63%** of the top R&D companies; **58%** of all global R&D
- **Bilateral U.S.-EU flows in R&D** represent the largest expenditures between any two international partners
    - In Europe, U.S. affiliates invested **$27.7** billion in R&D, ~ **61%** of total global R&D expenditures by U.S. foreign affiliates of **$45.7** billion in 2011
    - In the US, R&D spending by European affiliates totaled **$33.4** billion, accounting for **75%** of all R&D performed by majority-owned foreign affiliates in the US).

Finally, he called for a strong STI Agreement between the two regions and the **involvement of SMEs** in this agreement.

Feedback from a European innovation agency

Evaluation of the EU-US S&T agreement and the need to integrate an innovation dimension (15 min)

Ms. Helena ACHESON, Head of Division, MFG Innovation Agency for ICT and Media Baden-Württemberg, Germany

Helena Acheson, as Head of Division of the **MFG Innovation Agency for ICT and Media** of the region **Baden-Württemberg (Germany)**, and as the co-author of the Review of the EU-US S&T Agreement conducted in 2013, discussed the integration of an **innovation dimension in the next EU-US S&T Agreement**.

After giving background information on EU-US S&T cooperation -a cooperation described as already strong and active- she affirmed the possibility of enhancing collaboration through various policy interventions and notably gave the audience an overview of the **recommendations** to EU policy-makers provided in the context of the **evaluation of the EU-US S&T Agreement (2013)**. She developed recommendations made in terms of **operational policies**, such as:

- **improving awareness-raising** on the advantages of EU-US STI cooperation
- enabling better coordination and promotion of **open access to research infrastructures,** and
- exploring the use of **co-funded schemes**.

Recommendations relating to the policy and strategy in this cooperation were also listed, such as the need to be more strategic and better reflect the changing dynamics on both sides of the Atlantic, notably by integrating the innovation dimension in the next agreement.

Next, Helena Acheson provided some useful context on **innovation policies and their institutional organization and strategy** in both the EU and the USA, notably underlining some political differences (e.g. no single US department is responsible for innovation policies; European Governments are more likely to take actions and intervene regarding innovation policies; the US industry funds constitute 62% of R&D funds compared to 54% in the EU) and stating that following the economic crisis, the two regions have adopted a same **focus on "Jobs and Growth"**, bringing the role of innovation again strongly into focus. Finally, she recalled the **role of clusters** in the innovation process and especially in **international cooperation**, as cluster networks can help companies with internationalization strategies, calling for the creation of **stronger linkages between distant clusters**.

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Session 2 - Opportunities for transatlantic RTDI business cooperation

This part of the workshop was dedicated to **introducing the opportunities for transatlantic research technological development and innovation (RTDI) business cooperation in EU and US funding programs.**

Horizon 2020 – the European funding programme - and transatlantic collaboration opportunities in RTDI between businesses

RTDI collaboration opportunities for businesses - supporting health-related businesses and transatlantic cooperation - through Horizon 2020 (25 min) and Q&A (15 min)

Mr. Laurent BOCHEREAU, Head of Unit "Health - Strategy", European Commission, Health Directorate

Laurent Bochereau, as Head of Unit "Health-Strategy" at the **Health Directorate of the European Commission**, spoke on the opportunities for transatlantic RTDI business cooperation in **European funding program** in the current Framework program **Horizon 2020**.

He began with background information on the European Research and Innovation Policy, its history, scope, budget and a few examples of projects funded by the Framework Programmes. The precedent Framework Program, **"FP7",** running during the period 2007-2013 was then presented, with a focus on the encouraging results of the **"Health cooperation program"** (e.g. 1,050 projects, 230 patent applications launched on 370 finished projects, 12,500 publications, 32 spin-offs created) and the statistics on the **participation of US organizations** in this sub-program (196 US participants, with a majority of universities and research organizations, but also 27 SMEs involved).

Mr. Bochereau then presented the **Horizon 2020 program**, its structure, the changes that it brings about (major simplification, instruments dedicated to SMEs) and the **budget dedicated to the health thematic** in this Framework Program, i.e. € 7.4 billion. He finally provided some practical information on the **opportunities and way to participate for a US entity** in the health thematic of the Horizon 2020 program (notably upcoming calls, advice on early project steps, a list of assistance services) and discussed a **few drivers for US entities** to participate in Horizon 2020.

Pictures: Mr. Laurent Bochereau with the BILAT USA 2.0. project representatives on the left, and with a representative from a biotech company on the right.

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US program(s) and transatlantic collaboration opportunities in RTDI between businesses

RTDI transatlantic collaboration opportunities for health related businesses – through the Small Business Innovation Research (SBIR) program at the US National Cancer Institute (NCI) (25 min) and Q&A (15 min)

Mr. Michael WEINGARTEN, Director at NCI SBIR & STTR Programs, National Institutes of Health (NIH), USA (online presentation)

Michael Weingarten, as Director at NCI SBIR and STTR programs of the **National Institutes of Health** (USA), discussed US health funding programs and the **opportunities for SMEs** in RTDI transatlantic collaboration, especially through the **SBIR (Small Business Innovation Research) program** at the US National Cancer Institute (NCI).

Mr. Weingarten notably introduced the **main NIH and NCI initiatives and programs dedicated** to help US SMEs face the challenges encountered in the process of RDI, and their results:

- the **NSF-NIH I-Corps Program** (designed to help SMEs address the barrier of entrepreneurial education)
- the **SBIR Phase IIB Bridge Award** (innovation funding opportunity designed to help SMEs overcome the "valley of death" between development and commercialization)
- the **NCI SBIR Investor Forum** (networking and workshop initiative for SBIR-funded companies and numerous investors, venture capitalists, strategic partners, and business leaders from biotech and pharmaceutical industries).

He also presented additional NIH programs open to SMEs and where US-EU collaboration was possible, such as the NCI Experimental Therapeutics Program (NExT) and the Therapeutics for Rare and Neglected Diseases Program (TRND). He ended with the **case study of a SBIR Awardee**, Insight Genetics, whose initial growth was enabled by the NCI funding.

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Session 3 – Panel Presentations

The Panel Presentations provided an opportunitiy to learn about the **experience and perspectives of individuals involved in transatlantic RTDI business cooperation.** The first panel was composed of **representatives from EU and US businesses**, who described their experiences through collaboration showcases on EU-US business collaboration in a session moderated by **Ms. Kirsten Rieth**, Senior Innovation Advisor at RTI International, USA. The second session was dedicated to presentations of **representatives from clusters and other facilitators** in businesses' international activities, moderated by **Ms. Helena Acheson**, MFG Innovation Agency for ICT and Media Baden-Württemberg, Germany.

Showcases of transatlantic business collaboration (health/ e-health field) in RTDI

EXCHANGE AROUND REAL-LIFE EXPERIENCE IN TRANSATLANTIC RTDI COLLABORATION OF COMPANIES AND SHARING OF GOOD PRACTICES, BARRIERS AND DRIVERS; Q&A

Moderator: Kirsten RIETH, Senior Innovation Advisor, RTI International, USA

Bigger, More Impactful Research Projects via Transatlantic Collaboration: A Case of a European Company

Dr. Engin VRANA, Director of Fundamental Research of Protip SAS, France, and Scientific Coordinator of IMMODGEL R&D Project funded by the European Union

Dr. Engin Vrana, as the Director of Fundamental Research of **Protip SAS**, a French firm specialized in artificial larynxes for human implant, and Scientific Coordinator of the IMMODGEL R&D Project, funded by the European Commission (under the FP7 program), gave a presentation on the **advantages of transatlantic collaboration** in terms of size **and impact on the research projects**, through the case study of Protip SAS in the IMMODGEL project.

After presenting the activities of Protip SAS, Dr. Vrana explained to the audience why his firm typically **needs more impactful research projects**. For instance the firm would like to be able to address big challenges such as adverse immune reactions to implants, but such challenges cannot be tackled within small collaborations as they **require various expertise and equipment**. Furthermore, before starting to deal with such ambitious goals, it is important for a company to **see the possibility of a big market access** in the near future, and to recognize that access to the USA for a European company is important. Moreover, this access also **guarantees an important impact for the collaborative project**.

Dr. Vrana then took the example of the **European project IMMODGEL**, established thanks to the previous collaboration between Protip SAS and **Brigham and Women's Hospital** (BWH), a prestigious US research lab located in Boston. He detailed the **advantages brought to the project by the involvement of a US partner**:

1. Access and exposure to US research networks
2. Differences in research approaches that create synergies,
3. Opportunity to establish a commercial presence in the USA for EU

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Engin Vrana concluded by **proposing immediate actions dedicated to policy makers that could facilitate transatlantic projects,** e.g. for the European Commission side to establish a list of documents that US partners are realistically able to provide, for the US side, the training of administrative officers on the handling of EU projects, and for both sides, creating a model consortium agreement that would cover the concerns of both EU and US partners. He finally gave **some recommendations for European partners in future transatlantic collaborations**, e.g. a consortium agreement in line with both sides' priorities and the establishment of early contacts with US partners' administrative staff.

Engineering Prowess of Portugal: Innovating, Investing and Inspiring. Kinematix: case study of opportunities and challenges.

Mr. Joseph TERNULLO, JD, MPH, President, Kinematix, USA, Inc.

Joseph Ternullo, as President of Kinematix in the USA, a Portuguese body dynamics company that entered the US market in 2013, detailed the experience of opening up offices in the USA and the **challenges faced** in this process.

Mr. Ternullo discussed the **early stage challenges faced by businesses in their international expansion**, of an internal nature - time zones, language and communication barriers affecting understanding, cultural variations, differences of values - as well as external, for example the lack of awareness on available government resources and how to access them, the allocation of scarce resources, the lack of an international network, administrative challenges, etc.

Mr. Ternullo suggested the following **possible solutions** to be offered by governments and **public policies** to help businesses tackle these challenges:

- Dedicate government staff to build awareness on available government resources to help businesses internationalize their activities
- Create globally-agreed standard documents, to facilitate international procedures, matchmaking, and mentoring between US and EU companies.

EU-US R&D collaboration between companies – challenges, obstacles and possible solutions from several collaboration cases

Dr. Elena CHEKHOVA, General Manager, Biotine Consulting Group, USA

Dr. Elena Chekhova, as the General Manager of the **Biotine Consulting Group** in the USA, a private company highly involved in transatlantic and international health RDI collaboration, shared her impressions on the course of different transatlantic research, development and clinical collaborations.

Dr. Chekhova started with Biotine's collaboration with a research institute in Belgium, and pointed out two main barriers encountered in this case, i.e. the **time spent on legal paperwork**, and difficulties to find patients for trials. Her conclusion on that case was mainly that "timing is everything" in international RDI collaboration, and has to be well-planned from the beginning.

She continued with a case of collaboration in which **technology transfers** especially were a source of problems, with **trust being key** in case of collaborations involving such transfers, concluding on the need for more face-to-face communication and more exchange from the beginning to bring common understanding.

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Dr. Chekhova also discussed the case of an important collaboration that did not come to a successful conclusion, in which a European academic researcher was willing to test a technology Biotine was working on, in its own biological system. In this case, legal negotiations were conducted, but were never completed partly due to the **lack of sample legal contracts** from which to base discussions and the divergence on this between different countries. She therefore concluded that understanding the different legal systems is key before starting international RDI collaboration.

Dr. Chekhova ended with a case of successful collaboration, in which a biotech company hired a **contract research organization in the EU** to run its research and development projects, but finally had to open an office in the EU to **guarantee full transparency** in the project and to facilitate successful collaboration.

How the International Trade Administration Can Help Your Company Identify and Capitalize on Overseas Business Opportunities

Matthew Hein, International Trade Specialist, U.S. Department of Commerce, International Trade Administration, Office of Health and Information Technology

Matthew Hein, as an international trade specialist in the area of e-health for the **International Trade Administration (ITA)**'s Department of Commerce, gave a presentation on the inputs of ITA in transatlantic collaborations.

He first presented ITA's structure and activities and focused on ITA's recent activities in Health Information and Technology. He underlined the **importance of the Health Information and Technology sector**, a commercial sector with significant opportunities worldwide for both products and services, with a significant shortage of workers, and also representing a big societal challenge in terms of citizen access to improved healthcare and treatment.

He finally presented **ITA's program "Select USA"** that promotes and facilitates business investments in the USA, having facilitated about $ 18 billion in investment to date, notably helping companies finding information to make investment decisions and connecting people to appropriate local level contacts. He reminded the audience of **interest in investing in the USA**, a country with Free Trade Agreements providing market-preferred access to 20 countries, a transparent, fair, stable business climate, high research and development investment and protection of intellectual property rights.

Showcases of cluster/facilitator support (health/ e-health field):

EXCHANGE ON TRANSATLANTIC RTDI COLLABORATION OF EU AND US COMPANIES THROUGH INTERMEDIARIES SUCH AS CLUSTERS; SUPPORT NEEDS, INTER-CLUSTERING; Q&A

Moderator: Ms. Helena ACHESON, MFG Innovation Agency for ICT and Media Baden-Württemberg, Germany

E-Health Cluster Development in Massachusetts

Mr. Laurance STUNTZ, Director, Massachusetts eHealth Institute at MassTech (MeHI)

Laurance Stuntz, as Director of the **Massachusetts eHealth Institute (MeHI)**, a division of the Massachusetts Technology Collaborative, a public innovation agency, opened the part of the workshop

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dedicated to clusters and other facilitators, by presenting the **Massachusetts e-Health Cluster** enhanced by the MeHI, and by giving some insight on the objectives of the cluster for 2014.

The **Massachusetts e-Health Cluster** presently gathers more than two hundred companies from the sector (with an objective of four hundred in 2020), and a wide range of stakeholders (e-health companies, capital investors, care providers, payers, academia, associations, public entities) around three programs dedicated to the e-health cluster development, the workforce development and the innovation promotion. Mr. Stuntz also analyzed the **Massachusetts e-health eco-system** in terms of workforce, medical facilities, clusters of research and educational institutions, entrepreneurial sector, innovation policies, venture capital community, top 100 enterprises, etc. and listed some basic **cluster growth facilitation factors** (e.g. **stakeholder collaboration,** growing and retaining e-health organizations and e-health talents, strengthening a global and national brand).

Mr. Stuntz concluded by addressing **collaboration with the EU,** stating that the many differences in health care systems have prevented many e-health companies from establishing international collaborations. However, he referred to the beginning process of interclustering between US clusters and EU clusters in the field of health and e-health as providing a new venue for possible international partnerships.

The Importance of clusters to drive competition, innovation and prosperity

Ms. Sarah Jane MAXTED, Research Manager, Harvard Business School

Sarah Jane Maxted, as Research Manager at the Institute for Strategy and Competitiveness of **Harvard Business School** and highly involved in the development of a **US Cluster mapping project** spoke about the importance of clusters to drive competition, innovation and prosperity.

After giving the audience background information on the **definition of clusters and the evolution of the term** through history, she explained the **importance of clusters in terms of economic outcomes**, with effects on prosperity, entrepreneurship and structural changes. She then introduced the US Cluster mapping project (http://clustermapping.us/), a national economic initiative that provides access to an interactive website with **cluster data and regional statistics** covering the US, launched few days before the workshop. She presented two cases of **international collaboration** within this project, with Mexico and the EU, and mentioned that the project team had already received feedback from international users on potential collaboration, aiming at an eventual development of such tool in their country. She indicated that the idea for the future development of the website was to develop it as a cross border community building tool.

Supporting multi-lateral collaboration in international development: examples, strategies, best practices

Mr. Loic ROCABOY, Senior Project Manager, ERAI business internationalization agency, Philadelphia

This presentation was cancelled due to unforeseen circumstances affecting the speaker. The presentation slides can nevertheless be found online among the presentations of the workshop.

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Boston Life Sciences University Cluster

Mr. Vinit NIJHAWAN, Managing Director Technology Development, Boston University

Vinit Nijhawan, as the Managing Director of Technology Development of **Boston University**, gave a presentation on the Boston Life Sciences Cluster and its EU collaboration.

First, he introduced the audience to the **Boston University research institution**, and analyzed the **US academic research ecosystem**, notably pointing at the increasing collaborations between the pharmaceutical industry and academia as this industry drives externalization of early-stage R&D. He also gave an overview of **the Boston Life Sciences Cluster and the Massachusetts Life Sciences Center**, an investment agency that supports life sciences innovation, research, development and commercialization.

Mr. Nijhawan described two **case studies of transatlantic collaboration** conducted by Boston University in the field of kidney disease diagnosis and breast cancer therapy. In the first case, a researcher from the Boston University School of Medicine collaborated with a researcher from the French National Centre for Scientific Research in Nice and a German company named EuroImmune. The latter became the worldwide exclusive licensee of the results, but it took three years before the license was finally agreed, and collaboration was sometimes difficult mostly due to cultural barriers and distance. In the second case, a researcher from Boston University's School of Public Health collaborated with a Dutch company. The initial mistrust from both sides led to excessive documentation of the project. Moreover, Dutch lawyers were not familiar with US University licensing, which significantly prolonged negotiations. Mr. Nijhawan concluded by urging the creation of common templates for transatlantic RDI agreements.

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Session 4 - Roundtable discussion

The idea of the **roundtable discussions on "Opportunities, barriers & drivers for transatlantic RTDI collaboration, focus on health/e-health" (60 min)** was to exchange around two main questions:

- "What challenges have you faced while collaborating with EU [or US] companies [partners?]? If necessary, prompt for specifics. "
- "If you could change anything, what would you change to improve collaboration with EU [or US] businesses?"

The session was moderated by **Svetlana KLESSOVA**, inno TSD, France, and brought together four high-level panelists with expertise on EU-US business collaboration:

- **Dr. Kate TORCHILIN**, CEO, Novaseek Research, co-founder and Board member of Mechanical Drugs Inc., USA
- **Dr. Anatole KLYOSOV**, founder emeritus and member of Scientific Advisory Board, Galectin Therapeutics (NASDAQ: GALT), USA
- **Mr. Maurice BERENGER**, CEO of Protip SAS, France
- **Mr. Stamatis N. ASTRA**, Chief Executive Officer, PhotOral Inc., USA

The general audience was invited to comment on the discussion points.

The panel discussion was opened with the question **"What are the bottlenecks you faced and possible solutions?"**

Kate Torchilin answered that she particularly saw challenges related to **regulations** (drug regulations for which the data protection in e-health was an even bigger issue) and the differences in how **Intellectual Property Rights** are handled in the US compared to the EU (EU: patent protection is delivered to first patent filer and product commercialization can only start after patent deposit vs. US: patent is delivered to the first patent filer who must also be inventor with the possibility of commercialization up to one year ahead of patent deposit (grace period)). She mentioned that **transparent information on potential differences in rules** is important so as to find a solution among collaboration partners to tackle with this divergence.

Maurice Berenger added that a budget constraint had been the reason for his company for going international and that building international partnership and a network through a collaborative R&D project had been an opportunity to put a foot in the US without incurring too much cost. According to

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his own experience, **personal relations** were the key to build a strong partnership, whereas funding could be a driver but not a solution.

Stamatis N. Astra pointed out that cultural differences and not being face to face could sometimes be a problem for successful collaboration, but that the main issue was non-adapted agendas and also different approaches to problems. He said that the **alignment of goals** was essential in the sense that the aspirations of each stakeholder had to be taken into account (academic: publication; start-up: funding; venture capitalist: exit).

Maurice Berenger stated the fact that there were many tools for partnership building, but that often European SMEs were **lacking the will to collaborate in international consortia**, as a "**pull factor**" was missing.

Anatole Klyosov said that each stakeholder had **internal procedures** and that they were easiest in private companies; he gave the example of a difficulty that could occur in public organizations (case: a German professor had agreed to do tests on compounds developed by a US company; for this activity, an agreement had to be set up and the Germany university lawyer proposed an agreement saying that the professor would get part of the IPR. Finally the collaboration couldn't be implemented, as the US company wasn't willing to share the IP rights, as they had invested 10 years of development and a large amount of money already).

The discussions on the second question **"If you were dreaming, what would you imagine?"** were as follows:

Anatole Klyosov pointed towards the **mismatch of regulations**; he said that if some of them were known beforehand, this would have been helpful, meaning that it could be good to develop guidelines with at least some examples.

At this point, several persons from the audience intervened as follows:

Mr. Malfroy-Carmine stated that it was difficult to **change the image of a country** that was "stuck in people's mind" and thus **communicating advantages of innovation in Europe** would be important. He gave the example of France were a support process was launched for SMEs to enhance innovation activity ("Credit import recherche").

Svetlana Klessova suggested the idea to US businesses of **establishing a small office in EU** for the support of R&D collaboration with Europe.

Sinan Tumer answered that a lot of companies wanted to keep the **IPR with their headquarters** (e.g. for SAP it had to be with their German headquarters) and that such office could only become a **liaison office**, nothing more (a legal entity status would be necessary); however, certainly it could be a bridge to Europe.

Elena Chekhova pointed out the **cost** for the setup of such office in Europe to which **Maurice Berenger** answered that entering Europe from the US was much more difficult than the other way round, but that low investment companies could be found to help businesses set up in Europe.

Linking to her question from before, Svetlana Klessova asked to the panelists: **"What would you change if you could?"**

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Kate Torchilin said that the **promotion of personal relationships and networks** from a government standpoint was essential, as she considered there were not enough people who knew both sides and that dedicated information (seminars, etc.) could be helpful.

Matthew Hein from the audience responded that such help could only be a small part and that knowing information and searching it would still remain in **everyone's own responsibility**.

A workshop participant intervened with another point, saying that **improving technology transfer** between academia (where innovation takes places) and industry (creation of new entities) was important. The person stated that for efficient technology transfer it needed to be simple for companies "to shop", which could be achieved if a **single structure** centralized technology transfer, linking both EU and US. He illustrated the idea, saying such structure could in the US be based on MassBio and in Europe on Inserm Transfer for example.

On this point, a person from the audience reminded that **Europe** was a **fragmented market**, saying "you are not dealing with Europe, but with different markets".

Helena Acheson confirmed that the counselors from EU Member States felt that the **ownership of the S&T Agreement was not completely shared by all countries** to which **Matthew Hein** answered that the European Commission represented 28 countries and that there was the clear question on where the boundaries for decisions/responsibilities between EU as a structure and Member States lay.

Retaking a previously mentioned point on cultural differences, **Svetlana Klessova** asked whether the panelists here saw a real difficulty.

Maurice Berenger stated that in his opinion this was not the case, but that it was mostly "**general personal issues**" that could interfere in international collaboration between EU and US.

Kate Torchilin added that the **differences** appeared more **between different kinds of institutions** (whereas e.g. academics from both sides were "close").

Stamatis N. Astra came back on the question "if you dreamed…" stating that according to him it was necessary to **go step by step**: he continued that the transatlantic tech transfer centralized office was a dream which wouldn't work, as he said he had already tried this in Europe. He stated that for successful collaboration "you just build direct partnerships by **asking all advice you can get** from different institutions".

Anatole Klyosov disagreed on the fact that "dreams couldn't become reality" and illustrated this through the example that a common currency (the Euro) in Europe once was a dream, but that now it is a reality.

On this encouraging statement, **Svetlana Klessova** closed the roundtable discussion, thanking all panelists for their contributions and interesting thoughts.

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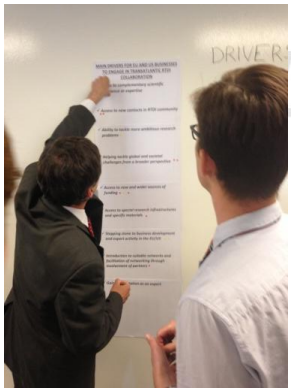
Wrap up and end of the Workshop

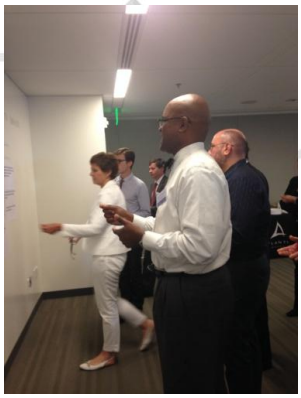
The workshop was concluded through a short **wrap up and concluding summary by Svetlana Klessova**, inno TSD, who thanked the speakers for their presentations and the audience for the valuable comments.

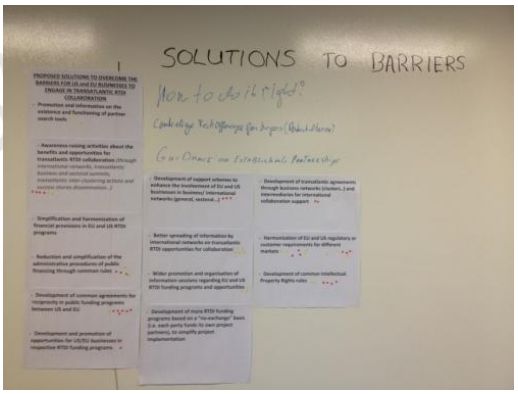
She notably concluded on the fact that progress is being made in terms of transatlantic cooperation, albeit slowly, and pointed out several factors of progress, notably the funding initiatives launched by the EU with opportunities for US firms to participate and the continued transatlantic dialog on harmonization, as well as more general factors such as globalization of science and technology, the existence of global challenges in the field of Health, energy, food, water, etc. and the rising R&D costs.

She reminded about the importance of the elements brought together which in a next step will be gathered into a **policy brief designated to EU and US policy makers as support for discussions on the next EU-US S&T Agreement.** She pointed out that the various examples on EU-US collaboration provided at the workshop will be important illustrations on how to better integrate the "innovation" dimension into the formal S&T Agreement.

The participants were invited to provide suggestions for drivers to EU-US STI business collaboration on a wall board and to vote for those they considered the most important. The same exercise was done to gather weighted feedback on recommendations for potential solutions.







The tables below show the results for both drivers and recommendations:

DRIVERS	Critically important	Very important
Access to complementary scientific experience and expertise	5	3
Access to new contacts in RDTI community	3	1
Ability to tackle more ambitious research problems	1	4
Helping tackle global and societal challenges from a broader perspective	2	0
Access to new and wider sources of funding	3	2
Access to special research infrastructures and specific materials	1	1
Stepping stone to business development and export activity in the EU/US	0	4
Introduction to suitable networks and facilitation of networking through involvement of partners	2	1
Gaining reputation as an expert	0	0

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Others from attendees…		
Access to technology	1	0
Technology transfer that works	0	0
New markets	0	0
Access to state of the art equipment	0	0
PROPOSED SOLUTIONS / RECOMMENDATIONS		
Promotion and information on the existence and functioning of partner search tools	0	2
Awareness-raising activities about the benefits and opportunities for transatlantic RTDI collaboration	4	2
Simplification and harmonization of financial provisions in EU And US RTDI programs	0	0
Reduction and simplification of the administrative procedures of public financing through common rules	3	2
Development of common agreements for reciprocity in public funding programs between US and EU	6	1
Development and promotion of opportunities for EU/US businesses in respective RTDI funding programs	1	0
Development of support schemes to enhance the involvement of EU and US businesses in networks	3	0
Better spreading of information by international networks on transatlantic RTDI opportunities for collaboration	0	5
Wider promotion and organization of information sessions regarding EU And US RTDI funding programs and opportunities	0	3
Development of more RTDI funding programs based on a “no-exchange” basis (ie each party funds its own project partners), to simplify project implementation	0	0
Development of transatlantic agreements through business networks and intermediaries for international collaboration support	2	0
Harmonization of EU and US regulatory or customer requirements for different markets	6	7
Development of common Intellectual Property Rights rules	4	2
Others from attendees…		
Centralize technology offerings for buyers	0	0
Guidance on establishing partnerships	0	0

Table 1. Assessment by attendees of critically important and very important drivers and solutions for enabling EU/US RTDI collaboration.

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ANNEXES

Workshop Program

08h30-09h00	Welcome registration, coffee & networking
	Session 1 – Opening
09h00-09h15	**Opening: Welcome** European Commission Representative, Workshop Organizers
09h15-09h50	**Input presentation:** ○ Scene Setting : BILAT USA 2.0 project goal, aim of the workshop (15 min) *Ms. Svetlana KLESSOVA, Director, inno TSD, France* ○ Transatlantic business driven collaborative health research : drivers, barriers and open issues (20 min) *Mr. Richard SATCHER, Sr. Business Manager, RTI International, USA*
09h50-10h05	**Industrial feedback from US:** ○ Transatlantic Research, Technological Development and Innovation (RTDI) cooperation of companies: sharing ideas (15 min) *Mr. O. Sinan TUMER, Sr. Director, SAP Co-Innovation Lab, USA*
10h05-10h20	**Feedback from a European innovation agency** ○ Evaluation of the EU-US S&T agreement and the need to integrate an innovation dimension (15 min) *Ms. Helena ACHESON, Head of Division, MFG Innovation Agency for ICT and Media Baden-Württemberg, Germany*
10h20-10h40	Coffee & networking
	Session 2 - Opportunities for transatlantic RTDI business cooperation
10h40-11h20	**Horizon 2020 – the European funding programme - and transatlantic collaboration opportunities in RTDI between businesses** ○ RTDI collaboration opportunities for businesses - supporting health-related businesses and transatlantic cooperation - through Horizon 2020 (25 min) ○ Q&A (15 min) *Mr. Laurent BOCHEREAU, Head of Unit "Health - Strategy", European Commission, Health Directorate*
11h20-12h00	**US program(s) and transatlantic collaboration opportunities in RTDI between businesses** ○ RTDI transatlantic collaboration opportunities for health related businesses – through the Small Business Innovation Research (SBIR) program at the US National Cancer Institute (NCI) (25 min)

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	○ Q&A (15 min) *Mr. Michael WEINGARTEN, Director at NCI SBIR & STTR Programs, National Institutes of Health (NIH), USA (online presentation)*
12h00-13h00	Lunch & networking
	Session 3 – Panel Presentations
13h00-14h20	**Showcases of transatlantic business collaboration (health/ e-health field) in RTDI:** Exchange around real-life experience in transatlantic RTDI collaboration of companies and sharing of good practices, barriers and drivers; Q&A *Moderator: Kirsten RIETH, Senior Innovation Advisor RTI International, USA* ○ Bigger, More Impactful Research Projects via Transatlantic Collaboration: A Case of a European Company *Dr. Engin VRANA, Director of Fundamental Research of Protip SAS, France, and Scientific Coordinator of IMMODGEL R&D Project funded by the European Union* ○ Engineering Prowess of Portugal: Innovating, Investing and Inspiring. Kinematix: case study of opportunities and challenges. *Mr. Joseph TERNULLO, JD, MPH, President, Kinematix, USA, Inc.* ○ EU-US R&D collaboration between companies – challenges, obstacles and possible solutions from several collaboration cases *Dr. Elena CHEKHOVA, General Manager, Biotine Consulting Group, USA* ○ How the International Trade Administration Can Help Your Company Identify and Capitalize on Overseas Business Opportunities *Matthew Hein, International Trade Specialist, U.S. Department of Commerce, International Trade Administration, Office of Health and Information Technology*
14h20-15h40	**Showcases of cluster/facilitator support (health/ e-health field):** Exchange on transatlantic RTDI collaboration of EU and US companies through intermediaries such as clusters; Support needs, inter-clustering; Q&A *Moderator: Ms. Helena ACHESON, MFG Innovation Agency for ICT and Media Baden-Württemberg, Germany* ○ E-Health Cluster Development in Massachusetts *Mr. Laurance STUNTZ, Director, Massachusetts eHealth Institute at MassTech (MeHI)* ○ The Importance of clusters to drive competition, innovation and prosperity *Ms. Sarah Jane MAXTED, Research Manager, Harvard Business School* ○ Supporting multi-lateral collaboration in international development: examples, strategies, best practices *Mr. Loic ROCABOY, Senior Project Manager, ERAI business internationalization agency, Philadelphia* ○ Boston Life Sciences University Cluster *Mr. Vinit NIJHAWAN, Managing Director Technology Development, Boston University*
15h40-16h00	Coffee & networking

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	Session 4 - Roundtable discussion
16h00-17h00	**Roundtable** ○ Opportunities, barriers & drivers for transatlantic RTDI collaboration, focus on health/e-health (60 min) ○ Exchange around two main questions: 1. What challenges have you faced while collaborating with EU [or US] companies [partners?]? *If necessary, prompt for specifics.* 2. If you could change anything, what would you change to improve collaboration with EU [or US] businesses? *Moderator: Svetlana KLESSOVA, inno TSD, France* Panelists (clusters and companies): ○ Dr. Kate TORCHILIN, CEO, Novaseek Research, co-founder and Board member of Mechanical Drugs Inc., USA ○ Dr. Anatole KLYOSOV, founder emeritus and member of Scientific Advisory Board, Galectin Therapeutics (NASDAQ: GALT), USA ○ Mr. Maurice BERENGER, CEO of Protip SAS, France ○ Mr. Stamatis N. ASTRA, Chief Executive Officer, PhotOral Inc., USA ○ General audience
17h00-17h15	**Wrap up and end of the Workshop** ○ Concluding summary, action items identified, next steps (15 min) *Ms. Svetlana KLESSOVA, Director, inno TSD*

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List of participants

Last Name	First Name	Company/Organization
Acheson	Helena	Innovation Agency for Information Technology and Media Baden-Württemberg
Antoine	Christophe	ADI
Aubrey	Kay Corry	Usability Resources Inc
Berenger	Maurice	Protip SAS
Blackman	Tiffany	Harvard University
Bochereau	Laurent	European Commission DG Research & Innovation
Burghardt	Corinna	Tufts University
Chekova	Elena	Biotine Consulting Group
Comte Keller	Tania	Physical Health Insights
Davison	Marylin	Sophia Antipolis Business Angels
Del Zoppo	Cinzia	General Consulate of Italy
DiLeo	Lucas	Broadland Advisors
Fadil	Eva	inno TSD
Fieschi	Fabien	General Consulate of France
Gamora	Georges	STMA, LLC

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Goff	William	Physical Health Insights
Gonsenhauser	Alan	Demand Revenue
Hein	Matthew	U.S. Department of Commerce, International Trade Administration
Henze	Peter-Paul	German Consulate
Hulot	Sandrine	French American Biotech Spring Board
Incio	Joao	MGH
Kaplan	Grant	MOITI
Klessova	Svetlana	inno TSD, France
Klyosov	Anatole	Galectin Therapeutics
Leskiw	Michael	MIT
Levy	Nancy	BostonLanding.us
Lossky	Mané	Cydan
Malfroy-Camine	Bernard	ViThera Pharma
Maxted	Sarah Jane	Harvard's Institute for Strategy & Competitiveness
McDonough	Britanny	MOITI
Miech	Jacky	MOITI
Mojtabai	Fatemeh	Novatarg Pharmaceuticals

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Nijhawan	Vinit	Boston University
Osborn	Elizabeth	Harvard University
Ouellette	Michelle	U.S. Dept of Commerce
Perry	Wayne	GCC
Piret	John	Newbury Piret & Co., Inc.
Poirier	Brian	U.S. Commercial Service
Pontivy	Jennifer	Harvard
Quezada	Fernando	Biotechnology Center of Excellence Corp.
Rieth	Kirsten	RTI International
Robie	Bruce	ARO Medical ApS
Rosenstock	Carol	Boston Children's Hospital
Satcher	Rick	RTI International
Shankaraiah	Ram	Massachusetts General Hospital
Shriwr	David	Massachusetts Institute of Technology
Stevenson	Anne	Massachusetts General Hospital
Stuntz	Laurance	MeHI
Taber	Magdalena	Self Employed

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Taciroglu	Ayse	Partners HealthCare
Ternullo	Joseph	Kinematix Inc.
Toews Moeling	Stephanie	MIT
Torchilin	Kate	Novaseek Research, Co-Founder & Board Member of Mechanical Drugs Inc.
Trevino	Richard	Boston University
Tumer	O. Sinan	SAP Co-Innovation Lab
Van Cauter	Maxime	WBI - Tufts
Van Fleit	Lynn	Diplomacy Matters Institute
Vrana	Engin	Protip SAS
Williams Jr	James	Wayne State University

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