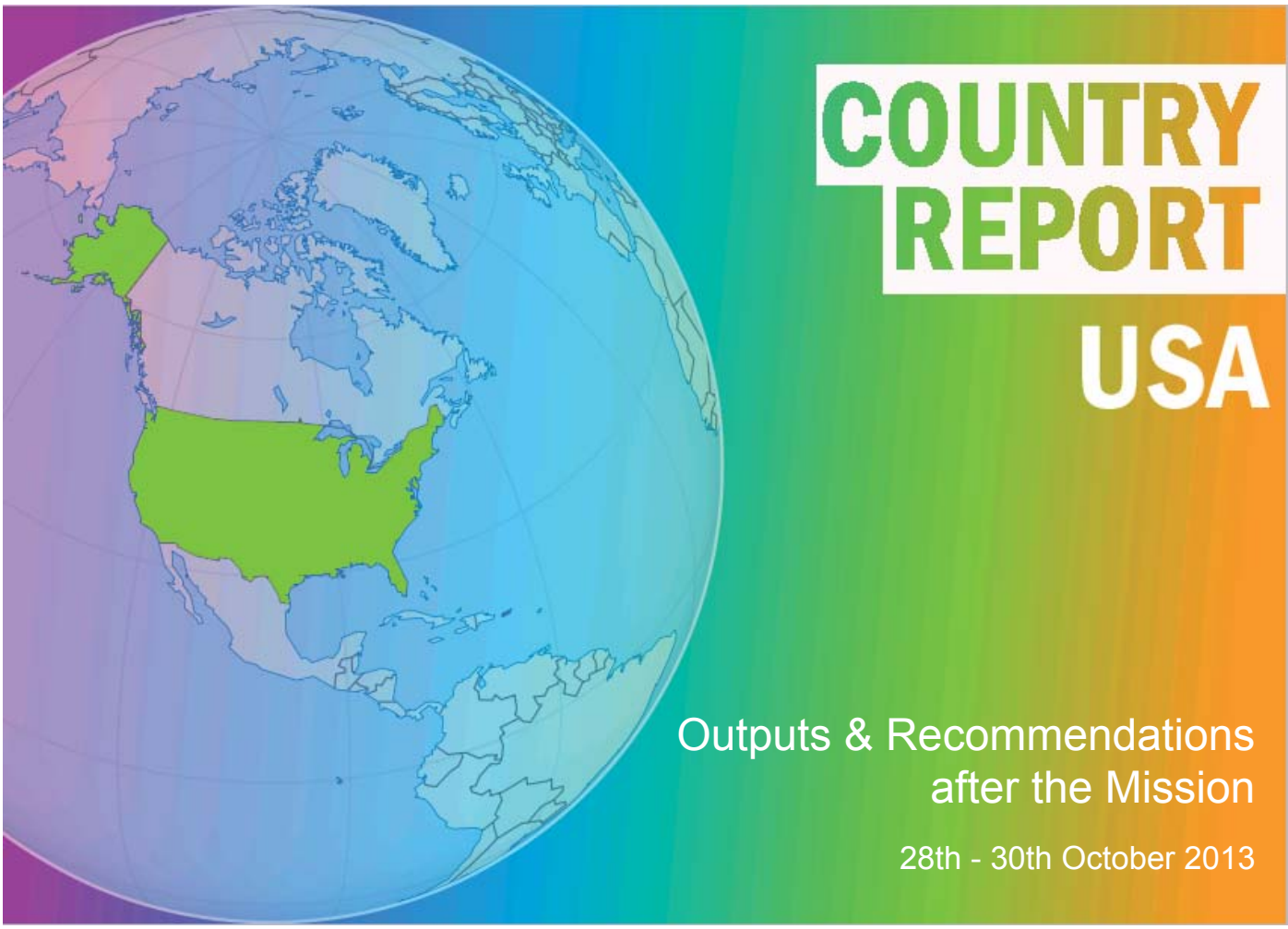
bioXclusters
European Innovation Worldwide



COUNTRY REPORT
USA

Outputs & Recommendations after the Mission

28th - 30th October 2013

European Contract N° SI2.612891 – 3/G/ENT/CIP/11/C/N04C011

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Report of the Mission

Objective

The objective of the mission in Boston (Massachusetts, United States of America –USA–) was to discover and detect key entry points of the biotech and medtech market in the USA and collaboration opportunities with the different organizations visited.

The USA represents a key market in life sciences, and notably for Personalized Healthcare. With a life sciences sector weighting $61 billion and counting about 1.455 companies, among which 300 quoted in stock exchange, the USA is without any doubt the top-leading economy on this market. The life sciences is indeed one of the most dynamic sector of the American economy were not less than $30 billion were invested for R&D in 2010. The American life sciences market alone accounts for 70% of the world turnover and for 15 % of the total sales of the biotechnologies market.

Within this huge market, Boston is the one of the major biotech region of the country. It is at the heart of "North East BioMed Corridor", going from Washington DC to Boston, by way Philadelphia and New York. In this area, figure the most prestigious universities specialized in the life sciences among which John Hopkins University as well as the big federal center of research, the National Institutes of Health (NIH).

The geographic distribution of biotech companies reveals a concentration in Boston. Most active American city in the Biotech field, Boston concentrates not less than 150 companies specialized in Biotechnology and a representation of many international pharmaceutical companies. Genzyme, a Sanofi company, has long been the largest employer in the industry in Massachusetts.

The top three NIH-funded independent hospitals in the US in 2012 are in Boston. Nine of the top 18 are in Massachusetts. The state accounts for 11.3% of the US-based drug development pipeline. Massachusetts-headquartered companies account for 5% of the global biologics pipeline.

During the mission, the BioXcluster group established good connections with different actors (from market experts to high-level organizations) in Boston in order to better support our SMEs to facilitate its strategy and guide their first steps towards the North American market.

The BioXcluster group had also the opportunity to participate in high quality training sessions focus on strategy and practical aspects to enter in the US market and, more specifically, the Boston region:

- Guidelines and requirements to establish a US entity.
- Prerequisites for navigating US regulatory environment & IP Strategy.
- Investors & Investments opportunities in the US for European SMEs.

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Agenda

The agenda for this 3-day mission was:

Day 1

Date	Hour	Topic
28/10	07:15	UMASS • Mark Trusheim, Bio-manufacturing Executive in Residence, UMASS Dartmouth
	08:30	WELCOME SESSION • Fabien Fieschi, Consul General of France in Boston
	09:00	SANOFI-GENZYME (I) • Paul Juniewvicz, Head of Oncology Business Opportunities, North America • Jessi Colund, Corporate Communications Senior Specialist • Stacy Cohen, VP Global Head of Business Development, MS, Genzyme
	12:30	TRAINING WORKSHOPS (I) - Establishing a US entity • Alexandre Suhas, CEO, Marie Landel & Associates
	14:00	CAMBRIDGE INNOVATION CENTER • Kevin Wiant, Managing Director, Venture Café Foundation
	15:00	MASSLANDER • Mr. Frank Bobe, Co-Founder, Masslander
	15:30	FORESTCITY, THE UNIVERSITY PARK • Peter Calkins, COO, Forest City
	19:00	NETWORKING DINNER

Day 2

Date	Hour	Topic
29/10	08:30	SANOFI-GENZYME (II) • Dr Sridaran Natessan, Vice President for External Innovation, member of the leadership team of the Prospective Strategic Initiative group, SANOFI
	09:00	BOSTON UNIVERSITY • Michael Donovan, VP, Real Estate & Facility Services, Boston University
	10:00	TRAINING WORKSHOPS (II) - Prerequisites for navigating US regulatory environment & IP Strategy • Karin Hollerbach, CEO and founder of Taku Group • Mark de Rosche, PHD, VP Regulatory Drugs, Biologics, Voisin Consulting
	14:30	MASSBIO & MSLC & MOITI • Peter Abair, Director, International and Economic Development, MASSBIO • Angus McQuilken, VP Comm & Marketing, MLSC • Danica Medeiros, Program Associate, MSLC • Diana La Muraglia, Director Int'l Business Dev., MOITI • Richard Elam, Exec Director, MOITI
	18:00	MIT KOCH INSTITUTE • Marta Murcia, PHD, Collaborative Program Administrator, KOCH Institute.

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Day 3

Date	Hour	Topic
30/10	09:00	TRAINING WORKSHOP (III) - Investors & Investments, what opportunities are there in the US for European SMEs? • Live demo of company (Stelar) pitch presentation to adapt for a partner or angel or venture capital firm • James Shanahan, Co-Founder, VP, Business Development, Ariana Pharmaceuticals SA • Karin Hollerbach, CEO and founder of Taku Group
	12:00	NETWORKING LUNCH • Bernie Rudnick, Ira Wallace, Shahin Gharakhanian, Andrew Luber, NovoBioPharma
	14:30	BOSTON CHILDREN'S HOSPITAL • Personal Genomics Research Program: Jane Amara, Associate Director, Technology & Innovation Development Office; David Altman, Senior MKT & COMM; Geoffrey Horwitz, Bus Dev. Associate • Industry & Academia Collaborations: Todd Kreuger, CFO, Claritas Genomics

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General overview after the mission and opportunities

- The US biotech and medtech market is of strategic importance as the United States is the largest market and leading healthcare consumer in the world.
- The Massachusetts biotechnology cluster, along with California's and North Carolina's, is among the largest and leading clusters in the nation and world. Boston, Massachusetts, offers a strong concentration of biotech and medtech companies, prestigious colleges and universities (especially Cambridge), state-of-art R&D centers, manufacturing facilities and incubator spaces. Major pharmaceutical companies as Sanofi, Pfizer, Biogen-Idec have a large research centers in Boston, that employ over 10,000 people alone.
- There is a recognized regional government commitment of support to the biotechnology industry. A 10-year, $1-billion, state-funded investment initiative is now being implemented. This is one of the major reasons why biotech industry has grown remarkably in the past few years.
- The most successful market entrants are those that, apart from offering high tech and innovative products, plan its entry strategy accordingly. Understanding of how business is traded in the US, before coming to the country, is critical. The companies need to perform extensive market research to be sure that their products/services will meet the requirements of the demanding US market. This will give the company a good indication of its potential for success in the US market.
- Companies should be realistic about the costs of entering the US market that is quite considerable. Due to a complex US legal system the entering company will require various legal steps, including negotiating partners' agreements, licensing, forming a joint venture, developing strategic alliances and/or establishing a subsidiary. The decision would depend on the circumstances of the particular company.
- However, visibility is a key factor to investors and customers alike and there is an expectation from both that the entering company works with experienced local business partners/advisors or establishes a subsidiary in the US market.
- Appropriate advisors – tax, legal, regulatory and operations - should be sought.
- The financing of the biotech and medtech sectors has been reinforced over the past few years with IPOs, FPOs, public and private sector, and venture capital. The overall rise in venture capital funding and other funding sources continues to provide good opportunities to the US biotech industry.
- The funding landscape has change in the recent years. Although now investors are more open to European and foreign companies, a strong and clear entry strategy is imperative (validated business plan, with first sales strategy and the proper legal entity for doing business in the US market, is mandatory).

Short description and feedback of each organization

The information is presented in different sections based on the objectives of the sessions:

a. Welcome Session
b. Possible collaboration agreements
c. SANOFI-GENZIME
d. Incubator Facilities and Organizations
e. Networking sessions
f. Research and innovation facilities
g. Training Workshops

a. Welcome Session

CONSULAT GÉNÉRAL DE FRANCE IN BOSTON

http://www.consulfrance-boston.org

- Fabien Fieschi, Consul General of France in Boston

Fabien Fieschi, Consul General of France in Boston since 2012. He has served as First Secretary at the French Embassy in Japan, in charge of bilateral questions and domestic affairs in Japan. He then joined the French Permanent Mission to the United Nations in New York as First Secretary in Charge of Human rights. He also served as Advisor of Strategic Affairs & Relations with European and Asian nations under Prime Minister François Fillon.

This opening reception organized with GENZYME CENTER in Cambridge allowed an in-depth preview to the week's events. The consul gave key figures of the US market, the Boston / Cambridge area, and the exchange between the European Union and the U.S.:

- US market is still huge. The EU and the US remain the largest markets in the world despite the emerging countries' growth. In Asia there is a huge investment for the future but EU and US firms remain profitable. The US manufacturing sector went offshore but this situation is reversing because the labor cost in Asia (China) raised ultimately.
- The EU and the US are building an agreement to reduce customs rights. Changing regulatory issues to become easier.
- Massachusetts is ranked 12th in the US in term of GDP. It has huge capacity to attract talent (129 universities) and a long industrial tradition with a strong focus on biotech and pharma. It is a huge financial place (one of the biggest pool of Venture Capital organization together with a strong public investment).

b. Possible collaboration agreements

UMASS http://www.umassd.edu
• Mark Trusheim, Bio-manufacturing Executive in Residence, UMASS Dartmouth
The opening meeting with Mark Trusheim, Bio-manufacturing Executive in Residence at UMASS Dartmouth, one of the most renowned Ivy League universities in the US launched into discussion for an MOU between University of Massachusetts Dartmouth (UMD) and the Massachusetts Accelerator for Biomanufacturing (MAB) between the BioXclusters partners and ERAI. <u>Open actions/collaborations:</u> The terms of this general framework will be exchanged on and executed in the coming weeks, but seeks to provide mutually beneficial exchanges between the regions and the respective UMD –MAB cluster in terms of providing soft landing accelerators to SMEs, collaborative events surrounding trade events, among other organized visits between the two areas to explore collaborations surrounding set areas of research.

MASSBIO & MSLC & MOITI http://www.massbio.org http://www.masslifesciences.com
• Peter Abair, Director, International and Economic Development, MASSBIO • Angus McQuilken, VP Comm & Marketing, MLSC • Danica Medeiros, Program Associate, MSLC • Diana La Muraglia, Director Int'l Business Dev., MOITI • Richard Elam, Exec Director, MOITI
Massachusetts Biotechnology Council (MassBio), a not-for-profit membership organization represents and provides services and support for the Massachusetts biotechnology industry and is the nation's oldest biotechnology trade association. It has 620 biotechnology companies, universities, academic institutions and others dedicated to advancing cutting edge research. 400 of them are biopharmaceuticals companies, 50% of them dedicated to drug development, 19% CMO/CRO, 6% diagnostics, 6% medical devices and 2% bioinformatics. MassBio drives innovation by creating a forum for the biotechnology community to come together, educating the public and policy makers, influencing public policy and advancing the economic interests of individual companies, as well as the sector as a whole.

The Massachusetts Life Sciences Center (MLSC) is an investment agency that supports life sciences innovation, research, development, and commercialization via a state-funded investment initiative. The MLSC is charged with implementing a 10-year, $1-billion, state-funded investment initiative.

The MLSC offers a comprehensive set of incentives and collaborative programs targeted to the life sciences ecosystem. These programs propel the growth that has made Massachusetts the global leader in life sciences. The MLSC creates new models for collaboration and partners with organizations, both public and private, around the world to promote innovation in the life sciences.

Massachusetts Office of the International Trade & Investment (MOITI) is the Commonwealth's primary international business development agency promoting trade and investment with global partners in Massachusetts and around the world. A mission should be organized in Europe in 2014.

MOITI is the main state organization capable of establishing MOUs with international organizations. Since MassBio is a membership organization, they are seldom involved directly in MOUs only if in support of MOITI's efforts. MLSC works as a subset of the state and therefore any arrangement would need to be initiated as well with MOITI.

It's important to note the structure of this triad of organizations that work closely with local partners to p an ever-thriving Supercluster.

Over the course of the past few years, several of the individual partners that make up the BioXclusters have had either memberships and/or MOUs with MOITI and MassBio. BioXclusters, viewing the state as an epicenter of life sciences would like to establish a general framework with MOITI and the two corresponding organizations.

The meeting between all three organizations allowed for a common understanding that each (Mass) organization on its own could not support individually the set MOU framework presented by the BioXclusters.

Open actions/collaborations:

BioXclusters agreed to establish several specific actions to be carried out over the course of the next year, starting with a meeting immediately during EuroBIO and present this specific request to MOITI / MassBio.

BOSTON UNIVERSITY - Bio Square Discovery and Innovation Center http://www.bu.edu/biosquare
• Michael Donavan, VP, Real Estate & Facility Services, Boston University, BIOSQUARE
BioSquare is a biomedical research and business campus with a state-of-the-art, built-to-suit research facilities with comprehensive tenant amenities and services. Covering 14 acres and offering over 2.5 million square feet of new laboratory and office space, BioSquare is situated in Boston's cosmopolitan South End, within one mile of the city's central business district and directly adjacent to the Boston University Medical Campus and Boston Medical Center. Open actions/collaborations: Collaborating with a tenant surrounding a specific area of research would be ideal to foster SMEs first steps into the Boston.

c. SANOFI-GENZIME

SANOFI-GENZIME http://www.genzyme.com and http://www.sanofi.us
• Paul Juniewvicz, Head of Oncology Business Opportunities, North America, SANOFI • Jessi Colund, Corporate Communications Senior Specialist, SANOFI – GENZYME • Stacy Cohen, VP Global Head of Business Development, MS, GENZYME • Dr Sridaran Natessan, Vice President for External Innovation, member of the leadership team of the Prospective Strategic Initiative group, SANOFI
Paul Juniewvicz, Head of Oncology Business Opportunities, North America, SANOFI Paul Juniewvicz shared his insight on the evolution of SANOFI throughout the years as the Head of Oncology Business Opportunities but also as the previous Global Head of Access to External Innovation, position that he held for several years. The Sanofi Oncology Division has dual headquarters in Cambridge, Massachusetts, and Vitry, France. Paul exchanged with the group regarding SANOFI's driving factors to partner or acquire a company, the chief determinant is whether the product addresses an « unmet medical need ». Since the year 2009, Sanofi has acquired over 32 companies, completed 91 in-licensing agreements and entered 3 joint-ventures. Opportunities across oncology include:

1. Molecular targets: small molecules, passive immunotherapies and adaptive immunotherapies at all stages.
2. Validated targets.
3. Translational medicines: Human tumor databases, etc.

In particular, Sanofi-Genzyme BioVentures acts as Sanofi's vehicle to access external innovation and has funded 7 early to mid-stage emerging product candidates. Another tool that helps Sanofi to access innovation is the Warp Drive Bio technology platform (http://www.warpdrivebio.com), launched in 2011 through a groundbreaking strategic partnership with Sanofi and with financing from Third Rock Ventures and Greylock Partners.

Jessi Colund, Corporate Communications Senior Specialist, SANOFI – GENZYME

Jessi Colund provided the group with a general background for both Genzyme and Sanofi as separate operating groups. Genzyme focuses on rare diseases and multiple sclerosis, while SANOFI, the global Giant and parent company focuses on generic medicines, consumer healthcare products, animal health, and serves as the world leader in human vaccines.

Stacy Cohen, VP Global Head of Business Development, MS, GENZYME

Stacy Coen gave BioXclusters an overview of Genzyme's MS and Rare Diseases portfolio and best practices and what Genzyme looks for in terms of partnering or bringing a product to market. The rare diseases division specializes in genetics, endocrinology, and cardiovascular-related diseases. The multiple sclerosis group, the newer of the 2 therapeutic areas is addressing a larger patient community and allowing Genzyme to transform the way patients are treated through personalized medicines and adapting therapies for neurological diseases.

Dr Sridaran Natessan, Vice President for External Innovation, member of the leadership team of the Prospective Strategic Initiative group, SANOFI

Dr. Sridaran Natesan is the Vice President for External Innovation at Sanofi. Dr. Natesan has witnessed the complete transformation of Boston – Cambridge area over the past 20 years into the top Life Sciences Hub / Supercluster, giving him a global perspective of the environment and opportunities for SMEs. Sridaran stressed the importance of relationship management and the engagement of the researcher throughout the process of technology transfer.

Sanofi and its family of acquired companies over the years engaged in a number of agreements to foster external innovation. There are several aspects to manage: scouting of technologies, management of alliances, and expertise and evaluation of the technology. Once the product has been selected the process is as follows:

a) Vet technology.

b) Bring in relevant experts from therapeutic area.

c) Create an external working group – meetings every other week to fast-track the progress and process.

d) Due diligence: create task force team or committee of 10-20 people to work directly with company in-house. Assign a dedicated Alliance Manager

Sanofi spends a minimum of 6 months per technology with a maximum of 12-18 months. 14 projects are funded with seed money for the idea. They don't focus on pre-clinical projects – too soon not strategic.

Then 2 options for these projects: a) it becomes a Sanofi projects or b) it becomes a company.

At the moment 6 projects are becoming companies for Drug delivery. Ex MIT Niddle free drug delivery – high tech devices.

Open actions/collaborations:

The visit to Genzyme Center offered a global overview of the state of both personalized medicine and oncology to the BioXclusters partners.

BioXclusters is encouraged to identify potential candidates for collaboration in the next couple months. They will be reviewed for further consideration and Sanofi and Genzyme both will provide candidates with valuable feedback upon vetting a product candidate, completing or not the Sanofi process.

d. Incubator Facilities and Organizations

CAMBRIDGE INNOVATION CENTER (CIC)

http://cic.us

- Kevin Wiant, Managing Director, Venture Café Foundation

Cambridge Innovation Center (CIC) is a start-up friendly co-working incubator with a wide range of pricing suited to provide simply a seat at a table up to a double private office ($350-2400). Since 1999, more than 1400 companies have chosen CIC as their home and many have gone on to prove their value to the world as startups. More than $1.8B of venture capital has been invested in companies that were headquartered at CIC. CIC is housing over 600 companies, most of them startups.

Kevin Wiant, Managing Director, Venture Café Foundation, has led a number of early stage high growth companies in the mobile, telecommunications, software, and web sectors. Kevin is passionate about helping Boston area start-ups connect with the resources they need to start and grow companies. Each Thursday, Kevin hosts Venture Café (http://www.vencaf.org), a casual meet-up group that convenes over beer at CIC each week to connect with both angel and venture capital firms. He also serves on the Board of Directors of Mobile Monday Boston and the MIT Enterprise Forum of Cambridge.

MASSLANDER ACCELERATOR

http://www.masslander.com

- Frank Bobe, PhD, MassLANDER

MassLANDER is an international organization of life science executives and investors based in Kendall Square, Cambridge, Massachusetts. It was founded in the belief that breakthrough innovation is happening around the world and that geographical distance and cultural differences create formidable challenges for entrepreneurs to expand their corporate development efforts to the US MassLander offers to the companies that join its network:

- Integration = act as a local player
- Visibility = media outreach, networking
- Communication = training session, one to one meeting and mentoring

A number of international groups have operations within CIC such as MassLander, France Springboard, France HubTech21, and several others. BioXclusters had the occasion to exchange with MassLander, led by Frank Bobe, PhD, an international bio/pharma senior executive.

Open actions/collaborations:

MassLander offers a 3-month package program for $20,000 to support a company's prep strategy, implantation strategy, facilitate introductions, and executive coaching via its seasoned executives from across the bio/pharma spectrum. The expected results of this program are measured by capital raised, partnership agreements signed and advisory board members recruited.

FOREST CITY, The University Park at MIT

http://www.forestcity.net/properties/work/science_technology/Pages/default.aspx

- Peter Calkins, COO, Forest City

Forest City

The Forest City Enterprises, Inc., is an NYSE-listed national real estate company with $10.6 billion in total assets. The Company is principally engaged in the ownership, development, management and acquisition of commercial and residential real estate and land throughout the United States.

Founded in 1920 and based in Cleveland, Ohio, Forest City's diverse portfolio includes hundreds of premier properties located throughout the United States. They are especially active in our core markets – New York, Washington, D.C., San Francisco, Boston, Dallas, Los Angeles and Denver – where they have overcome high barriers to entry and developed a unique franchise.

The University Park

Located at the absolute confluence of the Cambridge life science cluster, cutting edge academia, and two longstanding residential neighborhoods, University Park is a thriving hub of activity with 10 research and office buildings, 250,000 square feet of hotel, restaurant and retail space, 674 residential units and structured parking for 2,700 cars.

University Park offers 1.3 million square feet of state-of-the-art research space supporting some of the most prominent institutions in the bioscience industry - including Alkermes, Inc., Partners HealthCare System and the corporate Headquarters of Millennium Pharmaceuticals.

Peter Calkins, COO, Forest City, shares leadership responsibilities for the Boston-based development team, and leads the planning and implementation of commercial or mixed-use projects throughout New England.

He gave the BioXclusters group a history of milestones that went into developing and forming the landscape of MIT and also an overview of the powerhouse of interdisciplinary research teams across the University Park.

Together with other executives, he also evaluates and develops new opportunities for joint venture / partnership relationships and mixed-use development projects. Mr. Calkins has personally directed the development of more than 1.5 million square feet of space at University Park.

e. Networking sessions

LOCAL LAW FIRMS SPECIALIZING IN BIOTECH AND TECHNOLOGY LAW

Peter Finn, Attorney, works with a number of Spanish companies including those from the Catalonia region. Peter is devoted to representing biotechnology and high technology companies in all aspects of corporate law, licensing and financing.

He represents clients in general financing including, technology transfer, joint ventures, corporate and strategic alliances, venture capital and mergers and acquisitions.

Peter sits on a number of Boards within the Cambridge / Boston community and is well-connected. He recently helped coordinate an MOU between the Israel economic development authorities and the Beth Israel Medical Center.

Open actions/collaborations:

Peter Finn would be interested to help BioXclusters explore other targeted opportunities.

LOCAL INVESTORS IN BIOTECH
Bernie Rudnick, Ira Wallace, Shahin Gharakhanian, Andrew Luber, NovoBioPharma NOVOBIO Pharma is an excellent source for helping SMEs who need funding. The team of four experts has experience across pharmaceutical, regulatory, legal, accounting, and financial experts. Ira Wallace and Andrew Luber are both based in Philadelphia, while Bernie and Shahin are based in Boston. Open actions/collaborations: BioXclusters will present several companies to the team end of Q1 2014.

f. Research and innovation facilities

THE DAVID H. KOCH INSTITUTE FOR INTEGRATIVE CANCER RESEARCH at MIT http:/ki.mit.edu
• Marta Murcia, PHD, Collaborative Program Administrator, KOCH Institute.
The Koch Institute brings scientists and engineers together to solve the problems of cancer. BioXclusters group received an in-depth tour of the Institute and was able to view the interior of the numerous labs within the facility. Open actions/collaborations: BioXcluster should exchange with their local research institutions and universities to target a potential collaborative effort within the key research areas.

BOSTON CHILDREN'S HOSPITAL http://www.childrenshospital.org/
• Jane Amara, Associate Director, Technology & Innovation Development Office; David Altman, Senior MKT & COMM; Geoffrey Horwitz, Bus Dev. Associate • Todd Kreuger, CFO, Claritas Genomics
Boston Children's Hospital is a 395-bed comprehensive center for pediatric health care. As one of the largest pediatric medical centers in the United States, Children's offers a complete range of health care services for children from birth through 21 years of age.

The hospital has approximately 25,000 inpatient admissions each year and 200+ specialized clinical programs schedule 557,000 visits annually. Last year it performed more than 26,500 surgical procedures and 158,700 radiological examinations.

Boston Children's Hospital is home to the world's largest research enterprise based at a pediatric hospital. More than 1,100 scientists comprise the research community, including 9 members of the National Academy of Sciences, 11 on-staff members of the Institute of Medicine and 9 members of the Howard Hughes Medical Institute. Current initiatives have attracted a record $225 million in annual funding, including more federal funding than any other pediatric facility.

Personal Genomics Research Program

Jane Amara is responsible for managing the daily operations of the Technology & Innovation Development Office (TIDO), working closely with the others in the office to support our collaborative strategic goals. Prior to joining TIDO, Jane worked in venture capital, overseeing investments into university spin-out companies in the UK. Before that, she worked in biotech business development, including five years identifying, evaluating, and executing transactions at Biogen Idec. Her industry experience also includes research and project management responsibilities at start-up and established companies, including Genzyme and ARIAD Pharmaceuticals.

Jane included several of her colleagues that work within the Technology & Innnovation Development Office. She also presented on resulting partnerships that stemmed from the numerous areas of research at Boston Children's Hospital.

Industry & Academia Collaborations

Claritas Genomics provides a great example of a diagnostic company that resulted from an unmet need within the hospital and laid the groundwork for an innovative informatics platform.

Claritas offered a presentation to the group and would be open to licensing in hospitals within the four regions.

The group was able to gain insight on how start-ups can stem from a hospital environment. The hospital was under construction; therefore, BioXclusters group were not able to tour the facilities.

g. Training Workshops

(I) - ESTABLISHING A US ENTITY

- Alexandra Suhas, CEO, Marie Landel & Associates

Alexandra Suhas is Partner and CEO of Marie Landel & Associates, a firm that is known for providing administrative, financial, and human resources and advisory services to European & American companies that have established operations in the US Alexandra provided the group with basic information on establishing a US entity, Delaware company information, corporate tax rates, and other practical information such as costs which will be incurred for doing business in the US (sales tax in the US is a pure cost and not recovered as it is in the European Union).

Alexandra's firm has worked with a number of international companies in the area and provides accounting and operational support.

(II) - PREREQUISITES FOR NAVIGATING US REGULATORY ENVIRONMENT & IP STRATEGY

- Mark de Rosche, PHD, VP Regulatory Drugs, Biologics, Voisin Consulting
- Karin Hollerbach, CEO and founder of Taku Group

Mark de Rosche, PHD, VP Regulatory Drugs, Biologics, Voisin Consulting

Dr. Mark De Rosch is responsible for the management of projects involving the design and implementation of global regulatory strategies for the development, registration, and maintenance of pharmaceutical and biotechnology medicinal products. His expertise is in development of regulatory strategies for drugs and biologics, especially including orphan and pediatric diseases.

Mark has more than 20 years' experience in industry in the development of pharmaceuticals, specifically in preparing teams for and leading discussions with regulatory agencies, including FDA (CDER, CBER, CDRH, VXDS), Health Canada, EMA, and EU National Agencies. His broad therapeutic experience includes hemophilia, cystic fibrosis/respiratory, auto-immune/rheumatology, oncology, pain, renal, and medical imaging/radiopharmaceuticals.

Dr. De Rosch gave the group an overview of the departments within the FDA, an in-depth look at the application process in several areas and what to expect with each step. He also gave some practical information regarding the timing for trials :

- Phase I: SMEs in Europe do not need to wait for final report in Europe to commence clinical trials in the US.
- Phase II : Allows for a broader scope and has the same protocol in the US as in Europe.
- Phase III : Recommends doing both US and Europe trials in parallel for study.

Mark also covered key US regulatory development tools in order to expedite development, evaluation, and marketing of new therapies such as Fast Track Approval, Accelerated Approval, as well as Breakthrough Therapy Designation and Priority Review.

He also covered orphan drug development outlining the set requirements to qualify as such and obtain the incentives therein. Also, relevant to the theme of personalized medicine, he provided a close-up comparison of Pediatrics regulation between the US and the EU.

Karin Hollerbach, CEO and founder of Taku Group

Dr. Karin Hollerbach is an Adviser to the Triana Group, and the founder and CEO of Triana's partner firm Taku Group. Dr. Hollerbach was selected this past year to serve as an ERAI Mobility Expert, a project underlined by the Rhône-Alpes region. A graduate of MIT, the University of California at Berkeley, and the University of California at San Francisco, she holds degrees in Molecular Biology, Electrical Engineering & Computer Science, and a PhD in Biomedical Engineering, as well as a certificate in Global Business.

During the three-day workshop, Karin provided two workshops: IP Strategy – Protecting Your Innovation and also led a demonstration along with the BioXclusters of the company STELAR to guide them in their presentation technique.

Dr. Hollerbach has a very clear approach to her material and utilizes to guide researchers or scientists to master a sales pitch. The material shared regarding IP Strategy was quite useful and encourages early stage and SMEs to think of their IP Strategy well in advance as this could have extreme repercussions if not addressed before approaching new markets rendering a product or technology at times without its key differentiating factor.

(III) - INVESTORS & INVESTMENTS, WHAT OPPORTUNITIES ARE THERE IN THE US FOR EUROPEAN SMES?

- James Shanahan, Co-Founder, VP, Business Development, Ariana Pharmaceuticals SA

James Shanahan has over 15 years' experience with business development and marketing for high tech and biotech companies. He is a serial entrepreneur having started multiple companies. Most recently, Jim was VP Business Development (and continues to consult with) of Ariana Pharmaceuticals, SA (Paris, France), a healthcare data intelligence company specializing in analyzing complex clinical and biomarker datasets.

James shared some critical information for start-up and SMEs to consider when positioning themselves for partnering opportunities or for exit strategy. He also highlights realistic expectations for companies to face when working with investors. The information provided was concise and to the point.

James presently works with the FACC in Boston to help companies with the angel and VC funding.

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