MedTech Accelerator by lifetech.brussels

Program overview [February - June 2017]

FEBRUARY

- 1 — KICKOFF SESSION & INTENDED USE
- 8 — EFFECTIVE COMMUNICATION & PITCH
- 17 — BUSINESS OPPORTUNITY IN QUESTION

MARCH

- 9 — QUALITY MANAGEMENT STANDARDS & CE MARKING
- 16 — WHAT IS YOUR VALUE PROPOSITION?
- 22 — PITCH NIGHT I

APRIL

- 19 — CUSTOMER JOURNEY
- 26 — TRACEABILITY & MATERIALS AND PROCESSES

LEGEND

- BUSINESS MODULES
- MEDTECH SPECIFIC MODULES
- PITCH SESSIONS

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MAY

- 4 — VALIDATION & CLINICAL TRIALS
- 11 — INTELLECTUAL PROPERTY & PITCH PRACTICE
- 17 — PRODUCT DEVELOPMENT

JUNE

- 24 — PITCH NIGHT II
- 1 — EXPORT YOUR SOLUTION
- 8 — HEALTH ECONOMICS
- 16 — REIMBURSEMENT & PITCH PRACTICE
- 21 — SEEKING FOR MONEY
- 29 — FINAL PITCH NIGHT

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Venue : impulse.brussels – Chaussée de Charleroi, 110 – 1060 Brussels

KICKOFF SESSION: DEFINITIONS AND TRENDS
(February 1, 2017 | 10-11am | by Kyun Thibaut, Covartim)

- What is a medical device? Definition as per Directive 93/42, difference with a drug and examples of devices
- Current trends in the Belgian medtech industry (regenerative medicine, ehealth, minimal invasiveness…)

INTENDED USE: PURPOSE OF THE MEDICAL DEVICE
(February 1, 2017 | 11.15am-1.15pm | by Peter Schrauwen, Rescop & Kyun Thibaut, Covartim)

- Nature of the medical device & specifics (competent authorities, regulations…): In Vitro Diagnostics, Software, Medical Device and Advanced Therapy Medicinal Products
- Classification method for risk level assessment of MD as per EU directive
- Labelling and Instructions for Use

EFFECTIVE COMMUNICATION & PITCH
(February 8, 2017 | 9am-1.15pm | by Fabrizio Giannotta, Biosilaris)

- Communication: definition, rules, model, (non)verbal language, effective listening
- Rudiments of a good pitch (structure and content)
- Communication medium (content and form)

BUSINESS OPPORTUNITY IN QUESTION
(February 17, 2017 | 9am-1.15pm | by Fabrizio Giannotta, Biosilaris)

- Who is your end user? What are his/her needs and wants?
- Detect a business opportunity: Which gain do you bring in? Which pain do you address? What is your competitive advantage compared to existing solutions?
- Value proposition : Determine your product-user fit
- Introduction to the minimal viable product (MVP)
- Introduction to ModelH, the Business Model Canvas for healthcare
- Case studies

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QUALITY MANAGEMENT STANDARDS
(March 9, 2017 | 9-11am | by Ruth Beckers, Qualix & Kyun Thibaut, Covartim)

- Overview of the EU regulatory framework and impact of recent changes post PIP implant issue
- ISO 13485: importance and certification process. How different is it from the product CE marking?
- Introduction to the US regulatory framework and main differences with the EU system

CE MARKING
(March 9, 2017 | 11.15am-1.15pm | by Peter Schrauwen, Rescop & Kyun Thibaut, Covartim)

- CE marking definition and importance
- Certification routes (as per EU directive annexes) & processes
- Major change management with the notified body after CE marking
- Post-market surveillance & recalls : what needs to be done for materiovigilance and how to communicate it

WHAT IS YOUR VALUE PROPOSITION?
(March 16, 2017 | 9am-1.15pm | by Fabrizio Giannotta, Biosilaris)

- Medical device market segmentation and quantification: How can your solution address a variety of potential end users? How do you prioritize them? What is your market (B2C or B2B)? What is the size of your market? Who are your direct and indirect competitors?
- Which market share do you expect to reach? (TAM, SAM, SOM market)

PITCH NIGHT I
(March 22, 2017 | 6-8pm |)

- Build up on a regular basis on your thematic and business learnings and present your project in front of various audiences

CUSTOMER JOURNEY
(April 19, 2017 | 9am-1.15pm | by Fabrizio Giannotta, Biosilaris)

- Develop your market traction: Who is your paying customer? How many are they? How to acquire customers and keep them? What is your customer/ user acquisition process (influencer, champion, leader, enabler, buyer…)? What is your cost of customer acquisition (COCA)?

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TRACEABILITY
(April 26, 2017 | 9-11am | by Kyun Thibaut, Covartim)

- Traceability throughout the development cycle : Design control according to ISO 13 485 and implementation
- Production management
- Unique Device Identifier (regulation in the US + EU)

MATERIALS & PROCESSES
(April 26, 2017 | 11.15am-1.15pm | by Kyun Thibaut, Covartim)

- Introduction to biocompatible materials, impact on their origin (animal, human…)
- Introduction to prototyping methods (stereolithography, functional mock ups…)
- Introduction to production techniques (3D printing, machining, thermoforming, moulding…)

VALIDATION
(May 4, 2017 | 9-11am | by Stéphan Ploquin, MD101 & Kyun Thibaut, Covartim)

- Introduction to biocompatibility, packaging, shelf life & sterilization validation
- Introduction to pre-clinical validation methods (e.g. simulated use, bench testing, in silico, in vitro, in vivo animals…)

CLINICAL TRIALS
(May 4, 2017 | 11.15am-1.15pm | by Anne-Laure Bailly, MD101 & Kyun Thibaut, Covartim)

- Clinical trials regulation and differences between pre-clinical, pre-market and post-market clinical trials
- Set up of a clinical trial and related documentation
- Reporting and follow up

INTELLECTUAL PROPERTY
(May 11, 2017 | 9-11am | by Philippe Laurent, MVVP)

- Technical analysis of a medical device from an IP/ IT law perspective: medical device, connected device and remote computing
- Communication protocols
- What IP on what element? (patent, copyright, trademark…)

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PITCH PRACTICE
(May 11, 2017 | 11.15am-1.15pm | by Fabrizio Giannotta, Biosilaris)

- Pitch practice with experts: get constructive feedback on content, form and body language

PRODUCT DEVELOPMENT
(May 17, 2017 | 9am-1.15pm | by Fabrizio Giannotta, Biosilaris)

- How does your product create value? What are your key activities, resources and partners? What are the key assumptions to be tested before heavily investing in product development?

PITCH NIGHT II
(May 24, 2017 | 6-8pm | by Fabrizio Giannotta, Biosilaris)

- Build up on a regular basis on your thematic and business learnings and present your project in front of various audiences

EXPORT YOUR SOLUTION
(June 1, 2017 | 9am-1.15pm | by Olivier Raimond, Stratex Consulting & Benoit Ligot, Sibelex)

- Country analysis: Where is the right country for my project to scale-up? What are the specific requirements and threats of the targeted market?
- Increase your market traction: How to modify your strategy as your business grow (business model scalability)? How to make sure you develop a strategic growth model compatible with the medical devices industry?
- Foreign market entry modes: What to export? Is your solution ready to go abroad? What resources should you look for? How to conduct a market study abroad? How can you find distribution channels?

HEALTH ECONOMICS
(June 8, 2017 | 9-11am | by Ernesto Noguiera, MD101 & Kyun Thibaut, Covartim)

- Definitions and terminology of health economics: Cost vs benefit ratio
- Cost utility matrix
- Health technology assessment

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REIMBURSEMENT
(June 16, 2017 | 9-11am | by Jean Creplet, Blue Belly Button & Kyun Thibaut, Covartim)

- Introduction to regulations in Belgium and differences with other countries (a.o. US)
- Introduction to the nomenclature
- Description of the global process for reimbursement in function of medical device types

PITCH PRACTICE
(June 16, 2017 | 11.15am-1.15pm | by Fabrizio Giannotta, Biosilaris)

- Pitch practice with experts: get constructive feedback on content, form and body language

SEEKING FOR MONEY
(June 21, 2017 | 9am-1.15pm | by Fabrizio Giannotta, Biosilaris & Pierre Detrixhe, InvestSud)

- How to build a financial plan?
- What are your financial needs? How to finance your solution & your company? From which mix of source(s)?
- Which subsidies can you ask for?

PITCH NIGHT III
(June 29, 2017 | 6-8pm | by Fabrizio Giannotta, Biosilaris)

- Build up on a regular basis on your thematic and business learnings and present your project in front of various audiences

MONTHLY CUSTOMIZED COACHING
(4h/ month/ project | by Nicolas Hubin, Charlotte Creplet & Jean Creplet, Blue Belly Button)

- Build a timeline and reach your medtech and business objectives in a structured manner
- Build and strengthen your value proposition
- Validate your key hypotheses
- Quantify your market and conduct a market study or improve your market traction
- …

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