Start thinking with the end in mind: Using the right Data in Clinical Development and Market Access

Time and Place

Wednesday, February 6th, 2019, 14:30 – 17:30

Bio[M] Biotech Cluster Development GmbH, Am Klopferspitz 19 a (IZB West II, 3. OG), 82152 Martinsried

Content

Data derived from real world scenarios is a game changer in clinical development and market access. How can therapeutic and diagnostic industry gain access to and make use of patient related data to facilitate development and market entry?

By now, the need to understand the patients pathway from initial symptoms to endstage / cure and the development of meaningful interventions is widely accepted and forced by health technology assessments. But integrated, patient centered thinking, may grant additional opportunities to develop better solutions faster. In this symposium, you will see, how clinical research is evolving, how and why Market Access should be integrated early into decision making and how patient derived insights and patient communities can help to develop better medicines.

Main topics

- The future of Clinical Trial Designs
- Real World Evidence Plus
- Around and Beyond the pill
- Market Access – study requirements and strategic insights
- Obtaining advice from HTA Institutions
- Added benefit – patients expectations and perspective
- Collect data – build evidence
- Validate protocol designs with patients

Goal

You will gain insight into a requirements and solutions to develop for, with and around the patients.

Target group

This symposium aimes at leaders, scientists, research, ClinOps and market access managers from biotech/ medtech sector who would like to gain relevant knowledge, how a patient focused strategy can be implemented.

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Speakers

Dr. Ute Simon, Head Clinical Research, Novartis Pharma GmbH
Dr. Timm Volmer, Founder, SmartStep Healthcare & Market Access Consulting GmbH
Dr. Reiner Lehmann, Founder, DontBePatient Intelligence GmbH

Novartis Pharma is one of the largest pharmaceutical companies. At Novartis, we use science-based innovation to address some of society's most challenging healthcare issues. We discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible.

SmartStep Healthcare & Market Access Consulting provides individualized and specialized consulting for the pharmaceutical and medical device industry in order to assist them get their products to achieve a rapid and effective market access.

DontBePatient Intelligence generates Real World Insights derived from Patients. Mapping of patient pathways, treatment patterns, unsolved medical needs, patient preferences and the set-up of dedicated patient communities create the fundament of decision making in Development Processes.

Registration

Electronic registration under: www.bio-m.org/patientderiveddata
Registration fee: 80 Euro (+ VAT) for academia, 130 Euro (+ VAT) for industry

Organisation

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Bio[M]-Seminar

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Agenda (Presentations will be given in English)

14:15 *Registration*

14:30 *Welcome*
Dr. Andreas Berghammer, Bio[M] Biotech Cluster Development

14:35 **Dr. Ute Simon, Head Clinical Research, Novartis Pharma GmbH**

The future of clinical development starts today
- Real world evidence „plus“
  - Incorporation of sources outside clinical trials
- “around and beyond the pill” initiatives
- Future of clinical trial designs
  - Patient centricity
  - Virtual sites
  - New technologies

15:10 **Dr. Timm Volmer, Founder, SmartStep Healthcare & Market Access Consulting GmbH**

It is never to early – Clinical Development and integrated Market Access Planning
- Why investing into Market Access?
- Study requirements for Health technology assessments
- Strategic insights and how to obtain advice from HTA-institutions?

15:45 *coffee break*

16:15 **Dr. Reiner Lehmann, Founder, DontBePatient Intelligence GmbH**

Patient Pathway – converting individual information into Real World Evidence – Or: Understanding the journey of an anonymous in the unknown
- How to identify and engage patients in the digital space
- Generate Data to inform target population selection, trial design and choice of endpoints through patient derived information
- Added benefit – Patients expectations and perspective
- From Data to Evidence – condensing individual information into relevant conclusions
- Build and strategically align with patient communities

16:50 *Exchange and networking at the buffet*