Optimizing Value
Regulatory and Market Access Considerations

3rd December 2019 - Bio-technopark, Schlieren, Zürich

NDA would like to invite you to join us for a morning seminar where our presenters will share their experiences and provide their insights and considerations in order to optimize the value of your development program.

The market access environment is getting increasingly challenging. The ability to develop plans and strategies for access, for today as well as tomorrow, is critical to bring new medicines to patients.

Agenda:

09:00 Welcome - Claes Buxfeldt, Director NDA HTA Advisory Board and Stephanie Krumholz, General Manager NDA Switzerland

09:15 Session 1: Challenges in drug development - Professor Steffen Thirstrup

10:15 Coffee break

10:35 Session 2: HTA and Europe - where are we heading? - Professor Mira Pavlovich - Ganascia

12:05 Concluding remarks and take home messages

13:15 - 15:30 Ask the Experts - To book a 20 min slot to speak directly with our experts send an email to ***anna.perrin@ndareg.com***

About the speakers

Claes Buxfeldt
HTA Director at NDA Group with over 20 years' experience in the market access and health economic areas. Claes has extensive experience in developing the market access strategy/payer evidence generation for drug development programs from pre-clinical to launch phase.

Stephanie Krumholz
General Manager of the Swiss NDA Affiliate with a demonstrated history of working in the pharmaceuticals and biotech industry across multiple therapeutic areas in all phases of drug development. Expertise in EU, US and Swissmedic Marketing Authorisation Filings and conducting Due Diligence.

Professor Steffen Thirstrup
Director NDA Advisory Board, Former Head of Division, Medicines Assessment and Clinical Trials, Danish Health and Medicines Authority, and CHMP member. Steffen is an expert in clinical development and regulatory strategies.

Professor Mira Pavlovich-Ganascia
NDA HTA Advisory Board member, practicing physician and former Deputy Director for HTA at the Hauté Autorité de Santé (HAS), France. Mira is an expert in HTA activities related to early dialogues with developers, disease-specific guidelines and methodology of assessment for reimbursement purposes.

Learning aspects

- How to secure value in your development program considering both regulatory and market access requirements
- Learn about how, when and why it is critical to consider HTA and market access requirements in your development program
- Understand how to mitigate differences in demands/requirements between regulatory and HTA bodies

Date: Tuesday 3rd of December 2019

Time: 09:00- 12:15 (opportunity to book 1-1 meetings from 13:15)

Venue: Bio-Technopark Schlieren-Zürich, Wagistrasse 25, CH-8952 Schlieren

Registration: RSVP by Friday 29th November 2019

REGISTER NOW

The seminar will be an open and interactive workshop with the opportunity to ask our presenters questions. Specific questions can also be sent in advance to zurich@ndareg.com Indicate if you would like to discuss them openly during the meeting, otherwise we can book separate meetings to discuss them after the seminar.

Contact: Stephanie Krumholz, General Manager Switzerland, +41 78 951 9929, or email s.krumholz@ndareg.com

If you are unable to attend please advise us no later than two days before the seminar.