



Title: Drug Development in the EU: Regulatory Standards, Support and New Approaches
Date Wednesday, 09 September 2020 (9:00 AM) – Thursday, 10 September 2020 (2:00 PM) Eastern Time (US & Canada)

Facilitators:

- **Andrea Laslop, Head of Scientific Office, Austrian Medicines and Medical Devices Agency**
- **Matthias Dormeyer, Managing Director, MDC Reg Affairs GmbH**
- **Sabine Haubenreisser, MSC,PHD, Principal Scientific Administrator, European Medicines Agency**
- **Karl-Heinz Huemer, Medical Assessor, Austrian Medicines and Medical Devices Agency**
- **Jan Mueller-Berghaus Head of Unit, German Federal Agency for Vaccine and Biomedicine**
- **Bjorn Oddvar Strom Senior Scientific Advisor Norwegian Medicines Agency**
- **Maria Concepcion Prieto Yerro Spanish Agency for Medicines and Medical Devices**

Agenda:

Day 1

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| 9:00 – 9:10 AM EST | Start of the webinar Day 1 - Welcome and introduction to the workshop • Andrea Laslop (10 min) |
| 9:10 – 9:45 AM EST | Legislative background of EU regulation of drugs • Matthias Dormeyer (35 min) |
| 9:45 AM – 10:30 AM EST | Regulatory interactions in scientific advice, joint advice EMA-HTA and PRIME • Andrea Laslop (45 min) |
| 10:30 – 10:45 AM EST | Refreshment Break (15 min) |
| 10:45 – 11:30 AM EST | Challenges in paediatric development • Karl-Heinz Huemer (45 min) |
| 11:30- 12:15 PM EST | How to get and keep the orphan designation • Matthias Dormeyer (45 min) |
| 12:15 -1:00 PM EST | Lunch Break (45 min) |
| 1:00- 2:00 PM EST | Interactive discussion and wrap up of the day • All speakers (60 min) |
| 2:00 PM EST | End of meeting Day 1 |



Day 2

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| 9:00 AM EST | Start of the webinar Day 2 |
| 9:00 – 9:45 AM EST | Different pathways to marketing authorization including early access <ul style="list-style-type: none">• Maria Concepcion Prieto Yerro (45 min) |
| 9:45 – 10:30 AM EST | Specific aspects and support of advanced therapies <ul style="list-style-type: none">• Jan Mueller-Berghaus (45 min) |
| 10:30-10:45 AM EST | Refreshment Break (15 min) |
| 10:45 – 11:30 AM EST | Use of real world evidence pre- and post-authorization <ul style="list-style-type: none">• Sabine Haubenreisser (45 min) |
| 11:30 – 12:15 PM EST | Lunch Break (45 min) |
| 11:30 – 2:00 PM EST | Interactive discussion and wrap up of the day <ul style="list-style-type: none">• All speakers (60 min) |
| 2:00 PM EST | End of meeting Day 2 |