22 November 2016
EMA/723535/2016
Corporate Stakeholders Department

# Agenda - EMA-EuropaBio Information Day

## 22 November 2016, 10:00 - 17:00, De Vere Venues – Canary Wharf, 1 Westferry Circus, London

| | Agenda item | Speaker | Time |
|---|---|---|---|
| 1. | Welcome | Robin Evers, Novo Nordisk | 10:00 – 10:10 |
| 2. | Opening keynote speech | Jordi Llinares-Garcia, EMA | 10:10 – 10:30 |
| | **International Cooperation with Medicines Agencies**<br>Session Moderated by Ronald Jager | | |
| 3. | EMA-HMA Network International Initiatives on Innovation | Martin Harvey - Principle international Affairs Officer, EMA | 10:30 – 10:40 |
| 4. | EMA collaborations with other regulatory agencies in the world (ICMRA) | Martin Harvey - Principle international Affairs Officer, EMA | 10:40 – 10:50 |
| 5. | Panel Discussion | • Colin McIff – FDA Regional Director, European Office<br>• Hideyuki Kondo – PMDA Liaison, EMA<br>• Emma Du Four – Head of International Regulatory Policy, AbbVie<br>• Marie-Hélène Pinheiro – Industry Stakeholder Liaison, EMA<br>• Martin Harvey, | 10:50 – 11:15 |

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

| | | | |
|---|---|---|---|
| | | Principle international Affairs Officer, EMA | |
| 6. | Q&A | All | 11:15 – 11:30 |
| | | | |
| **Lunch Break 11:30-12:00** | | | |
| **Innovation and Development Support**<br>Session Moderated by: Jordi Llinares-Garcia | | | |
| 7 | EMA early dialogue tool kits | Rob Hemmings - Chairperson, SAWP, Member, CHMP | 12:30 – 12:50 |
| 8 | PRIME first experiences | James Kennard - Director Regulatory Affairs, Biogen | 12:50 – 13:10 |
| 9 | PRIME scheme panel discussion | • Martina Schussler-Lenz - Vice Chairperson, CAT<br>• Nick Meade, Genetic Alliance UK<br>• Leeza Osipenko – Associate Director, NICE<br>• James Kennard - Biogen | 13:10 – 13:40 |
| 10 | Q&A | All | 13:40 – 14:00 |
| **Evidence Generation During Medicinal Life-Cycle**<br>Session Moderated by Fergus Sweeney | | | |
| 11 | Experience to date supporting product through development; | Thorsten Vetter – Scientific Administrator, Scientific Advice, EMA | 14:00 – 14:15 |
| 12 | EMA update on Adaptive Pathways pilot | Francesca Cerreta – Senior Scientific Officer, Scientific Advice, EMA | 14:15 – 14:30 |
| 13 | What are the real-world evidence tools and how can they support decision making? | Alison Cave - Scientific Administrator, Inspections, Human Medicines Pharmacovigilance & Committees, Surveillance & Epidemiology, | 14:30 – 14:45 |

| | | | |
|---|---|---|---|
| | | EMA | |
| 14 | Q&A | All | 14:45 – 15:00 |
| **Coffee Break 15:00-15:20** | | | |
| 15 | What kind of real world evidence industry is generating? When and with what objective? | Maurille Feudjo Tepie - Observational Research Director, Amgen | 15:20 – 15:35 |
| | | Martine Zimmerman – Vice President of Global Regulatory Affairs, Alexion | 15:35 – 15:50 |
| | | Agathe Le Hay – Head of European HEOR, Market Access Europe, Novo Nordisk | 15:50 – 16:05 |
| 16 | Evidence generation during medicinal life-cycle, multi-stakeholder panel discussion | • Julian Isla - Dravet Foundation<br>• Rosa Giuliani - ESMO<br>• Leeza Osipenko - NICE | 16:05 – 16:35 |
| 17 | Q&A | All | 16:35 – 16:50 |
| | | | |
| 18 | Closing remarks | • Marie-Hélène Pinheiro Industry Stakeholder Liaison, EMA<br>• Robin Evers, Novo Nordisk | 16:50 – 17:00 |