### Monday, 29 June 2020

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>KEYNOTE</td>
</tr>
<tr>
<td>09:30</td>
<td>#SPOTLIGHT 5: EVDAS Updates</td>
</tr>
<tr>
<td>10:00</td>
<td>#DMD02: Antimicrobial Resistance at global level: What can ICMRA do?</td>
</tr>
<tr>
<td>10:30</td>
<td>#S0006: Biologicals and Biosimilars – Science versus Regulation</td>
</tr>
<tr>
<td>11:30</td>
<td>Lunch &amp; Learn</td>
</tr>
<tr>
<td>12:00</td>
<td>Enabling and Leveraging Research and Innovation - How Does this Impact Regulatory Standards</td>
</tr>
<tr>
<td>12:30</td>
<td>How Regulatory Science Shapes Policy</td>
</tr>
<tr>
<td>13:30</td>
<td>When Does the Scientific Question Change the Evidence Generation Paradigm?</td>
</tr>
<tr>
<td>15:30</td>
<td>Comparing accelerated approval pathways among EMA, FDA and PMDA</td>
</tr>
<tr>
<td>16:30</td>
<td>Advancing Effective Use of Digital Health Technologies in Parkinson’s Disease</td>
</tr>
<tr>
<td>17:30</td>
<td>Making Patient Engagement the New Normal: Real World Realities for Working with Patients</td>
</tr>
<tr>
<td>18:00</td>
<td>Networking</td>
</tr>
</tbody>
</table>

### Tuesday, 30 June 2020

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>#SPOTLIGHT 5: EVDAS Updates</td>
</tr>
<tr>
<td>10:00</td>
<td>Globalisation of PV Regulations and Requirements</td>
</tr>
<tr>
<td>11:00</td>
<td>Patient Involvement in the Development and Safe Use of Medicines</td>
</tr>
<tr>
<td>12:00</td>
<td>Lunch &amp; Learn</td>
</tr>
<tr>
<td>13:00</td>
<td>Pharmacovigilance ‘Then and Now’ - How Has PV Changed?</td>
</tr>
<tr>
<td>14:00</td>
<td>Update on ICH safety topics</td>
</tr>
<tr>
<td>15:00</td>
<td>“ICH Clinical Trials and Pharmacovigilance - Preparing for the Future”</td>
</tr>
<tr>
<td>16:00</td>
<td>Personalised Healthcare: A Systems Upgrade Worth Investing In?</td>
</tr>
<tr>
<td>17:00</td>
<td>Networking</td>
</tr>
</tbody>
</table>

**Topics:**
- Topic 5: Regulatory Science
- Topic 9: Medical Affairs
- Topic 2: Pharmacovigilance
- Topic 4: Value & Access
- Topic 14: Health Policy
**Wednesday, 01 July 2020**

**Topic 3: Data Standards**

- **09:00** #S0213: Big Data Task Force: So what happens next?
- **10:00** #S0711: The Future of Healthcare s Digital, Genomic and Collaborative - Is the EU Policy and Regulatory Framework Ready? How Can Emerging Technologies Be Transforming?
- **11:00** #S0309: How Do We Realise the Benefits of Data Sharing While Maintaining Patient Trust?

**Topic 1: Clinical Trials**

- **09:00** #DIAmond 1: Coordinated European Approach to Solve the Problem of Shortages - Is it Possible?
- **10:00** #DIAmond 12: ICH at 30 - What Will Come the Next 30 Years?
- **11:00** #S0106: A Development Support Environment in Europe that Adapts to the Future Challenges of Innovation - Needs and Expectations

**Topic 7: CMC**

- **09:00** #DIAmond 4: Regulation and Enforcement Impacting Medicine Manufacturing and Supply in a Globalised Context
- **10:00** #DIAmond 11: Does the current regulatory framework enable future science and technology along the product lifecycle?
- **11:00** #DIAmond 10: Can Home Nursing replace Site Visits to address the need for Social Distancing in pandemic situations?

**Topic 8: Medical Devices**

- **09:00** #S0706: Ensuring Quality throughout the Supply Chain - Update on nitrosamine impurities case
- **10:00** #S0807: Digitisation of Systems and Technology (AI)
- **11:00** #S0611: Promising digital tools for simplifying variations- how to connect dots and to make it happened?

**Topic 13: Clinical Operations**

- **09:00** #S0312: How Do We Realise the Benefits of Data Sharing While Maintaining Patient Trust?
- **10:00** #S0112: Clinical Trials Go Digital – Electronic Endpoints: Opportunities and Challenges
- **11:00** #S0607: Telematics Strategy in the EU: Global and Regional Considerations for 2020-2025

**Topic 6: Regulatory Operations**

- **09:00** #DIAmond 13: Bringing down barriers for access for gene and cell therapies in Europe
- **10:00** #S0809: Mind the Gap - Disentangling the Maze of Drug-Device Combination Product Approval in the EU
- **11:00** #S0107: Complex Clinical Trials – Driving Innovation

**Lunch & Learn**

- **12:00**

**13:00** Is Europe ready to define quality standards for Real World Data (RWD) sources?

**14:00** Case Studies in Applying Artificial Intelligence or Machine Learning

**15:00** Professional development in senior level roles and leveraging value across generations in a team

**16:00** Complex Clinical Trials – Driving Innovation

**17:00** Clinical Trial Regulation: State of Play – Are We Ready?

**18:00** Industry - Regulator Dialogue: Tailor-made Regulatory Guidance for Non-clinical to Clinical Development

**19:00** Networking

**Thursday, 02 July 2020**

**Topic 7: CMC**

- **09:00** #DIAmond 5: ICH at 30 - What Will Come the Next 30 Years?
- **10:00** #DIAmond 12: RA Leadership Forum: Critical Deliverables in Global Regulatory Teams
- **11:00** #S0606: ISO 14155: 2020 Revision of Medical Devices Good Clinical Practice

**Topic 8: Medical Devices**

- **09:00** #DIAmond 4: MDR Implementation – Status Quo
- **10:00** #DIAmond 11: Understanding and Applying the ICH E17 guideline on Multiregional Clinical Trials (MRCT): A Regulator’s and Industry Perspective
- **11:00** #DIAmond 10: How to promote patient centricity? - Based on experiences of clinician and head of regulatory agency

**Topic 13: Clinical Operations**

- **09:00** #S0312: Bringing down barriers for access for gene and cell therapies in Europe
- **10:00** #S0112: Clinical Trials Go Digital – Electronic Endpoints: Opportunities and Challenges
- **11:00** #S0607: Telematics Strategy in the EU: Global and Regional Considerations for 2020-2025

**Topic 6: Regulatory Operations**

- **09:00** #DIAmond 13: At the interface of two EU legislations – Multi stakeholder efforts to implement MDR Article 117 for drug delivery combinations
- **10:00** #S0809: Mind the Gap - Disentangling the Maze of Drug-Device Combination Product Approval in the EU
- **11:00** #S0107: Complex Clinical Trials – Driving Innovation

**Lunch & Learn**

- **12:00**

**13:00** Digitisation of Systems and Technology (AI)

**14:00** Chat with Professionals

**15:00** Promising digital tools for simplifying variations- how to connect dots and to make it happened?

**16:00** Telematics Strategy in the EU: Global and Regional Considerations for 2020-2025

**17:00** Effective Outsourcing in Regulatory Operations

**18:00** Networking

**Friday, 03 July 2020**

**Topic 13: Clinical Operations**

- **09:00** #S0312: Bringing down barriers for access for gene and cell therapies in Europe
- **10:00** #S0112: Clinical Trials Go Digital – Electronic Endpoints: Opportunities and Challenges
- **11:00** #S0607: Telematics Strategy in the EU: Global and Regional Considerations for 2020-2025

**Topic 6: Regulatory Operations**

- **09:00** #DIAmond 5: At the interface of two EU legislations – Multi stakeholder efforts to implement MDR Article 117 for drug delivery combinations
- **10:00** #DIAmond 11: Understanding and Applying the ICH E17 guideline on Multiregional Clinical Trials (MRCT): A Regulator’s and Industry Perspective
- **11:00** #DIAmond 10: How to promote patient centricity? - Based on experiences of clinician and head of regulatory agency

**Lunch & Learn**

- **12:00**

**13:00** Digitisation of Systems and Technology (AI)

**14:00** Chat with Professionals

**15:00** Promising digital tools for simplifying variations- how to connect dots and to make it happened?

**16:00** Telematics Strategy in the EU: Global and Regional Considerations for 2020-2025

**17:00** Effective Outsourcing in Regulatory Operations

**18:00** Networking