

21 September 2017  
EMA/195334/2017  
Committees and Inspections

## Programme for the 2017 EU GCP IWG Workshop

03-05 October 2017 in Budapest (Hungary)

Chair: Laura Pioppo (EMA)

Co-Chair: Dora Hermann (HU-OGYEI)

### **Day 1 – Tuesday, 03 October 09:00-17:45**

Time	Topic	Speaker
09:00-09:30	Welcome and introduction with training purpose and objectives	Csilla Pozsgay (HU-General Director)
	<b>1. Sponsor site inspections</b>	
9:30-10:40	<ul style="list-style-type: none"> <li>• Centralised monitoring</li> <li>• Computer system validation:               <ul style="list-style-type: none"> <li>– How to apply the theoretical knowledge in practice</li> <li>– Different strategies on computer system validation</li> <li>– Typical deviations identified during inspections</li> </ul> </li> </ul>	Willem Verweij (NL-IGZ)  Balall Naeem (UK-MHRA)  Ib Alstrup (DK-DKMA)
10:40-11:00	Q&A	All
11:00-11:30	Coffee Break	
11:30-13:00	<p><b>BREAK OUT Session A</b>—Discussions on case studies on centralised monitoring and inspections of computer system validation</p> <p><i>Groups:</i></p> <p><i>Room Hungaria: groups 1 - 4</i></p> <p><i>Room Continental: groups 5 - 6</i></p> <p><i>Room Buda: groups 7 - 8</i></p> <p><i>Room Pest: groups 9</i></p>	Panel: Willem Verweij (NL- IGZ)  Balall Naeem (UK-MHRA)  Ib Alstrup (DK-DKMA)

Time	Topic	Speaker
13:00-14:00	Lunch Break	
14:00-15:00	Feedback session	All
	<b>2. Difficulties when performing un-announced GCP inspections</b>	
15:00-15:40	<ul style="list-style-type: none"> <li>Difficulties when performing un-announced GCP inspections</li> </ul>	Dorota Kurnik (PL-URPL)
15:40-16:00	<b>Coffee Break</b>	
	<b>3. GCP international collaboration</b>	
16:00-17:00	<ul style="list-style-type: none"> <li>GCP inspection in Thailand and ASEAN cooperation on Bioequivalence study</li> <li>Practical experiences in GCP inspections in Republic of Moldova</li> <li>Regulatory framework for Malaysian GCP inspection, inspection findings and future collaboration</li> </ul>	Rachada To-a-nan (Thailand-FDA) Lina Gudima (Republic of Moldova-AMED) Yam Pei Ching (Malaysia-NPRA)
17:00-17:30	Q&A	All
17:30-17:45	Conclusions and feedback on Day 1	All

### **Day 2 – Wednesday, 04 October 09:00-17:00**

Time	Topic	Speaker
09:00-09:05	Introduction to day 2	
	<b>4. Patient Reported Outcome (PRO)/e-PRO: what to consider during a GCP inspection</b>	
09:05-09:45	<ul style="list-style-type: none"> <li>PRO/e-PRO: what to consider during a GCP inspection</li> </ul>	Lisbeth Bregnhøj (DK-DKMA)
	<b>5. GCP inspections of phase I units</b>	
09:45-10:30	<ul style="list-style-type: none"> <li>GCP inspections of phase I units - the Italian perspective</li> <li>GCP inspections of phase I units - the Hungarian perspective</li> </ul>	Angela Del Vecchio (IT-AIFA) Dora Hermann (HU-OGYEI)
10:30-11:00	Q&A	All
11:00-11:30	<b>Coffee break</b>	

Time	Topic	Speaker
11:30-13:00	<b>BREAK OUT Session B</b> —Discussions on case studies on inspections of PRO/e-PRO  <i>Groups:</i>  <i>Room Hungaria: groups 1 - 4</i> <i>Room Continental: groups 5 - 6</i> <i>Room Buda: groups 7 - 8</i> <i>Room Pest: groups 9</i>	Panel: Lisbeth Bregnhøj (DK-DKMA)  Dora Hermann (HU-OGYEI)  Fabrizio Galliccia (IT-AIFA)
13:00-14:00	<b>Lunch break</b>	
14:00-15:00	Poster Session <sup>1</sup>	All
	<b>6. Updates on the Clinical Trials Regulation no. 536/2014</b>	
15:00-15:40	<ul style="list-style-type: none"> <li>Overview of the procedure for authorising clinical trials</li> <li>EU Portal and Database: developments</li> </ul>	Laura Pioppo (EMA)
15:40-16:00	<ul style="list-style-type: none"> <li>Overview of the Implementing Act and transition period</li> </ul>	Maja Leon Grzymkowska (COM) - via TC
16:00-16:20	<b>Coffee break</b>	
16:20-16:50	Q&A session	All
16:50-17:00	Conclusions and feedback on day 2	
18:00-22:30	<b>Social event</b>	

### Day 3 – Thursday, 05 October 09:00-13:00

Time	Topic	Speaker
09:00-09:05	Introduction to day 3	
	<b>7. GCP inspections of biosimilars - assessors' perspectives</b>	
09:05-9:45	<ul style="list-style-type: none"> <li>Biosimilars – complex structures, comparable drugs</li> <li>Biosimilars – Assessor's perspective: Clinical key points</li> </ul>	Krisztian Fodor (HU-OGYEI, CAT member)  Francesca Serone (IT-AIFA, CHMP assessor) - via TC
9:45-10:05	Q&A session	All
	<b>8. Inspections of oncology trials</b>	
10:05–10:45	<ul style="list-style-type: none"> <li>Oncology trials—points to consider for inspection including patient safety aspects and including efficacy aspects (use of RECIST and common issues),</li> </ul>	Sinead Curran & Marie Callaghan (IE-HPRA)

Time	Topic	Speaker
10:45-11:15	<b>Coffee Break</b>	
11:15-11:45	Oncology trials-2 case studies	Sinead Curran & Marie Callaghan (IE-HPRA)
11:45-12:00	Q&A session	All
12:00-13:00	<b>Conclusions of workshop and distribution of certificates</b>	

---