

Agenda GCP Training

Podgorica - 26 & 27 June



Day 1

June 26th 2019

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|---------------|---|
| 09:00 – 09:15 | ● Registration |
| 09:15 – 09:30 | ● Introduction of COMBACTE consortium (Claire-Marie Martis) |
| 09:30 – 10:15 | ● Medicine development process and national legislation (Jelle Lyskawa) |
| 10:15 – 11:15 | ● GCP principles (Ingrid Klingmann) |
| 11:15 – 11:30 | ● Coffee break |
| 11:30 – 12:00 | ● Exercise 1: in groups and plenary (Ingrid Klingmann, Miranda Hopman, Annemarie van 't Veen and Jelle Lyskawa) |
| 12:00 – 13:00 | ● Set up of a trial at the investigator's site (Ingrid Klingmann) |
| 13:00 – 14:00 | ● Lunch |
| 14:00 – 14:30 | ● Exercise 2: in groups and plenary (Ingrid Klingmann, Miranda Hopman, Annemarie van 't Veen and Jelle Lyskawa) |
| 14:30 – 15:15 | ● Quality assurance measures in clinical trials (Annemarie van 't Veen) |
| 15:15 – 15:30 | ● Coffee break |
| 15:30 – 16:45 | ● Break-out session clinical investigators (Ingrid Klingmann)
● Break-out session laboratory investigators (Annemarie van 't Veen) |
| 16:45 – 17:15 | ● CLIN-Net & LAB-Net (Miranda Hopman and Annemarie van 't Veen) |
| 17.15 – 17.30 | ● Plenary discussion about clinical & laboratory collaboration (Ingrid Klingmann, Miranda Hopman and Annemarie van 't Veen) |
| 19.30 – 22.30 | ● Networking dinner event |



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This research project receives support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° 115523 | 115620 | 115737 resources of which are composed of financial contribution from the European Union Seventh Framework Programme (FP7/2007-2013) and EFPIA companies in kind contribution.

Day 2

June 27th 2019

08:45 – 09:00	●	Registration
09:00 – 09:45	●	Study Documentation (Karin van Beek)
09:45 – 10:15	●	Exercise 3 (plenary): study documentation (Ingrid Klingmann)
10.15 – 10.45	●	Ethical review (Ingrid Klingmann)
10:45 – 11:00	●	Coffee break
11:00 – 12:00	●	Critically important Trial Management aspects (Ingrid Klingmann)
12:00 – 12:45	●	Exercise 4: in groups and plenary (Ingrid Klingmann, Miranda Hopman, Annemarie van 't Veen and Jelle Lyskawa)
12:45 – 13:45	●	Lunch
13:45 – 14:15	●	Conclusions & feedback from site teams: our next steps for our COMBACTE trial (I. Klingmann and M. Hopman)
14:15 – 15:00	●	Final Examination

The GCP team



Ingrid
Klingmann



Miranda
Hopman



Claire-
Marie
Martis



Jelle
Lyskawa



Karin van
Beek



Annemarie
van 't Veen



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