

Agenda GCP Training

Belgrade – 19&20 November 2019

Day 1

19 November 2019

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 (Ingrid Klingmann)
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, Karin van Beek and Annemarie van 't Veen)
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, Karin van Beek and Annemarie van 't Veen)
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 and Annemarie van 't Veen)
19.30 – 22.30	● Networking dinner event



Day 2

20 November 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, Karin van Beek and Annemarie van 't Veen)
12:45 – 13:45	●	Lunch
13:45 – 14:15	●	Conclusions & feedback from site teams: our next steps for our COMBACTE trial (Ingrid Klingmann and Annemarie van 't Veen)
14:15 – 15:00	●	Final Examination

The GCP team



Ingrid
Klingmann



Claire-Marie
Martis



Miranda
Hopman



Karin van
Beek



Annemarie
van 't Veen



innovative
medicines
initiative



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.