

Agenda

GCP Training Rome, Italy



Day 1

June 11th 2018

09:00 – 09:15	● Registration
09:15 – 09:30	● Introduction of COMBACTE consortium (Miranda Hopman)
09:30 – 09:45	● CLIN-Net (Miranda Hopman)
09:45 – 10:00	● LAB-Net (Tomislav Kostyanev)
10:00 – 11:00	● Medicine development process and national legislation (Jelle Lyskawa)
11:00 – 11:15	● Coffee break
11:15 – 12:00	● GCP principles (Ingrid Klingmann)
12:00 – 12:30	● Exercise 1: in groups and plenary (Ingrid Klingmann, Miranda Hopman, Tomislav Kostyanev and Jelle Lyskawa)
12:30 – 13:30	● Lunch
13:30 – 14:00	● Quality assurance measures in clinical trials (Tomislav Kostyanev)
14:00 – 14:45	● Set up of a trial at the investigator's site (Ingrid Klingmann)
14.45 – 15.30	● Exercise 2: in groups and plenary (Ingrid Klingmann, Miranda Hopman, Tomislav Kostyanev and Jelle Lyskawa)
15.30 – 15.45	● Coffee break
15.45 – 17.15	● Break-out session clinical investigators (Ingrid Klingmann) ● Break-out session laboratory investigators (Tomislav Kostyanev)
17.15 – 17.45	● Plenary discussion about clinical & laboratory collaboration: (Ingrid Klingmann, Miranda Hopman and Tomislav Kostyanev)
18.30 – 21.30	● Networking dinner event



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Day 2

June 12th 2018

08:45 – 09:00	● Registration
09:00 – 09:45	● Study Documentation (Jelle Lyskawa)
09:45 – 10:15	● Exercise 3: in groups and plenary (Ingrid Klingmann and Jelle Lyskawa)
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, Tomislav Kostyanev 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



Tomislav
Kostyanev



Claire-Marie
Martis



Jelle
Lyskawa



Claudia
Recanatini



Esther
Pots



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