

CLINICAL Trialist Summer School 2019

PROGRAMME

Wednesday 19 June

19:00-20:00	RECEPTION
20:00	Welcome Dinner

Thursday 20 June

08:00-08:10	Welcome and Introduction to the Course
08:10-09:00	Introduction to Clinical Trials and the recapitulation of online webinar
09:00-10:00	Components of Clinical Trials
10:00-10:15	<i>Coffee Break</i>
10:15-10:45	(Topic on Statistics/Trial Methods) TBD
10:45-11:05	(Topic on Statistics/Trial Methods) TBD
11:05-11:25	(Topic on Statistics/Trial Methods) TBD
11:25-12:30	Statistical Considerations in Trials, Analytic Approaches, Sample Size/Power
12:30-13:30	<i>Lunch</i>
13:30-13:45	Introduction to Afternoon Workshop and Instructions
13:45-16:00	Workshop “Design a clinical trial” in subgroups supervised by TAs
16:00-16:15	Coffee break
16:15-19:00	Presentation and critique of clinical trials
20:00	<i>Dinner</i>

Friday 21 June

08:30-09:00	What mistakes should be avoided in clinical trials? Comment from Deputy Editor of NEJM
09:00-09:30	Publish or Perish: How to Have a Successful Career in Clinical Research? Perspective from Editor in Chief of EJHF
09:30-10:00	What mistakes should be avoided in clinical trials? Comment from the experience trialist
10:00-10:15	<i>Coffee Break</i>
10:30-12:00	Interactive analysis exercise
12:00-13:00	<i>Lunch</i>

13:00-13:30	Introduction to workshop exercise
13:30-15:00	Data Analysis /Abstract Workshops
15:00-15:15	<i>Coffee Break</i>
15:15-16:30	Presentation of Abstracts
16:30-19:00	<i>Social Event</i>
20:00	<i>Dinner</i>

Saturday 22 June

09:00-09:30	Ethical Considerations in Trials
09:30-10:00	Serving as a Site Investigator or/and National Leader
10:00-10:30	Topic on Statistics/Trial Methods TBD
10:30-12:00	Building a career in Clinical Investigation – coffee and cakes, feedback and final conclusions
12:00-13:00	<i>Lunch</i>
13:15	Bus to airport

Topic on Statistics/Trial Methods - to be considered

- Recurrent event analysis versus time to first event analysis
- Superiority versus non-inferiority design, intention to treat versus per protocol analysis
- Types of endpoints, hierarchical approach in endpoint analyses
- Types of randomization, types of blinding, cross-over design
- Non-linear modeling
- Power analysis in complex designs
- What to do with missing data?
- Meta-analyses: tips and tricks, standard approach versus individual patient data based