

CCBIO / NeuroSysMed Course: Clinical Trials - 29/9-1/10

Day 1 – 29/9 -Auditorium 2 BB-building

Zoom link day 1: <https://uib.zoom.us/s/67901388344>

09.30-10.00 Registration

Welcome

10.00-13.00

Part I. Clinical trials

- **10: 00** Welcome
- **10: 05** Bjørn Tore Gjertsen, Bergen Why clinical trials? What is a clinical study? - Fysisk
- **10: 30** Nina Jebsen, Bergen Study design - Fysisk
- **10: 55** Hilde Marie Andersen, Merck Clinical trials from pharmaceutical companies' perspective - Digital

11:20 – 11.35 Coffee break

- **11: 35** Ann Rita Halvorsen, The Norwegian Cancer Society Why clinical trials from the patients' perspective - Fysisk
- **12: 00** Magne W. Fredriksen, MS-forbundet. Why clinical trials from the patients' perspective - Digital
- **12: 25** Caroline Engen, Bergen Ethics - Fysisk

Lunch: 13.00-14:00

14:00-16:30

Part II. GCP overview

14:00 – 14:40 Anne Mathilde Kvamme, Bergen and Samantha Scarlett, Bergen

An overview of the following subjects will be given: GCP principles, Planning, Authorities, Responsibilities and Tasks, Sponsor – PI – DMC / committees – Samantha Fysisk, Anne Mathilde kanskje digital

Part III. Running a clinical trial

14:40 – 15:20 Anne Mathilde Kvamme, Bergen and Samantha Scarlett, Bergen

An overview of the following subjects will be given: Protocol, IMP Recruitment and inclusion, Patient information/consent, safety, deviations, medical notes and CRF completion, study drug, study archive – Samantha Fysisk, Anne Mathilde kanskje digital

15:20 – 15:40 Coffee break

Part IV. Formalities and regulations

15:40 – 16:30 Anne Mathilde Kvamme, Bergen and Frøydis Helene Ulvåg Rikardsen, Bergen

An overview of the following subjects will be given: Monitoring, insurance, NorCRIN, study registries, data protection and contracts – Frøydis fysisk, Anne Mathilde kanskje digital

Day 2 – 30/9 Store Auditorium Haukeland universitetssykehus

Zoom link day 2: <https://uib.zoom.us/s/67991711512>

Kl. 9.00 -11.00

Part V. Practicalities

- **09:00 Oddbjørn Straume, Bergen** How to write a protocol? - Fysisk
- **09:25 Vetle Nordli Syverud, Bergen** Applications and funding - Fysisk
- **09:50 Anna Stephansen, Bergen** Ethical Committee - Digital
- **10:15 Cecilie Gjerde, Bergen** NoMa - Fysisk
- **10:40 Oddgeir Selaas, Bergen** Clinical pharmacy and clinical trials - Fysisk

11.00 – 11.20 Coffee break

Kl. 11.20 -13.00

Part VI. Translational research protocols

- **11:20 Line Bjørge, Bergen** Translational research in clinical trials - Fysisk
- **11:45 Hani Gabra, Oxford** Design of translational research protocols - Digital
- **12:10 Reidun Kopperud, Bergen** Biobanking - Fysisk
- **12:35 Charamlampos Tzoulis, Bergen** From bench to bedside - Fysisk

Lunch + Group work: 13.00-15:30

15.30-16.30

Part VII. How can clinical trials become part of normal clinical operations?

- **15.30 Hanne F. Harbo, Oslo** How can clinical trials become part of normal clinical practice? - Digital
- **16.00 Åsmund Flobak, Trondheim and Hege Russnes, Oslo** Genomic profiling becomes part of clinical standard of care for cancer patients with advance disease - Digital

Day 3- 1/10 Store Auditorium Haukeland universitetssykehus

Zoom link day 3: <https://uib.zoom.us/s/62933955022>

Kl. 9.00 -12.30

Part VIII. How to succeed?

- **09: 00 Tone Skår, Bergen:** The user perspective - Fysisk
- **09: 25 Ole Bjørn Tysnes, Bergen** The NO-ALS trial - Rational and implementation - Fysisk
- **09: 50 Anne Kristine Lehmann, Bergen and Øivind FG Torkildsen, Bergen** The RAM-MS trial - Integration of clinical trials between different departments - Fysisk
- **10: 15 Marion Solheim, UiB, Bergen** Communication - Fysisk

10:35 – 10.50 Coffee break

- **10:50 Kristina Lindemann, Oslo** NSGO - from a Nordic interest group to a global leader in clinical trials - Digital
- **11: 25 Christian Beisland, Bergen:** Clinical studies in surgery – is it challenging - Fysisk
- **12:00 Fredrik Hellem Schjesvold, Oslo:** "How to attract industry trials?" - Fysisk

12.30-13.30. Lunch

13.30 – 15.30

Part IX. Clinical trials in the future

- **13:30 Karina Dahl Steffensen, Vejle:** Decision aids - Digital
- **13: 55 Ketil Widerberg, Oslo** How artificial intelligence can improve clinical trials? - Digital
- **14:20 Ingrid Haldorsen, Bergen** Future role of diagnostic imaging in clinical trials - Digital
- **14:45 Roger Strand, Bergen** Sociotechnical imaginaries of clinical trials - Fysisk
- **15:10 Kjell Morten Myhr, Bergen** "One stop shop" - Fysisk

Kl 15.30 -16.00

Summary and conclusion