



FLIMS 15 PROGRAMME

SATURDAY 22 JUNE 2013

12:00 – 16:00 Registration & Sandwich Buffet
15:30 – 16:15 1st Faculty Meeting (all faculty – Flem 1)

16:30 – 17:00 **Welcome and Workshop overview**
Chairs: Patrick Schöffski, Stephen Hahn, Jan Bogaerts, Johann S. de Bono

- ✓ Welcome and Workshop overview
- ✓ Announcement Lina Cassol Fellowship Grant
- ✓ Introduction of the faculty, staff, IT & Onsite Organisation

17:00 – 17:45 Lecture 1
Introductory lecture: Questions to ask yourself in designing a CT
Speaker: Johann de Bono

18:00 – 20:30 **Protocol Development Group Session 1**
All Faculty and students gather at the PDG meeting points in the Lounge and go to their respective PDG break-out rooms.

In this first session students present their study concept with 4 slides. Faculty & students then discuss draft protocol concept sheets identifying the single key question in each concept proposal

PDG 1 Room: Flem 1	PDG 2 Room: Flem 2	PDG 3 Room: Belmont 1*	PDG 4 Room: Belmont 2*	PDG 5 Room: Flem 3
PDG 6 Room: Cauma 1*	PDG 7 Room: Cauma 2*	PDG 8 Room: Greina*	PDG 9 Room: Primula*	PDG 10 Room: Cresta*

*Meeting rooms situated in the Belmont Building

20:45 **Welcome drink & Dinner**
Please sit at the assigned table to your Protocol Development Group



15th joint ECCO-AACR-EORTC-ESMO Workshop 'Methods in Clinical Cancer Research'
Waldhaus Flims, Switzerland, 22 – 29 June 2013

SUNDAY 23 JUNE 2013

07:00 – 08:00
08:00 – 09:45

Breakfast
Lecture Session 1
Chairs: Patrick Schöffski

08:00 **Lecture 2:** Phase I trials of chemotherapy and targeted drugs
Patrick Schöffski
08:35 **Lecture 3:** Phase II trials (+ trials spanning phase I & II)
Robert Maki
09:10 **Lecture 4:** Biomarkers & adaptive Clinical trial design
Bill Barry

09:45 – 10:00

Coffee break

10:00 – 12:00

Lecture Session 2
Chair: Corneel Coens

10:00 **Lecture 5:** Basic biostatistics for the clinical trialist (part I)
Susan G. Hilsenbeck
10:40 **Lecture 6:** Basic biostatistics for the clinical trialist (part II)
Susan G. Hilsenbeck
11:20 **Lecture 7:** Phase III trials
Ian Judson

12:00 – 13:00

Lunch

13:00 – 15:45

Protocol Development Group Session 2
Faculty will continue to guide students in the preparation of the protocol concept sheets

15:45 – 16:15

Coffee break

16:15 – 17:15

Small Discussion Groups - Session 1
(Optional - Advance sign-up is required as space is limited to 20 Pax)

SDG 1 Room: Flem 1	Practical aspects of studies involving laboratory biomarkers Chris Takimoto, Ed Kim, Percy Ivy
SDG 2 Room: Computer Room	Software for sample size computation: how do I calculate my PHASE II protocol? Corneel Coens, Matthew Sydes
SDG 3 Room: Belmont 1	Biomarker-based trial designs: from early adaptive to phase III Xavier Paoletti, Sumithra Mandrekar

17:30 – 18:30

Small Discussion Groups - Session 2
(Optional - Advance sign-up is required as space is limited to 20 Pax)

SDG 4 Room: Flem 1	Phase I trial endpoints, novel designs Ian Judson, Chris H. Takimoto, Xavier Paoletti
SDG 5 Room: Flem 2	Practical aspects of studies involving IMAGING biomarkers Sumithra Mandrekar, Percy Ivy
SDG 6 Room: Belmont 1	Randomised Phase II trials Robert Maki, Emma Hall
SDG 7 Room: Computer Room	Software for sample size computation: how do I calculate my PHASE III protocol? Jan Bogaerts, Susan G. Hilsenbeck

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- 18:30 – 19:30 Individual work on protocols
- 19:30 Dinner
- 20:45 – 22:45 **Meet-your-Expert session**
(Advance sign-up is required – Jugendstilsaal)
- 20:45 Individual work on protocols

21:30	Protocol concept sheets due - optional
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MONDAY 24 JUNE 2013

- 07:00 – 08:00 Breakfast
08:00 – 09:00 Individual work on protocols
08:00 – 08:55 2nd Faculty Meeting (all faculty – Flem 1)

09:00 PROTOCOL CONCEPT SHEETS DUE

09:00 – 10:30 **Lecture Session 3**

Chair : Charles Thomas

09:00 Lecture 8: Integrating surgery in multi-modality trials – implications for design, endpoints and quality control

Piotr Rutkowski

09:30 Lecture 9: Special considerations in trials of radiation therapy – implications for design, endpoints and quality control

Reshma Jagsi

10:00 Lecture 10: Special considerations in combined treatment trials (Chemo-radiation) - implications for design, endpoints and quality control

Stephen M. Hahn

10:30 – 10:45 Coffee break

10:45 – 12:30 **Lecture Session 4**

Chair: Stephen Hahn

10:45 Lecture 11: Prognostic and predictive markers for patient selection

Ed Kim

11:30 Lecture 12: How to implement biomarker questions into statistical design

Sumithra Mandrekar

12:10 **Discussion**

12:30 – 13:30 Lunch

13:30 – 16:30 **Protocol Development Group Session 3**

- Concept sheets returned to the students.
- Faculty and students will continue to discuss protocol details.

16:30 – 19:00 Individual work on protocols

19:00 Dinner

20:30 – 21:30 **Meet-your-expert session**
(Advance sign-up is required – Jugendstilsaal)



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TUESDAY 25 JUNE 2013

07:00 – 08:30 Breakfast

08:30 – 10:15 **Lecture Session 5**
Chair: Emiliano Calvo

08:30 **Lecture 13:** Role of pharmacokinetics & pharmacodynamics in clinical trials
Chris H. Takimoto

09:15 **Lecture 14:** CRM and model-guided methods for dose finding trials: practical aspects of implementation
Xavier Paoletti

10:00 **Discussion**

10:15 – 10:45 Coffee break

10:45 – 12:30 **Lecture Session 6**
Chair: Sema Erdem

10:45 **Lecture 15:** Ethical principles in the conduct of clinical trials (incl. specimen ownership)
Ian Judson

11:20 **Lecture 16:** Patient-oriented endpoints/ QoL
Corneel Coens

11:55 **Round Table:** Ethical issues and informed consent - a case-based discussion
Sema Erdem & Corneel Coens

- ✓ **Case presentation 1: Ian Judson**
- ✓ **Case presentation 2: Sandrine Marraud**
- ✓ **Case presentation 3: Christian Dittrich**

Discussion

12:30 – 13:30 Group photo and lunch

13:30 – 15:30 **Protocol Development Group Session 4**
Protocols are presented and further discussed

15:45 – 16:00 Coffee break

16:00 – 18:00 **Meet-your-expert session - in parallel with the SDG sessions and individual work on protocols**
(Advance sign-up is required – Jugendstilsaal)

16:00 – 17:00 **Small Discussion Groups - Session 3**
(Optional - Advance sign-up is required as space is limited to 20 Pax)

SDG 8 Room: Flem 1	Radiotherapy trials Stephen M. Hahn , Charles Thomas, Reshma Jaggi
SDG 9 Room: Flem 2	Paediatric clinical trials Birgit Georger , Percy Ivy
SDG 10 Room: Belmont 1	Surgical clinical trials Piotr Rutkowski , Serge Evrard, Corneel Coens



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17:00 – 18:00 **Small Discussion Groups - Session 4**
(Optional - Advance sign-up is required as space is limited to 20 Pax)

SDG 11 Room: Flem 1	Biobanking and set-up of translational research Sandrine Marreaud, Ed Kim
SDG 12 Room: Flem 2	Trials involving immunological approaches and/or vaccines (practical session) Lesley K. Seymour, Patrick Therasse
SDG 13 Room: Belmont 2	Pharmacokinetic - pharmacodynamic studies, pharmacogenomics and success for drug development Chris H. Takimoto, Emiliano Calvo
SDG 14 Room: Belmont 1	Combination trials Johann S. de Bono, Steve Hahn

18:15 – 21.15 Group Activity & Dinner

21:15 **Individual work on protocols**

21:30	PROTOCOL DRAFTS DUE - OPTIONAL
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WEDNESDAY 26 JUNE 2013

07:00 – 08:00 Breakfast
08:00 – 09:30 Individual work on protocols

09:30 PROTOCOL DRAFTS DUE – MANDATORY

09:30 – 10:45 **Lecture Session 7**

Chair: Susan Hilsenbeck

09:30 Lecture 17: Reading the literature with a critical eye

Jan Bogaerts

10:05 Lecture 18 & 19: Data and safety monitoring and independent study review -
Regulatory and other practical issues

Sandrine Marreaud & Corneel Coens

10:45 – 11:15 Coffee break

11:15 – 12:30 **Lecture Session 8**

Chair: Ed Kim

11:15 Lecture 20: Common errors in statistics

Jan Bogaerts

11:50 Lecture 21: Improving patient participation in cancer clinical trials

Sema Erdem

12:30 – 13:30 Lunch

13:45 – 16:15 **Protocol Development Group Session 5**

Funding and implementation aspects

16:15 – 16:30 Coffee break

16:30 – 19:00 Individual work on protocols

16:30 – 18:00 Course Directors' meeting (Flem 1)

19:00 Dinner

20:30 Individual work on protocols



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THURSDAY 27 JUNE 2013

- 07:00 – 08:00 Breakfast
08:00 – 09:00 Individual work on protocols
- 09:00 – 09:45 **Lecture Session 9**
Chair: Jan Bogaerts
- 09:15 Lecture 22: Translating cancer research into targeted therapeutics
Speaker: Johann de Bono
- 09:45 – 10:00 Coffee break
- 10:00 – 13:00 **Protocol Development Group Session 6**
Final protocol discussion (MOC module)
- 13:00 – 14:00 Lunch
- 14:30 – 15:30 Faculty meeting (3) – (Flem 1)
- 13:30 – 17:30 Individual work on protocols

18:00	FINAL PROTOCOL DUE
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- 20:00 Reception (Lounge)
20:30 Dinner (Jugendstilsaal)

FRIDAY 28 JUNE 2013

- As of 05:30 Breakfast

DEPARTURE

- 05:30 Shuttle to Zurich Airport
06:45 Shuttle to Zurich Airport
08:00 Shuttle to Zurich Airport