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15<sup>th</sup> joint ECCO-AACR-EORTC-ESMO Workshop 'Methods in Clinical Cancer Research'  
Waldhaus Flims, Switzerland, 23 – 29 June 2013

# FLIMS 15 PROGRAMME

SATURDAY 22 JUNE 2013

12:00 – 16:00 Registration & Sandwich Buffet  
15:30 – 16:15 1<sup>st</sup> 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

<b>PDG 1</b> Room: Flem 1	<b>PDG 2</b> Room: Flem 2	<b>PDG 3</b> Room: Belmont 1*	<b>PDG 4</b> Room: Belmont 2*	<b>PDG 5</b> Room: Flem 3
<b>PDG 6</b> Room: Cauma 1	<b>PDG 7</b> Room: Cauma 2*	<b>PDG 8</b> Room: Greina*	<b>PDG 9</b> Room: Primula*	<b>PDG 10</b> Room: *

\*Meeting rooms situated in the Belmont Building

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



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**SUNDAY 23 JUNE 2013**

07:00 – 08:00 Breakfast

08:00 – 09:45 **Lecture Session 1**

**Chairs: Patrick Schöffski, Johann S. de Bono**

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: Lara Lusa**

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 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)

<b>SDG 1</b>	<b>Practical aspects of studies involving LABORATORY biomarkers</b> <b>TBC, Lara Lusa, Ed Kim</b>
<b>SDG 2</b>	<b>Software for sample size computation: how do I calculate my PHASE II protocol?</b> <b>Roger Ahern, Catherine Fortpied</b>
<b>SDG 3</b>	<b>Biomarker-based trial designs: from early adaptive to phase III</b> <b>Xavier Paoletti, Sumithra Mandrekar</b>

17:30 – 18:30 **Small Discussion Groups - Session 2**

(Optional - Advance sign-up is required as space is limited to 20 Pax)

<b>SDG 4</b>	<b>Phase I trial endpoints, novel designs</b> <b>Ian Judson, Chris H. Takimoto, Xavier Paoletti</b>
<b>SDG 5</b>	<b>Practical aspects of studies involving IMAGING biomarkers</b> <b>Eric Aboagye, Lara Lusa, Percy Ivy</b>
<b>SDG 6</b>	<b>Randomised Phase II trials</b> <b>Robert Maki, Sumithra Mandrekar</b>
<b>SDG 7</b>	<b>Software for sample size computation: how do I calculate my PHASE III protocol?</b> <b>Jan Bogaerts, Susan G. Hilsenbeck</b>



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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

<b>21:30</b>	<b>Protocol concept sheets due - optional</b>
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**MONDAY 24 JUNE 2013**

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

**09:00 PROTOCOL CONCEPT SHEETS DUE**

09:00 – 10:30 **Lecture Session 3**

**Chair : Stephen Hahn**

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: Bonnie Glisson**

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

**TBC**

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

**Sumithra Mandrekar**

12:00 Lecture 13: How to implement imaging surrogates around Clinical Trials

**Eric Aboagye & TBC (EORTC)**

12:30 – 13:30 Lunch

13:30 – 16:15 **Protocol Development 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 – 10:20 **Lecture Session 5**  
**Chair: Eric Aboagye**
- 08:30 Lecture 14: Role of pharmacokinetics in clinical trials  
**Chris H. Takimoto**
- 09:05 Lecture 15: CRM and model-guided methods for dose finding trials: practical aspects of implementation  
**Xavier Paoletti**
- 09:40 Lecture 16: Haematology as a role model for drug development  
**TBC**
- 10:15 – 10:45 Coffee break
- 10:45 – 12:30 **Lecture Session 6**  
**Chair: Roger Wilson**
- 10:45 Lecture 17: Ethical principles in the conduct of clinical trials (incl. specimen ownership)  
**Ian Judson**
- 11:20 Lecture 18: Patient-oriented endpoints / Q o L  
**Corneel Coens**
- 11:55 Round Table: Ethical issues and informed consent - a case-based discussion  
**Roger Wilson & Corneel Coens**
- ✓ **Case presentation 1: Ian Judson**
  - ✓ **Case presentation 2: Sandrine Marreaud**
  - ✓ **Case presentation 3: Christian Dittrich**
- Discussion
- 12:30 – 13:30 Group photo and lunch
- 13:30 – 15:30 **Protocol Development 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)

<b>SDG 7</b>	<b>Radiotherapy trials</b> <b>Stephen M. Hahn</b> , Charles Thomas, Reshma Jagsi
<b>SDG 8</b>	<b>Paediatric clinical trials</b> <b>Birgit Georger</b> , Percy Ivy
<b>SDG 9</b>	<b>Surgical clinical trials</b> <b>Piotr Rutkowski</b> , Serge Evrard, Catherine Fortpied



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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 10	<b>Biobanking and set-up of translational research</b> <b>TBC, Ed Kim</b>
SDG 11	<b>Trials involving immunological approaches and/or vaccines (practical session)</b> <b>Lesley K. Seymour, Tim Illidge</b>
SDG 12	<b>Pharmacokinetic - pharmacodynamic studies</b> <b>Pharmacogenomics and success for drug development</b> <b>Chris H. Takimoto, Johann de Bono, Emilio Calvo</b>
SDG 13	<b>Drug combination trials</b> <b>Johann S. de Bono, Marcelo Marotti, Lillian Siu</b>

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 19: Reading the literature with a critical eye

**Jan Bogaerts**

10:05 Lecture 20 & 21: 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 22: Common errors in statistics

**Jan Bogaerts**

12:20 Lecture 23: Improving patient participation in cancer clinical trials

**Roger Wilson**

12:45 – 13:45 Lunch

13:45 – 16:15 **Protocol Development 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 – 09:15	Individual work on protocols
09:15 – 09:50	<b><u>Lecture Session 9</u></b> <b>Chair: Jan Bogaerts</b>
	09:15 Translating cancer research into targeted therapeutics <b>Speaker: Johann de Bono</b>
09:50 – 10:05	Coffee break
10:05 – 13:00	<b><u>Protocol Development Session 6</u></b> 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

<b>18:00</b>	<b>FINAL PROTOCOL DUE</b>
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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