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

<table>
<thead>
<tr>
<th>PDG 1</th>
<th>Room: Flem 1</th>
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<tbody>
<tr>
<td>PDG 2</td>
<td>Room: Flem 2</td>
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</table>
| 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: *

*Meeting rooms situated in the Belmont Building

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

| SDG 1 | Practical aspects of studies involving LABORATORY biomarkers
TBC, Lara Lusa, Ed Kim |
| SDG 2 | Software for sample size computation: how do I calculate my PHASE II protocol?
Roger Ahern, Catherine Fortpied |
| SDG 3 | 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 | Phase I trial endpoints, novel designs
Ian Judson, Chris H. Takimoto, Xavier Paoletti |
| SDG 5 | Practical aspects of studies involving IMAGING biomarkers
Eric Aboagye, Lara Lusa, Percy Ivy |
| SDG 6 | Randomised Phase II trials
Robert Maki, Sumithra Mandrekar |
| SDG 7 | Software for sample size computation: how do I calculate my PHASE III protocol?
Jan Bogaerts, Susan G. Hilsenbeck |
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
**MONDAY 24 JUNE 2013**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>07:00 – 08:00</td>
<td>Breakfast</td>
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<tr>
<td>08:00 – 09:00</td>
<td>Individual work on protocols</td>
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<tr>
<td>08:00 – 09:00</td>
<td>2nd Faculty Meeting (all faculty – Flem 1)</td>
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<tr>
<td><strong>09:00</strong></td>
<td><strong>PROTOCOL CONCEPT SHEETS DUE</strong></td>
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<tr>
<td>09:00 – 10:30</td>
<td>Lecture Session 3</td>
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<td>Chair: Stephen Hahn</td>
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<tr>
<td>09:00</td>
<td>Lecture 8: Integrating surgery in multi-modality trials – implications for design, endpoints and quality control</td>
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<tr>
<td>Piotr Rutkowski</td>
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<tr>
<td>09:30</td>
<td>Lecture 9: Special considerations in trials of radiation therapy – implications for design, endpoints and quality control</td>
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<tr>
<td>Reshma Jagsi</td>
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<tr>
<td>10:00</td>
<td>Lecture 10: Special considerations in combined treatment trials (Chemo-radiation) - implications for design, endpoints and quality control</td>
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<td>Stephen M. Hahn</td>
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<td>10:30 – 10:45</td>
<td>Coffee break</td>
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<tr>
<td>10:45 – 12:30</td>
<td>Lecture Session 4</td>
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<td>Chair: Bonnie Glisson</td>
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<tr>
<td>10:45</td>
<td>Lecture 11: Prognostic and predictive markers for patient selection</td>
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<td>TBC</td>
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<td>11:30</td>
<td>Lecture 12: How to implement biomarker questions into statistical design</td>
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<tr>
<td>Sumithra Mandrekar</td>
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<tr>
<td>12:00</td>
<td>Lecture 13: How to implement imaging surrogates around Clinical Trials</td>
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<tr>
<td>Eric Aboagye &amp; TBC (EORTC)</td>
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<tr>
<td>12:30 – 13:30</td>
<td>Lunch</td>
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<td>13:30 – 16:15</td>
<td>Protocol Development Session 3</td>
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<td>- Concept sheets returned to the students.</td>
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<td>- Faculty and students will continue to discuss protocol details.</td>
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<td>16:30 – 19:00</td>
<td>Individual work on protocols</td>
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<td>19:00</td>
<td>Dinner</td>
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<tr>
<td>20:30 – 21:30</td>
<td>Meet-your-expert session</td>
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<td>(Advance sign-up is required – Jugendstilsaal)</td>
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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 / QoL
            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)

<table>
<thead>
<tr>
<th>SDG 7</th>
<th>Radiotherapy trials</th>
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<tbody>
<tr>
<td></td>
<td>Stephen M. Hahn, Charles Thomas, Reshma Jagsi</td>
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<tr>
<td>SDG 8</td>
<td>Paediatric clinical trials</td>
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<td>Birgit Geoerger, Percy Ivy</td>
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<tr>
<td>SDG 9</td>
<td>Surgical clinical trials</td>
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<td>Piotr Rutkowski, Serge Evrard, Catherine Fortpied</td>
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</tbody>
</table>
17:00 – 18:00  **Small Discussion Groups - Session 4**  
(Optional - Advance sign-up is required as space is limited to 20 Pax)

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

18:15 – 21.15  **Group Activity & Dinner**

21:15  **Individual work on protocols**

21:30  **PROTOCOL DRAFTS DUE - OPTIONAL**
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
THURSDAY 27 JUNE 2013

07:00 – 08:00 Breakfast
08:00 – 09:15 Individual work on protocols
09:15 – 09:50 Lecture Session 9
  Chair: Jan Bogaerts
  09:15 Translating cancer research into targeted therapeutics
  Speaker: Johann de Bono
09:50 – 10:05 Coffee break
10:05 – 13:00 Protocol Development 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

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