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>PDG 2</th>
<th>PDG 3</th>
<th>PDG 4</th>
<th>PDG 5</th>
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<tbody>
<tr>
<td>Room: Flem 1</td>
<td>Room: Flem 2</td>
<td>Room: Belmont 1*</td>
<td>Room: Belmont 2*</td>
<td>Room: Flem 3</td>
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<td>PDG 6</td>
<td>PDG 7</td>
<td>PDG 8</td>
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<td>PDG 10</td>
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<tr>
<td>Room: Cauma 1*</td>
<td>Room: Cauma 2*</td>
<td>Room: Greina*</td>
<td>Room: Primula*</td>
<td>Room: Cresta*</td>
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</table>

*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
   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
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
MOONDAY 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)
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 Marreaud
         ✓ Case presentation 3: Christian Dittrich

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)

<table>
<thead>
<tr>
<th>SDG 8 Room: Flem 1</th>
<th>Radiotherapy trials</th>
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<tr>
<td></td>
<td>Stephen M. Hahn, Charles Thomas, Reshma Jagsi</td>
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<tr>
<th>SDG 9 Room: Flem 2</th>
<th>Paediatric clinical trials</th>
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<td>Birgit Geerger, Percy Ivy</td>
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<tr>
<th>SDG 10 Room: Belmont 1</th>
<th>Surgical clinical trials</th>
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<tbody>
<tr>
<td></td>
<td>Piotr Rutkowski, Serge Evrard, Corneel Coens</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 11    | Room: Flem 1 | Biobanking and set-up of translational research  
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<tr>
<td></td>
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<td>Sandrine Marreaud, Ed Kim</td>
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</tbody>
</table>
| 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**
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
THURSDAY 27 JUNE 2013

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>07:00</td>
<td>Breakfast</td>
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<tr>
<td>08:00</td>
<td>Individual work on protocols</td>
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<tr>
<td>09:00</td>
<td>Lecture Session 9</td>
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<tr>
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<td>Chair: Jan Bogaerts</td>
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<tr>
<td>09:15</td>
<td>Lecture 22: Translating cancer research into targeted therapeutics</td>
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<td>Speaker: Johann de Bono</td>
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<td>09:45</td>
<td>Coffee break</td>
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<tr>
<td>10:00</td>
<td>Protocol Development Group Session 6</td>
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<td>Final protocol discussion (MOC module)</td>
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<td>13:00</td>
<td>Lunch</td>
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<tr>
<td>14:30</td>
<td>Faculty meeting (3) – (Flem 1)</td>
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<tr>
<td>13:30</td>
<td>Individual work on protocols</td>
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<tr>
<td>18:00</td>
<td>FINAL PROTOCOL DUE</td>
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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>20:00</td>
<td>Reception (Lounge)</td>
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<tr>
<td>20:30</td>
<td>Dinner (Jugendstilsaal)</td>
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FRIDAY 28 JUNE 2013

As of 05:30 Breakfast

DEPARTURE

<table>
<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>05:30</td>
<td>Shuttle to Zurich Airport</td>
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<tr>
<td>06:45</td>
<td>Shuttle to Zurich Airport</td>
</tr>
<tr>
<td>08:00</td>
<td>Shuttle to Zurich Airport</td>
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