ADAPTIVE DESIGNS AND
MULTIPLE TESTING PROCEDURES
WORKSHOP 2012, HEIDELBERG

SCIENTIFIC PROGRAM – OVERVIEW

THURSDAY, JULY 5

09:00 – 10:30	Registration and Reception
10:30 – 10:45	Welcome Addresses: Prof. Dr. Joachim Kirsch (Vice Dean, Medical Faculty Heidelberg) and Prof. Dr. Meinhard Kieser (Director Institute of Medical Biometry and Informatics, Heidelberg)
10:45 – 12:30	Session 1: Sample Size Re-Estimation
12:30 – 13:30	Lunch break
13:30 – 15:15	Session 2: Multiple Testing (1)
15:15 – 15:45	Coffee break
15:45 – 16:45	Invited Session
16:45 – 17:00	Coffee break
17:00 – 18:45	Session 3: Seamless Phase II/III Designs and Dose-Finding
19:15 – 20:00	Guided Tour
20:00	Conference Dinner

FRIDAY, JULY 6

08:30 – 10:15	Session 4: Time-to-Event Data and Confidence Intervals
10:15 – 10:30	Coffee break
10:30 – 12:15	Session 5: Multiple Testing (2)
12:15 – 12:30	Coffee break
12:30 – 14:15	Session 6: Selection of Treatments or Populations
14:15	Meeting of Working Group "Adaptive Designs and Multiple Testing Procedures" of IBS-DR and ROeS

Scientific Program – Detailed Time Schedule

Thursday, July 5

09:00 – 10:30	**Registration and Reception**

10:30 – 10:45   **Welcome Addresses:**
Prof. Dr. Joachim Kirsch (Vice Dean, Medical Faculty Heidelberg)
Prof. Dr. Meinhard Kieser (Director Institute of Medical Biometry and Informatics, Heidelberg)

10:30 – 12:30   **Session 1: Sample Size Re-Estimation**
Chair: Ekkehard Glimm (Basel), Helmut Schäfer (Marburg)

Simon Schneider (Göttingen), Heinz Schmidli (Basel): Blinded and unblinded internal pilot study designs for clinical trials with over-dispersed count data

Katharina Ingel, Antje Jahn-Eimermacher (Mainz): Adaptive sample size re-estimation for recurrent event data

Frank Miller (Södertälje/SWE), Tim Friede (Göttingen): Blinded continuous monitoring of the nuisance parameter in clinical trials

Stefan Englert, Meinhard Kieser (Heidelberg): Evaluation of sample size adaptation rules in clinical studies aiming at an overall performance optimization

Florian Klinglmüller, Franz König (Wien): Testing primary and secondary endpoints in adaptive designs with sample size reassessment for promising interim results

12:30 – 13:30   **Lunch break**

13:30 – 15:15   **Session 2: Multiple Testing (1)**
Chair: Willi Maurer (Basel), Martin Posch (London)

Ajit Tamhane, Dror Rom (Evanston/USA): An improved Hommel-Hochberg hybrid procedure

Gerhard Hommel (Mainz): p-values are random variables – are they really?

Klaus Strassburger, Helmut Finner (Düsseldorf): Randomized p-values and randomized empirical distribution functions in multiple testing

Kornelius Rohmeyer (Hannover), Florian Klinglmüller (Wien): gMCP – an R package for graphical multiple test problems

Kathrin Stucke, Meinhard Kieser (Heidelberg): Sample size calculation for three-arm non-inferiority trials with Poisson distributed count data

15:15 – 15:45 **COFFEE BREAK**

15:45 – 16:45 **INVITED SESSION**
       CHAIR: MEINHARD KIESER (HEIDELBERG)

Sue-Jane Wang (Silver Spring/USA): Adaptive designed clinical trials and their associated multiplicity issues including FDA's currently thinking and perspectives

Hsien-Ming James Hung (Silver Spring/USA): Statistical considerations and multiplicity issues in active control trial designs

16:45 – 17:00 **COFFEE BREAK**

17:00 – 18:45 **SESSION 3: SEAMLESS PHASE II/III DESIGNS AND DOSE-FINDING**
       CHAIR: STEFAN ENGLERT (HEIDELBERG), JAMES HUNG (SILVER SPRING/USA)

Cornelia Ursula Kunz (Warwick), Tim Friede (Göttingen): Adaptive treatment selection in seamless phase II/III trials using short-term endpoints

Lisa Hampson (Lancaster), Christopher Jennison (Bath): Optimal data combination rules in seamless phase II/III clinical trials

Maximo Carreras (Basel), Georg Gutjahr (Bremen): Seamless phase II/III adaptive designs with treatment selection based on drug exposure, toxicity and response

Alexandra Graf, Peter Bauer (Wien): Maximum type I error rate inflation in multi-armed clinical trials with interim sample size modifications

Georg Gutjahr (Bremen), Björn Bornkamp (Basel): MCP-mod without guesstimates

19:15 – 20:00 **GUIDED TOUR**

20:00   **CONFERENCE DINNER**

Friday, July 6

08:30 – 10:15   **Session 4: Time-to-Event Data and Confidence Intervals**
           Chair: Werner Brannath (Bremen), Gernot Wassmer (Köln)

Sandra Ligges (Münster), Gernot Wassmer (Köln): Estimation of the hazard ratio in adaptive designs with sample size readjustment

Sebastian Irle, Helmut Schäfer (Marburg): Interim design modifications in time-to-event studies

Rene Schmidt, Joachim Gerss (Münster): Two-stage adaptive designs with test statistics with arbitrary dependence structure based on the inverse normal method

Dominic Magirr, Thomas Jaki (Lancaster): Simultaneous confidence intervals that are compatible with closed testing in adaptive designs

Sylvia Schmidt, Werner Brannath (Bremen): Informative simultaneous confidence intervals

10:15 – 10:30   **Coffee break**

10:30 – 12:15   **Session 5: Multiple Testing (2)**
           Chair: Gerhard Hommel (Mainz), Ajit Tamhane (Evanston/USA)

Jens Stange, Thorsten Dickhaus (Berlin): An effective number of tests

Marsel Scheer (Düsseldorf): Exceedance control of the number of false rejections in multiple testing

Thorsten Dickhaus, Jakob Gierl (Berlin): Simultaneous test procedures in terms of p-value copulae

Eric Derobert, Julie Perez (Paris): A parametrized strategy of gatekeeping, keeping untouched the probability of having at least one significant result

Geraldine Rauch, Meinhard Kieser (Heidelberg): Multiplicity adjustment for composite binary endpoints

12:15 – 12:30   **Coffee break**

12:30 – 14:15   **SESSION 6: SELECTION OF TREATMENTS OR POPULATIONS**
                         CHAIR: TIM FRIEDE (GÖTTINGEN), THOMAS JAKI (LANCASTER)

Gernot Wassmer, Silke Jürgens (Köln): Designing issues in population enrichment designs

Ekkehard Glimm (Basel): Clinical trial designs with delayed selection of the primary comparison

James Wason, Jack Bowden (Cambridge): Multi-stage drop-the-loser designs

Jack Bowden (Cambridge), Ekkehard Glimm (Basel): Conditionally unbiased and near unbiased estimation for multi-stage drop-the-losers designs

Matthew Sydes, Mahesh Parmar (London): Flexible trial design in practice. Stopping arms for lack-of-benefit and adding research arms mid-trial in STAMPEDE: a multi-arm multi-stage randomised controlled trial

14:15   **MEETING OF WORKING GROUP "ADAPTIVE DESIGNS AND MULTIPLE TESTING PROCEDURES" OF IBS-DR AND ROeS**