

# ComplexClin

## Statistics for complex design of clinical studies

**Innovation area:** Health

**Key Innovator:** Marit Holden

**Partners:** Smerud Medical Research, UiO, NR

**Research staff scientists:** Ingunn Fride Tvete (principal investigator, NR), Lars Holden (NR), Inge Christoffer Olsen (Smerud), Nils Meland (Smerud), Magne Aldrin (NR), Morten Wang Fagerland (Oslo University Hospital)

**Additional reference group:** Marit Holden (NR), Arnoldo Frigessi (UiO), Knut Terje Smerud (Smerud), Ørnulf Borgan (UiO), Eva Skovlund (UiO)

**International contacts and collaborators:** Alan Agresti (University of Florida, USA), Gianpaolo Scalia Tomba (University of Rome II, Italy), Stephen Senn (University of Glasgow)

### Scope:

Produce a novel Bayesian statistical approach for design enrichment, to allow for a joint analysis of clinical trials with different complex designs. Increase competence in statistical methods for non-inferiority trials.

### Results in 2012 and plans:

We have developed a new method for taking special design features of trials into consideration for conducting a joint analysis of the results from several trials. We define a Bayesian hierarchical joint model for a parallel and cross-over trial for individual patient data (IPD), where the parallel trial has an active (medication) run-in period in order to exclude no or low responding patients. The work was published in *Clinical Trials* in 2012; *An approach to combining parallel and cross-over trials with and without run-in periods using individual patient data*, by Tvete et al. We believe our work to have both a practical and an academic contribution. On a practical level, it contributes in the increasing need for analyses of clinical trials with different designs. It also makes an academic contribution in synthesizing complex research results in social science. Hopefully our research findings can be utilized in the society and more precisely in the pharmaceutical industry by educational marketing. Smerud is hiring a couple of candidates from the (sfi)<sup>2</sup> career day.

In 2013, the Society for Clinical Trials (FKLUT) organizes a member seminar where sfi scheme is presented for Norwegian biotech / pharmaceutical stakeholders. Arnoldo Frigessi and two Smerud researchers will participate, Smerud lead the meeting. The idea is to generate interest and hopefully build bridges toward more (medicine) industry interest for (sfi)<sup>2</sup>.

### Papers:

Tvete, IF; Olsen, IC; Fagerland, M; Meland, N; Aldrin, M; Smerud, KT; Holden, L. An approach to combining parallel and cross-over trials with and without run-in periods using individual patient data. *Clinical Trials*, 2012; Vol. 9 (2): 164-175.