



Minipig Research Forum Pre-Congress Meeting

The CONFIRM initiative is delighted to invite you for the Pre-Congress Meeting at the MRF venue, on Wednesday the 16th of May 2018 with the following program:

- 14:00 General Meeting of CONFIRM and what is the aim of CONFIRM
Presentation and update of Step-1: Interlaboratory Validation Study
Plenum discussion of options for Step-2 initiatives
- 15:00 Coffee Break and networking
- 15:30 Presentation "The translation potential of porcine disease models from an immunological perspective" by Professor François Meurens, Oniris, Nantes, France
Presentation and description of the Step-1 Interlaboratory Study Design, by Linda Allais, Charles River, Lyon, France
- 16:45 Closing remarks

To participate, please sign up when registering for the MRF meeting on www.minipigresearchforum.org member login site. If you already have signed up for the MRF meeting, then send an e-mail to contact@minipigresearchforum.org to sign up for the Pre-Congress Meeting.

**To learn more about the CONFIRM initiative,
visit <https://minipigs.dk/knowledge-base/the-confirm-initiative/>**



INTERLABORATORY STUDY PROGRAMME: CALL FOR PARTICIPATION

One major goal of the **CO**llaborative **N**etwork **F**or **I**mmunological Safety **R**esearch in **M**inipigs (CONFIRM) is the coordination of interlaboratory studies relevant to immunological safety evaluation in Göttingen Minipigs. A multi-step interlaboratory study programme is being elaborated.

Step-1 is an interlaboratory validation study to demonstrate that reproducible results in Göttingen Minipigs can be independently generated by several laboratories to achieve better regulatory acceptability. The study plan will be purposely restricted to state-of-the-art objectives: measurement of standard toxicological parameters, biobanking, and immunological safety endpoints (TDAR assay: anti-KLH IgM & IgG ELISA; standard lymphocyte subset analysis; histological examination of main lymphoid organs/tissues). One reference immunosuppressive agent (daily oral cyclosporine) will be used as a benchmark in 4-5-month-old Göttingen Minipigs (3 animals/sex/group) treated for 4 weeks with a 2-week recovery period. Every participating laboratory will be requested to formerly agree to the study plan and methods after an open discussion to reach reasonable agreement. Optional endpoints can be added to the study plan provided the core study plan is strictly followed. Results will be published collectively by representatives of all participating laboratories.

Step-2 will follow a different approach: evaluating the feasibility and relevance of innovative techniques and read-outs to improve nonclinical immunological safety evaluation and further demonstrate the predictive value of Göttingen Minipigs. The Step-2 framework will include several independent studies, each focused on one goal/area, either to address dedicated safety evaluation strategies related to reference immunotoxicants (e.g. immune check-point inhibitors, vaccines, recombinant cytokines, small immunomodulating molecules...) or to qualify and validate novel readouts or models (such as immunogenicity assessment, immunogenomics, novel cytometry or cell imaging techniques, development of transgenic animals, predictive assays of pseudo-allergic reactions...). Discussions on proposed outlines of step-2 studies will start during the next Minipig Research Forum to be held in Barcelona in May 2018. This will be a genuinely research-focused approach thriving on close interactions between participating laboratories.

The CONFIRM initiative would be happy to count on your active participation to all or selected parts of this interlaboratory programme. You can express your interest by sending an e-mail to: HDP@minipigs.dk.