Newsletter IMPACTT

Dear Member of the IgY-study team,

We are happy to tell you that we just included the 22 patient into the study. More than 10% of the patients are therefore recruited. Many thanks to all sites who have talked to lots of patients and who organized screening visit after screening visit to achieve this and to get the study going. Still, we need a joint effort to reach our goal of 180 patients. To make this happen, we did a first step and found new sites and new countries who are very committed to the IgY-study.

Investigator Meeting in Dublin

Again, we conducted an investigator meeting within the ECFS-Conference. Nearly 40 participants joined us there. Many of them were representatives of sites from new countries. The study is actually running in Germany, Belgium, Sweden and Italy. In Czech Republic the submission process is about to start. For practical pharmaceutical reasons we have decided to freeze the activities in France. However, there are interested sites in Ireland, Hungary, Austria and Switzerland and we hope that we will start the study in those countries soon. Introduction and Status presentations shown at the investigator meeting in Dublin can be downloaded from the intranet (for access to the intranet please s.below).

Why do patients participate in clinical studies? – The IMPACTT-questionnaire:

In Dublin, the IMPACTT questionnaire was presented as well.
For Workpackage 7 (dissemination, exploitation & patient representation) of the IMPACTT project, Cystic Fibrosis Europe has set up a questionnaire survey. Cystic Fibrosis Europe is a network of national patient associations. Aim of the survey is to find out which information patients would like to receive when taking part in a clinical study and how this information can be improved in future projects. The questionnaires as well as a description how it works to participate in the survey will be send to the participating sites.

Amendment of study protocol 1.4

After the first results from Germany were available, the inclusion criterion "precipitins between 0 and 1" had to be discussed among the central laboratory (Prof. Niels Hoiby), the Coordinating investigator Prof. Antje Schuster and the IMPACTT coordinator Prof. Anders Larsson. The final decision was to modify the inclusion criterion: it is not obligatory any more. The precipitins are still measured, but do not lead to automatic exclusion of patients who have no signs of Pseudomonas infection (2 negative respiratory

samples), but precipitins of 2 or more. We will provide an information sheet how to interprete precipitin values soon. The amendment has already been approved by the German, the Swedish and the Belgian authorities and Ethic committees.

Your contact if you have any questions: Dr.Jutta Bend +49 (0) 228-98780-47

Recruitment period

We have prolonged the recruitment period to July 2013.

Intranet:
Any study documents are uploaded to the Impactt intranet http://intranet.impactt.eu.

If you need Log-In data for you or your study team, please send a short email to Dorothea Bremer (dbremer@muko.info).

Meetings:
Germany: 15. Deutsche Mukoviszidose- Tagung, 15-17 November 2012 in Würzburg.

Links:

Impactt website	**www.impactt.eu**
ClinicalTrials.gov Identifier: NCT01455675	http://www.clinicaltrials.gov/ct2/show/NCT01455675?term=PsAer-IgY&rank=1
German study listing	http://muko.info/forschung/forschungsansaetze/klinische-studien/cf-studien-in-deutschland/impactt.html

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Impressum (see also contacts in your Investigator Site File)

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