

EMPIRE 14th Steering Committee meeting



15TH STEERING COMMITTEE MEETING MEETING MINUTES

Date and venue: 3 June 2022, 09:00–11:00 CET, online meeting (videoconference)

Participants:

Martina Koziar Vašáková Sanja Dimic Janjic Nesrin Mogulkoc Michael Studnicka Anton Penev Zoran Arsovski Jakub Gregor Klaus-Uwe Kirchgässler Julia Spielhofer

Absent:

Marta Hájková Mordechai Kramer Katarzyna Lewandowska Veronika Müller Jasna Tekavec-Trkanjec

The meeting minutes are accompanied by the official presentation of the 15th SC meeting and summarise discussion from the 15th SC meeting.

Current state, contracts

 Refreshed communication with Romania in February – follow-up after the decision about the EMPIRE continuation (IBA)

Analyses & publications

- o *Comorbidities (Jovanović)*: published in Respiratory Research
- o Long-term survival and switch (Adir, Koziar Vašáková): new analysis in June
- o *Pirfenidone in diagnostic groups (Májek, Gregor, Koziar Vašáková)*: revised version reviewed again, there is another reviewer suggesting minor revision
- Correlation of response to antifibrotic treatment with adverse events to antifibrotic drugs in IPF patients from the EMPIRE registry (Jovanović): analysis to be completed after investigator's initial review
- o 6 analyses to be specified and initiated:
 - Crepitus: Michael Studnicka
 Analysis to be specified by investigator (a new PhD student in autumn)
 - Quality of life: Katarzyna Lewandowska Analysis to be specified by investigator
 - Genetics in Czech and Turkish cohorts: Nesrin Mogulkoć
 Analysis to be specified by investigator, communication with Dr Kriegová to be continued with the support of Martina Koziar Vašáková. Inclusion of David Schwarz Nesrin Mogulkoć
 - COVID-19 in IPF patients: Nesrin Mogulkoc
 Analysis to be specified by investigator
 Centres will be asked to complete information about COVID-19 infection in their patients and about their vaccination (IBA)



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- Longitudinal weight change in IPF patients treated with antifibrotics:
 Nesrin Mogulkoc
 - Analysis to be specified by investigator
- Protective effect of antifibrotics against lung cancer: Nesrin Mogulkoc Analysis to be specified by investigator

HRCT repository

- o Launched in October using TatraMed software and services
- Two Czech hospitals (Hradec Králové, Brno) have signed the contract, others in negotiation (reminder) (IBA)
- o Reminder to Warsaw and Budapest, contract proposal to be sent to Ege (IBA)

PD-L1 IIS

- Preparation of the study temporarily stopped with regard to uncertainties of prospective data collection (continuation of the EMPIRE registry and availability of clinical data)
- Ege University will investigate eventual analysis of PD-L1 in their samples in Turkey (commercial or research-based mode of collaboration) (Nesrin Mogulkoc)

Nintedanib IIS

- Analysis of short- and long-term clinical outcome of patients treated with nintedanib with different characteristics
- o Investigator: Martina Koziar Vašáková
- o To be completed in June

EMPIRE continuation after 2022

- Roche expressed their interest to support the registry with up to 100,000 EUR per year for 3 years
- o BI still in discussion
- No funding from 1 July 2022. Full budget for EMPIRE has not been consumed to date – BI will examine ways to transfer remaining amount, which would be used for the reimbursement of data managers in Q3 (and eventually Q4) / 2022.
- Martina Koziar Vašáková and IBA will prepare a new version of the study protocol to reflect inclusion of other pulmonary fibroses

Summary of tasks for the next period

- Piloting phase of the HRCT repository IBA will approach centres from regarding contract amendment, continuous communication with centres that already received this proposal.
- o Further phase of the Nintedanib IIS (analyses, interpretation, final report).
- Preparation of a new protocol

The 16th Steering Committee will probably take place in Barcelona during ERS (early September 2022).

Drafted by: Jakub Gregor

Approved by: M. Koziar Vašáková