

12TH STEERING COMMITTEE MEETING MEETING MINUTES

Date and venue: 5 November 2020, 09:00–11:00 CET, online meeting
(videoconference)

Participants:

Martina Vašáková
Dragana Jovanovic
Biserka Jovkovska Kaeva
Mordechai Kramer
Katarzyna Lewandowska
Nesrin Mogulkoc
Veronika Müller
Jasna Tekavec-Trkanjec

Michael Studnicka
Jakub Gregor
Klaus Kirchgässler
Grzegorz Leszak
Julia Spielhofer
Simona Littnerová
Hanneke van Bree

Absent:

Natalia Stoeva
Martina Šterclová

Marta Hájková

The meeting minutes accompany the official presentation of the 12th SC meeting and summarise discussion from the 12th SC meeting.

Current state, contracts

- There are still centres that have not yet signed the contract and enter few or no patients in the registry. **IBA to contact their representatives and find out whether contract will be signed and whether they are still interested in participation.**
- Contract between MU and Ege University still under negotiation. Problems in the management, probably no chance to sign. **IBA and N. Mogulkoć to proceed.**
- Pending communication with Romanian representatives (last reminder sent on 15 June and 5 Oct 2020, no reaction to date).
- New centre in Bulgaria: Military Medical Academy Sofia (**to be contacted by IBA**).
- Preliminary express of interest from Ukraine; only preliminary information from BI
- If there is no chance for official contract, a research cooperation still can be established with the registry; however, the investigators would get no payment for it.

Outcomes & publications

- 5 IF papers from the EMPIRE registry published in total (the most recent one on bleeding in Drug Safety)
- 6 papers in various stages of preparation:
 - *Comorbidities (Jovanović)*: completed by Dragana Jovanović after and updated and extended analysis: medical writers to complete authorship

- issues and to submit. Respiratory Research was suggested as the first-choice publishing medium during the meeting.
- *Genetics in Czech IPF patients (Doubková)*: in preparation
- *Long-term survival and switch (Adir, Vašáková)*: analysis updated; draft of the paper expected from medical writers within upcoming weeks
- *Intercountry differences in IPF patients (Kolonics-Farkas, Müller)*: in preparation
- *Adverse events vs. antifibrotic treatment (Jovanović)*: to be started
- *Pirfenidone in diagnostic groups (Májek, Gregor, Vašáková)*: almost complete, to be submitted in ERJ. **Authors to send their Col forms to Jakub.**
- 5 analyses to be specified and initiated:
 - Crepitus: Michael Studnicka
Cooperation on the analysis by IBA and M. Studnicka's statistician.
Analysis to be specified by investigator
 - 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
IBA will send contact of M. Doubková (Czech genetic analysis) to N. Mogulkoć
 - Risk assessment: Nesrin Mogulkoc
Analysis to be specified by investigator
 - **IIS to be specified** and supported by BI: Martina Vašáková

Pirfenidone effectiveness in diagnostic groups (SDU)

- Final analytical report sent to Roche
- Additional analysis using a different statistical approach (propensity score instead of adjustment for selected parameters) – to be finalised and discussed (IBA, M. Vašáková)
- Manuscript to be finalised and submitted to ERJ
- **Final report to be written by end of 2020 (IBA, M. Vašáková)**

HRCT repository

- Grant agreement of MU with Roche currently to be signed by MU
- Further support – in negotiation
- To be launched by end of 2020
- Participation confirmed from most of the largest centres in CZ, HU, PL, TR. **Other countries representatives are asked to kindly send update to J. Gregor.**

PD-L1 study

- Support of the study from Roche approved, currently waiting for grant agreement proposal from Roche. The study is considered as “interventional” due to blood sampling.
- Hradec Kralove, Bulovka, Thomayer Hospital, Olomouc (CZ), Warsaw 1st Dpt (PL), Ege (TR), Budapest (HU), Dubrava??? (HR, participation will probably be cancelled due to COVID-19 obligations). **Please send any updates to J. Gregor.**

COVID-19 study

- Preliminary interest in investigating effects of COVID-19 disease in IPF patients

- Investigator: Nesrin Mogulkoć
- Occurrence of COVID-19 in EMPIRE patients can be indicated in follow-up forms in the section *Associated disorders*.
- More details on the study and eventual support to be specified.

Summary of tasks for the next period

- IBA, N. Mogulkoc will discuss alternative ways of contract between MU and EGE University
- IBA will contact centres without signed contract to find out their interest in continuation and signing the contract. IBA will contact the new centre in Bulgaria.
- The pirfenidone effectiveness in diagnostic groups study must be finalised by 31 December 2020, including the final report.
- Strong focus on the finalisation of manuscripts that have been under preparation. Co-authors are asked to kindly send their feedbacks, forms etc. at their earliest convenience, so that the publication process is not delayed.
- New analyses to be specified by investigators and launched from January 2021.
- All updates regarding the participation of centres in the HRCT and PD-L1 study should be sent to IBA (J. Gregor).

The 13th Steering Committee will be held in spring 2020; the settings will depend on the epidemic situation.

Drafted by: Jakub Gregor

Approved by: Martina Vašáková