

14TH STEERING COMMITTEE MEETING MEETING MINUTES

Date and venue: 10 November 2021, 10:00–12:00 CET, online meeting (videoconference)

Participants:

Martina Vašáková
Mordechai Kramer
Katarzyna Lewandowska
Nesrin Mogulkoc
Veronika Müller
Anton Penev
Zoran Arsovski
Marta Hájková

Dragana Jovanovic
Jakub Gregor
Annette Kilwing
Julia Spielhofer
Petra Ovesná
Hana Zelinková

Absent:

Martina Šterclová
Michael Studnicka

Jasna Tekavec-Trkanjec

The meeting minutes are accompanied by the official presentation of the 14th SC meeting and summarise discussion from the 14th SC meeting.

Current state, contracts

- No recent contact from Bulgaria, IBA to refresh communication
- IBA recently contacted from Ukraine, Ivano-Frankivsk, contract proposal sent
- General University Hospital in Prague joins the project
- A new form for COVID-19 vaccination data in the registry added
- Dragana Jovanovic will leave the Steering Committee, Serbia will be represented by Sanja Dimic Janjic
- New analyst at IBA – Petra Ovesna to replace Simona Littnerova

Proposals for the modification of the registry:

- 6MWT – if the test was performed, further items should be added: 1) test completed yes/no, 2) if not, state duration (s) and reason why the patient did not complete the test
- COVID-19 vaccination – add further doses (6)

Analyses & publications

- New recently published paper – genetics and antifibrotic therapy in Czech patients (Therapeutic Advances in Respiratory Disease 2021)
- *Comorbidities (Jovanović)*: completed and to be submitted by medical writers
- *Long-term survival and switch (Adir, Vašáková)*: pending (MW x authors)
- *Intercountry differences in IPF patients (Kolonics-Farkas, Müller)*: re-submitted in Frontiers in Medicine

- *Pirfenidone in diagnostic groups (Májek, Gregor, Vašáková)*: rejected in ERJ and Plos Medicine, currently waiting for review in Plos One for over 2 months – authors recommend waiting for ca 1 month yet before eventual retraction
- *Correlation of response to antifibrotic treatment with adverse events to antifibrotic drugs in IPF patients from the EMPIRE registry (Jovanović)*: in preparation, consultation regarding the analytical outputs requested
- 5 analyses to be specified and initiated:
 - Crepitus: Michael Studnicka
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
 - Risk assessment: Nesrin Mogulkoc
Analysis to be specified by investigator

HRCT repository

- Launched in October using TatraMed software and services
- Czech hospitals contacted with a request to join the study and sign an amendment to their contracts
- Hospitals outside Czechia will be contacted soon with English version of the amendment.

PD-L1 IIS

- Grant agreement proposal pending between IBA and Roche.
- Need to obtain permission to import samples to Serbia from Serbian MoH – cannot be obtained without a contract between IBA and Belgrade University, which cannot be concluded without the IBA–Roche agreement.

Nintedanib IIS

- Analysis of short- and long-term clinical outcome of patients treated with nintedanib with different characteristics
- Investigator: Martina Vašáková
- First phase completed and sent to PI – description of patient cohorts and their clinical characteristics

EMPIRE continuation after 2022

- 4 scenarios discussed (see the accompanying presentation): S1 – 0 votes, S2 – 0 votes, S3 – 3 votes, S4 – 5 votes.
- Current EDC to be subdued and terminated, only f-up can be recorded; new EDC to be launched during 2022 if this mode of project continuation is approved and financially supported.
- Preliminary costs for all 4 variants was presented and will be provided to sponsors for further consideration and review.

Summary of tasks for the next period

- IBA will contact centres without signed contract to find out their interest in continuation and signing the contract.

- **Modification of the registry structure regarding 6MWT and COVID-19 vaccination.**
- **Piloting phase of the HRCT repository – IBA will approach centres from regarding contract amendment, continuous communication with Czech centres that already received this proposal.**
- **Completion of PD-L1 IIS administrative issues and launch of the study (IBA, Dragana Jovanović).**
- **Further phase of the Nintedanib IIS (analyses, interim review of results).**

The 15th Steering Committee will be held in spring 2022; the settings will depend on the epidemic situation.

Drafted by: Jakub Gregor