

13TH STEERING COMMITTEE MEETING MEETING MINUTES

Date and venue: 21 April 2021, 14:00–16:00 CET, online meeting (videoconference)

Participants:

Martina Vašáková
Mordechai Kramer
Katarzyna Lewandowska
Nesrin Mogulkoc
Veronika Müller
Anton Penev
Michael Studnicka

Jakub Gregor
Klaus Kirchgässler
Grzegorz Leszak
Julia Spielhofer
Karel Hejduk
Simona Littnerová

Absent:

Zoran Arsovski
Martina Šterclová
Dragana Jovanovic

Marta Hájková
Jasna Tekavec-Trkanjec

The meeting minutes accompany the official presentation of the 13th SC meeting and summarise discussion from the 13th 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. Response rate to last contact in November 2020 was poor (2 centres). **IBA to contact centres and find out whether contract will be signed and whether they are still interested in participation. If no response is received, the representatives will be officially informed about termination of cooperation and their user accounts will be closed.**
- Recent contacts with BI Bulgaria – new centres in the country might join EMPIRE. All necessary documentation and support provided from IBA.

Analyses & publications

- 5 IF papers from the EMPIRE registry published in total, other manuscripts in various stage of development.
- *Comorbidities (Jovanović)*: completed by Dragana Jovanović after and updated and extended analysis. The paper and remarks from Mi. Studnicka were extensively discussed after the SC meeting. **IBA to provide feedback on statistical queries and calculate adjusted HR for survival. Finalisation of the paper by MW agency and authors.**
- *Genetics in Czech IPF patients (Doubková)*: submitted in Therapeutic Advances in Respiratory Disease
- *Long-term survival and switch (Adir, Vašáková)*: analysis updated; third draft of the paper waiting for feedback from authors.
- *Intercountry differences in IPF patients (Kolonics-Farkas, Müller)*: in preparation
- *Pirfenidone in diagnostic groups (Májek, Gregor, Vašáková)*: submitted in ERJ

- *Correlation of response to antifibrotic treatment with adverse events to antifibrotic drugs in IPF patients from the EMPIRE registry (Jovanović): in preparation*
- 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
- *Survival and lung function in IPF patients treated with antifibrotics (extension of the pirfenidone radiological study) (Studnicka): to be specified after ERJ reviewers feedback on the SDU paper.*

Pirfenidone effectiveness in diagnostic groups (SDU)

- Study finalised, final report approved, manuscript submitted in ERJ

HRCT repository

- To be launched in June on a platform used in most of Czech and Slovak EMPIRE hospitals
- Pilot phase of images collection by Sep/Oct 2021 in CZ and SK.
- Group of radiology experts approved by previous SC voting: Helmut Prosch (Austria), Eva Kočová (Czechia), Diana Manolescu (Romania), Pál Maurovich Horvát (Hungary), Recep Savas (Turkey)
- Scoring proforma structure in preparation. It will be implemented as a separate form in the EMPIRE registry.
- New versions if informed consent will be provided that reflects an option to provide images further to OSIC.

PD-L1 IIS

- Waiting for grant agreement proposal from Roche.
- Serbian investigators to provide protocol updates – *Dragana Jovanović, Jelena Kotur.*
- Need to obtain permission to import samples to Serbia from Serbian MoH – *in cooperation of Belgrade university and IBA.*

Nintedanib IIS

- Analysis of short- and long-term clinical outcome of patients treated with nintedanib with different characteristics
- Investigator: Martina Vašáková
- Supported by BI; contract amendment and design in preparation

AstraZeneca interest in EMPIRE

- Preliminary interest of AZ in EMPIRE data; *further specification and negotiation by IBA and Martina Vašáková*
- Framework of the study and eventual support to be specified
- Eventual voting and approval of SC after a more detailed proposal is received
- Information to BI and Roche in line with existing agreements

EMPIRE continuation after 2022

- Current contracts by 30 June 2022
- Support of BI and Roche from July 2022 onwards in negotiation
- Transfer of the EMPIRE database to a new platform in 2022 at the latest (the current TrialDB platform will become obsolete)
- Inclusion of other ILDs – create a different eCRF (new database), or extend the current one for IPF? **IBA to organise “single-blinded” voting on SC members’ attitude to the future of EMPIRE: no continuation, continuation with IPF, continuation with IPF and other ILDs, continuation with other ILDs only.**
- The three points – further registry support, transfer to a new platform, and way of inclusion of other ILDs – are mutually connected and should be decided as a whole.
- Martina Vašáková asked to remain in the position of Principal Investigator

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.**
- **Strong focus on the finalisation of manuscripts that have been under preparation.**
- **Piloting phase of the HRCT repository to be managed by IBA.**
- **Completion of PD-L1 IIS administrative issues and launch of the study (IBA, Dragana Jovanović).**
- **Martina Vašáková and IBA to design the Nintedanib IIS and set up its framework with BI (SAP, amendment, budget)**
- **Martina Vašáková and IBA to negotiate with AZ and provide SC, BI and Roche with outputs if any.**
- **Voting on EMPIRE’s future and inclusion of other ILDs.**

The 14th Steering Committee will be held in autumn 2021; the settings will depend on the epidemic situation.

Drafted by: Jakub Gregor

Approved by: Martina Vašáková