

MEETING MINUTES – 8TH SC MEETING IN PARIS DURING ERS INTERNATIONAL CONGRESS

Date Place: 15 September 2018, 19:15 – 21:30, Paris, Hotel Mercure Paris Porte de Versailles Expo

Participants:

Martina Vašáková	Martina Šterclová
Veronika Müller	Filip Kňážek
Nesrin Mogulkoc	Marta Hájková
Jasna Tekavec-Trkanjec	Katarzyna Lewandowska
Natalia Stoeva	Biserka Jovkovska Kjaeva
Michael Studnicka (last hour)	Ruza Stevic (radiologist - deputy of prof. Jovanovic)

This meeting minutes are accompanying the official presentation of the 8th SC meeting and are summarizing the discussion from the 8th SC meeting.

Current status

- **2 new countries** – Macedonia and Austria are officially joining the registry in September 2018
- **Turkish centres** - Centres from Turkish respiratory society will receive information, that they may join the registry separately and that prof. Mogulkoc is already part of EMPIRE
- **New Polish SC member** - Prof. Kus is getting retired – new SC member for Poland will be doctor Katarzyna Lewandowska
- **The New Informed Consent** will be translated to the national languages by IBA with the proof of certification by a professional company. Afterwards email with the translated IC will be sent by IBA and will contain also information regarding the missing informed consent and new version of IC signature
- **Ethics Committee approval** - Multicentre EC approval is possible in Slovakia, Hungary, Bulgaria – Mr. Kňážek will contact SC members for check up, in other countries local EC approval will be required – IBA will send an reminder email
- **HRCT scans** - It needs to be found out in what way will the HRCT scans be sent and to where, also in what way will the images be anonymised (e.g. we will write the IPF ID on the image)
From the last SC meeting: *This item would be obligatory for all patients with HRCT at admission and with at least one more HRCT during follow-up.* It is currently in the process
- **Support of registry** - Starting from 2019, there should be new contracts with **BI and Roche**, both will be supporting EMPIRE Registry. Legal department of Masaryk University (MU) will prepare template contract (in cooperation with prof. Vašáková, BI and Roche)

Voting, analysis and publications

- **Voting** - SC members will be voting by emails – answer: agree/disagree
- **Samy Suissa manuscript + agreement** - Additional analysis for the manuscript of Samy Suissa has been agreed unanimously (voted). The cooperation/ confidentiality agreement has to be

signed with the professor – legal department of MU is already working on it, though it can take same time, as professor is not an European citizen

- **Blood samples biomarkers study** – prof. Jovanovic will provide information. The transportation of the samples should be covered by BI/IBA, probably separate protocol and informed consent would have to be made + it has to be registered on clinicaltrials.gov, SC voted for it
- **Analysis for prof. Mogulkoc** – professor will provide the analysis specification document for A: Risk stratification model for IPF patients; B: Relationship between IPF and cancer
- **Main focus for the next 12 months** will be to fully focus on the current analysis + summary reports and **prepare as many publications as possible**, also from the abstracts submitted
- **Damir Herman** - SC do not want Damir Herman to join/ help with the registry, voted unanimously

eCRF changes

- **PPI distinguishing** - There has to be found a way how to distinguish the use of PPI for IPF and use of PPI as a comedication for the antiulcerotic therapy in the database (call it differently, e.g. antireflux, antiulcerotics – this term though include more drug categories – PPI, H2-antihistaminics, mucoprotectives, antacids etc.) in order to use it for the analysis for Tanja Tran and for the future. It should be changed in all data retrospectively
- **BMI - Hazard ratio** – currently the “standard” to which we are comparing is overweight. The standard should be normal weight and under/overweight should be there for the comparison
- **Blood gases Turkey** - Turkey has been filling all of the blood gases (O2, CO2) in mmHg instead of kPa, has to be recalculated – Datamanagement of IBA should change it
- **KCO, DLCO units** - Also in Turkey they would need to add to the parameters KCO and DLCO in the database units of ml (min.mmHg.L) ml/mmHg/min
- **GAP score** – unable to perform = the patients are not able to breathe, therefore + 3 points
- **Anonymization of the data** - There is a problem with the anonymization of the data. It would be much harder with searching for the correct and actual patient in the database. As sometimes there were 2 patients with the identical date of birth and the database asked if it is the same person, doctors could check the initials and find out if yes or no. Now, if we would have just month/year left, it would be impossible to identify if it is one or more people. Therefore if the month/year would be the same, there has to be an algorithm in the database made, which will compare the two patients fully – altogether with all of the parameters filled in, in order to find out if it is identical person or not. Prof Studnicka suggested that there should be a special way (it works like this in clinical studies) where the physicians can see and identify the patients directly in the database, but the IBA people cannot see them. IBA will look for solutions.

Rules, contracts

- **Dead patients** - We will not be adding patients that have already died into the registry retrospectively
- **BI help** - SC members do not really want any help from BI, if the BI would be commenting the outcomes it would not be an independent registry anymore according to professor Vašáková
- **BI (sponsors) informing** - It is not possible to inform BI 60 days prior, as sometimes the authors do not know the date when they will publish. Doctors will inform IBA as soon as they will have the manuscript finalized and ready. IBA will then send the manuscript to BI.
- **Contract with centres** - There may be problem with the contract with the centres in Poland and Turkey. In Hungary it can take more than 2 months till it will reach the legal department. In Turkey prof. Mogulkoc is using 2 assistants from secretarial agency for filling in the data – it will not be possible to pay them anymore. She wanted BI Turkey to send money to IBA and then IBA to send the money to BI Turkey back. The assistants could be an employees of the BI Turkey. Prof. Vašáková is strictly against this as people working with the database cannot be employees of pharmaceutical company.
- **Individual data information** - According to prof. Vašáková and doc. Dušek, each centre should receive an individual report where they would be asked for completion of data into database. They would see what data are there missing in their forms/ what is bad there/ what is there to be improved. These report will be made by IBA datamanager. The email will contain also information regarding the missing informed consent and new version of IC signature

ARIANE IPF

- Theoretical proposal of prof. Vašáková to host the host the concrete analysis from ARIANE IPF project under one already working registry (meant EMPIRE). This could be very legislatively demanding and may not be possible. IBA will check possibilities with the legal department
- SC members agreed that EMPIRE is open for collaboration, but firstly we need to publish our data and outcomes into publications and then we can start to speak about other possibilities and future collaborations

9th Steering Committee meeting will be held in Geneva during CIPF meeting 1st - 2nd April 2019. Professor Mogulkoc will need to get a separate invitation

Drafted by: Filip Kňázek

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