

10TH STEERING COMMITTEE MEETING IN MADRID MEETING MINUTES

Date and venue: 28 September 2019, 15:00 – 17:00, M, IFEMA, Feria de Madrid
Avda. del Partenón, Madrid, Spain

Participants:

Martina Vašáková	Michael Studnicka
Radu Crisan-Dabija	Martina Šterclová
Marta Hájková	Jakub Gregor
Dragana Jovanovic	Jana Gregorová
Katarzyna Lewandowska	Karel Hejduk
Nesrin Mogulkoc	Teo Soon-Siong
Veronika Müller	Mirela Mirt Dabić
Irina Strambu	Richard Fritz

This meeting minutes accompany the official presentation of the 10th SC meeting and summarise discussion from the 10th SC meeting.

Current state

- Total number of registered patient have risen to **3,233** but **199** patients must have been excluded from analysis due to unknown date of diagnosis, admission visit or changed diagnose
- In the registry there are now **3,114 valid patients** (mid-September 2019)
- The registry now covers **50** centres from **11** countries
- **1** Czech centre **terminated** the cooperation
- The new contracts between Masaryk University (MU) and centres have been already **signed at 30 centres. 20 centres have not been signed** yet.
- **2 new countries** are interested in participation in registry (**Latvia and Romania**)
- **2 new centres** are interested in participation in registry (**Poland and Slovakia**)
- Communication with Latvia representative and Polish centre (Lublin) will be refreshed (**IBA**), as there has been no response to date.
- Negotiation with Romanian centres and 1 Slovak centre underway (**IBA** to proceed).

News in the registry

- Financial support by Roche CZ will be terminated after signing the new contract with Roche Global.
- Boehringer Ingelheim RCV and Roche Global will be finance supporting of registry until **September 2022**.
- **QoL questionnaire** – current licence for QoL questionnaire (EQ-5D-3L) has been prolonged to **2021**.
- A new easier QoL questionnaire will be chosen after finishing the current licence.

Overview of SC members' votes since previous meeting

- 3 approved analysis from 9th meeting in Geneva were accepted without any objection (Metformin, Cancer in IPF patients, Antifibrotics AEs)
- 4th analysis Risk assessment had an objection – lack of some suggested parameters in the registry and partial duplication with the paper by Tanja Tran and Samy Suissa.

Outcomes & publications

- 2 new papers with IF approx 3.5 were published during this year.
- 3 new papers are in process. Lead authors are Tanja Train, Abigél M. Kolonics-Farkas and Dragana M. Jovanovic.
- 4 analyses were finalised and sent to the lead authors – first versions of 2 analyses for Dragana Jovanovic and 2 for Nesrin Mogulkoc
- 1 analysis for Nesrin Mogulkoc (risk assessment) and 1 for Martina Vašáková (SDU pirfenidone) are in process
- No reaction from co-authors of manuscripts – Steering Committee agreed on solution with non-reaction co-authors. **If a co-author does not respond** for two weeks, it is assumed that **he/she agrees with the manuscript** and all discussed changes/queries.

HRCT subproject

- Current status
 - The HRCT project has gained approval by Ethics Committee.
 - Protocol, informed consent and request form for radiologists were finalised and sent to EMPIRE centres.
 - Informed consent is currently available in Czech and English version. **IBA** will arrange translation to other languages if required.
 - User manual and request for participation were sent to EMPIRE centres. 6 positive responses to date – Kragujevac, Gdansk, Linz, Izmir, Hradec Kralove, Nitra.
 - The HRCT project is still waiting for financial support by Roche and/or BI.
- All members of SC and IBA were kindly asked by Prof. Vasakova to emphasize and support centres in participation in this project, since it offers a unique research opportunity and high number of HRCT images.
- All materials (protocol, budget, informed consent, guide) should be sent in current versions to BI and Roche for further consideration (**IBA**).

PD-L1 project

- Current status
 - Protocol and informed consent have been finalised.
 - The transport of plasma samples from participating centres to the Belgrade laboratory will be coordinated and ordered by IBA.
 - Determination of PD-L1 can help to divide patient to two groups (sensitive/non sensitive to antifibrotic treatment).

Publication submission

- BI and Roche are entitled to approve any manuscript, posters, lectures, presentation, abstract before its publication. (To protect a patentable invention or to avoid disclosure of Confidential Information, trade secrets or know-how).

Discussion

- **Dragana Jovanovic** discussed a problem with the termination of her full-time job with the School of Medicine Belgrade. She will keep SC and IBA informed about the progress, eventual personal changes in the centre, and possibility to continue as an EMPIRE SC member.
- Problem with signing of contract between MU and centres
 - A big problem is communication between legal departments.
 - **SC members** of each country will send their demands to IBA and **IBA** will try to arrange the communication and to provide explanation to legal departments in EMPIRE centres. A primary objective is to leave investigators out from legal issues and set up communication channel as **EMPIRE centre legal dept. – IBA – MU legal dept.**
- Voting about new papers
 - The Steering committee agreed with **Abigél M. Kolonics-Farkas** (Ph.D. student of Veronica Muller) to be the lead author of “**Intercountry differences**” paper. Data from all countries will be used for this analysis and paper.
 - **ANCA** analysis – **Nesrin Mogulkoc** should give proposal to analysis about ANCA (by means of properly filled analysis request form).
 - The Steering committee agreed with **Katarzyna Lewandowska** will be the lead author of the **QoL** paper (in cooperation with **IBA**).
 - “**Crepitus**” analysis/paper will be led by **Michael Studnicka**. Analysis will be performed in **cooperation between his statisticians and IBA statisticians** with primary data staying in hands if IBA.
- **ARIANE-IPF**
 - The Steering Committee agreed to **initiate a negotiation** with representatives of the ARIANE-IPF project.
 - Martina Šterclová will attend the ARIANE meeting at ERS together with Nesrin Mogulkoc and communicate the opinion and attitude of the SC of the EMPIRE registry
 - The Steering Committee agreed with eventual cooperation with ARIANE-IPF upon condition that ARIANE-IPF will be a consortium of registries, where EMPIRE will have the representatives of the countries according to the number of the patients in the registry and will have the “veto rights” on use of their own data for IIS.

11th Steering Committee will be held in St. Petersburg, end of May 2020.

Drafted by: Jana Gregorová
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Approved by: Martina Vašáková