



EMPIRE
(IPF)

European **M**ulti**P**artner **I**PF **R**Egistry 5th international SC meeting

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EMPIRE status

EMPIRE (European MultiPartner IPF REgistry)

- International, multicentre, observational, non-interventional registry of IPF patients in Central and Eastern Europe
- Currently involved 5 countries (CZ, SK, PL, HU, RS, HR, TR)
 - Isreal is going to join the registry
 - Communication with Macedonia
 - No information about Russia
- Currently entered more than 1.500 patients



Submission of abstracts to BI

- Any planned publication (written, oral or audio-visual) has to be sent to BI prior to submission. This is requested by BI to ensure that there is no legal consequences for the company and to allow comments on the content as a non-binding consultancy.



Votes

- **2 recent SC votes with declines**
 - Data for BI Israel
 - Protocol for cooperation with University Clinic Salzburg/ prof. Studnicka
- **BI analysis per country**
 - Not processed yet



Sponsors

- Contract with Boehringer Ingelheim RCV was prolonged till the end of 2019
- Roche in the Czech Republic just started to support the registry – the outcomes are reports in the CZ
- TC with Roche headquarters about possible cooperation – no feedback with proposals from their side yet



Analysis - summary

- Annual report for the whole registry and country reports – once a year
- Data export – twice a year
- If any request appears, needs to be announced in advance (at least 1-2 months) – not few days before ERS submission
- Local/ country reports – responsibility of SC member to inform IBA about abstracts



Analysis specification

- **For each analysis needs to be specified:**
 - Hypothesis
 - Parameters (Tlco, FVC ...)
 - Time intervals
 - What groups of patients which will be compared
- **Fill in the form for analysis specification**



Analysis - rules

- **Data of EMPIRE registry**
 - Approved by SC members
- **Local/ country analysis**
 - SC member has to be informed and approved
 - Request in advance (2 months)
- **Data of center**
 - Only data export available





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Involved countries

Current status of EMPIRE – involved countries

- Czech Republic (10 sites)
- Hungary (5 sites)
- Poland (8 sites)
- Slovakia (6 sites)
- Serbia (3 sites)
- Turkey (1 site)
- Croatia – (2 sites)
- Israel - **in progress**



Newcomer

- **Israel**
 - Is going to join the registry
- **Poland**
 - 2 new sites join the registry
- **Croatia**
 - 1 new site join the registry
- **Serbia**
 - 2 new sites join the registry

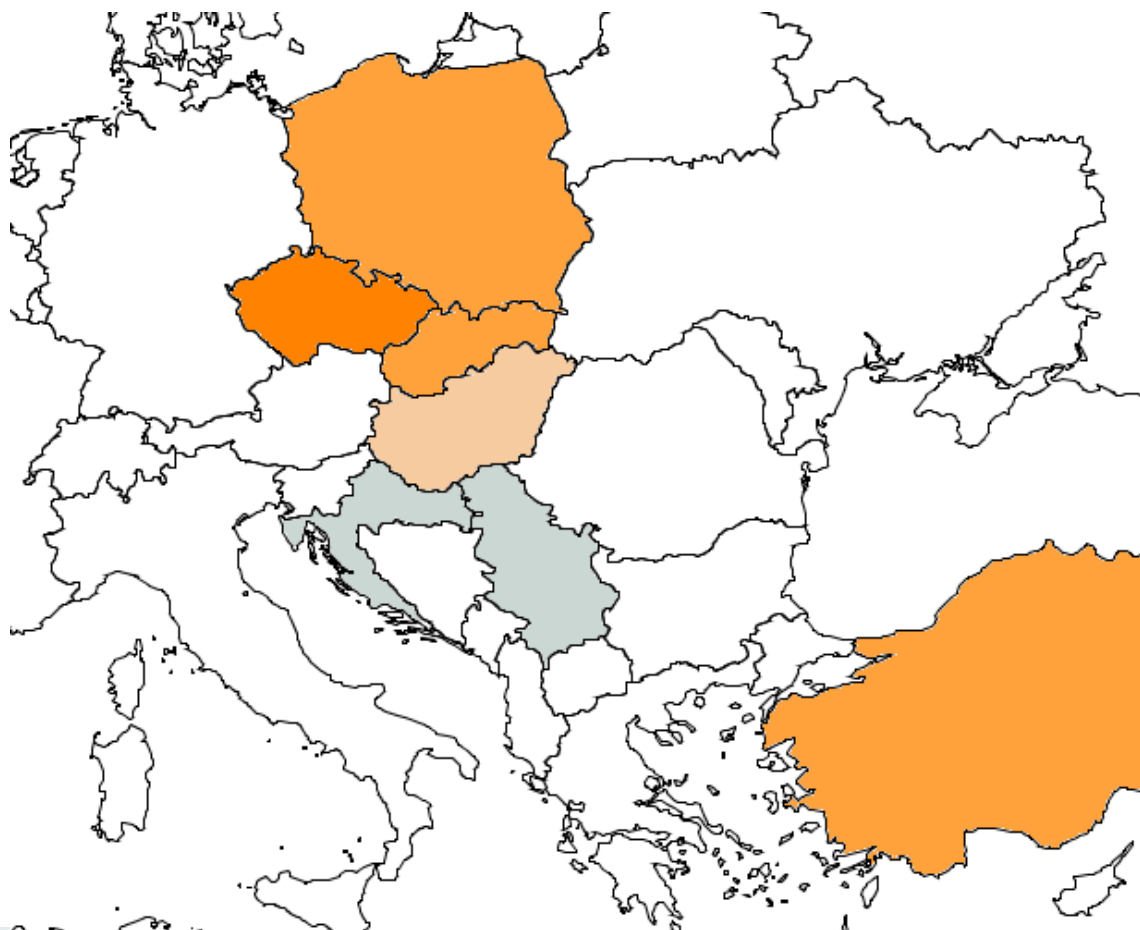


Representation of countries in EMPIRE registry

n=1 384 (As of 22 Dec 2016)

	N (%)
Czech Republic	669 (48.3%)
Poland	241 (17.4%)
Turkey	217 (15.7%)
Slovakia	115 (8.3%)
Hungary	96 (6.9%)
Serbia	31 (2.2%)
Croatia	15 (1.1%)

■ >500 ■ 100–500 ■ 50–100 ■ <50



Number of patient according to the countries

Country	Number of entered patients in year 2016	Total number of patients
Czech Republic	168	704
Poland	143	263
Turkey	221	245
Slovakia	66	125
Hungary	61	114
Croatia	15	17
Serbia	17	34
Total	691	1 502

Status on the date: 1.3.2017





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Organization changes

Organisational and upcoming changes

- Our Institute (IBA) will become part of Faculty of Medicine, Masaryk University
- Since 1.10.2017 IBA MU will no longer exist
- During the transition process some changes will come as requested by Faculty of Medicine (changes in contracts with investigators, SC members)
- Some changes will come with upcoming EU regulation on GDPR (General Data Protection Regulation)





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Meeting minutes – 4th SC

Minutes from 4th SC meeting

Changes of eCRF

- In FUP form added:
 - PaO₂
 - PaCO₂
 - pH
 - Sao₂
 - O₂ saturation (arterial/capilar)
 - 6MWT test – yes/no
- Changed FVC calculation





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Technical issue

Quality of life form

- **The importance of EuroQol (EQ)**
 - If EQ is not evaluated during follow-up visit (if the doctor forget to give the patient EQ), patient can not be considered as valid in the future (not possible to set it up in the current EDC system)
 - How to solve this? Confirmation of validation – doctor confirms in the system that EQ was not performed (not obliged to enter any reason, can be misused in all future cases and no quality of life form will be collected/evaluated)
 - Leave it as it is or change the validation?





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Publication in progress

Submitted abstracts for ERS

- Analysis of comorbid conditions in 1210 IPF patients from the EMPIRE registry. Jovanović D.
- Idiopathic pulmonary fibrosis (IPF) patients in Poland – preliminary cohort analysis of EMPIRE registry. Lawandovska H.
- Can clinical data predict rapid decline of lung function in idiopathic pulmonary fibrosis (IPF) patients? Muller V.
- Does timeliness of diagnosis influence survival and treatment response in idiopathic pulmonary fibrosis? Real-world results from the EMPIRE registry. Vašáková M.
- The impact of Bronchoalveolar lavage fluid (BAL) in prognosis in patients with idiopathic pulmonary fibrosis (IPF): the Czech part of EMPIRE Registry analysis. Lošťáková V.





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**Thank you for attendance on the
5th international SC meeting**