



EMPIRE  
(IPF)

# European **M**ulti**P**artner **I**PF **R**Egistry 6th 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 8 countries (CZ, SK, PL, HU, RS, HR, TR, IL)
  - Austria and Bulgaria is going to join the registry
  - Communication with Macedonia
- Currently entered more than 1.900 patients



# Current status of EMPIRE – involved countries

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



# Newcomers

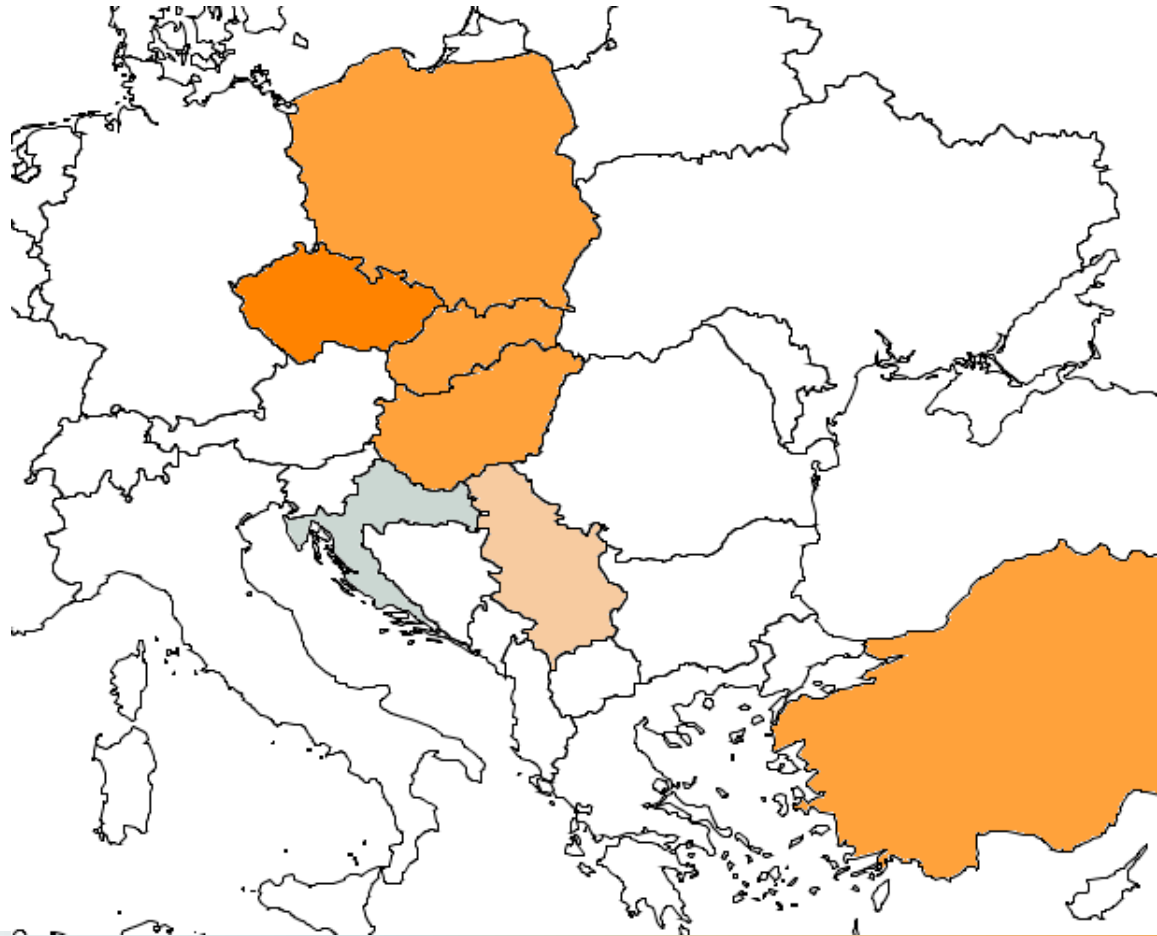
- **Israel**
  - One site joined the registry
  - Another site (prof. Adir) is going to join
- **Hungary**
  - 1 new site joined the registry
- **Croatia**
  - 1 new site joined the registry



# Representation of countries in EMPIRE registry

n=1806 (As of 24 July 2017)

|                | N (%)       |
|----------------|-------------|
| Czech Republic | 762 (42.2%) |
| Turkey         | 341 (18.9%) |
| Poland         | 323 (17.9%) |
| Hungary        | 148 (8.2%)  |
| Slovakia       | 145 (8.0%)  |
| Serbia         | 55 (3.0%)   |
| Croatia        | 32 (1.8%)   |



■ ≥500 ■ 100–499 ■ 50–99 ■ <50



# Number of patient according to the countries

| Country        | Number of entered patients in year 2017 | Total number of patients |
|----------------|---|--------------------------|
| Czech Republic | 104                                     | 786                      |
| Poland         | 95                                      | 347                      |
| Turkey         | 142                                     | 363                      |
| Slovakia       | 29                                      | 149                      |
| Hungary        | 57                                      | 158                      |
| Croatia        | 19                                      | 34                       |
| Serbia         | 26                                      | 58                       |
| Israel         | 2                                       | 2                        |
| <b>Total</b>   | <b>474</b>                              | <b>1 897</b>             |

Status on the date: 1.9.2017



# Sponsors

- Active contract with Boehringer Ingelheim RCV till the end of year 2019
- With Roche Czech Republic is preparing IIS study to support the registry in CZ – outputs are analysis based on the Czech patients
- Roche headquarters is planning IIS study as well, will be further discuss during ERS







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## **Vote overview**

## Vote overview

- Please be aware that application for vote system has changed. Currently using Survey Monkey system, all users informed. If any problem appears, please let me know.
- Several votes since last Steering committee meeting, not all closed with clear result



# Vote overview – Roche headquarter cooperation

- **Cooperation with Roche headquarter based on IIS study**
  - Already discussed in SC at Krakow (CIPF)
  - Proposed study: Assessing pirfenidone effectiveness in possible UIP and possible/probable IPF patients and characterizing natural history of IPF progression
- ✓ **Approved by all SC members**



# Vote overview – Bleeding complication

- **Bleeding complication at Nintedanib**

- Bleeding of any location in patients treated with nintedanib, versus pirfenidone, versus other treatment or nothing, and risk factors such as age, smoking, cardiovascular comorbidity, renal comorbidity, surgery, and medication - warfarin, acylpyrin and related substances, pradaxa, xarelto, clopidogrel, other antiplatelet drugs, possibly a combination of blood clotting agents.

✓ **Approved by all SC members**



# Vote overview – Ofev reimbursement

- **Permanent reimbursement of Ofev in the Czech Republic**
  - High risk of reimbursement rejection, as happened in the case of Esbriet. Results will not be further published.
- ✓ **Approved by all SC members except Slovakia**
- ✓ **Vote from SK is missing**



# Vote overview – Country specific analysis for BI

- **EMPIRE registry (overall and country specific).**
  - Provide data analysis of EMPIRE registry (overall and country specific) to Boehringer Ingelheim – baseline characteristics and outcomes of nintedanib treatment – in overall population and in nintedanib treated population.
- ✓ **Approved by all SC members except Hungary**
- ✓ **Vote from HU is missing**





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**Publication in progress**

# Submitted abstracts for ERS

- Analysis of comorbid conditions in 1210 IPF patients from the EMPIRE registry. Jovanovic D. (oral presentation)
- Does timeliness of diagnosis influence survival and treatment response in idiopathic pulmonary fibrosis? Real-world results from the EMPIRE registry. Vašáková M.
- Can clinical data predict rapid decline of lung function in idiopathic pulmonary fibrosis (IPF) patients? Muller V.
- Idiopathic pulmonary fibrosis (IPF) patients in Poland – preliminary cohort analysis of EMPIRE registry. Lawandovska H.





# EMPIRE manuscripts

- **Samy Suissa is working on publications from EMPIRE registry**
- **First manuscript on Description of EMPIRE registry already prepared and send to SC members for comments**
- **Manuscript accepted in the Clinical Respiratory Journal**
- **Will be submitted to ERJ**



# IIS study proposals

- **Planned IIS studies**

- At last SC meeting proposal by Veronika Müller → Cross country differences in EMPIRE (different profile of IPF patients per country)
- Further specification of analysis not yet given
- Any new suggestions?





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**Organization changes**

# Organizational changes

- EMPIRE project is transferred to Faculty of Medicine, Masaryk University
- Prepared new version of protocol with rules of publication
- All contracts are directly with Faculty of Medicine, Masaryk University



# Steering committee contracts

- For SC members is prepared long-term contract
- To all members send in advance by email
- It is necessary that all SC members attending SC meeting are signed in Attendance list → fee is based on that list
- Contracts are valid after they are published in the registry of contracts (given by Czech law)
- For SC meeting in Milan, separate one day contract



# Steering committee contracts

- All steering committee members are signing today:
- two contracts (4 copies)
  - 1 contract for SC meeting in Milan (2 copies)
  - 1 long-term contract for SC meetings in the future (2 copies)
  - 2 tax questionnaires (for each contract)



# Reimbursement of payments

- **Change of payments of FUP forms**
  - Number of FUP forms is increasing, but there is no rule when FUP forms are paid (retrospective forms)
  - System has to change according to the calendar year
  - Since Q3/2017 all FUP forms entered in 2017 will be paid till the end of year 2017
  - In year 2018 no FUP forms from 2017 or older will be reimbursed
  - FUP forms where the patients was not examined are not reimbursed





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**eCRF changes**



# Minutes from 5th SC meeting

- **Changes of eCRF (not processed yet)**
  - Patients considers lung transplantation (Y/N)
    - Patient refused
    - Comorbidities
    - Age
    - Not applicable
  - GAP score (calculation)
  - Blood gases – examination not performed





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**Thank you for attendance on the  
6th international SC meeting**