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(IPF)

# European **M**ulti**P**artner **I**PF **R**Egistry 4th international SC meeting

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- Spánková apnoe – nové položky
- Ukončování léčby – nestačí pouze end of observation → reports vs analysis
- Validace – dokument – překlad do lokálních jazyků?
- DNA sekvenování - dokument





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**Changes in eCRF**

# Changes in eCRF

- In Enrollment form new section added
- Related to the associated disorders question
- If sleep-disorder breathing, then further question should be filled up



# Sleep-disordered breathing

- Examination for sleep-disordered breathing performed (yes/no)
- Epworth sleeping scale (number of points)
- The result of printing examination
- AHI (apnea index/ hypopnea)
- ODI (number of desaturation per hour)
- T90 (% sleep time in O2 saturation below 90%)
- Result (selection)
  - Mild disorder (AHI < 15)
  - Moderate disorder (AHI 15-30)
  - Severe disorder (AHI > 15)
- Positive pressure airway therapy (yes/no)



# Analysis

- Frequency and content of report for each country
- Once a year is enough? Regular analytical report?
- If required often, please inform us that we can add it to the plan of analysis
- Data export – twice a year



# 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)
  - Turkey is ready to join (waiting for contract)
  - In process of negotiation – Russia, Israel?
  - Do not have information on Croatia
- Currently entered more than 1.000 patients



# Sponsors

- Contract with Boehringer Ingelheim RCV is signed till the end of the year 2016
- New contract for another period will be prepared
- Currently working on contract with Boehringer Ingelheim Turkey – contract with RCV is not covering Turkey and needs to be separate contract with BI Turkey
- Probably another companies will be interested to join the registry – Roche





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**Involved countries**

# Current status of EMPIRE – involved countries

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



# Newcomer

- **Turkey**

- Is finally joining the registry 😊

- EGE University Medical School

- **Poland:**

- New centres are joining

- Waiting for approval of EC

- School of Medicine, Jagiellonian University, Krakow
    - University Hospital, Poznan



# Newcomer

- **Croatia is joining the registry:**
  - Waiting for approval of EC and RA
  - Possibly 5 centres will join
    - Dubrava University Hospital
    - Rijeka University Hospital
    - Split University Hospital
    - Zagreb University Hospital
    - Zadar General Hospital



# Representation of countries in EMPIRE registry

N = 1039

	N (%)
Czech Republic	636 (61.2 %)
Poland	195 (18.7 %)
Slovakia	103 (10.0 %)
Hungary	74 (7.1 %)
Serbia	31 (3.0 %)



# Number of patient according to countries

Country	Number of newly entered patients in 2016	Total number of patients
Czech Republic	119	636
Slovakia	49	103
Poland	86	195
Hungary	36	74
Serbia	16	31
<b>Total</b>	<b>306</b>	<b>1039</b>

Status on the date: 30.8.2016





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## Meeting minutes – 3rd SC

## Minutes from 2nd SC meeting

- No suggestion for initiated studies were sent
- Changes of calculation of FVC - do we need to change it?





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**Technical issue**

# Feedback from analyst

- Based on entered data and processed analysis some inconsistency in data occurred:

## Inconsistency in forms therapy and FUP

- when treatment starts, no data about spirometry are usually available
- This can be solved if PI will enter FUP and treatment at the same or at least close date



# Feedback from analyst

## Long-term follow up of patient

- Extremely high values of VC (in some patients grow and it should fall in patients with IPF)
- Long-term survival





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**Publication in progress**

# Processed analytical outputs and abstracts

- Does early diagnosis of idiopathic pulmonary fibrosis matter? Real- life results from the EMPIRE registry (Vašáková et al.)
- Influence of HRCT on prognosis of patients with IPF (Vašáková et al.)
- Effect of pirfenidone on decline of lung functions in comparison with other treatment modalities in Czech patients with IPF (Žurková et al.)
- Influence of parameters on survival of patients with IPF (Doubková et at.)





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**Thank you for attendance on the  
3rd international SC meeting**