



EMPIRE  
(IPF)

# 15<sup>th</sup> EMPIRE Steering Committee meeting

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# Agenda

- Current status of the EMPIRE registry, news in the registry
- Manuscripts in progress, publications
- Analyses and ongoing IIS
- Continuation of EMPIRE after 06/2022





# Current state of the registry

# Number of patients by countries in the EMPIRE registry

Country	Number of patients
Czech Republic	1513 (34.7%)
Turkey	873 (20%)
Poland	678 (15.6%)
Hungary	306 (7%)
Israel	293 (6.7%)
Slovakia	242 (5.6%)
Serbia	163 (3.7%)
Austria	134 (3.1%)
Croatia	117 (2.7%)
Bulgaria	25 (0.6%)
Macedonia	12 (0.3%)

Patients in EMPIRE registry  
n = 4,492

Patients excluded from  
analysis  
n = 136

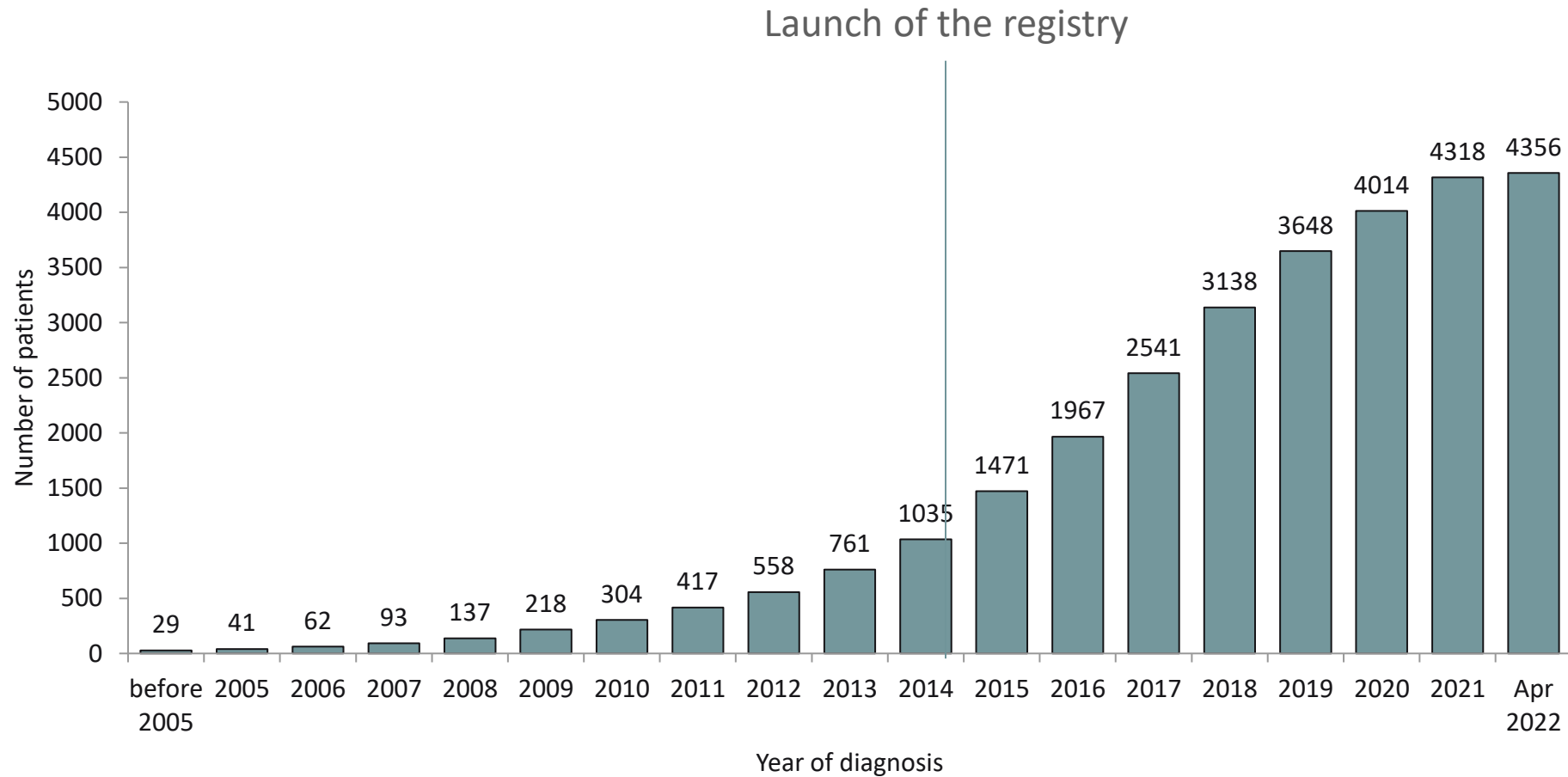
*Change of diagnosis*  
*No information about:*

- *date of diagnosis*
- *date of enrolment visit*

**Patients available for  
analysis  
n = 4,356**

# Number of newly diagnosed patients

n = 4,356



# New countries/centres interested in participation

Country	Comment
Romania	Refreshed contact from Radu Dabija

# How we are doing – example Q1/2022

Hospital	Entry	F-up
Acibadem City clinic Tokuda hosp. Pulmonary dep.	1	1
České Budějovice - Plicní oddělení	1	13
Clin. Centre of Serbia - Clinic for Pulm. Diseases	7	7
Clinical Research Center Salzburg GmbH	3	18
EGE University - Department of Pulmonary Medicine	27	218
FN Brno - Plicní klinika	12	88
FN Motol - Pneumologická klinika	6	41
FN Olomouc - Plicní klinika	6	54
FN Ostrava - Klinika TRN	10	52
FN Plzeň - Klinika TRN	2	23
FNHK - Plicní klinika	3	87
Inst. of Tuberc. and Lung Dis. Warsaw - I Dep	6	34
Inst. of Tuberc. and Lung Dis. Warsaw - III Dep	0	6
Jihlava - Plicní odd.	1	2
Kroměříž - Pneumologicko-alergolog. Odd.	0	3
Levice - Ambulancia pneumológie a ftizeológie	1	2
Nemocnice Na Bulovce – Plicní klinika	6	9
Nový Jičín - Plicní odd.	2	22
Pécs University - Department of Pulmonology	1	2
Semmelweis University - Department of Pulmonology	33	41
Szpital Gdańsk. Uniw. Med. - Klin. Alerg. i Pneum.	3	87
Thomayerova nemocnice - Pneumologická klinika	6	168
University Hospital Dubrava - Dep. of pulmonology	4	12
<b>Total</b>	<b>141</b>	<b>990</b>

Country	Entry forms	F-up forms
AT	3	18
BG	1	1
CZ	55	562
HR	4	12
HU	34	43
PL	9	127
RS	7	7
SK	1	2
TR	27	218
<b>Total</b>	<b>141</b>	<b>990</b>





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# Analyses & publications



# Published articles (IF journals)

## 2022

- Jovanović D, Šterclová M, Mogulkoć N, Lewandowska K, Müller V, Hájková M, et al. Comorbidity burden and survival in patients with idiopathic pulmonary fibrosis: the EMPIRE registry study. Respiratory Research 2022.

## 2021

- Kolonics-Farkas A, Šterclová M, Mogulkoć N, Lewandowska K, Müller V, Hájková M, et al. Differences in baseline characteristics and access to treatment of newly diagnosed patients with IPF in the EMPIRE countries. Frontiers in Medicine 2021.
- Doubková M, Kriegová E, Littnerová S, Schneiderová P, Šterclová M, Bartoš V, et al. DSP rs2076295 variants influence nintedanib and pirfenidone outcomes in idiopathic pulmonary fibrosis: a pilot study. Therapeutic Advances in Respiratory Disease 2021.

## 2020

- Kolonics-Farkas A, Šterclová M, Mogulkoc N, Kus J, Hájková M, Müller V, Jovanovic D, Tekavec-Trkanjec J, Littnerová S, Hejduk K, Vašáková M. Anticoagulant use and bleeding risk in Central European patients with idiopathic pulmonary fibrosis (IPF) treated with antifibrotic therapy: real-world data from EMPIRE. Drug Safety 2020; 43(10): 971–980. Times cited: 3 (Web of Science), 3 (Scopus)
- Tran T, Šterclová M, Mogulkoc N, Lewandowska K, Müller V, Hájková M, Kramer MR, Jovanović D, Tekavec-Trkanjec J, Studnicka M, Stoeva N, Hejduk K, Dušek L, Suissa S, Vašáková M. The European MultiPartner IPF registry (EMPIRE): validating long-term prognostic factors in idiopathic pulmonary fibrosis. Respiratory Research 2020; 21: 11. Times cited: 19 (Web of Science), 17 (Scopus)

## 2019

- Barczy E, Starobinski L, Kolonics-Farkas A, Eszes N, Bohacs A, Vašáková M, et al. Long-term effects and adverse events of nintedanib therapy in idiopathic pulmonary fibrosis patients with functionally advanced disease. Advances in Therapy 2019; 36(5): 1221–1232. Times cited: 5 (Web of Science), 6 (Scopus)
- Žurková M, Eva Kriegová E, Kolek V, Lošťáková V, Šterclová M, Bartoš M, et al. Effect of pirfenidone on lung function decline and survival: 5-yr experience from a real-life IPF cohort from the Czech EMPIRE registry. Respiratory Research 2019; 20: 16. Times cited: 38 (Web of Science), 37 (Scopus)

## 2018

- Doubková M, Švancara J, Svoboda M, Šterclová M, Bartoš V, Plačková M, et al. EMPIRE Registry, Czech Part: Impact of demographics, pulmonary function and HRCT on survival and clinical course in idiopathic pulmonary fibrosis. The Clinical Respiratory Journal 2018; 12(4): 1526–1535. Times cited: 24 (Web of Science), 29 (Scopus)



# Articles in preparation/submitted

- **Short- and long-term outcome of pirfenidone treatment in definite, probable and possible idiopathic pulmonary fibrosis**  
Lead author: Martina Vašáková  
Current status: revised MS under review in PLOS One
- **Outcomes in patients with IPF in the EMPIRE registry treated with pirfenidone or nintedanib: impact of switching to a second antifibrotic therapy after discontinuation of the first antifibrotic**  
Lead author: Yochai Adir  
Current status: to be re-analysed (June)
- **Correlation of response to antifibrotic treatment with adverse events to antifibrotic drugs in IPF patients from the EMPIRE registry**  
Dragana M. Jovanović  
Current status: paper in preparation, analysis to be completed after investigator's initial review



# Analyses – to be initiated

- Analyses previously agreed by the SC, but without specification to date
- **Crepitus**  
Investigator: Michael Studnicka
- **Quality of life**  
Investigator: Katarzyna Lewandowska
- **Genetics in Czech and Turkish cohorts**  
Investigator: Nesrin Mogulkoć
- **COVID-19 in IPF patients**  
Investigator: Nesrin Mogulkoć



# Analyses – to be proposed and approved

- Analyses to be approved by SC
- **Extension of the pirfenidone radiological study (SDU)**  
Investigator: Michael Studnicka
- **Longitudinal weight change in IPF patients treated with antifibrotics**  
Investigator: Nesrin Mogulkoć





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# Subprojects, IIS

# HRCT Repository

- Repository ready from October 2021
- Cooperation with Czech centres – two contracts signed (Brno, Hradec Králové), technical part in preparation
- Centres abroad – waiting for response (Warszawa, Budapest)



# PD-L1 biomarkers

- Study preparation temporarily stopped
- Long process of contract preparation at Roche
- Prospective part of samples collection would require continuation of the EMPIRE core project and clinical data collection

# Nintedanib study

- Objective: analysis of short- and long-term clinical outcome of patients treated with nintedanib with different characteristics (FVC, HRCT, age, rapid/slow progression)
- IIS led by Martina Vašáková and supported by BI
- Current state: to be completed in June







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# EMPIRE in 2022 and onwards...?

# Current state

- The centres will be informed that IPF clinical data will not be reimbursed from 1 July 2022
- Database remains open – centres can still complete their patient records and ask for a complete export of their data.
- Future support – BI and Roche expressed high interest in further support

Dear colleagues, dear EMPIRE collaborators,

we are contacting you to update you on the current status of data collection and the future of the project. First of all, we would like to thank you very much for your long-term collaboration and sharing of valuable data on the treatment of patients with IPF, which have contributed to a number of important findings and professional outcomes.

Unfortunately, the existing contracts with the companies that have supported our project for a long time will expire on 30 June 2022. Although we have been negotiating with both companies and the Steering Committee for the continuation of the EMPIRE project since the end of 2021, it is now clear that from 1 July 2022 the funds that we have been using to cover your time and work to enter data into the registry, at least symbolically, will no longer be available. Therefore, we would like to inform you that the reimbursed data collection in the EMPIRE registry will end on 30 June 2022.

However, we by no means wish to completely discontinue any project activities. The database will remain open for data entry for a few more months. This can be used, for example, to complete the data of patients who are currently being treated in your hospital. We will then, if you wish, provide you with a complete and comprehensive export of your centre's data, which can be used to create further outputs. Given the size and complexity of the database, there are also many research topics that can be developed into an analysis (either at the level of a single country or an entire registry) and subsequent publication (article, conference paper).

Whether data collection on IPF or other ILDs will continue will be decided in the coming weeks and months. We will of course keep you informed of further developments.

We thank you very much for your understanding and hope that our collaboration will continue in the future. In fact, the EMPIRE project and its outputs, which by the way are available on the website <https://empire.registry.cz/>, have shown that this collaboration makes sense.

Best wishes

The EMPIRE team

Prof. Martina Vašáková, Jakub Gregor, Karel Hejduk, Lucie Martykánová, Petra Ovesná

