



EMPIRE
(IPF)

European **M**ultipartner **I**PF **R**egistry

12th SC meeting

Martina Vašáková¹, Jakub Gregor²

¹ Thomayer Hospital, Prague, Czech Republic;

² Faculty of Medicine, Masaryk University

Agenda

- Current state of the registry
- Analyses and publications
- Subprojects, IIS
- Miscellaneous, discussion



COVID-19 era

- Difficult times for all of us
- Delayed response from IBA – sorry, we have only been temporarily enlisted to the war with the coronavirus epidemic 😞 (analyses, predictive models, IT services).
- Higher interest of media and public in health issues
- Opportunity to disseminate information on respiratory diseases

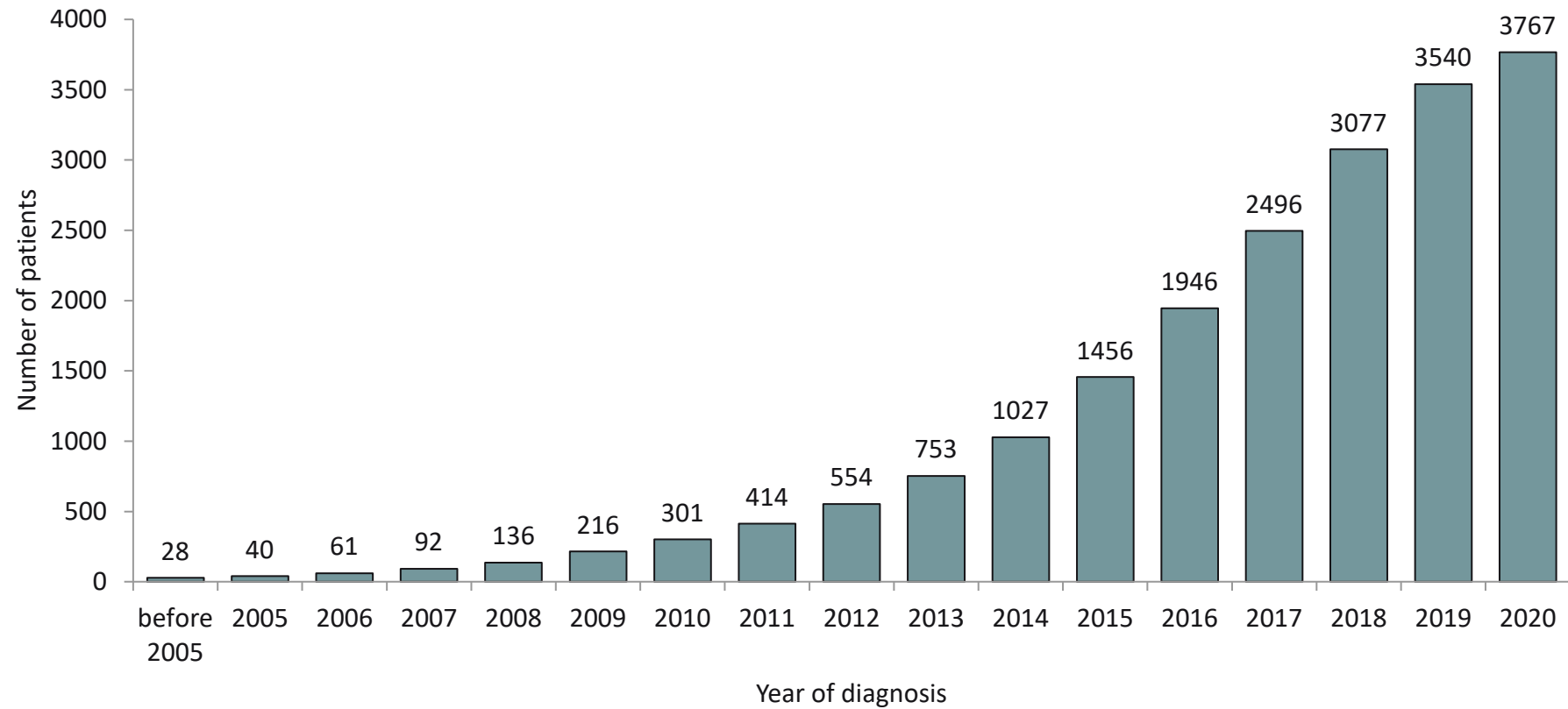




Current state of the registry

Number of newly diagnosed patients

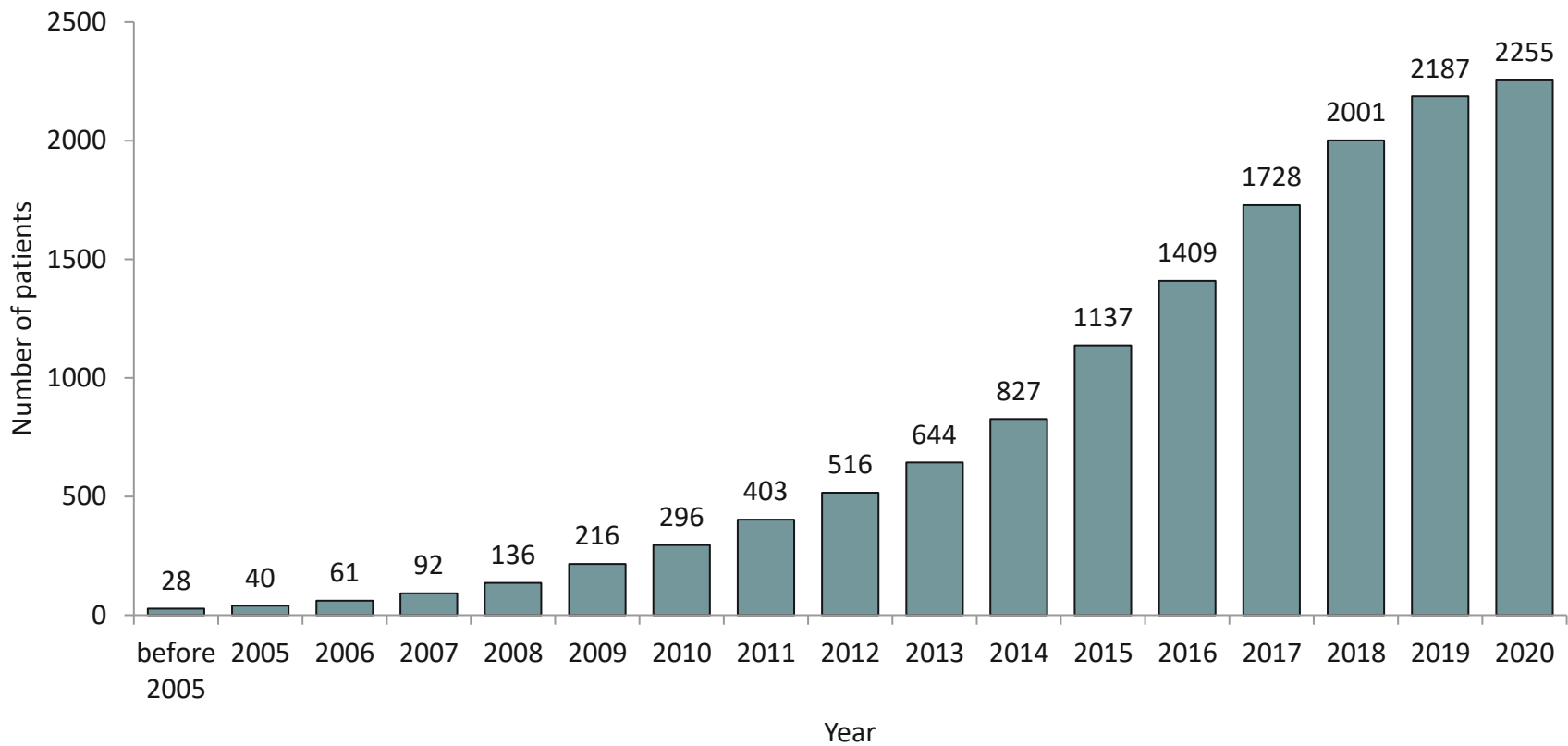
n = 3,767



Number of patients under follow-up

n = 3,767

Year	Number of terminated follow-ups (with known date)
2010	5
2011	6
2012	27
2013	71
2014	91
2015	119
2016	218
2017	231
2018	308
2019	277
2020	159
Total	1512



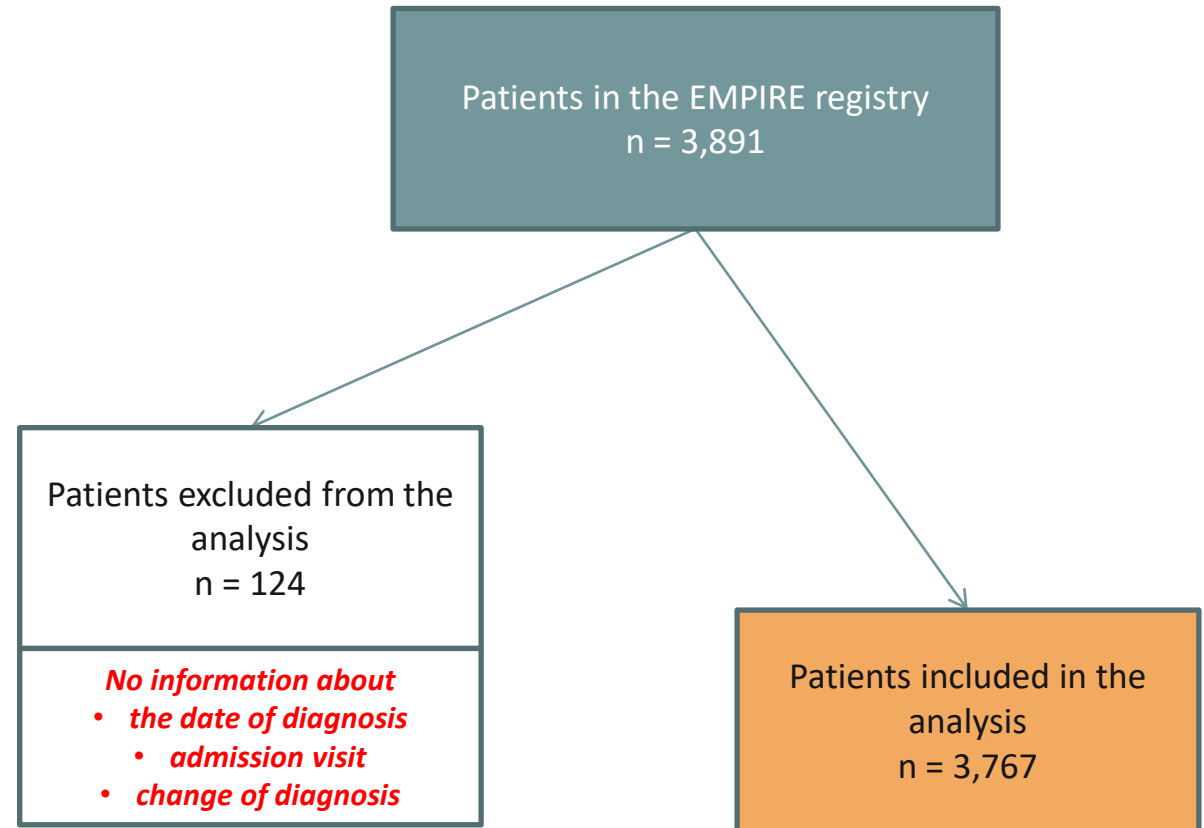
The number of patients in the EMPIRE registry monitored in a given year is reduced by the number of patients with terminated follow-up due to death (n = 1,045), lung transplantation (n = 80), patients lost from follow-up (n = 333), other (n = 54).
The date of death is unknown in 16 patients.



Number of patients by countries in the EMPIRE registry

n = 3,767

	Number of patients
Czech Republic	1271 (33.7%)
Turkey	729 (19.4%)
Poland	593 (15.7%)
Hungary	289 (7.7%)
Israel	250 (6.6%)
Slovakia	232 (6.2%)
Serbia	155 (4.1%)
Austria	113 (3.0%)
Croatia	108 (2.9%)
Bulgaria	19 (0.5%)
Macedonia	8 (0.2%)



Overview of contracts

Country	No. of centres with signed contract	No. of centres without signed contract	
Czech Republic	14	2	Hospital Znojmo Regional Hospital Pardubice
Hungary	2	4	Nat. Korányi TBC and Pulm. Institute, Budapest Debrecen University Clinical Centre, Debrecen Petz Aladár County Teaching Hospital, Győr University of Szeged, Szeged
Poland	4	5	Medical University of Silesia, Katowice Jagiellonian University, Kraków Medical University of Łódź, Łódź Poznan University of Medical Sciences, Poznań Medical University of Warsaw
Slovakia	3	4	University Hospital Bratislava L. Pasteur University Hospital Košice University Hospital Martin, St. Svorad's Specialised Hospital Zobor, Nitra
Serbia	2	2	Clinic for Lung Diseases Knes Selo, Niš Institute for Pulmonary Diseases of Vojvodina, Sremska Kamenica
Turkey	0	1	Ege University Medical School, Izmir
Croatia	1	1	Split University Hospital Center, Split
Israel	0	2	Clalit Health Services through the Rabin Medical Centre, Petah Tikva Carmel Medical Center, Haifa
Bulgaria	1	0	
Austria	2	0	
Macedonia	1	0	
Total	30	21	

New countries/centres interested in participation

Country	Comment
Romania	Communication with Irina Strambu and Radu Crisan-Dabija (feedback on 11/6, then one reponse and one reminder sent from IBA on 15/6 and 5/10, respectively)
Bulgaria	Military Medical Academy Sofia (to be contacted)
Ukraine	Preliminary express of interest, information from BI

How we are doing – example Q3/2020

Clinical centre	Entry forms	F-up forms
Acibadem City clinic Tokuda hosp. Pulmonary dep.	2	7
Clin. Centre of Serbia - Clinic for Pulm. Diseases	5	19
Clinical Research Center Salzburg GmbH	6	37
České Budějovice - Plicní oddělení	1	11
EGE University - Department of Pulmonary Medicine	23	189
FN Brno - Plicní klinika	13	70
FN Motol - Pneumologická klinika		16
FN Olomouc - Plicní klinika	6	64
FN Ostrava - Klinika TRN	2	58
FN Plzeň - Klinika TRN	2	21
FNHK - Plicní klinika	4	66
Inst. of Tuberc. and Lung Dis. Warsaw - I Dep		28
Inst. of Tuberc. and Lung Dis. Warsaw - III Dep	2	19
Levice - Ambulancia pneumológie a ftizeológie	2	
Jihlava - Plicní odd.		1
Kroměříž - Pneumologicko-alergolog. odd.		2
Levice - Ambulancia pneumológie a ftizeológie		9
Nemocnice Na Bulovce – Plicní klinika	2	47
Nový Jičín - Plicní odd.	3	21
Pécs University - Department of Pulmonology	4	8
Semmelweis University - Department of Pulmonology	1	33
Szpital Gdańsk. Uniw. Med. - Klin. Alerg. i Pneum.	5	53
Thomayerova nemocnice - Pneumologická klinika	6	130
University Hospital Dubrava - Dep. of pulmonology	3	32
Total	92	941

Country	Entry forms	F-up forms
AT	6	37
BG	2	7
CZ	39	507
HR	3	32
HU	5	41
PL	7	100
RS	5	19
SK	2	9
TR	23	189
Total	92	941





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Outcomes & publications

Published articles (IF journals)

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: 1 (WoS)**
- 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: 4 (WoS)**

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: 4 (WoS)**
- 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: 20 (WoS)**

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: 12 (WoS)**



Articles in preparation

- **Comorbidity burden in patients with idiopathic pulmonary fibrosis: the EMPIRE registry study**
Lead author: Dragana M. Jovanović
Current status: revised paper to be finalised by medical writers after a complete update of the analysis
- **Genetics in Czech IPF patients**
Lead author: Martina Doubková
Current status: in preparation after extension and update
- **Survival and lung functions of IPF patients with and without switch of antifibrotic therapy (preliminary title)**
Lead author: Yochai Adir
Current status: analysis extended and updated, provided to medical writers, draft expected in upcoming weeks



Articles in preparation

- **Intercountry differences in IPF patients**

Lead author: Abigél M. Kolonics-Farkas

Current status: paper in preparation

- **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

- **Short- and long-term outcome of pirfenidone treatment in definite, probable and possible idiopathic pulmonary fibrosis**

Lead author: Martina Vašáková

Current status: paper almost completed, to be submitted in ERJ

Please send me your Col form



Analyses

- **Correlation of response to antifibrotic treatment with adverse events to antifibrotic drugs in IPF patients from the EMPIRE registry**

Investigator: Dragana Jovanovic; presented at ERS 2020

- **Cancer incidence among IPF patients in EMPIRE registry**

Investigator: Nesrin Mogulkoc; first round of analysis done

- **The effect of metformin on clinically relevant outcomes in IPF patients in the EMPIRE registry**

Investigator: Dragana Jovanovic; presented at ERS 2020



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 Mogulkoc
- **Risk assessment (originally intended for Int J Mol Sci, invitation acceptance cancelled by lead authors due to a different journal scope)**
Investigator: Nesrin Mogulkoc



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Subprojects, IIS

Pirfenidone effectiveness in diagnostic groups (SDU)

- Final analytical report sent
- Additional analysis using a different statistical approach (propensity score instead of adjustment for selected parameters) – to be finalised and discussed
- Manuscript to be finalised and submitted



HRCT Repository

Current status of financial support

- Reduction of costs for launch and 1st year operation
- Direct support from Roche (half of costs) – contract pending at Masaryk University

Cooperation with OSIC

- SC members agreed on cooperation with OSIC in the form of building a standalone EMPIRE-HRCT repository and subsequent provision of images to the OSIC database



HRCT Repository

Radiological centres

- Czech Republic, Poland, Hungary, Turkey – confirmed attendance of the “largest” centres in terms of patient numbers
- Other countries – kindly send update



PD-L1 biomarkers

- Support of the study from Roche (approved)
- Protocol, budget proposal and informed consent have been prepared
- Categorised as interventional (blood samples) – waiting for contract proposal from Roche

Country/site	Number of samples	Collection – prospective	Collection – retrospective	Collection – routine	Collection – for the study
Czechia					
Hradec Kralove	50	yes	no	yes	no
Bulovka	20	yes	no	yes	no
Thomayer Hospital	40	yes	no	no	yes
Olomouc	20	yes	yes	yes	yes
Turkey					
Ege	400	yes	yes	yes	yes
Hungary					
Budapest	100	yes	no	yes	no
Croatia					
Dubrava	40	yes	no	no	yes



Miscellaneous, discussion