European MultiPartner IPF REgistry
2nd international SC meeting

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EMPIRE (European MultiPartner IPF REgistry)

- **International, multicentre, observational, non-interventional registry** of IPF patients in Central and Eastern Europe
- It is independent and opened for multisource support from different subjects
- It is opened to other newly coming partners
- The ownership of data and the access to the data: national pneumologic societies
- **Steering Committee** involves deputies from all participating countries
- Statistical outcomes for purposes of reimbursement (health insurance companies), real-life efficacy of treatment (pharma companies), clinical investigations- epidemiology, prognosis, subgroups comparisons

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(IPF)

EMPIRE registry

- Cooperation of Central and Eastern European countries in IPF epidemiology, diagnosis and treatment
- Support of national and European clinical research on IPF- epidemiology, genetics…
- Opportunity to publish data in respected respiratory journals
- Chance for Ph.D. students
- Pool of patients for clinical studies
- Tool for negotiations with healthcare insurance companies and regulatory organs- new treatment modalities in IPF

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IPF registry- what are the demands and expectations?

- **High threshold scientific registry- huge amount of information, including highly specialized investigations, central reading and approval of some data- very demanding on the people involved**
  - **What you get-** subcohort of IPF patients from the centers of excellence, specialized on IPF, high scientific value, no real life situation, no chance to have real epidemiologic data
- **Low threshold clinical registry- less information, no central reading, only consultation on demand**
  - **What you get-** real life picture of all patients with IPF who are diagnosed and treated with antifibrotic treatment, almost all of the patients who are not on specific treatment, the results are closer to real epidemiology of IPF and show real life treatment with outcome and prognosis

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Collected data

- **Simple to fill in- only 10 pages CRF in total**
- **Inclusion criteria:**
  - Confirmed diagnosis of idiopathic pulmonary fibrosis (IPF)
  - Patient´s consent
- **Endpoints**
  - FVC decrease
  - TL_{CO} decrease
  - Death
- **Data- patients' characteristics and medical history, diagnosis and disease management, functional parameters, HRCT, quality of life (EuroQoL questionnaire)**
- **Safety reporting for the new antifibrotic drugs- also compulsory for reimbursement of new highly innovative drugs**
- **Follow-up of the patients until death- every 3-6 months**
- **Data management and statistical analyses are done by Masaryk University, Institute of Biostatistics and Analyses (IBA), Brno, Czech Republic**

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Outcome of the registry

Primary outcome:

- **To estimate IPF incidence, prevalence and mortality in Central and Eastern Europe**

Secondary outcome:

- **To describe basic characteristics (e.g. age, gender, risk factors etc)**

Tertiary outcome:

- **To describe real life approach to IPF in participating countries:**
  - diagnostic algorithm
  - treatment patterns and management of patients
  - treatment outcomes (treatment response, overall survival) and quality of life
  - resource utilization
- **To determine number of patients suitable for enrolment in clinical trials**

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Investigator initiated studies from EMPIRE

- Regional (national) and Central-Eastern European epidemiologic data on IPF
- Clinical research- knowledge on patients prognosis, functional parameters and HRCT changes in time
- Compare current treatment with new modalities in real clinical life
- Projects can be proposed by each member- considered by Steering Committee and approved by chair
- Ownership of published data- first author- author of proposal and author of manuscript, co-authors consecutively listed according number of patients enrolled to registry

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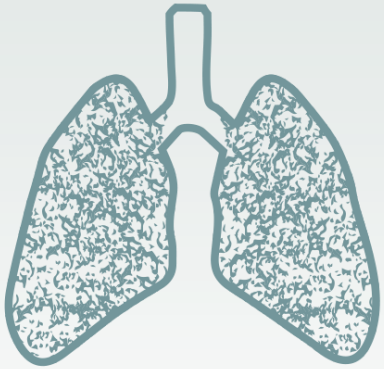
Involved countries

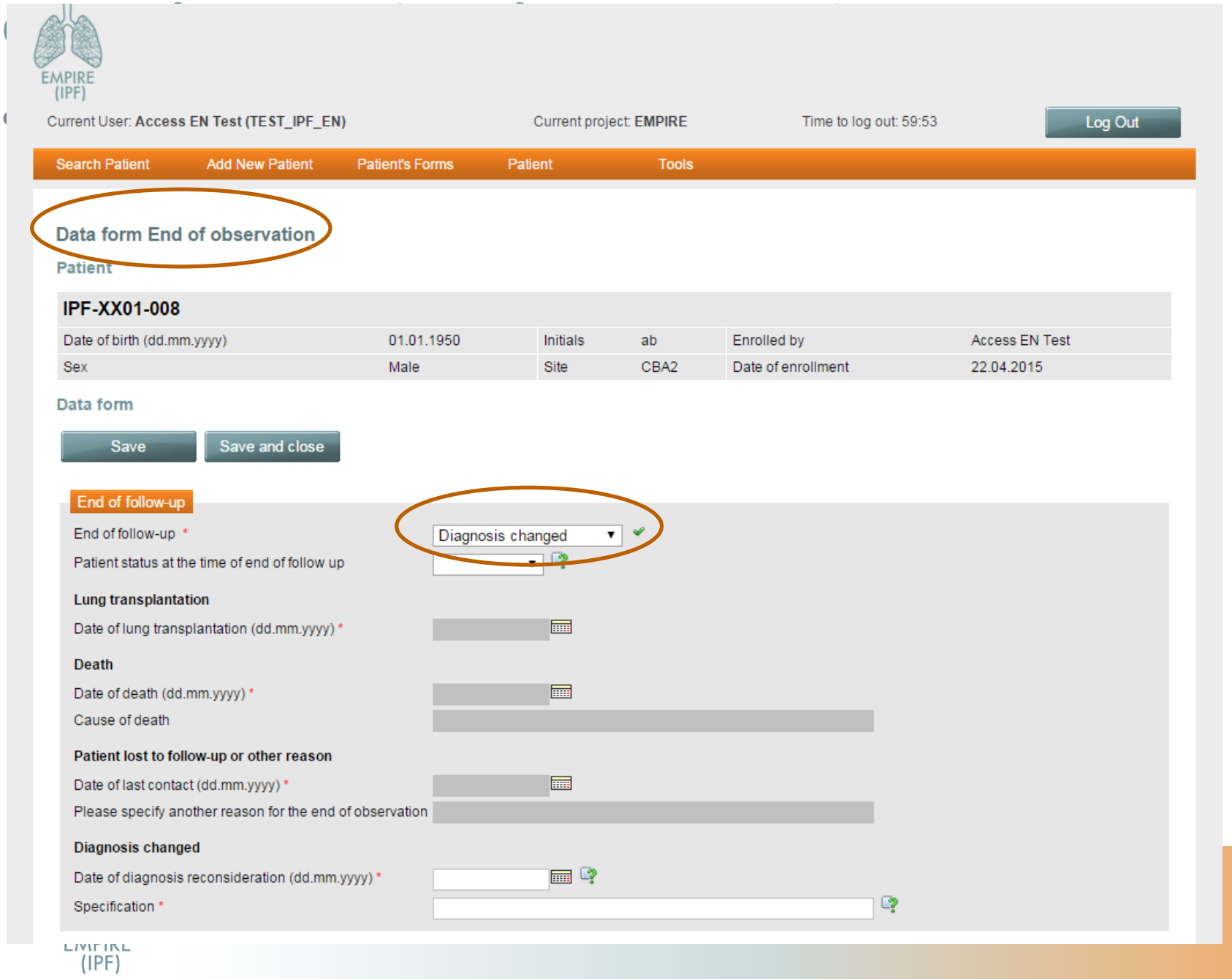
Current status of EMPIRE – involved countries

- **Czech Republic**
  - 10 sites already participating in IPF registry in the Czech Republic
- **Hungary (5 sites)**
- **Poland (6 sites)**
- **Slovakia (6 sites)**
- **Serbia (1 site)**
- ***Turkey, Israel* – in progress**

EMPIRE (IPF)



eCRF changes since last SC meeting


EMPIRE
(IPF)
Current User: Access EN Test (TEST_IPF_EN)
Current project: EMPIRE
Time to log out: 59:53
Log Out
Search Patient
Add New Patient
Patient's Forms
Patient
Tools
Data form End of observation
Patient
IPF-XX01-008
Date of birth (dd.mm.yyyy) 01.01.1950
Initials ab
Enrolled by Access EN Test
Sex Male
Site CBA2
Date of enrollment 22.04.2015
Data form
Save
Save and close
End of follow-up
End of follow-up *
Diagnosis changed
Patient status at the time of end of follow up
Lung transplantation
Date of lung transplantation (dd.mm.yyyy) *
Death
Date of death (dd.mm.yyyy) *
Cause of death
Patient lost to follow-up or other reason
Date of last contact (dd.mm.yyyy) *
Please specify another reason for the end of observation
Diagnosis changed
Date of diagnosis reconsideration (dd.mm.yyyy) *
Specification *
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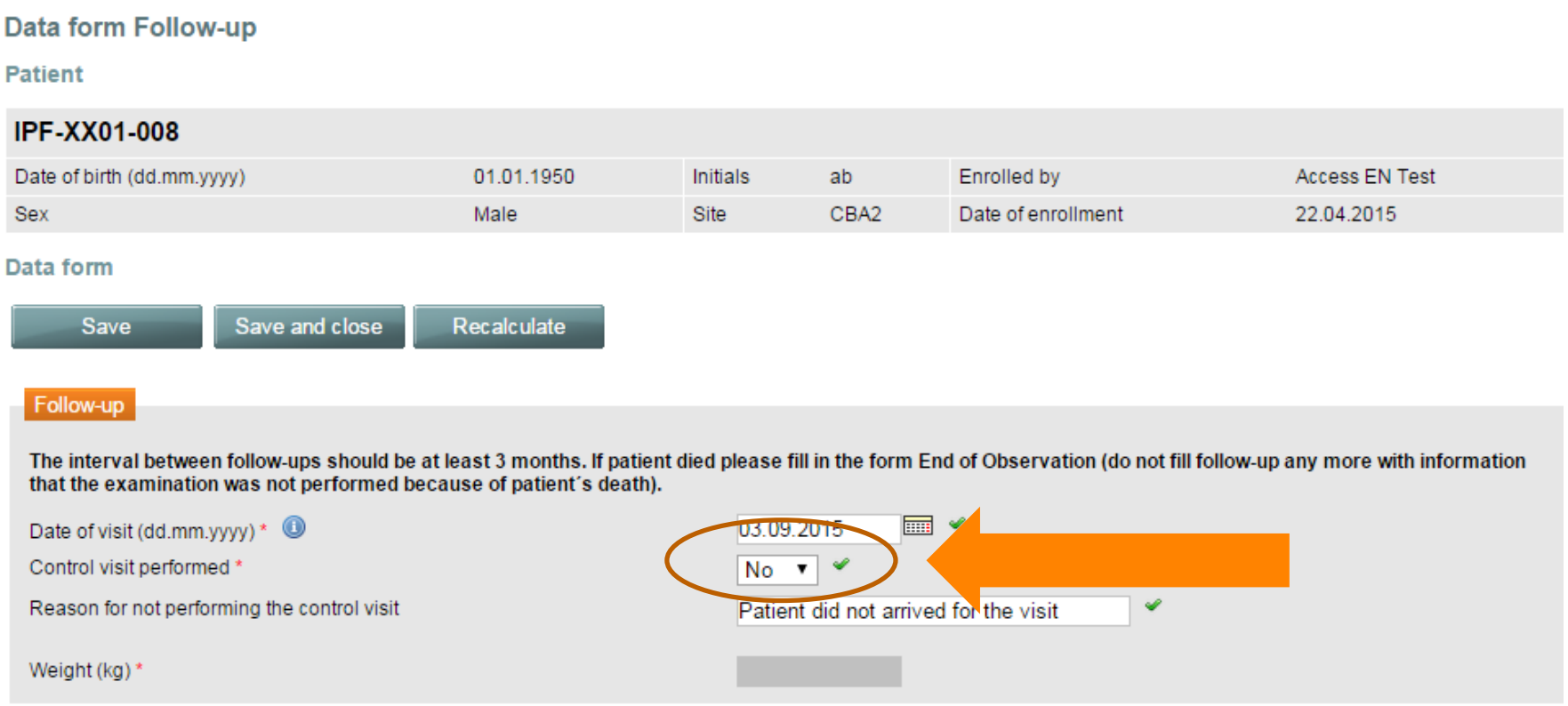
eCRF changes since last SC meeting

- Validation criteria



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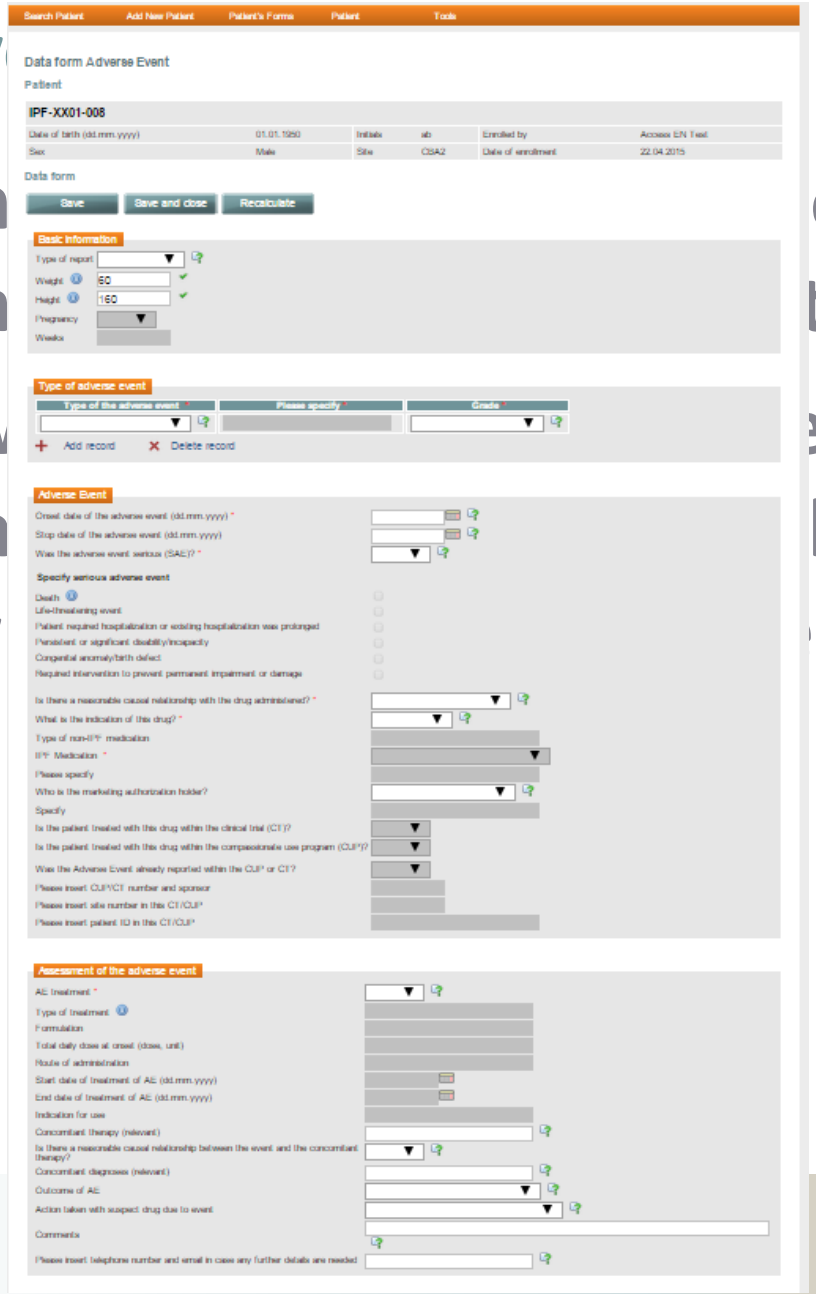
Adverse Ev

- Based on onsor (BI) we have fina t form
- From nov elated to drugs wh horization holder w partment
- Reduced



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Frequently asked question(s)

FAQ

- **Where to enter FVC information?**
  - FVC data are part of the Follow-up form only
  - Discrepancy: Protocol Data collection time points (p.10)

MONTH/DATE	DATA COLLECTED
0m	Entry form, Treatment
Every 3m/6m	Treatment, Follow-up Information, Quality of life form, Hospitalisation, Adverse Event [illegible] AE occurred)
End of observation	End of observation

? Protocol adjustment ?

- **Man: *(FVC)**100)/((27.63 - (0.112 * *age at the timeof diagnosis*)) * *heigh on the Enrollment form*/1000)**
- **Woman: *(FVC)**100)/((21.78 - (0.101 * *age at the timeof diagnosis*)) * * *heigh on the Enrollment form* /1000)**

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Predicted value

- Man: *(FVC)**100)/((27.63 - (0.112 * *age at the time of diagnosis*)) * *height on the Enrollment form*/1000)
- Woman: *(FVC)**100)/((21.78 - (0.101 * *age at the time of diagnosis*)) * * *height on the Enrollment form* /1000)

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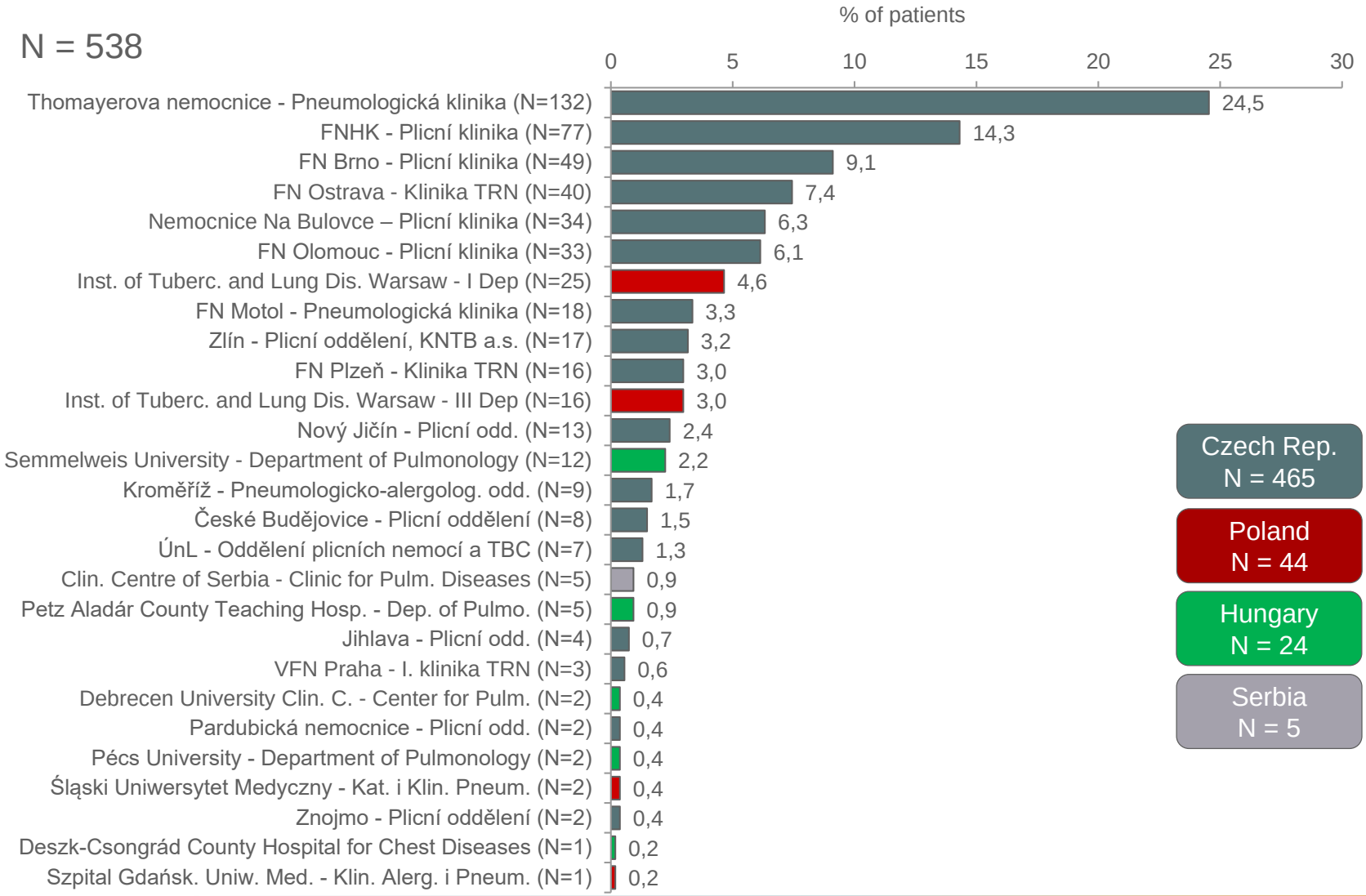
Data analysis

Data export 31AUG2015

Number of patients in EMPIRE registry

N = 538



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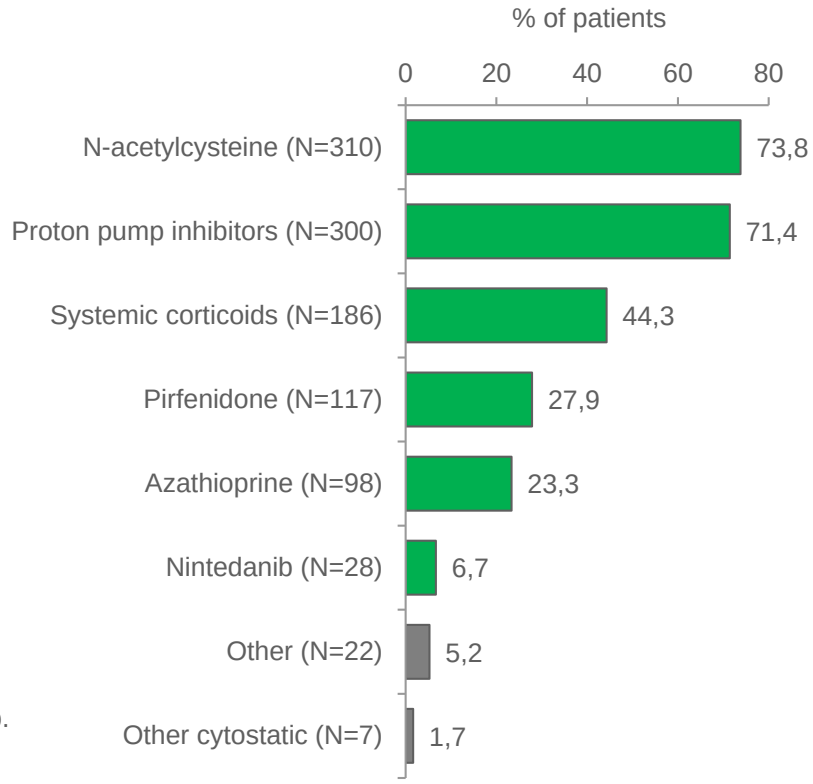
Pharmacological treatment

N = 538

Type of treatment (known N)	N (%)
Pharmacological treatment (N=503)	420 (83.5%)
Rehabilitation (N=501)	203 (40.5%)
Oxygen therapy (N=503)	145 (28.8%)
Lung transplantation (N=501)	79 (15.8%)
Clinical Study (N=502)	39 (7.8%)

1 patient could have more types of treatments during follow up.
1 patient with pharmacological treatment could use more drugs during follow up.

N = 420



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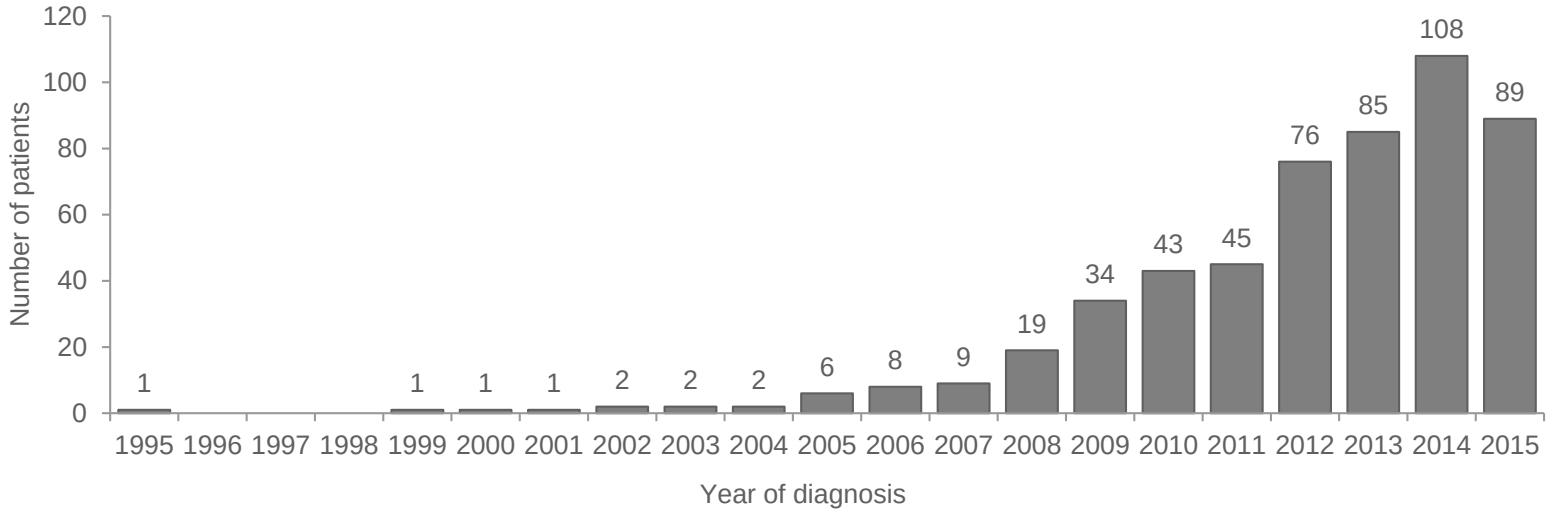
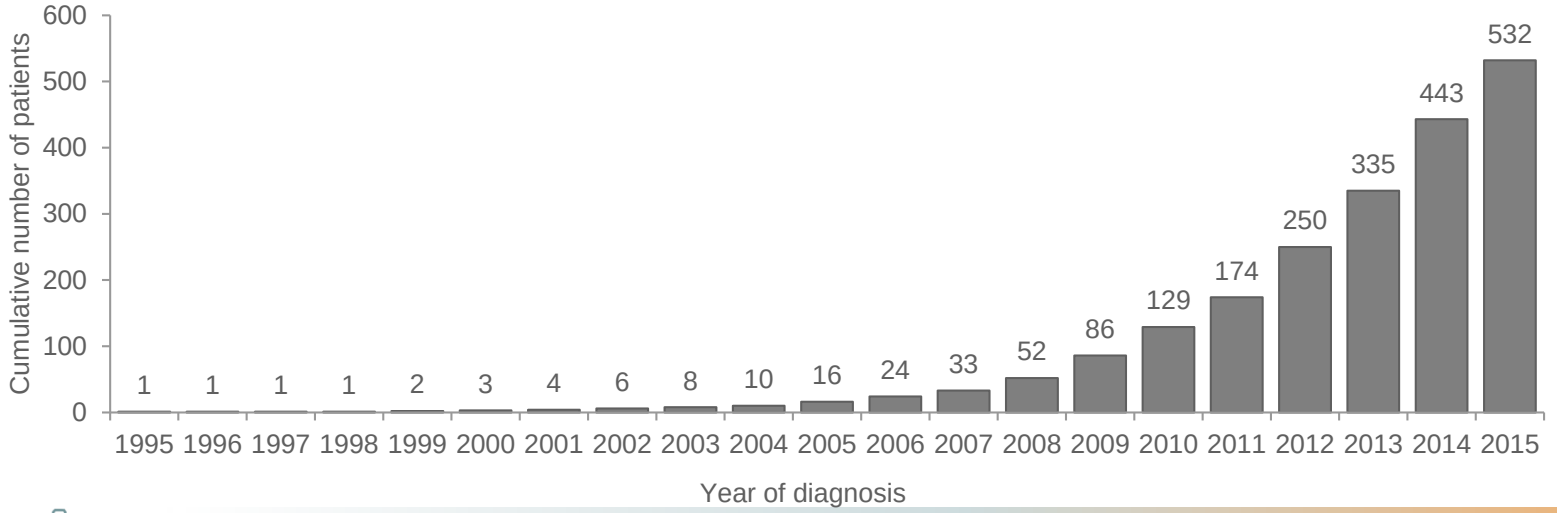
Time of diagnosis

N = 538





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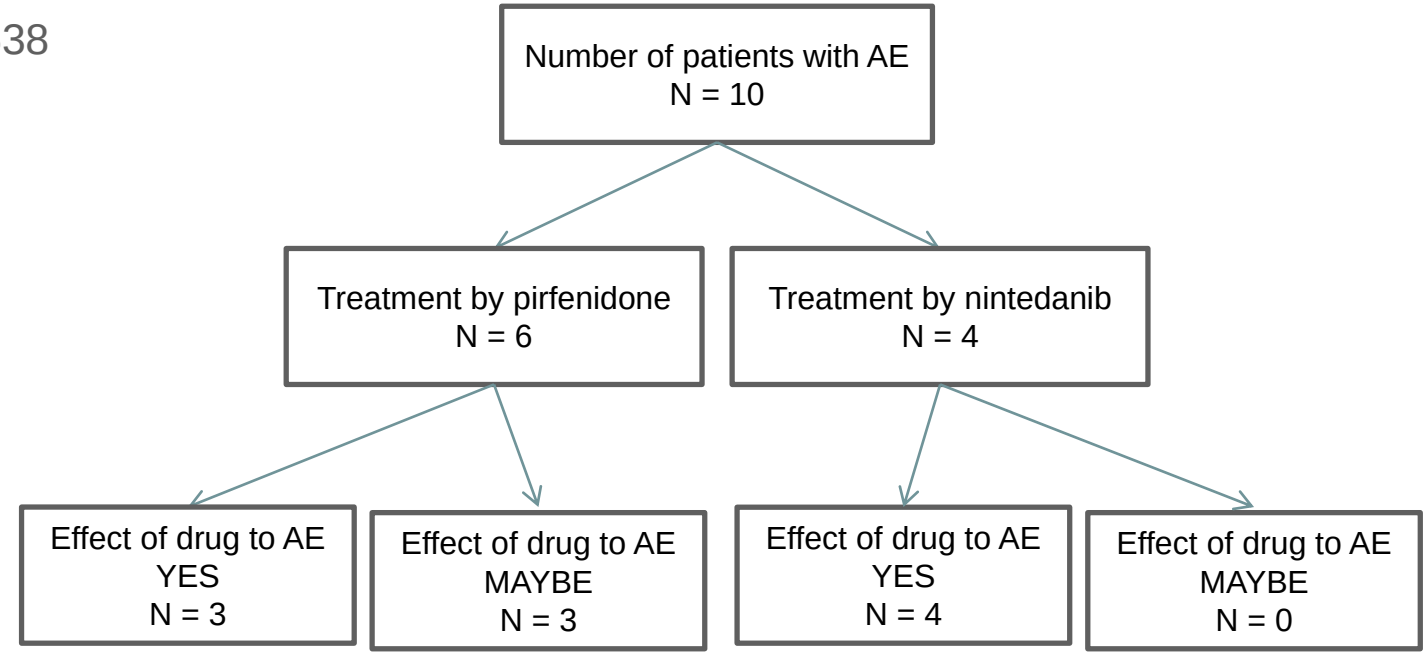
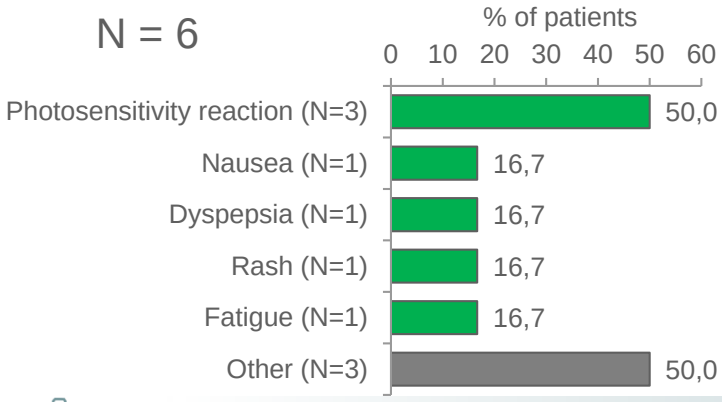
No information about date of diagnosis in 6 patients.

Adverse events (AE)

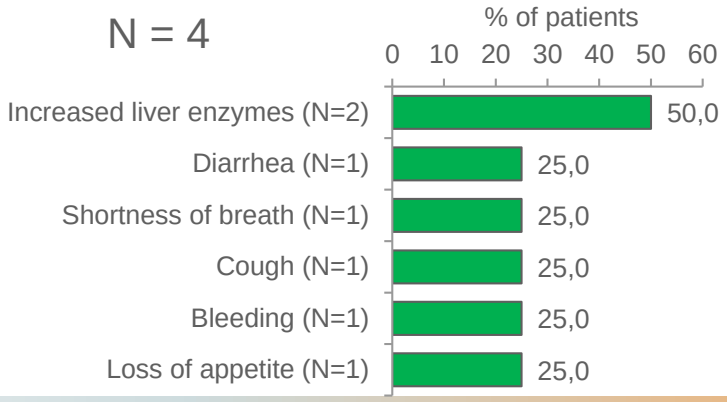
N = 538



N = 6



N = 4



No information about type of AE in 1 patient with nintedanib

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Current and further projects on EMPIRE data

The projects currently running in EMPIRE registry

- Early diagnosis of IPF- does it influence survival?
- Phenotypes of IPF (only the Czech part)
- Genetics if IPF (only the Czech part)
- Others???

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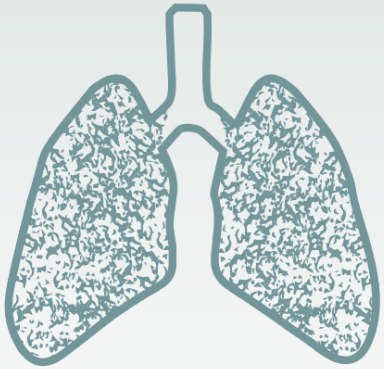
To be discussed

- Opinion with web site and protocol
- Protocol change?
- Independency should be emphasized- multisource financial support is invited
- In IPF registry should be optimally all cases of IPF, not only the treated ones
- This ppt available on EMPIRE website?

EMPIRE (IPF)



Thank you for attendance on the 2nd international SC meeting