

EMPIRE = European Multicentric IpF REgistry

1st Steering Committee meeting, PRAGUE

Lenka Pavlovská, Project Manager

- Czech Registry
- EMPIRE registry - core information
- Ownership/Publication/Contract
- Timelines/Milestones
- Granting Access
- Case Report Form – CRF
- Practical demonstration



THE CZECH REGISTRY

- Czech registry
 - Started - June 2012, ass. prof. Martina Vašáková

CURRENTLY:

- 10 participating sites
- 369 enrolled patients



Willingness to spread the registry to other countries

EMPIRE

European Multicentric IpF Registry *2014

non-interventional registry of IPF
patients in the Czech Republic and
Central and Eastern Europe



THE EMPIRE REGISTRY - CORE INFORMATION

- Financial support: funding



Boehringer Ingelheim

- Sponsor: responsible for initiating, conducting and financing the Project



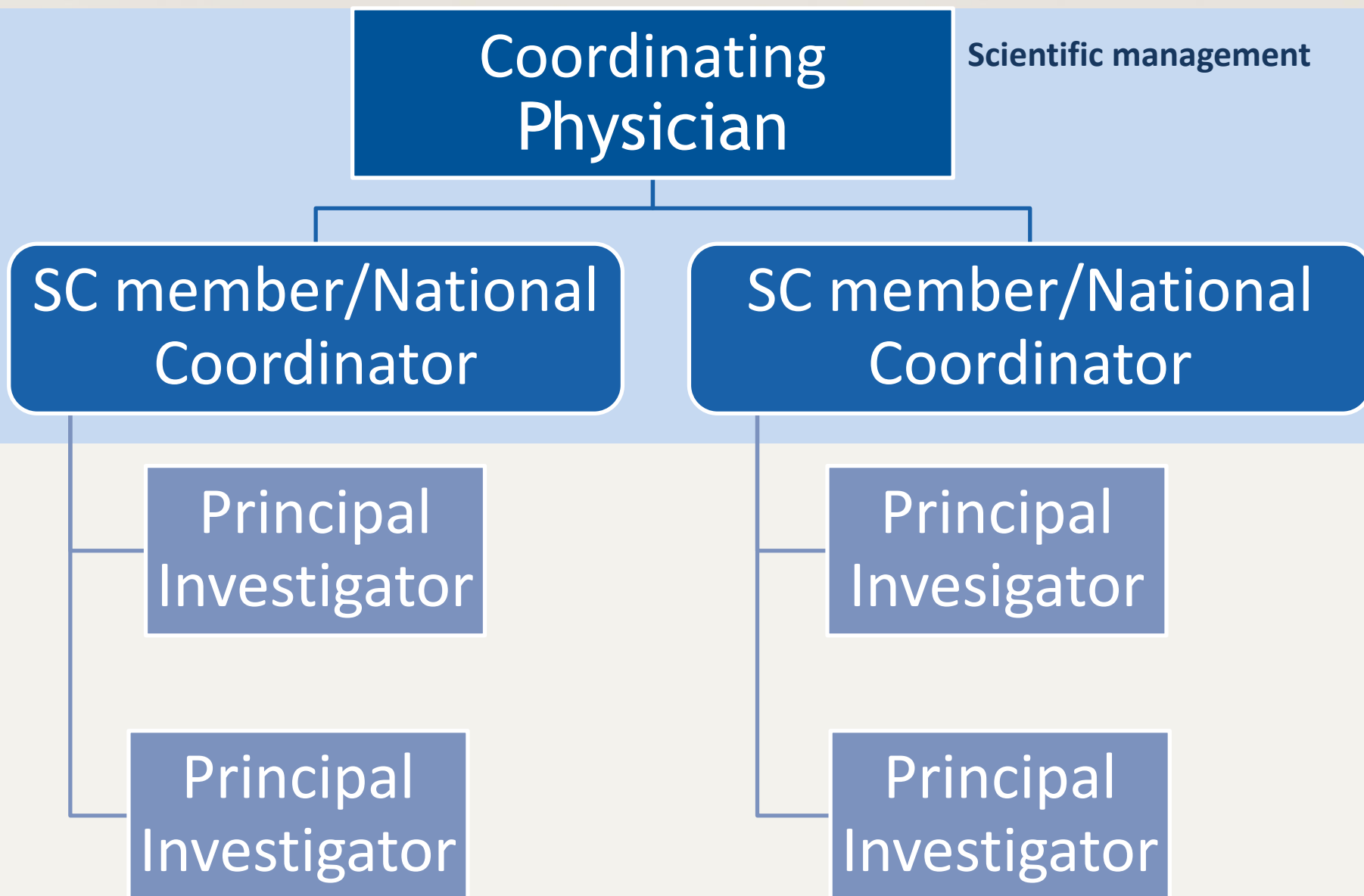
- Coordinating physician: responsible for scientific aspects of the Project and chairing the Steering Committee

ass. prof. Martina Vašáková

OBJECTIVES

- To estimate IPF incidence, prevalence and mortality in Central and Eastern Europe
- To describe basic characteristics (e.g. age, gender, risk factors etc.) of patients with IPF
- To describe real life approach to IPF in participating countries from Central and Eastern Europe:
 - » diagnostic algorithm
 - » treatment patterns and management of patients with idiopathic pulmonary fibrosis
 - » treatment outcomes (treatment response, overall survival) and quality of life
 - » resource utilization
- To determine number of patients suitable for enrolment in clinical trials.

Organogram



Ass. Prof. Martina Vašáková

SLOVAKIA

POLAND

HUNGARY

CZECH REP.

Hájková

Kus

Muller

Šterclová

Principal Investigator

Principal Investigator

Principal Investigator

Principal Investigator

Principal Investigator

Principal Investigator

Principal Investigator

Principal Investigator



OWNERSHIP/PUBLICATION/ CONTRACT

- Data owner
 - Each site is owner of own data

- Publication
 - Any oral or written presentation can be done after prior approval of National Coordinator and Coordinating Physician
 - Have to be send for BI review 60 days in advance

CONTRACT

- For the whole life-cycle of the project (starting with 2015 and 2016)
- With each participating doctor

PAYMENTS

- On quartely basis (1st in April, after data validation)
 - Retrospective data – **5,- € per record (CZE)**
 - Prospective data
 - Baseline data: **40,- € per record**
 - Follow – up: **30,- € per record**



REQUIREMENTS

National Coordinators



RA/EC submission

Participating physician



Enroll/follow up patients



Inform Consent Form collection

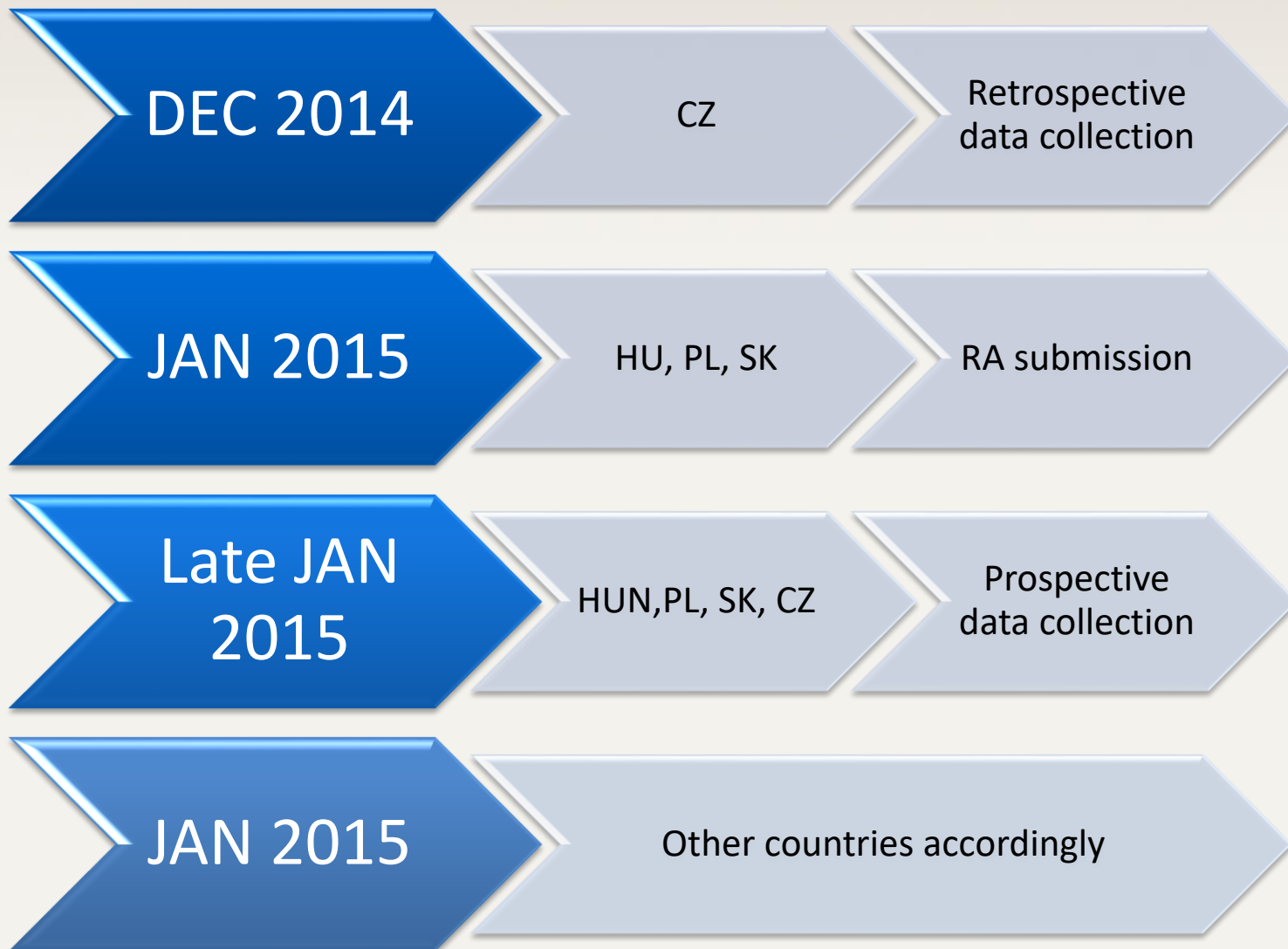


AE reporting



TIMELINES/MILESTONES

Timelines/milestones



= on quartely basis =

MAR 2015

All

Data
validation

APR 2015

All

1st
payment

FEB 2016

IBA

1st data
analysis



GRANTING ACCESS

Physician to request access



IBA to Confirm with Principal Investigator/National Coordinator



IBA to grant access



IBA to send ID to physician
Cc Principal Investigator/National coordinator





CASE REPORT FORM

- eCRF divided into phases and forms

PHASES

Enrollment

- Enrollment form

Treatment

- Treatment form

Follow-up

- Follow-up form

Adverse Event

- Adverse Event Form

Lost of Contact

- Lost of Contact

FORMS

- Timelines**

0 month

Every 3/6 months

End of observation

- Form**

- Enrollment form
- Treatment form

- Treatment
- Follow-up
- QoL
- Hospitalization
- AE form – if occurred

- End of observation
- Lost of Contact

- SAE, BI marketing authorization holder**

!!FILL IN THE SAE FORM TEMPLATE!!



PRACTICAL DEMONSTRATION



www.empire.registry.cz

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THANK YOU