PRactice of VENTilation in Critically Ill PEDiatric Patients (PRoVENT-PED)

Steering committee meeting

Agenda

- introduction
- endpoints
- results pilot studies
- team
- planning

Introduction - Objectives

- to describe practice of ventilatory support
- to identify potentially modifiable factors

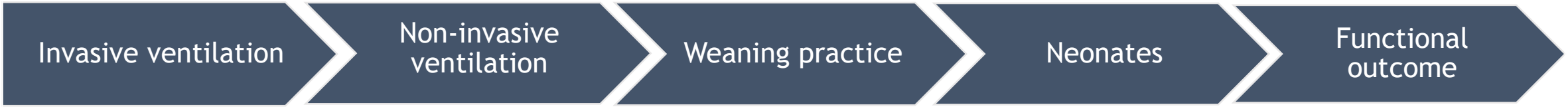
Introduction - Hypotheses

- practice of ventilatory support varies substantially
- potentially modifiable factors are associated with outcome

Introduction - Study Design

- 10 years
- 2 periods of 4 weeks/year
- (optional) extra period (epidemic/pandemic)

Introduction - ‘Adaptive Study’



Introduction - Patients

Eligible:

- aged 0-18 years
- admitted to a participating PICU
- receiving ventilatory support > 12 hours

Exclusion:

- premature patients

Introduction - Data to be Collected

- patient characteristics
- ventilator settings and parameters (at day 0-3)
- adjunctive respiratory therapies
- outcomes (at ICU discharge)

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Endpoints

- key ventilator settings and ventilation parameters (primary)
- incidence of PARDS
- duration of ventilatory support
- LOS in ICU
- mortality rates

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Results Pilot Studies

- 2 Dutch hospitals
- July/August 2023
- 42 patients

Results Pilot Studies - Feasibility

	Time (minutes)
Inclusion	2
Demographics	2
Medical history	1
Severity score	
• PIM	2
Daily visit	14
Follow-up	3
Total	24

	Time (minutes)
Inclusion	2
Demographics	2
Medical history	1
Severity score	
• PRISM	12
Daily visit	14
Follow-up	3
Total	34

Results Pilot Studies - Feasibility

- PIM III instead of PRISM III
- PARDS criteria
- FSS scale

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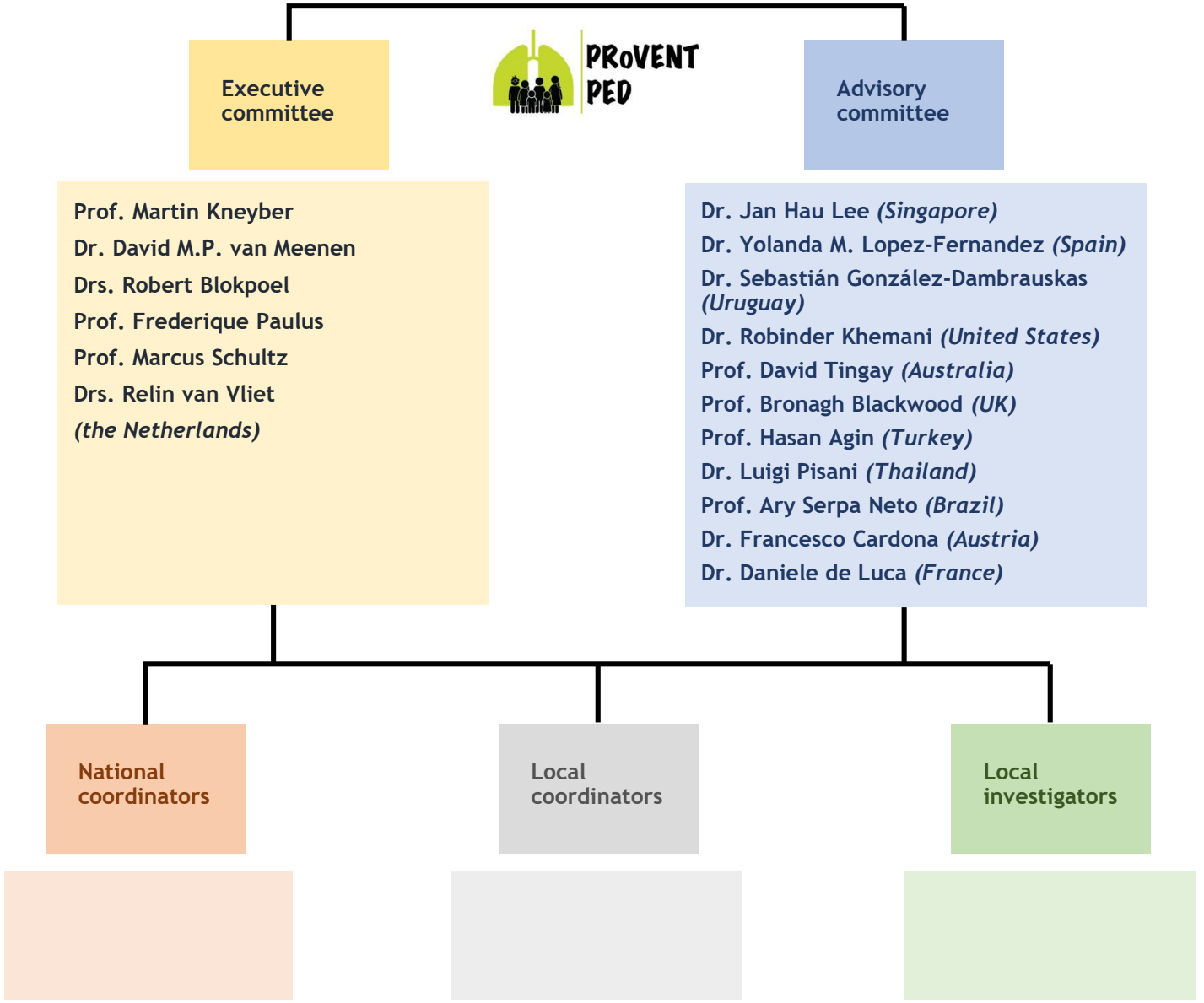
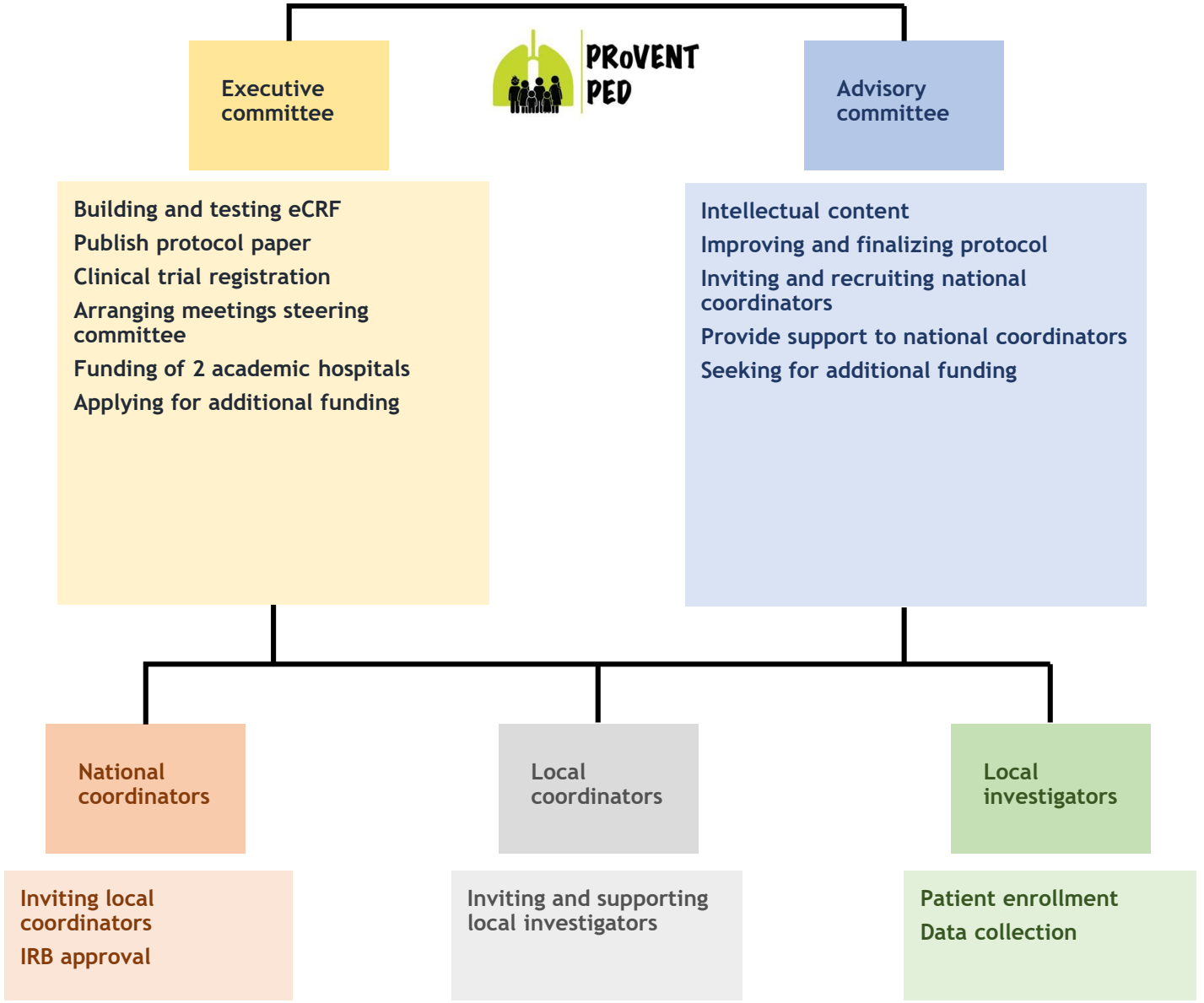
Team


Executive committee
PROVENT PED
Advisory committee
Prof. Martin Kneyber
Dr. David M.P. van Meenen
Drs. Robert Blokpoel
Prof. Frederique Paulus
Prof. Marcus Schultz
Drs. Relin van Vliet
(the Netherlands)
Dr. Jan Hau Lee (Singapore)
Dr. Yolanda M. Lopez-Fernandez (Spain)
Dr. Sebastián González-Dambrauskas (Uruguay)
Dr. Robinder Khemani (United States)
Prof. David Tingay (Australia)
Prof. Bronagh Blackwood (UK)
Prof. Hasan Agin (Turkey)
Dr. Luigi Pisani (Thailand)
Prof. Ary Serpa Neto (Brazil)
Dr. Francesco Cardona (Austria)
Dr. Daniele de Luca (France)
National coordinators
Local coordinators
Local investigators

Team


Executive committee
PROVENT PED
Advisory committee
Building and testing eCRF
Publish protocol paper
Clinical trial registration
Arranging meetings steering committee
Funding of 2 academic hospitals
Applying for additional funding
Intellectual content
Improving and finalizing protocol
Inviting and recruiting national coordinators
Provide support to national coordinators
Seeking for additional funding
National coordinators
Local coordinators
Local investigators
Inviting local coordinators
IRB approval
Inviting and supporting local investigators
Patient enrollment
Data collection

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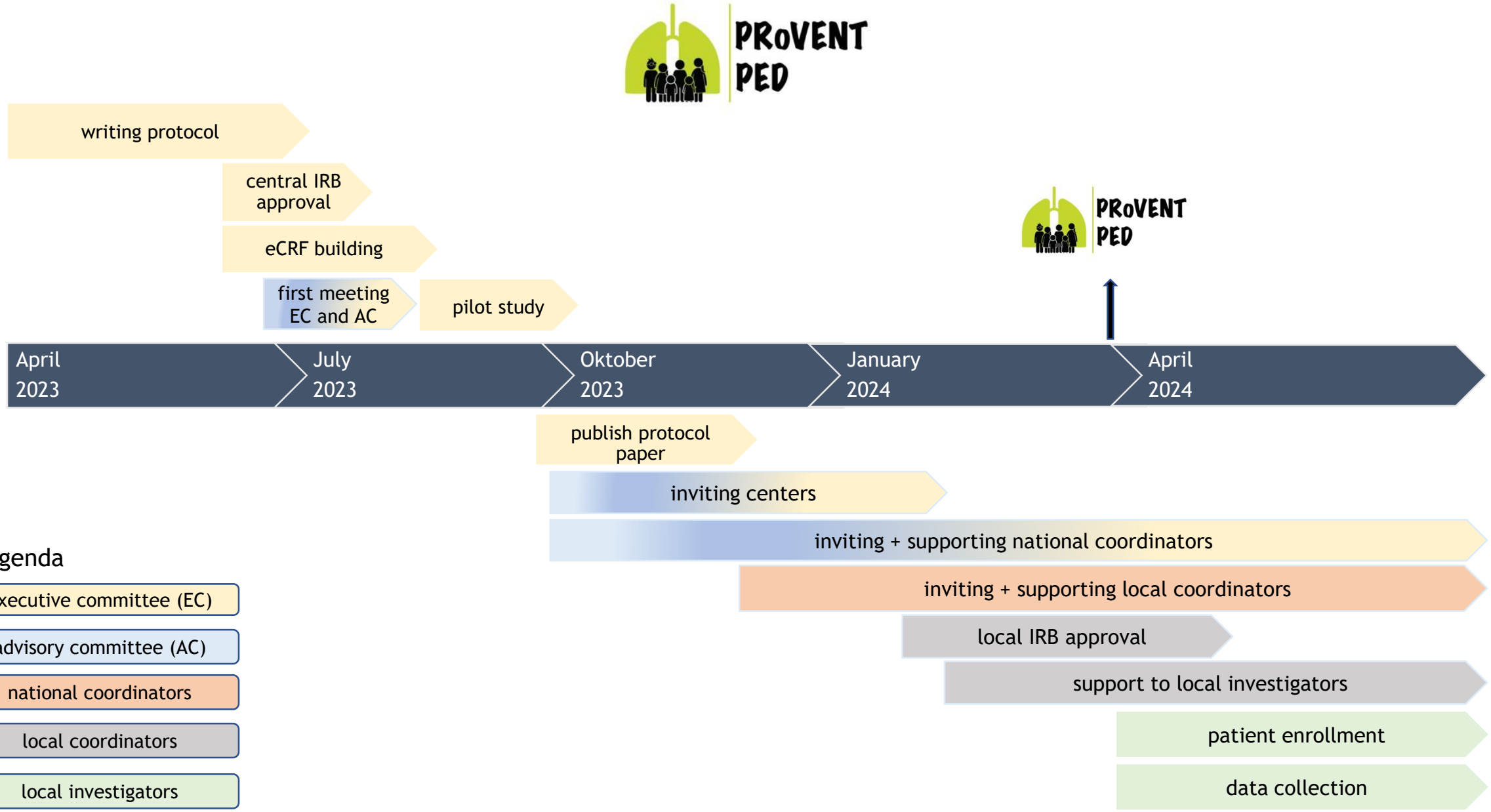
PROVENT PED
writing protocol
central IRB approval
eCRF building
first meeting EC and AC
pilot study
PROVENT PED
April 2023
July 2023
Oktober 2023
January 2024
April 2024
publish protocol paper
inviting centers
inviting + supporting national coordinators
inviting + supporting local coordinators
local IRB approval
support to local investigators
patient enrollment
data collection
Legenda
executive committee (EC)
advisory committee (AC)
national coordinators
local coordinators
local investigators