

# Access to treatment

in PH groups 1 & 4 (PAH & CTEPH)



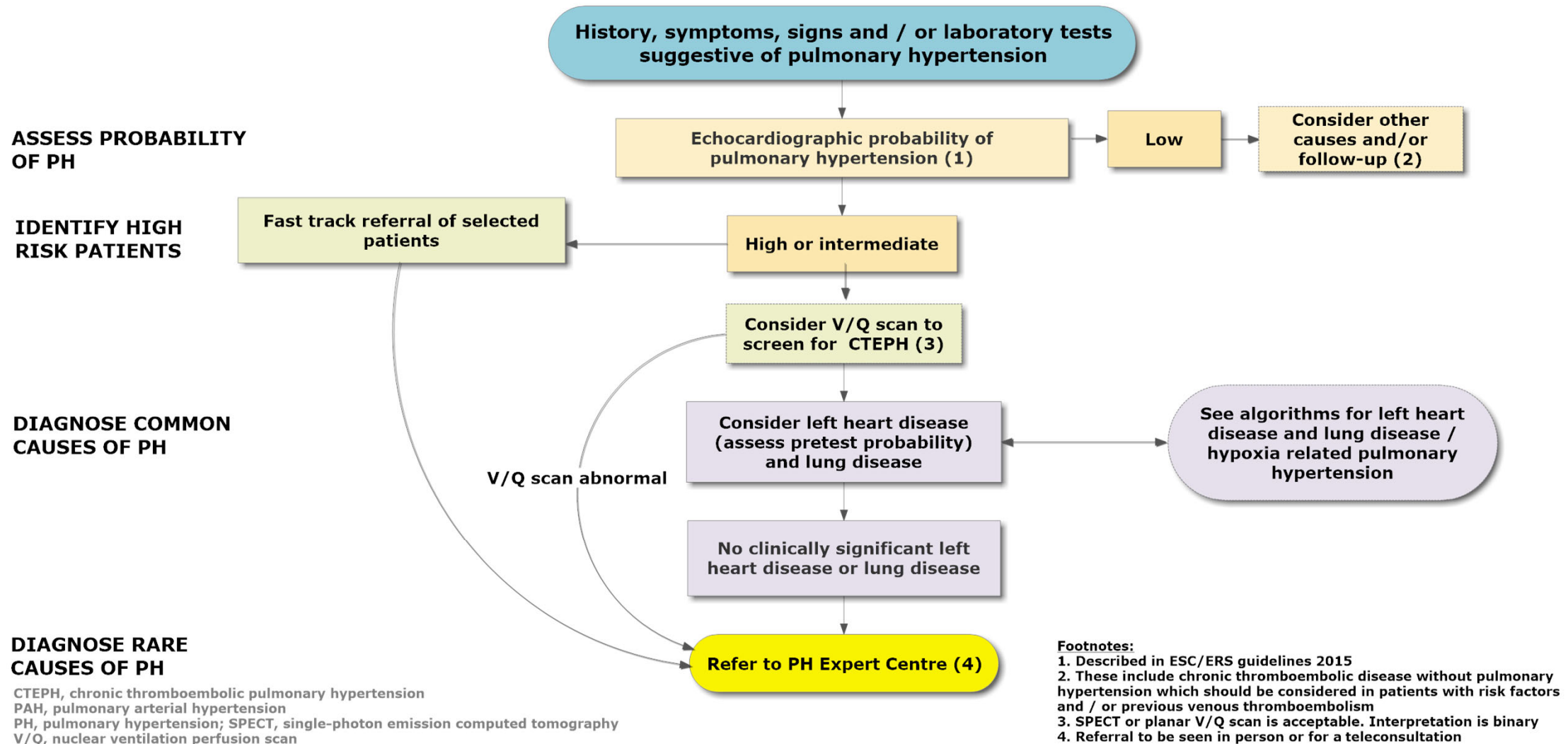
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# Access to PH treatment – main determinants

- Awareness
  - among medical staff and populations at risk
- Reliable differential diagnosis
  - to identify those with PAH and CTEPH among millions of PH patients
- Local availability of medical and interventional Tx
  - access to approved drugs and validated interventions - unrestricted by cost

# NEW ALGORITHM FOR DIAGNOSIS OF PULMONARY HYPERTENSION AND ITS CAUSES: Triage of urgent cases and diagnosis of common conditions



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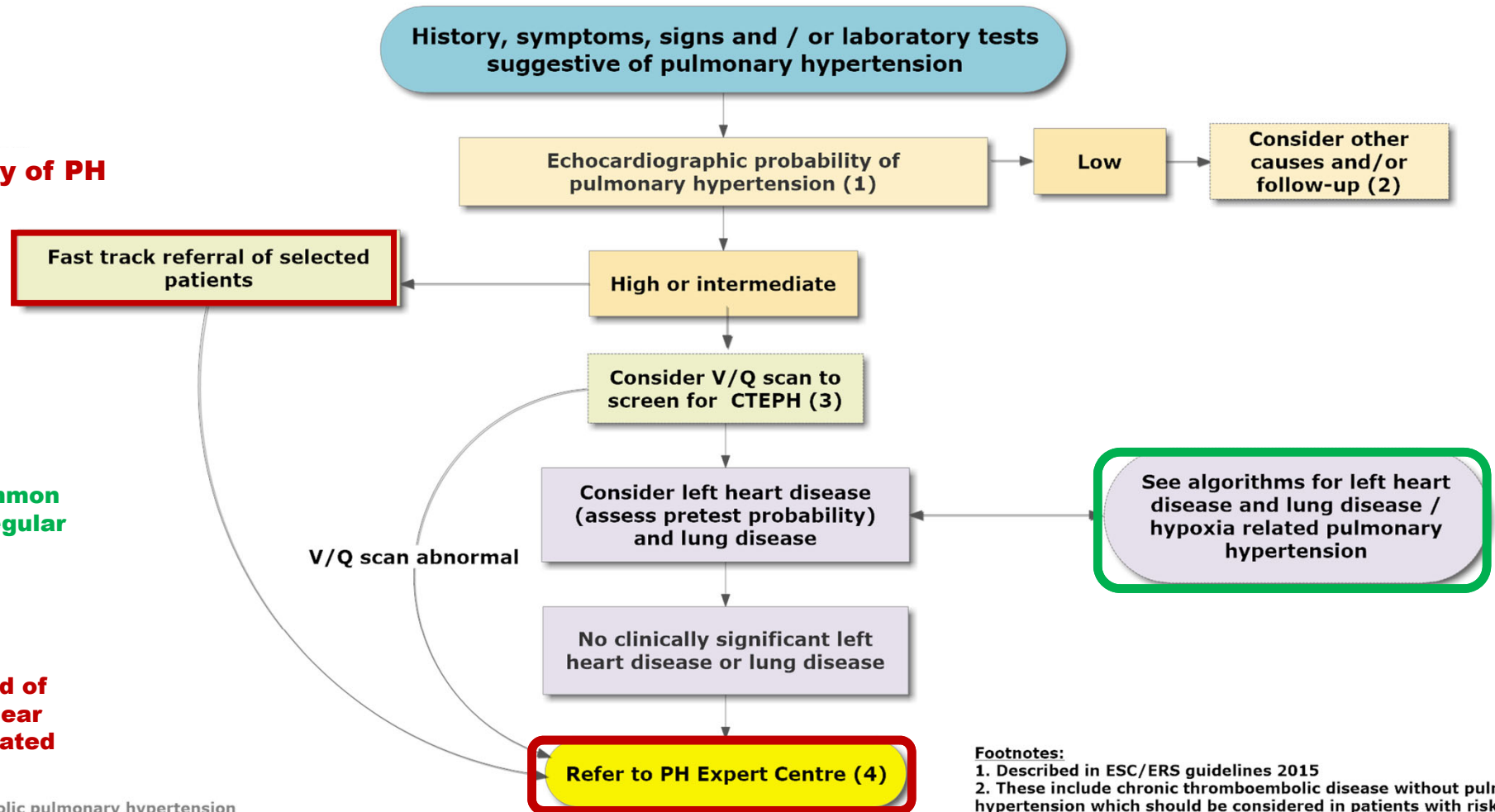
**Asses probability of PH**

**Identify patients  
at high risk of  
PAH/CTEPH**

**Direct pts with common  
PH, group 2-3, to regular  
HCP**

**Refer pts suspected of  
PAH/CTEPH or unclear  
severe PH to dedicated  
Expert Centres**

CTEPH, chronic thromboembolic pulmonary hypertension  
PAH, pulmonary arterial hypertension  
PH, pulmonary hypertension; SPECT, single-photon emission computed tomography  
V/Q, nuclear ventilation perfusion scan

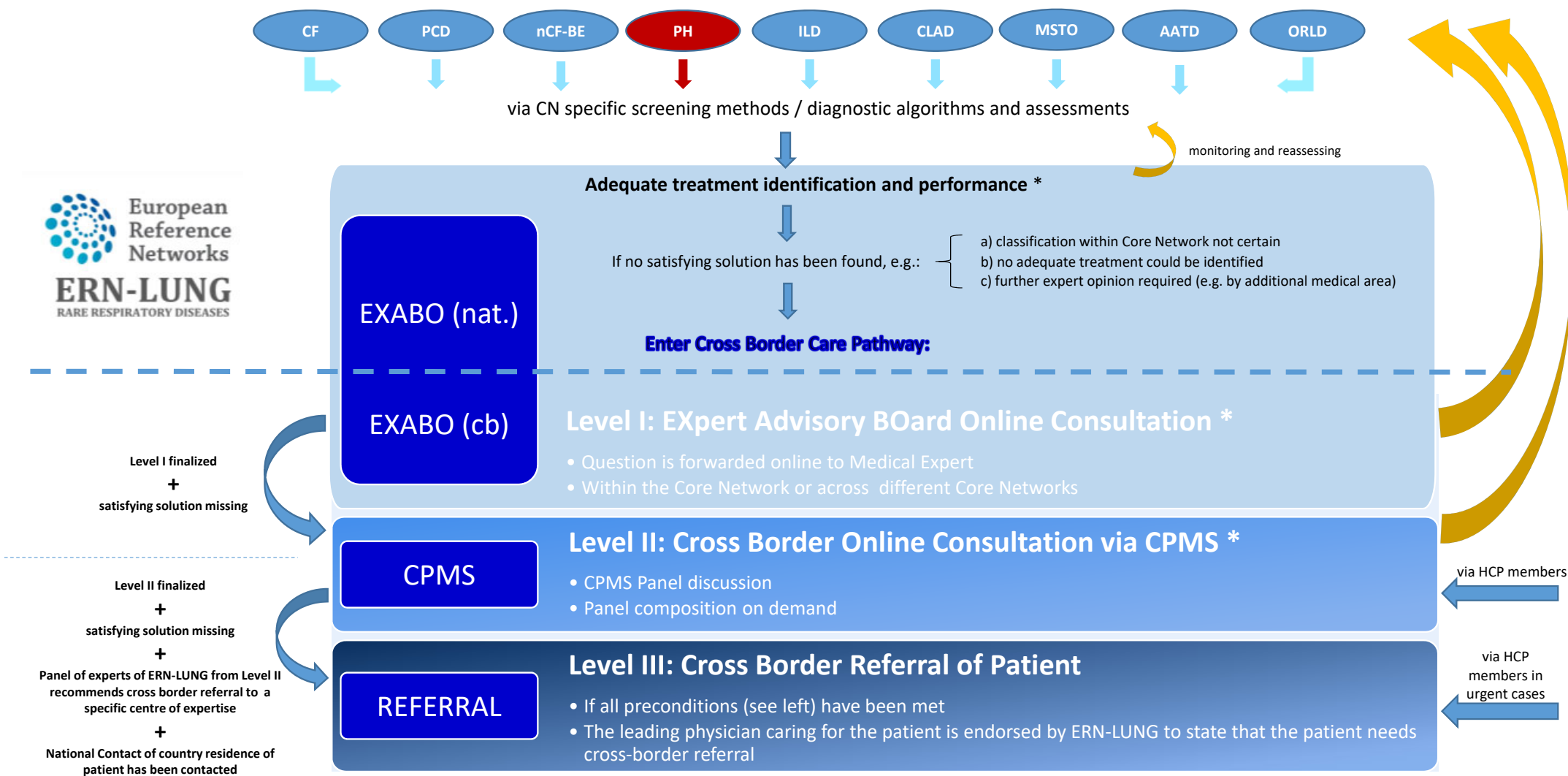


### Footnotes:

1. Described in ESC/ERS guidelines 2015
2. These include chronic thromboembolic disease without pulmonary hypertension which should be considered in patients with risk factors and / or previous venous thromboembolism
3. SPECT or planar V/Q scan is acceptable. Interpretation is binary
4. Referral to be seen in person or for a teleconsultation

# ERN-LUNG: Patient Pathway via Core Networks for specific diagnosing and Cross Border Care

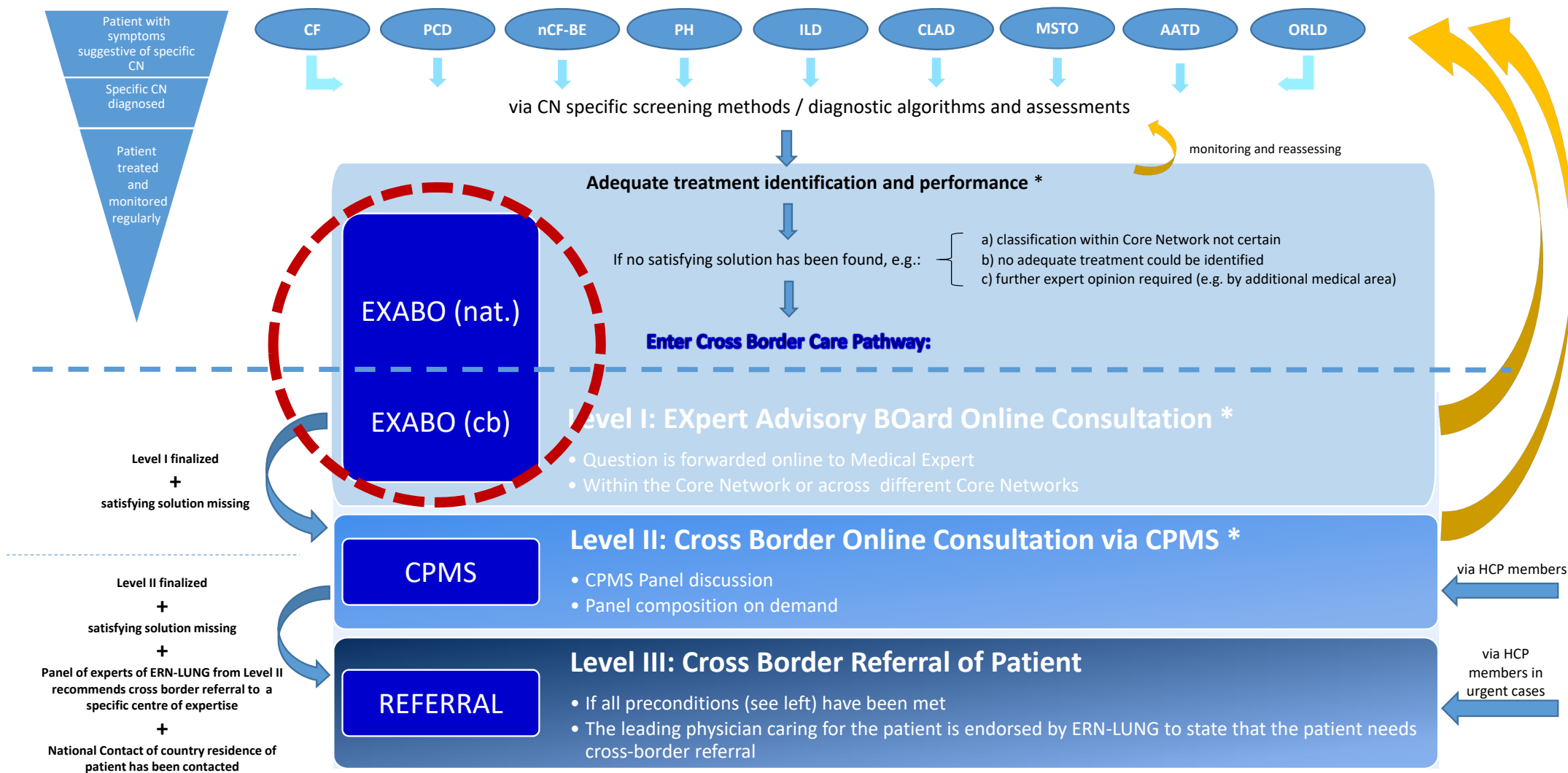
Patient with unclear respiratory disease referred by tertiary centre (e.g. local, regional, national referral/Supporting Partner referral) sent to presumed specific ERN-LUNG Core Network



\* As soon as satisfying solution identified, pathway will be left and patient referred either to a dedicated HCP-CN Member or to a non-ERN clinical centre at a national level

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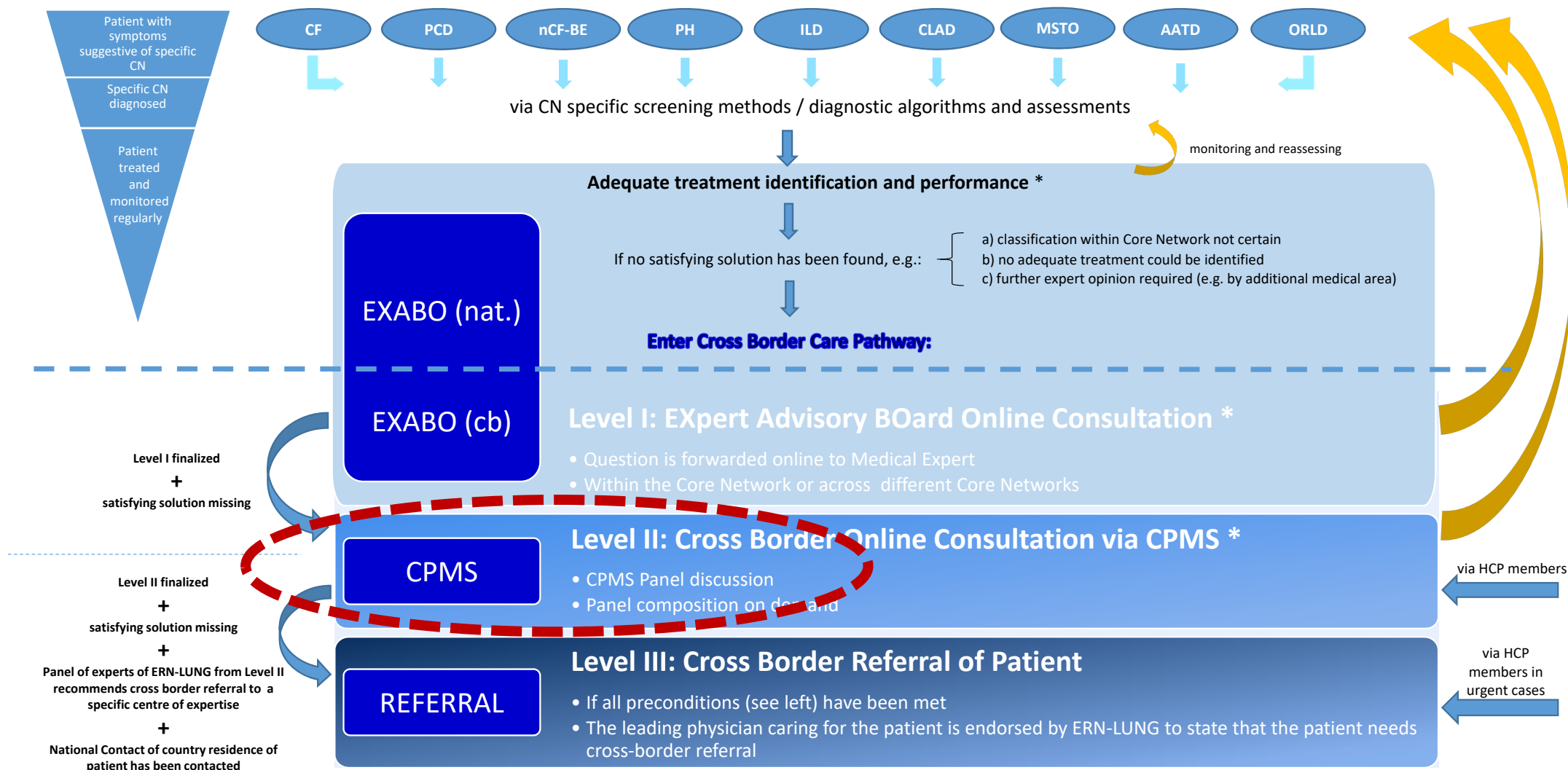
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Member HCP Affiliated Partner Patient Organization



## Competency Requirements: Minimum patient numbers & procedures



| Indicator                                                                | Minimum # required / HCP / year |          |
|--------------------------------------------------------------------------|---------------------------------|----------|
|                                                                          | Adult                           | Children |
| Minimum number of TOTAL patients (visited, treated or followed) per year | 200                             | 30       |
| Minimum number of NEW patients per year                                  | 50                              | 10       |
| Key diagnostic procedures per year                                       |                                 |          |
| Acute vasoreactivity challenge                                           | 20                              | 10       |
| Right heart catheterization                                              | 100                             | 20       |
| Pulmonary angiography                                                    | 50                              | 10       |
| Doppler echocardiography                                                 | 100                             | 30       |
| Ventilation/perfusion lung scan (V/Q lung scan)                          | 50                              | 0-10     |
| Lung function tests with DLCO                                            | 100                             | 20       |
| Cardio-pulmonary exercise testing                                        | 20                              | 0-10     |
| 6 min walking test                                                       | 200                             | 30       |
| Biomarkers: BNP and troponin                                             | 200                             | 30       |

irreversible

# CTEPH DIAGNOSIS AND THERAPY AVAILABILITY SEE

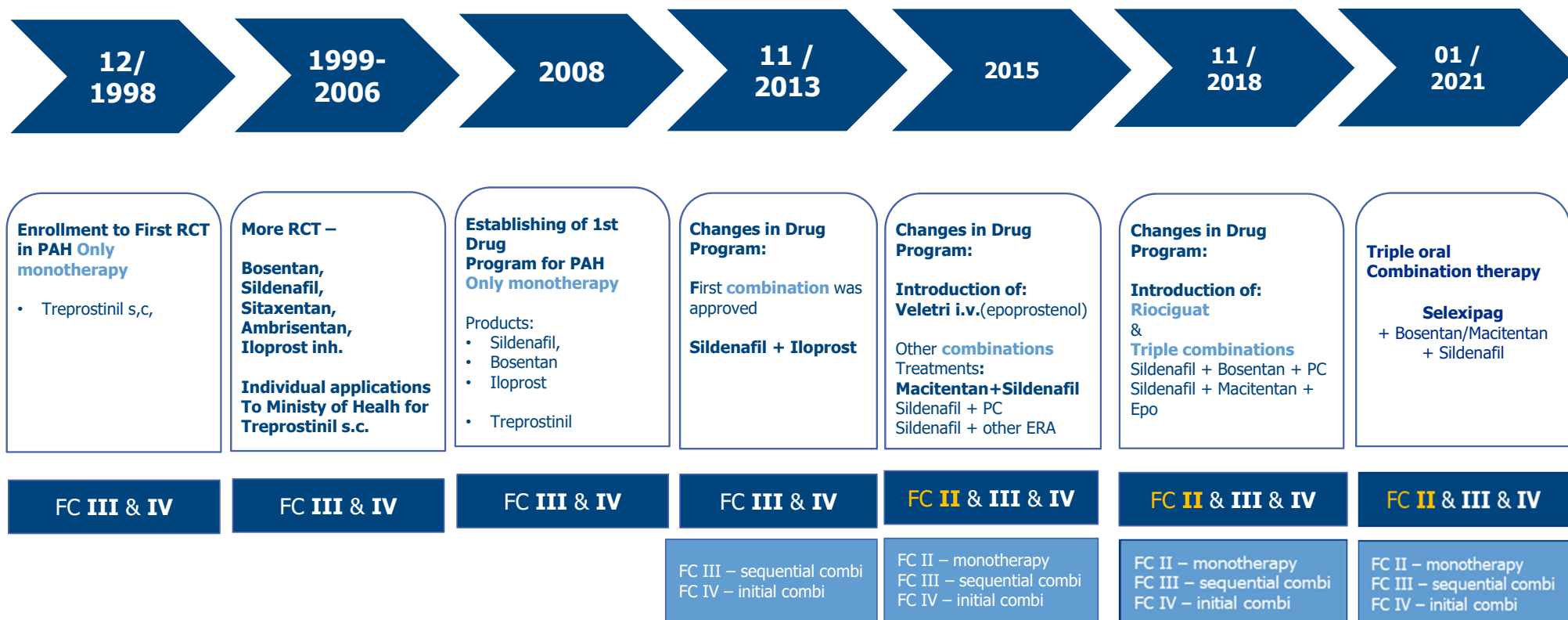
|            | Population (mil) | Scintigraphy | Final diagnosis | CTEPH team | Vasodilataio n therapy | BPA                         | PEA                       |
|------------|------------------|--------------|-----------------|------------|------------------------|-----------------------------|---------------------------|
| Poland     | 37.8             | yes          | yes             | yes        | 15 centers             | 8 centers                   | 2 centers                 |
| Romania    | 19.1             | no           | 3 centers       | yes        | 6 centers              | 1 + pts are referred abroad | Pts are referred abroad   |
| Czech Rep. | 10.7             | yes          | yes             | yes        | 1 center               | 1 center                    | 1 center                  |
| Hungary    | 9.8              | Only Q       | yes             | yes        | yes                    | 1 center                    | Pts are referred abroad   |
| Serbia     | 8.7              | Only Q       | 4 centers       | yes        | 4 centers              | 2 centers                   | 1+Pts are referred abroad |
| Bulgaria   | 6.9              | Only Q       | 3 centers       | No         | No                     | 1 center                    | Pts are referred abroad   |
| Croatia    | 4.1              | yes          | 1 centre        | yes        | 1 center               | Pts are referred abroad     | Pts are referred abroad   |
| Slovenia   | 2.1              | yes          | yes             | yes        | 1 center               | AKH Vienna                  | AKH Vienna                |

# Therapy for PAH/CTEPH

- PAH
  - three classes of drugs, new coming...
  - all approved based on RCT
  - some Tx **expensive/complex** (continuous IV/SC administration)
  - upfront double/triple combination - **up-titrated, lifelong**
- CTEPH
  - surgery – percutaneous angioplasty – and/or drugs
  - **complex/costly** one-time (surgery) or **serial** (angioplasty) procedure
  - drugs as pre-treatment and for persistent CTEPH - **lifelong**

# Poland – Access to drug therapy in PAH

## Journey from enrollment to first RCTs to reimbursed triple therapy...



# Access to treatment for PAH/CTEPH - challenges for the future

- Support of **tele-medicine triage** in suspected PH
- Broader access to **CPMS (national and cross-border)** in complex PH cases
- Immediate **access to all validated therapies** for PAH and CTEPH
- In view of progressive pulmonary vascular changes irreversibly affecting QoL and survival **delays in effective Tx are unacceptable**
- Each patient with PAH and suboptimal treatment effects should be discussed with **collaborating lung transplantation team**.





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