



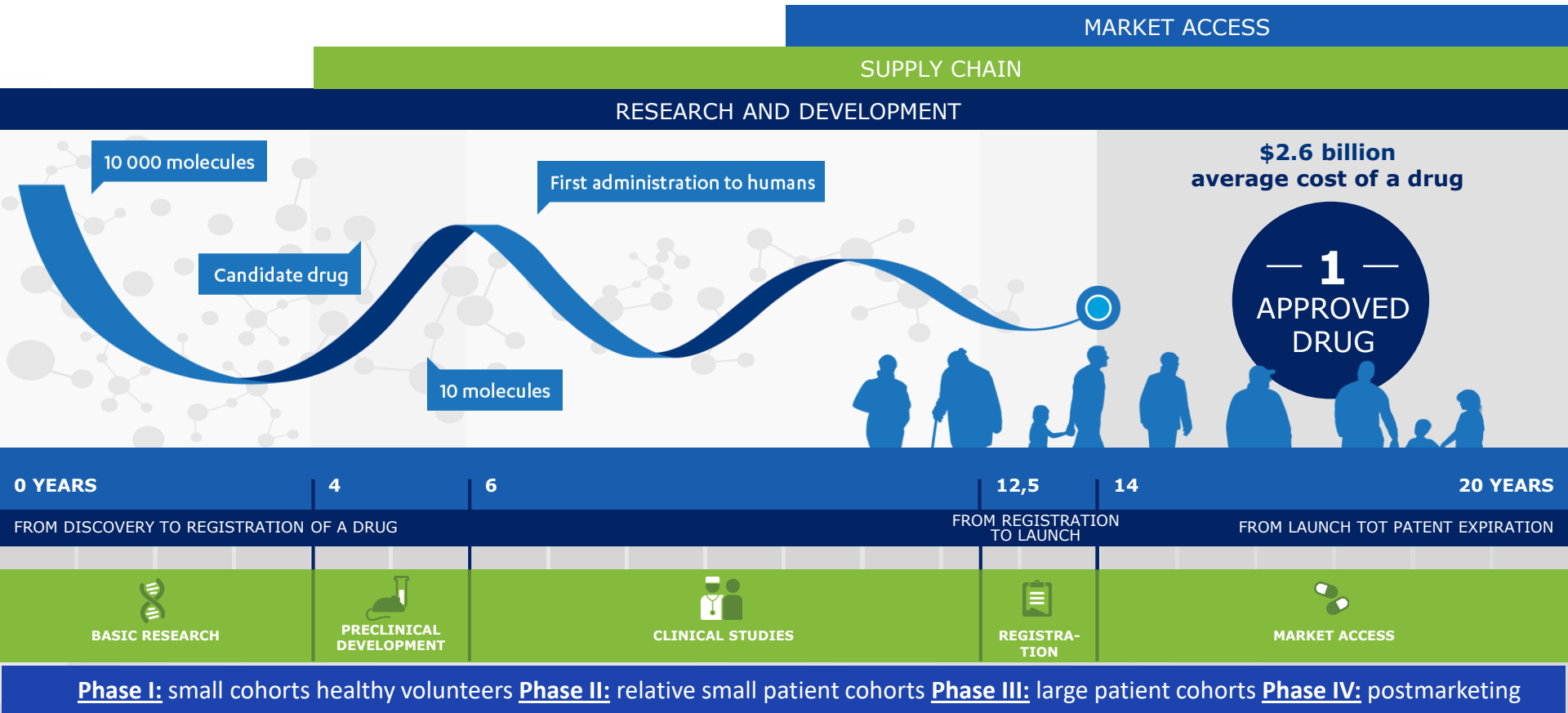
# Challenges in Exploratory Clinical Research

*Maarten van den Boer, MD  
Exploratory Patient Study Clinical Leader  
Janssen Pharmaceuticals*

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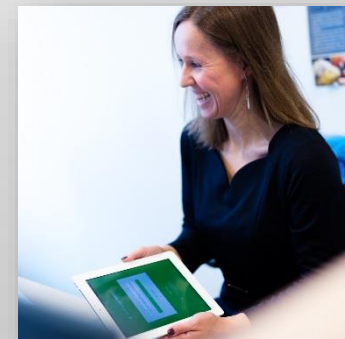
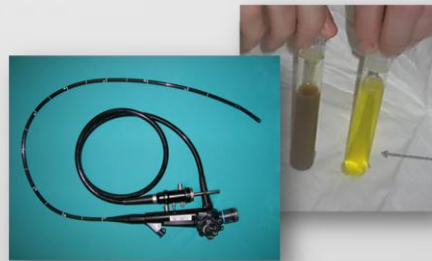


# What we are used to...



# Increasing complexity of early clinical trials through innovation, new techniques and adaptive trial designs

- Implementation of study specific and safety related biomarkers;
- Introduction special procedures (CSF, biopsy, different types of fluid sampling);
- Implementation and use of novel technologies, wearables and devices (e.g. smartphone applications,etc.);
- Adaptive trial design.



# Bringing patient into early phase clinical trials

- More combination protocols (including SAD, MAD and patient parts)
- Need for early patient data readout in order to reduce timelines and costs
- Patients are treated by Health Care Professional (HCP), who often work in hospital environment
- Majority of hospitals are still in a learning cycle to expand their clinical trial expertise to include phase 1 trials
- There is an urgent need for increased patient engagement;
  - for example by contacting patient organisations, exploring options on social media, etc.



6/14/2019



Challenges in Exploratory Clinical  
Research



COLOGY

# Roadblocks



## Trial related

Complex

Strict phase 1 I/E criteria  
leading to high screening  
failure

## Patient related

No therapeutic benefit

Limited Proximity phase 1  
facility

Limited knowledge

## Investigator related

No therapeutic benefit

Often placebo controlled

No phase 1 capacity

Limited scientific interest

Less publication possibilities

Less compensation

Limited in time

# Redirecting Phase 1 patient trials to hospitals and patients

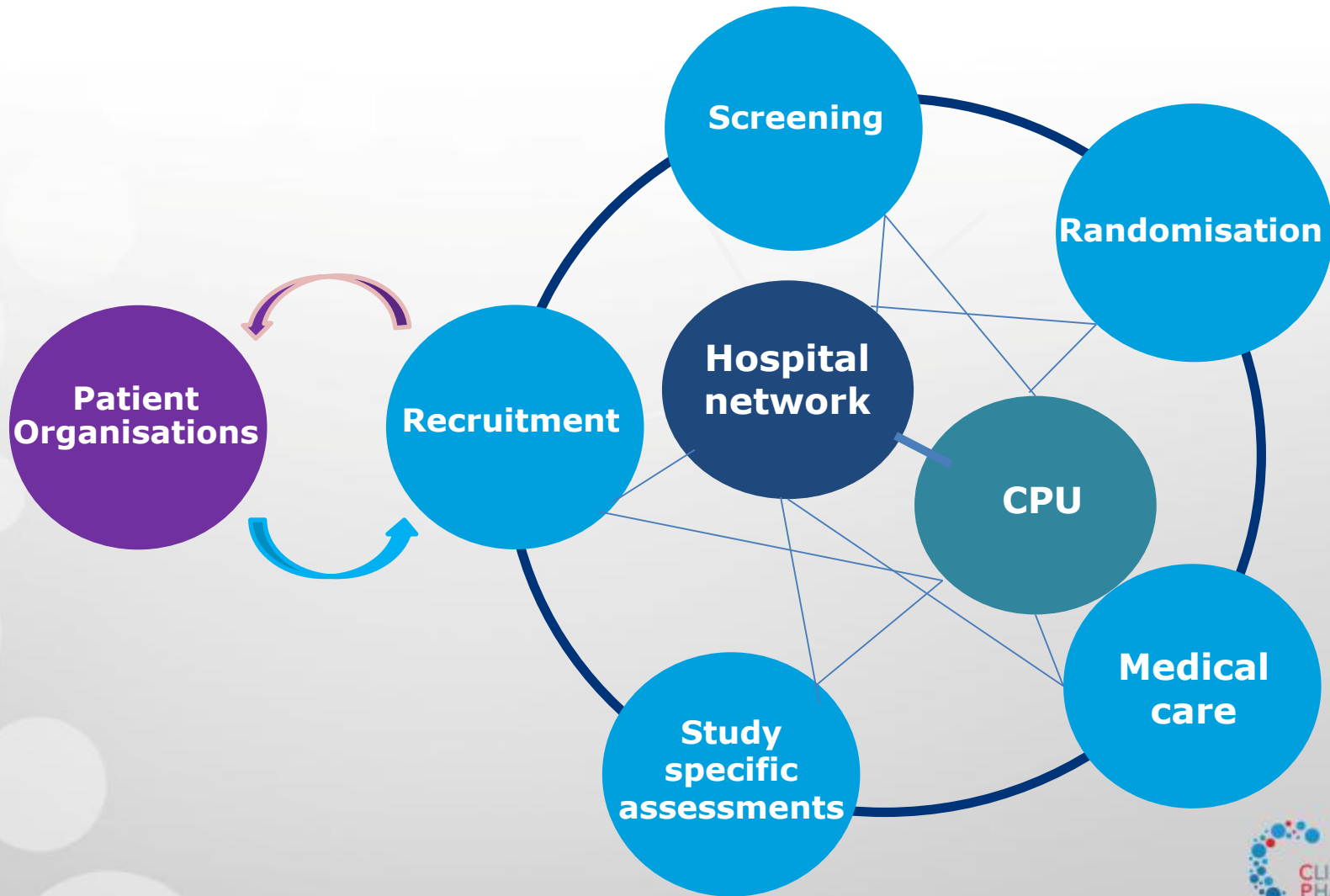
## Patient Centric

- Responsible HCP always involved;
- Trials nearby home, reducing travelling time;
- Possibility of home visits.

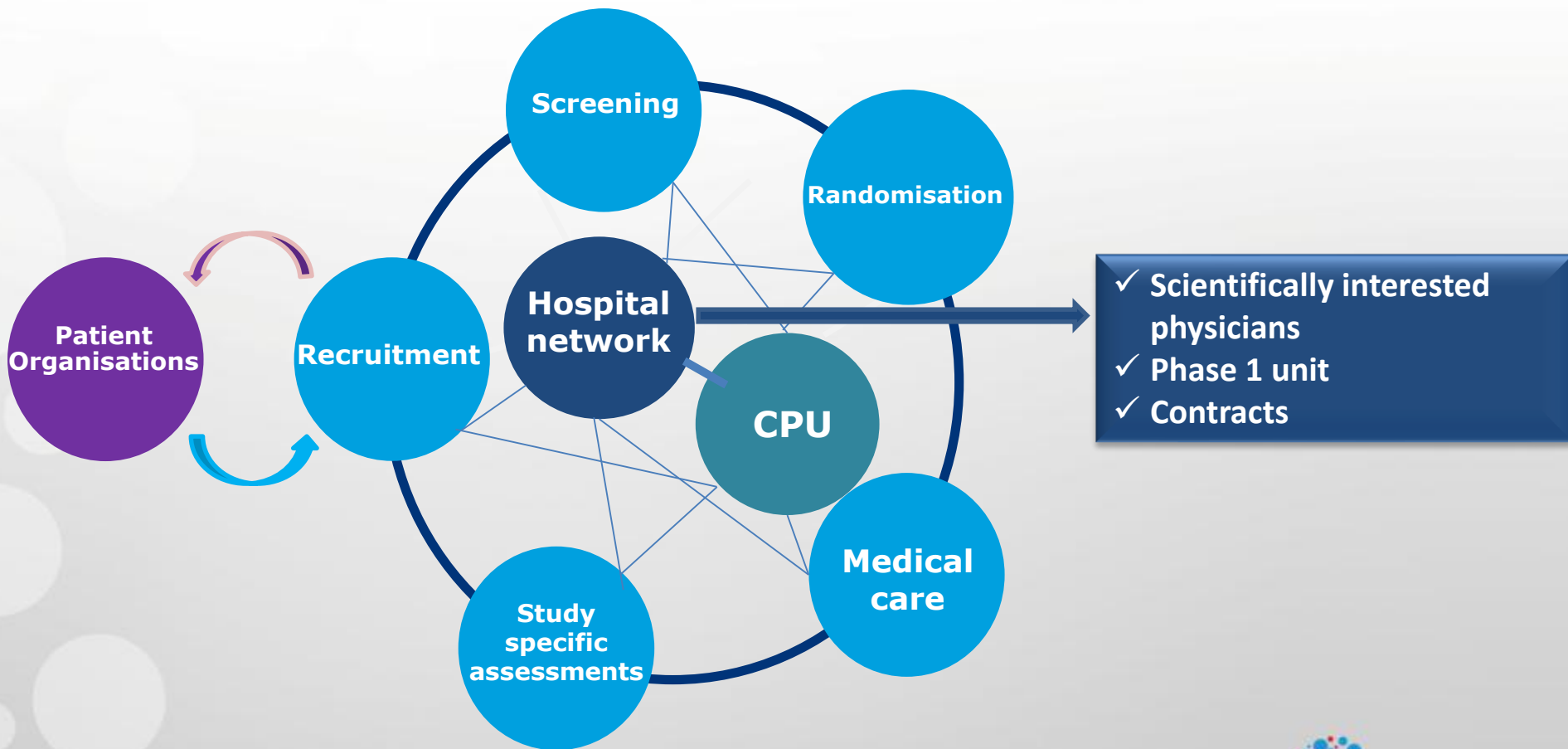
## Investigator Centric

- Always individual contact with research physician of CPU;
- Early involvement in I/E criteria;
- PI role or recruiting role;
- Different levels of support (logistical, administrative, trial execution);
- Possibility to support at any location;
- Contracts in place to speed up timelines.

# | Patient trials: Flexible trial execution

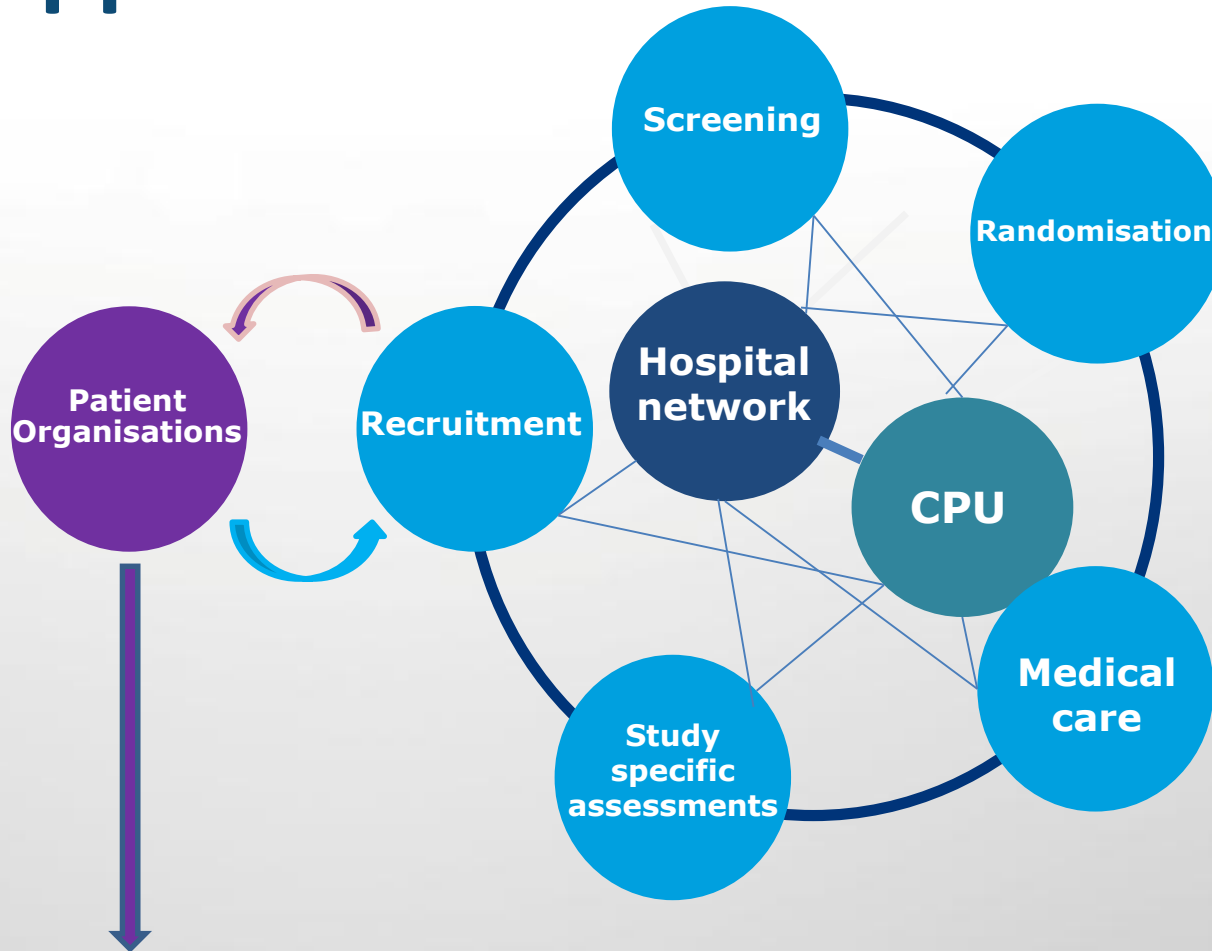


# Patient trials: Need for hospital networks



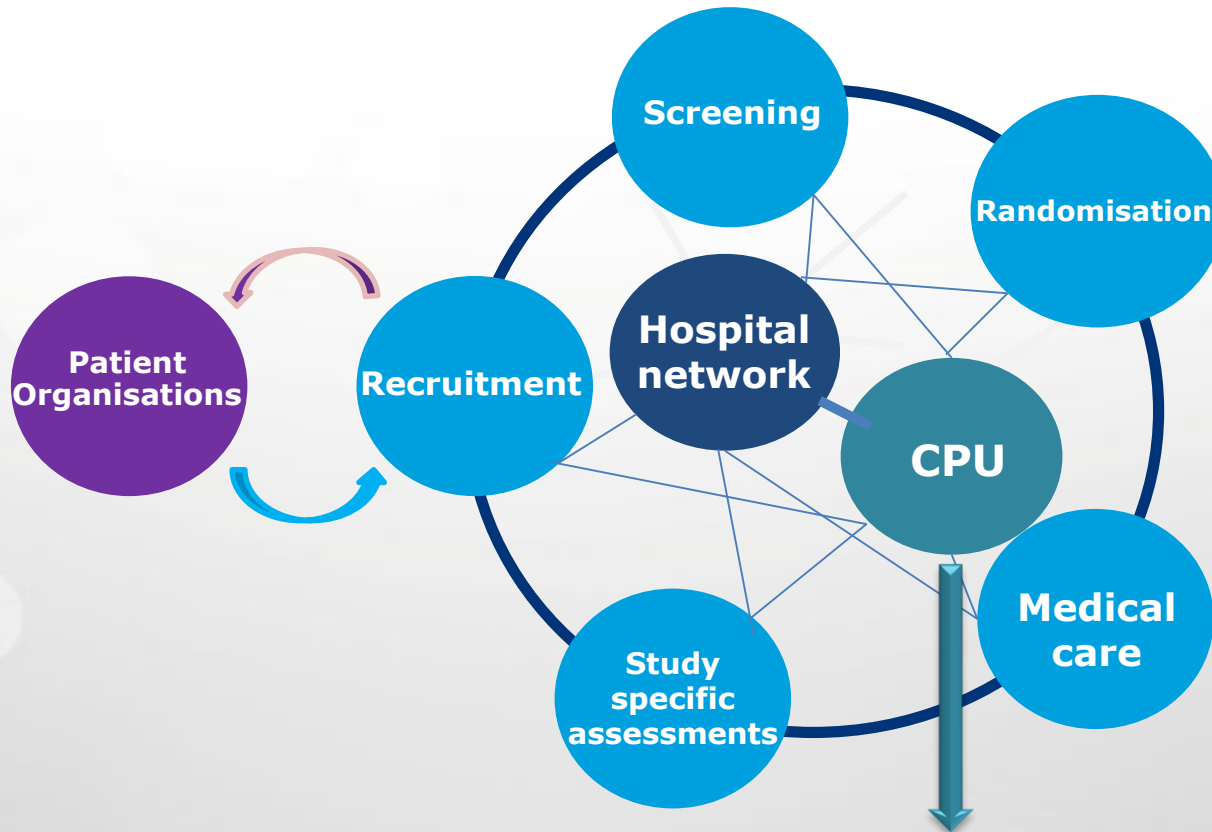


# | Support at different levels



Recruitment can be supported by recruitment officers and contact with patient organisation

# Approaches to support patient trials



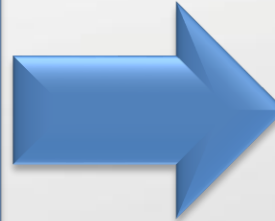
- Patient trials can be conducted at different sites and settings with the quality of Phase 1 trials.
- Mobile unit equipped with Medical and Lab equipment (centrifuges, fridges, freezers, scales, ...) and an electronic Data Capture system
- Support can vary from providing validated equipment to full trial conduct

# Critical selection points during feasibility

- Database
- Social media
- Advertisement
- Patient organisation



- Recruitment
- HCP
- Hospital Unit
- Support
- Mobile Unit



Define Roles and Responsibilities in contracts and work orders



Feasibility study



Kill

Not Ready

Go ahead

# Studies are investigator centric and tailor made

1 PI

1 Trial center

# Support models

# PI's

# Trial centers

# Support models

# Trial designs - HCP in the role of PI

## Trial execution at Hospital site

- Logistical, administrative support and performing of trial assessments
- HCP can act as a recruiter only and/or perform Trial specific assessments (as defined in R&R)
- Possible use of mobile Unit

**HCP  
in the role of PI**

## Trial execution at CPU

- HCP : referral only or perform trial specific asesments (as defined in R&R)
- CPU: Full Trial execution

# Trial designs - CPU in the role of PI

## Trial execution at Hospital Site

- Logistical, administrative support and performing of trial assessments
- HCP can act as a referral and perform Trial specific assessments (as defined in R&R)

**CPU assumes the role  
of PI**

## Trial execution at CPU

- HCP: referral only or perform trial specific assessments at CPU ( as defined in R&R)
- CPU: Full Trial execution

# Key Messages

- World of clinical trials is changing
  - *High need of quick early patient data*
  - *Cost & timeline reduction*
- Recruitment and trial execution in early patient trials is challenging
- Building HCP network is crucial for recruitment
- Patient centricity is mandatory
- Move towards investigator centricity



| Thank you