



European Network of Paediatric Research at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How Paediatric Research Networks can help drug development

Mark Turner



Why networks?

Significant increase in trials and participants

Delays are now significant

...Networks can address all of these issues

Why networks?

Most work to optimise trial conduct in children has been done already

- In many cases there is good practice to apply

If you are having to design solutions to clinical trial challenges then you are not using your time effectively

Your KOLs may not have expertise in trial conduct or regulatory issues relevant to PIP / PSP design

...Networks can address all of these issues

Clinical Research Networks

Support advancement of knowledge by facilitating the diffusion of:

Information

Studies

- Generic resources

Expertise

- Added value
- Avoid reinventing the wheel

Data

- Databases
- Links to epidemiology resources

Clinical Research Networks

Support advancement of knowledge by facilitating the diffusion of:

Information

Studies

- Generic resources

Expertise

- Added value
- Avoid reinventing the wheel

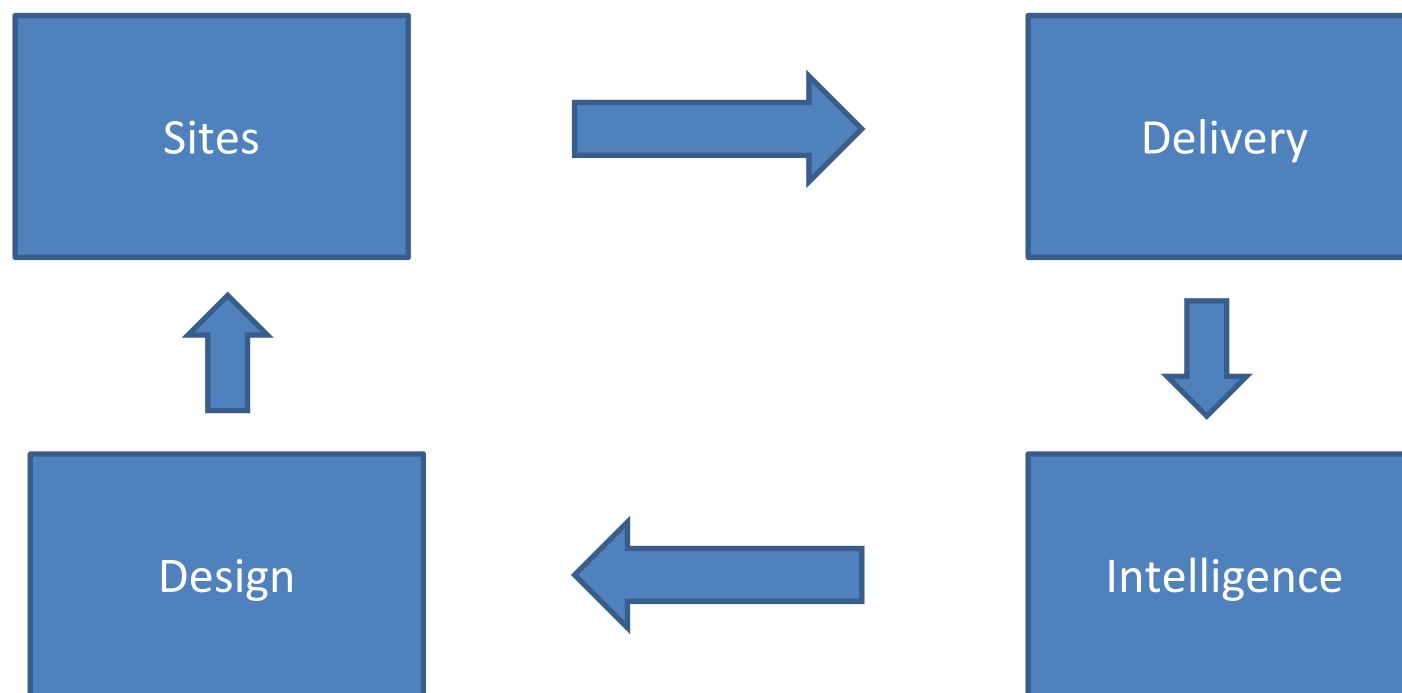
Data

- Databases
- Links to epidemiology resources

Few networks
can do all of
these but it is
worth asking if
they can

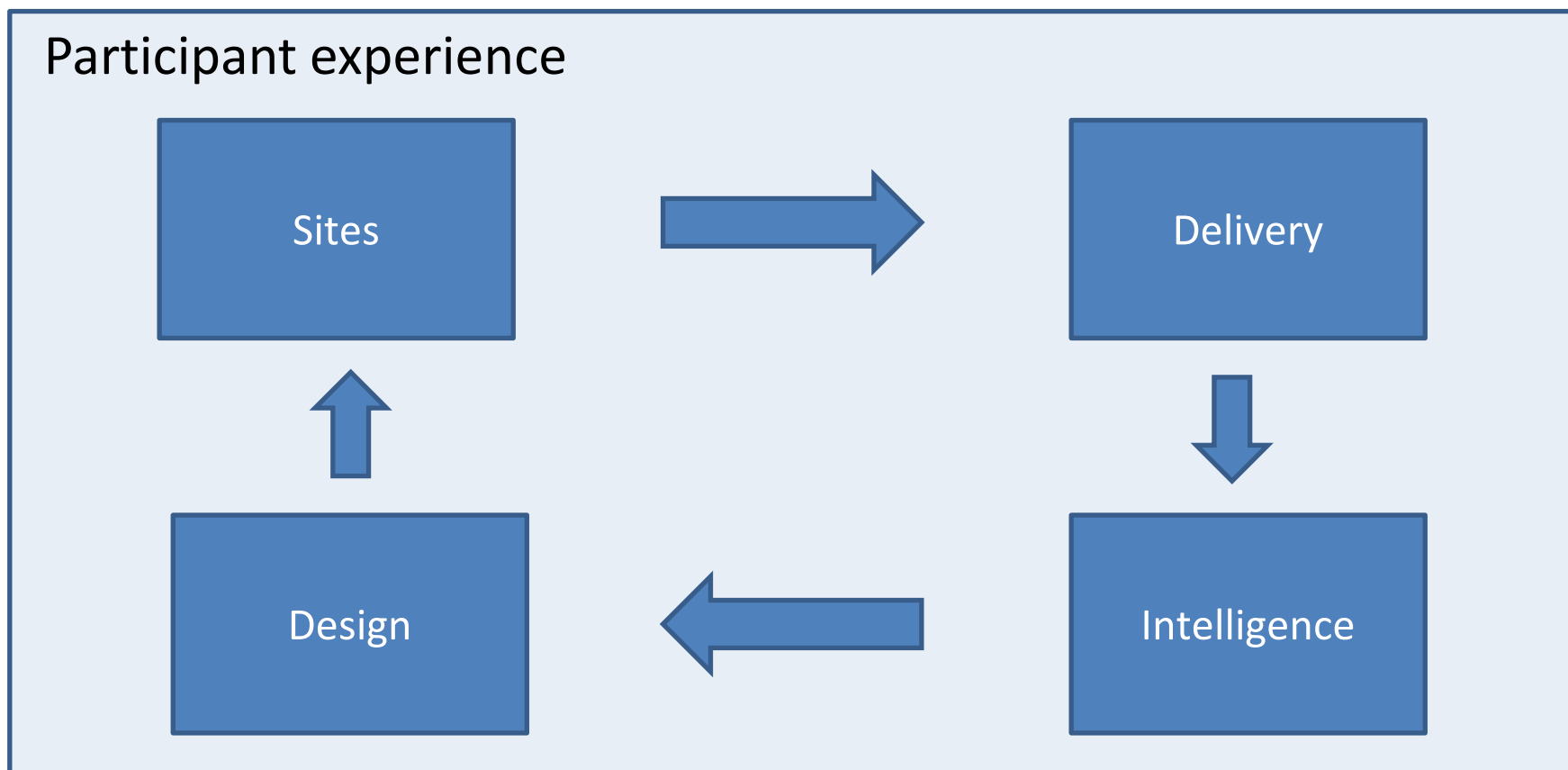
Clinical Research Networks

Facilities are available to all Sponsors and Funders across all therapeutic areas



Clinical Research Networks

Facilities are available to all Sponsors and Funders across all therapeutic areas



Participant Experience

Rights / Ethics

“No research for us without us”

Operational

Therapeutic need

Study design / Acceptability

Documentation

Participant Experience

Rights / Ethics

“No research for us without us”

Operational

Therapeutic need

Study design / Acceptability

Documentation



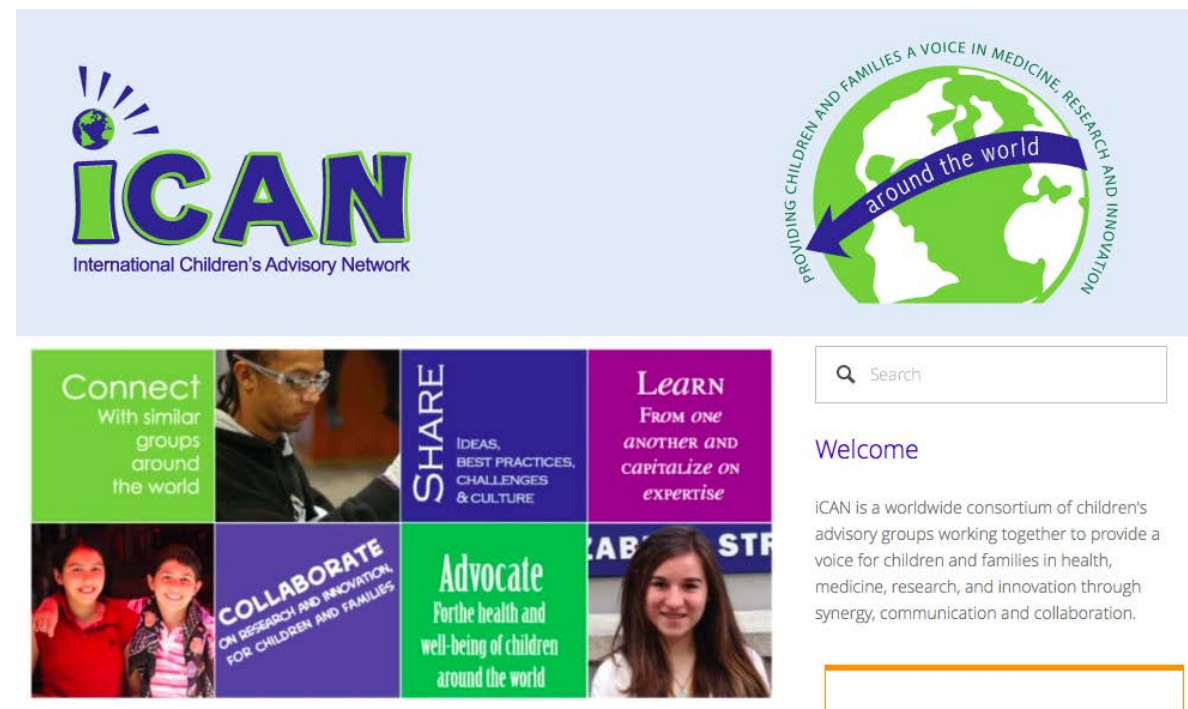
Young People's Advisory Groups

Facilitated groups

Awareness of trial processes

Comment on

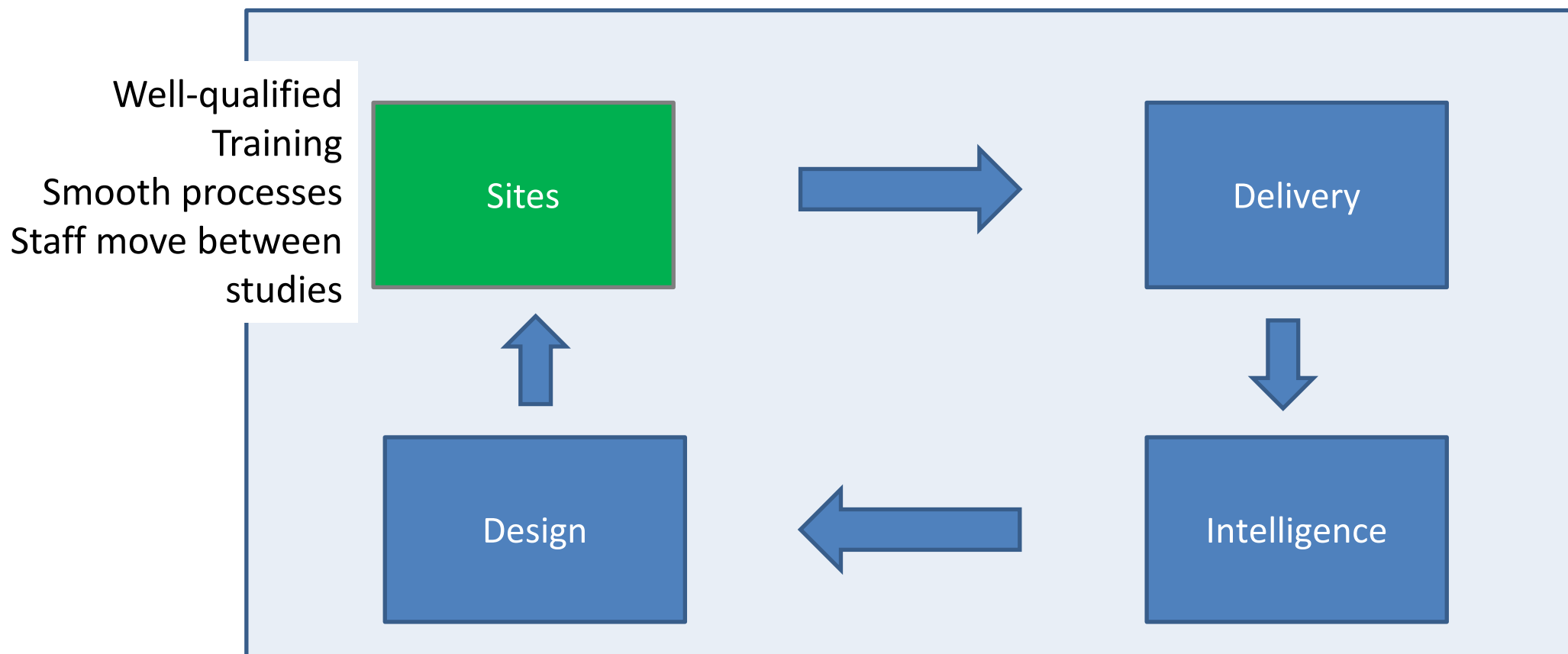
- Therapeutic need
- Outcomes
- Assessments
- Formulations
- Trial documentation



<http://www.icanresearch.org>

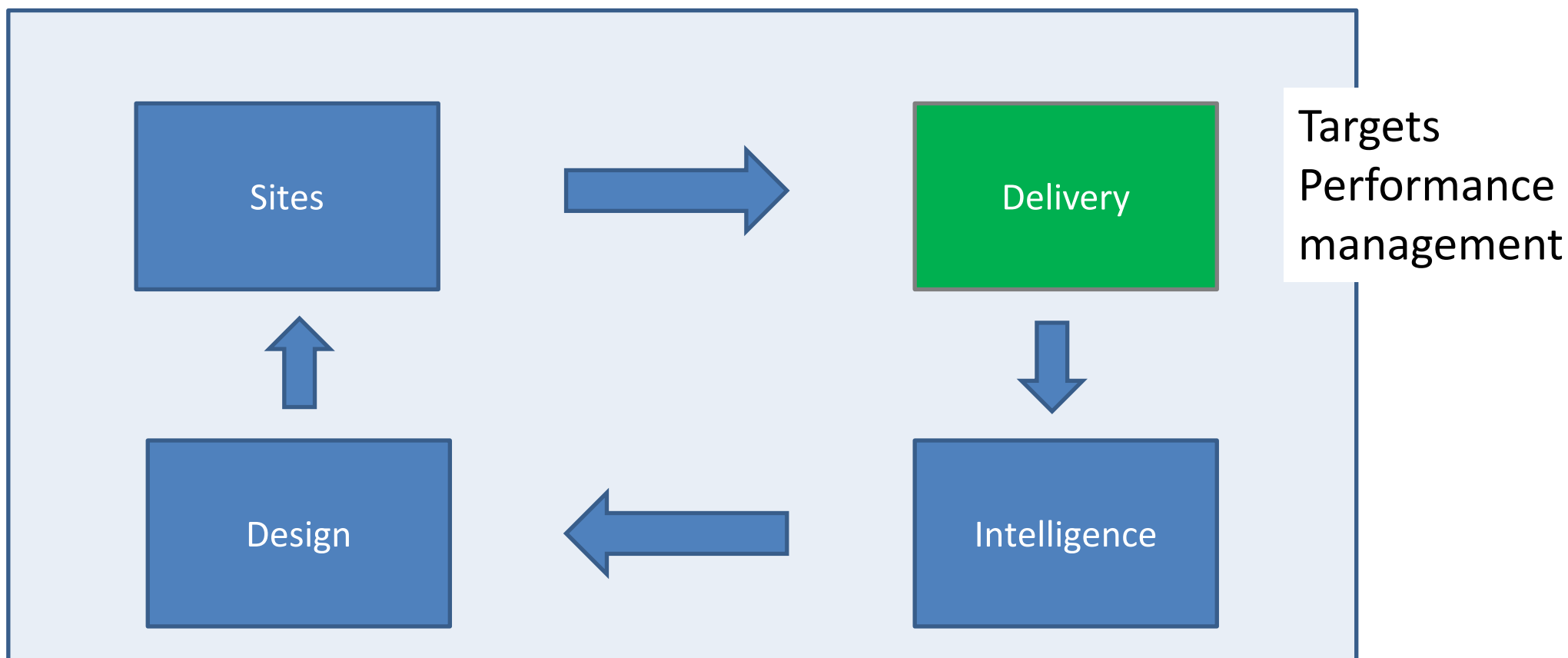
Well-developed Clinical Research Networks

Facilities are available to all Sponsors and Funders across all therapeutic areas



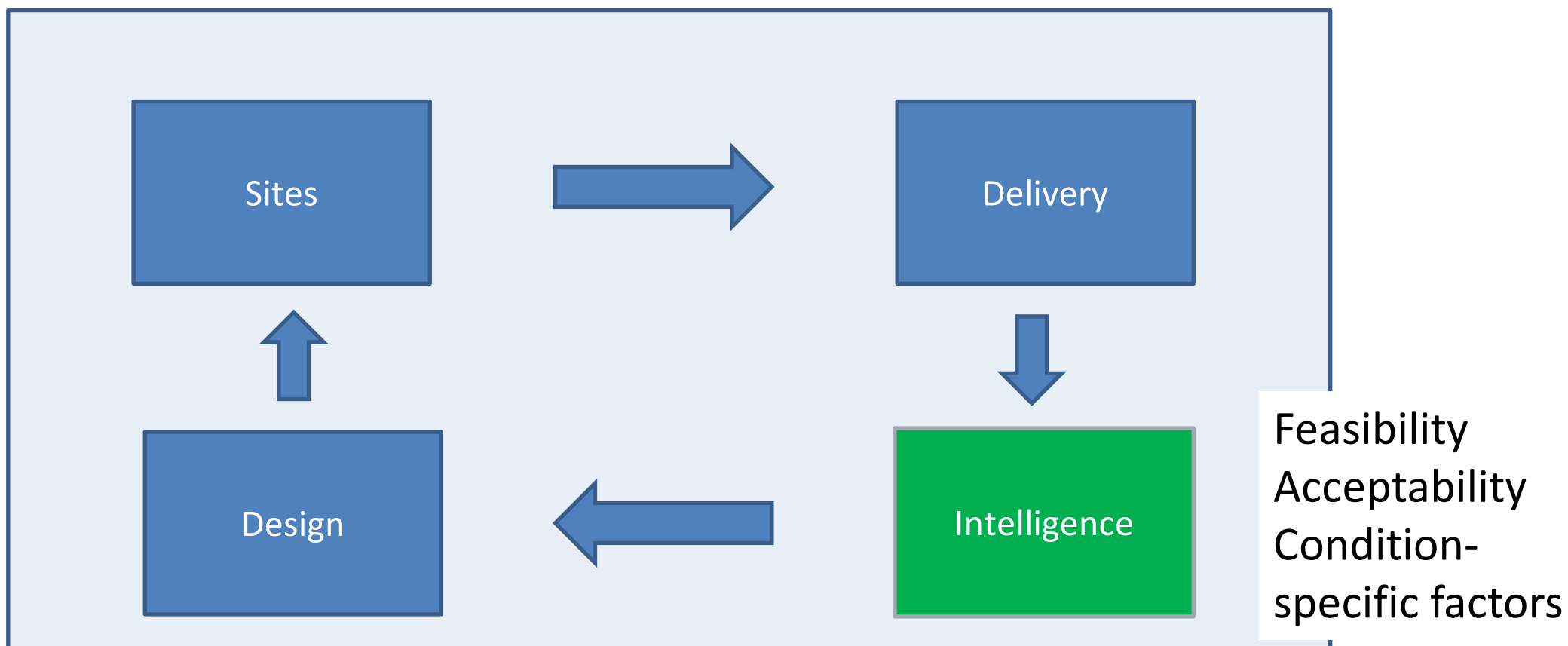
Well-developed Clinical Research Networks

Facilities are available to all Sponsors and Funders across all therapeutic areas



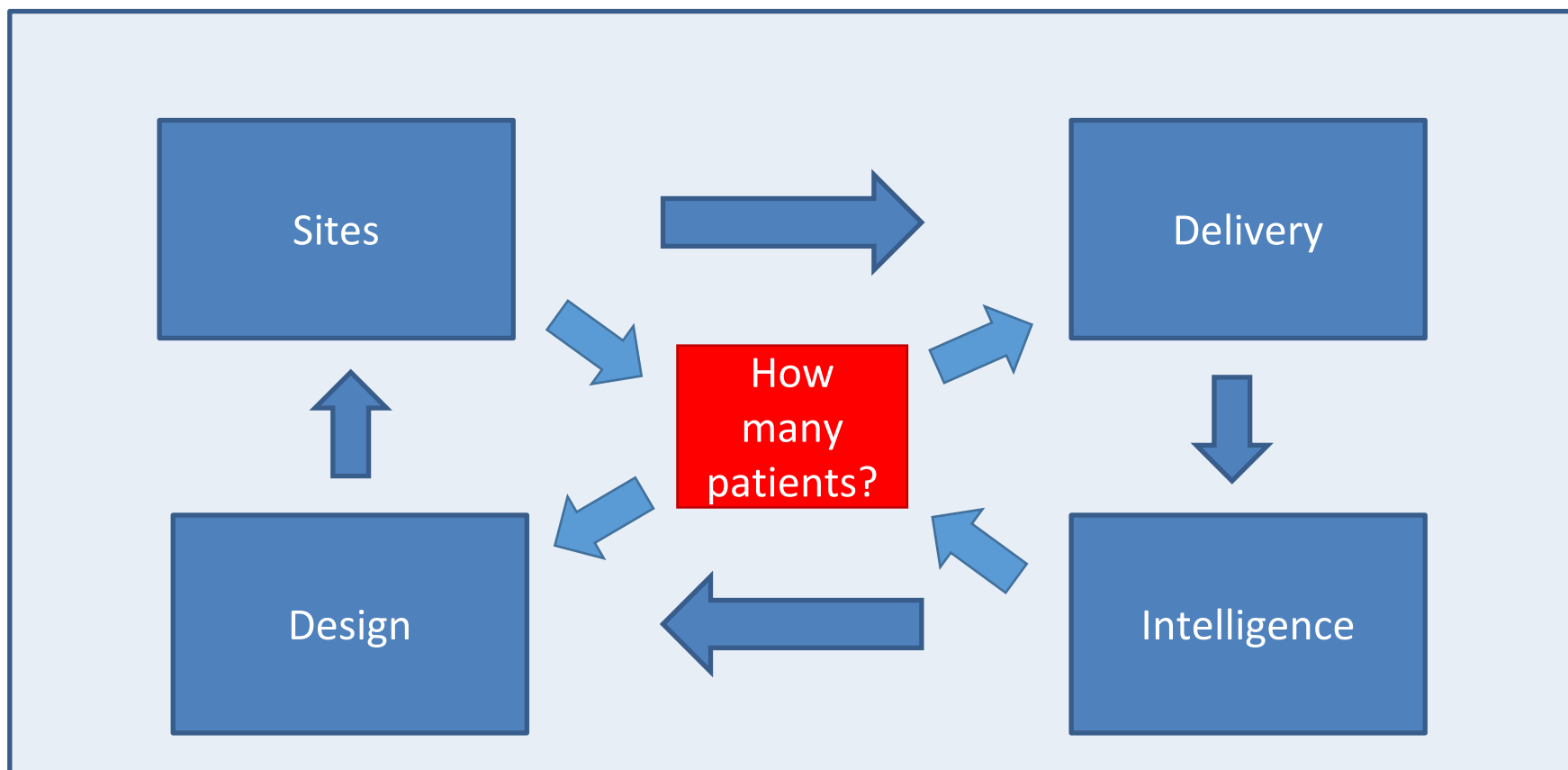
Well-developed Clinical Research Networks

Facilities are available to all Sponsors and Funders across all therapeutic areas



Well-developed Clinical Research Networks

Facilities are available to all Sponsors and Funders across all therapeutic areas



How to use networks

Potential entry points:

Identify therapeutic need

Due diligence

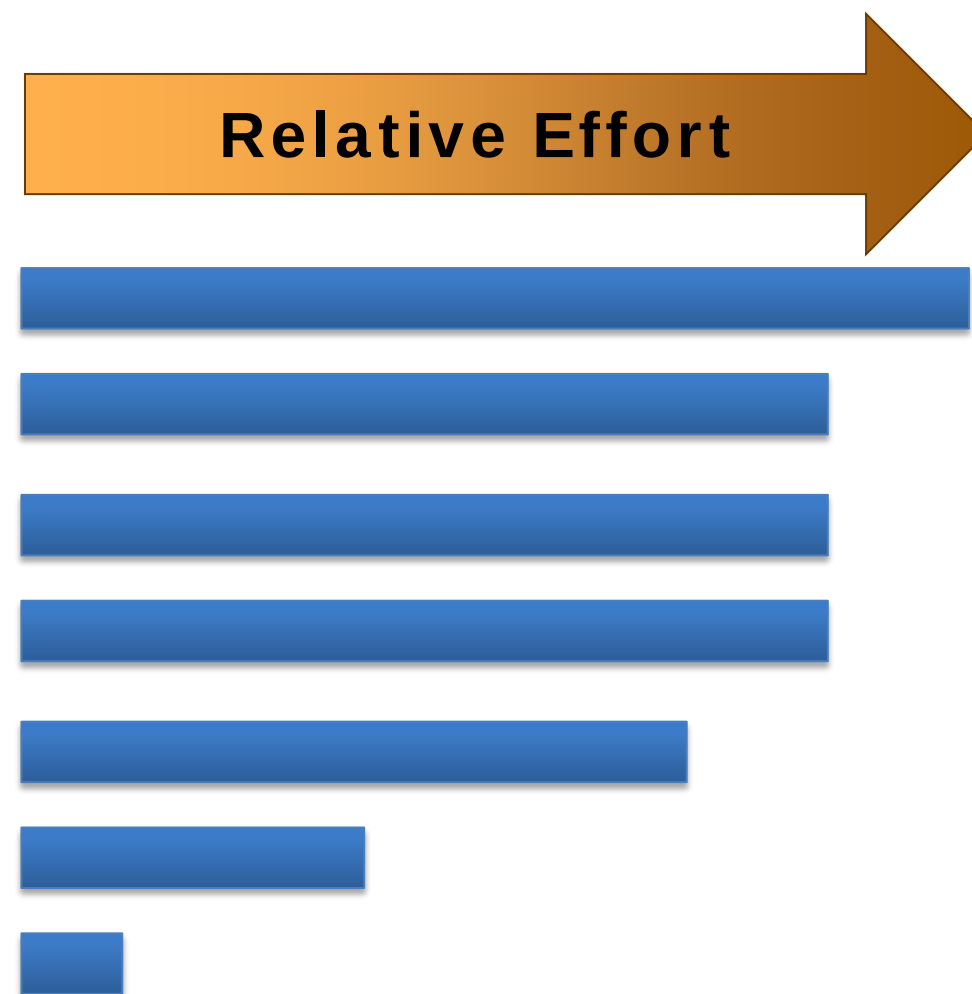
Pre-IND

Develop PIP

Develop protocol

Implement protocol

Rescue protocol



How not to use networks

Potential entry points:

Identify therapeutic need

Due diligence

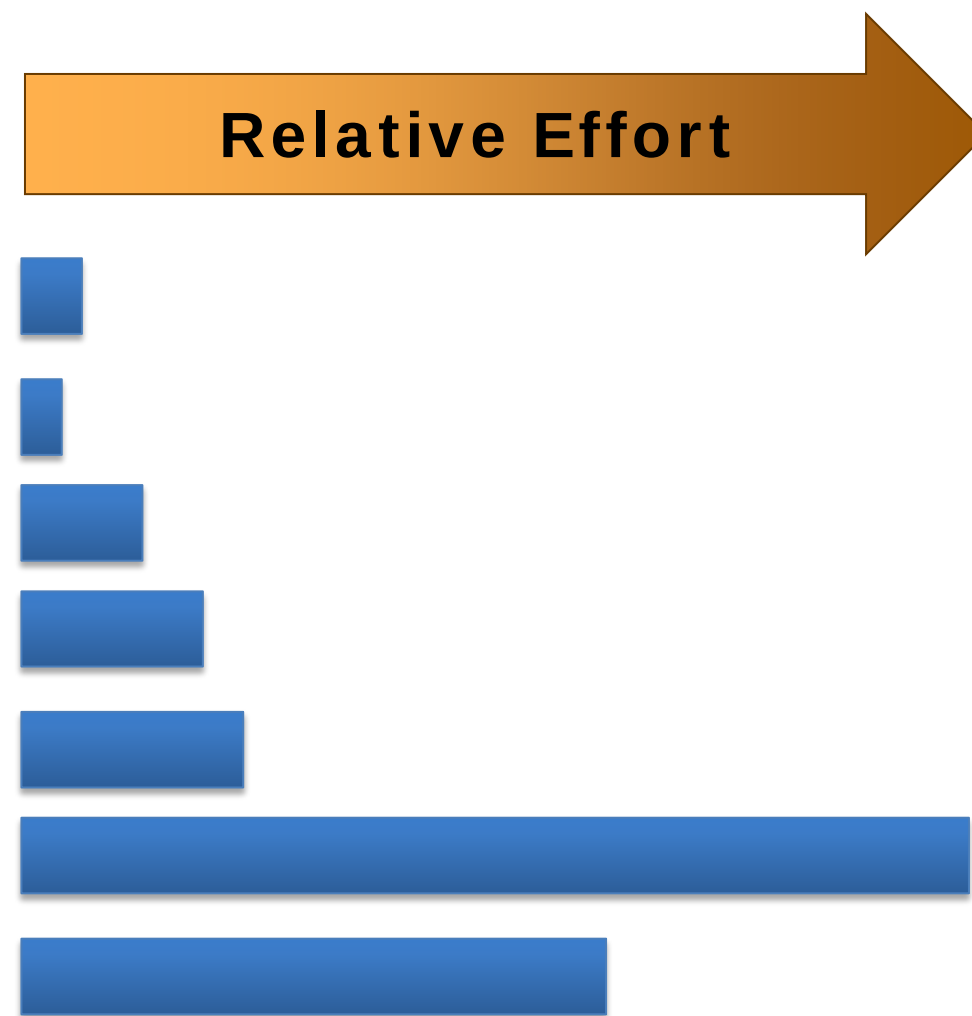
Pre-IND

Develop PIP

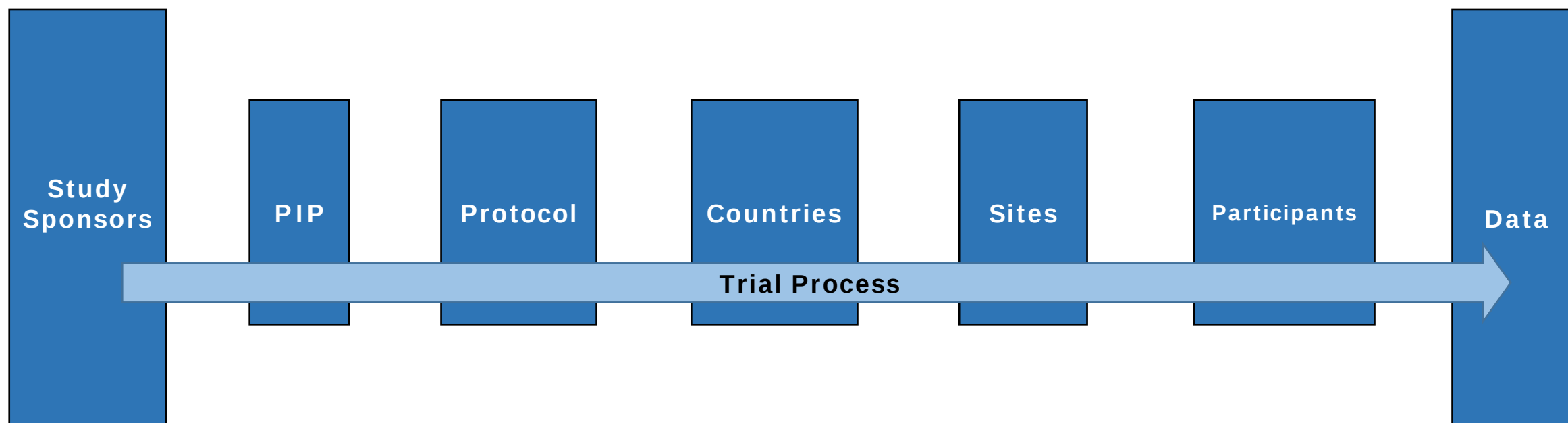
Develop protocol

Implement protocol

Rescue protocol

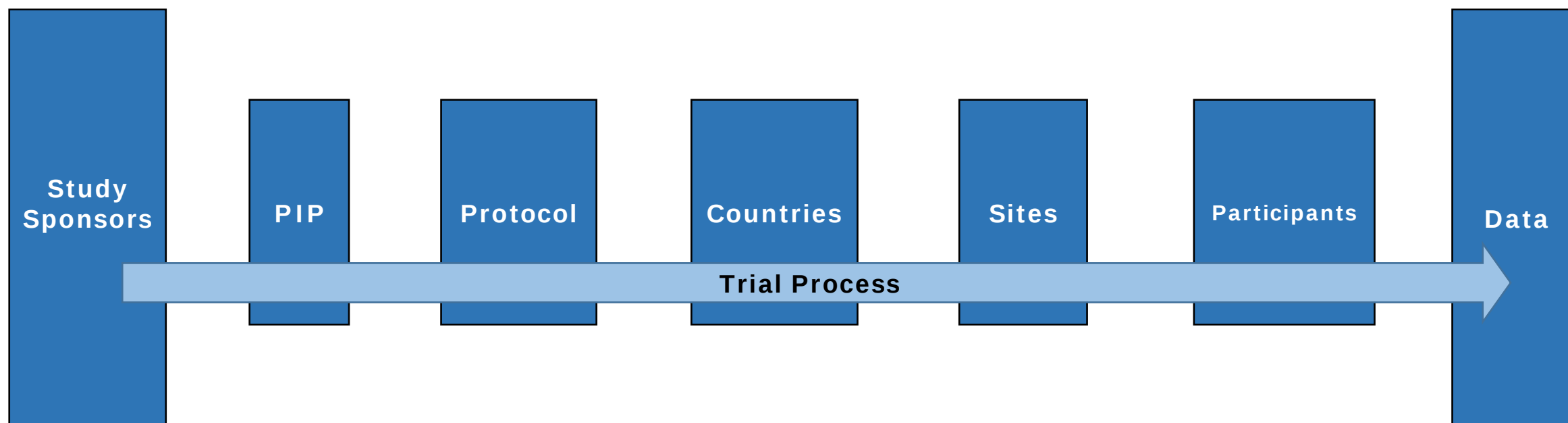


What can networks do?



What can networks do?

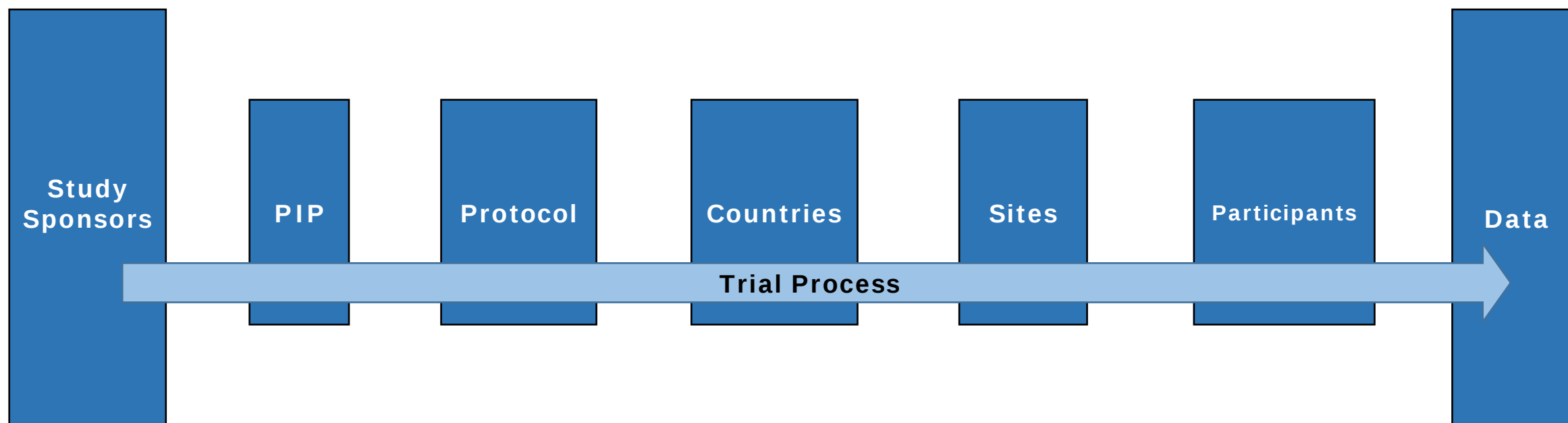
Trial Implementation



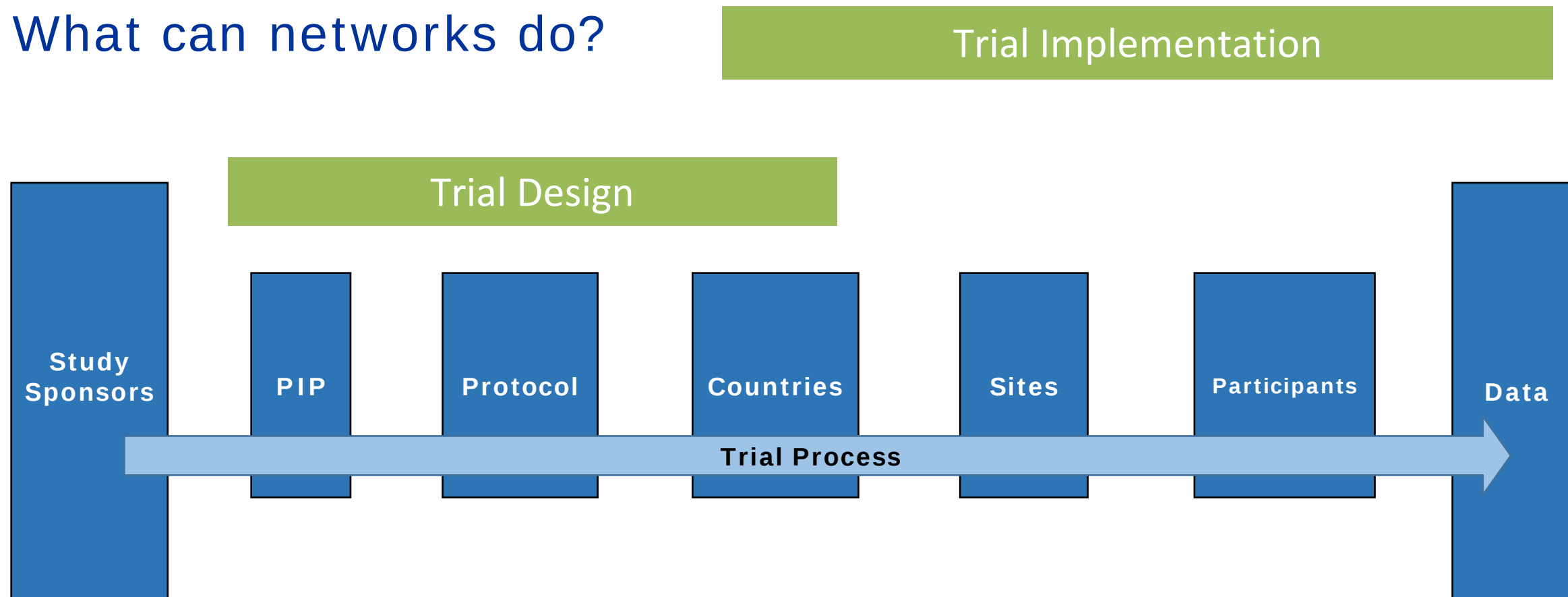
What can networks do?

Trial Implementation

CORE BUSINESS FOR MANY NETWORKS



What can networks do?



How can (some) networks help study design?

Real-world data about incidence / feasibility

Identify similarities / differences between adult and children

Using adult data to minimise studies in children

- See extrapolation concept paper

Standard of care

Which assessments / outcomes are feasible

How can (some) networks help study design?

Real-world data about incidence / feasibility

Identify similarities / differences between adult and children

Using adult data to minimise studies in children

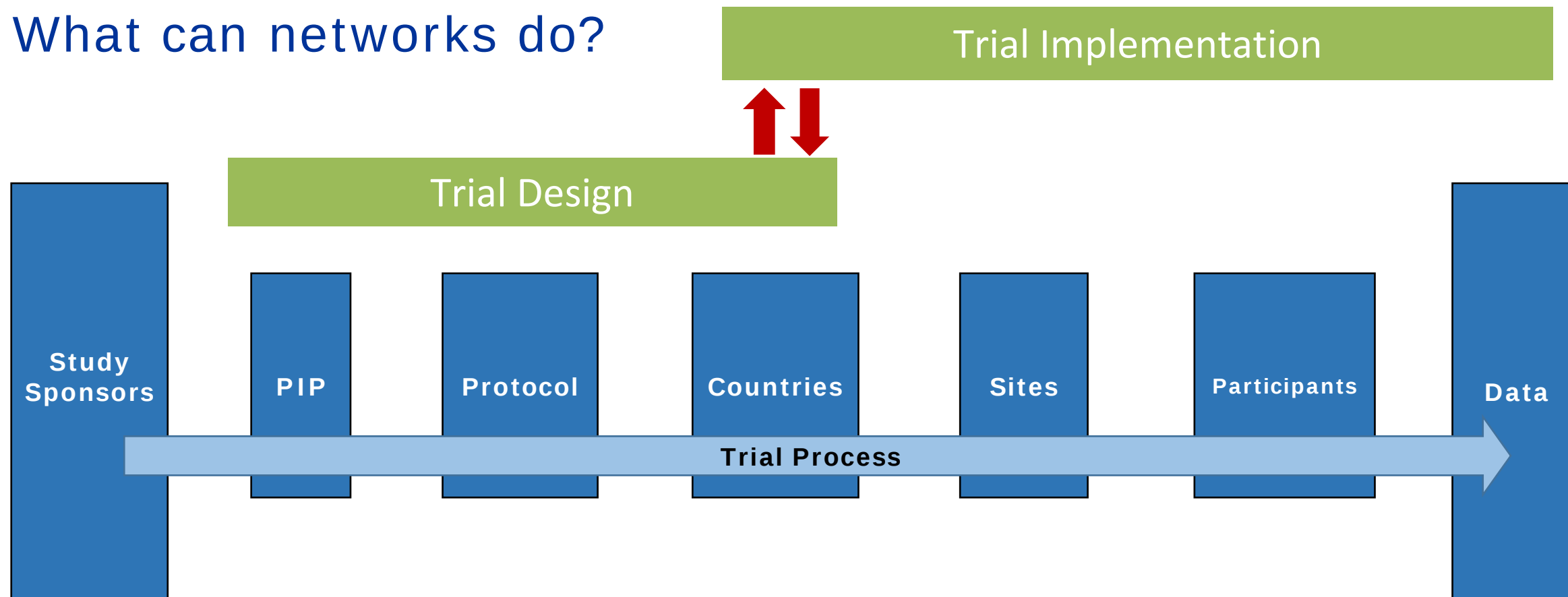
- See extrapolation concept paper

Standard of care

Which assessments / outcomes are feasible

Direct help or
signposting

What can networks do?



Mutual learning

Not all networks can do all these tasks

Nevertheless, they can contribute to some of these activities

We all need to learn from each other: networks and companies can learn from each other

EnprEMA and most networks are not funded. The networks are often voluntary and try to help when they can

You get what you pay for (most of the time)

Networks will improve

IMI2 potential call



Topic: Creation of a pan-European Paediatric Clinical Trials Network

How to use networks

Contact early

Single contact point in the network and your organization

- “Business Relationship Manager”

Develop horizontal links within your organization so that the corporate memory is enriched by working with networks

Thank you for your attention

Further information

European Network of Paediatric Research at the European Medicines Agency
([Enpr-EMA](#))

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

Send a question via our website www.ema.europa.eu/contact

Follow us on  **@EMA_News**