Better Science, Better Health
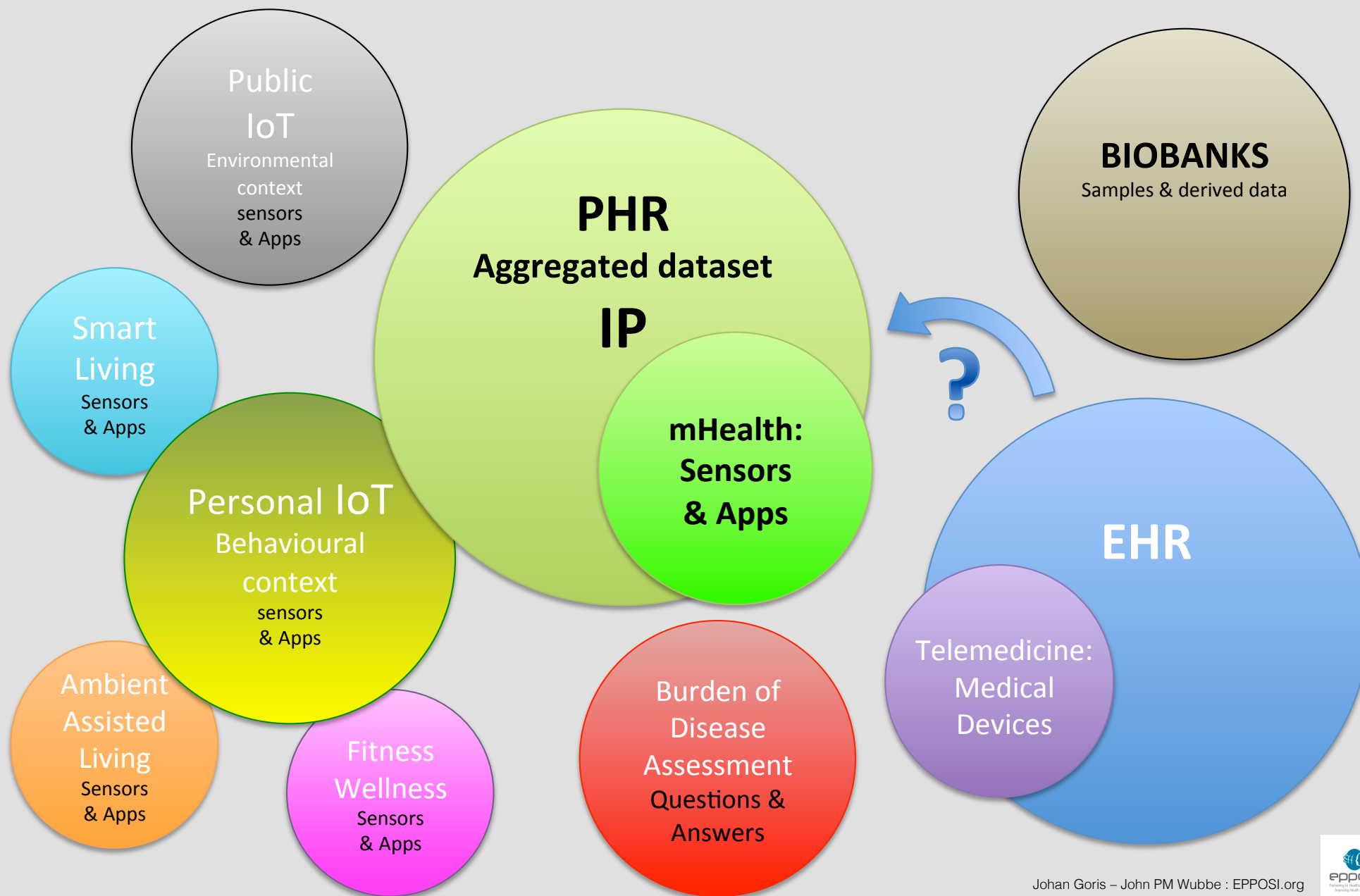## New Healthcare Models

Fostering Collaboration to
Accelerate Better Patient Outcomes

John Wubbe, EPPOSI: Secretary General
EUDiPPA: European Digital Peer Patient Alliance, Science Policy Officer and CEO

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Partnering for Healthcare solutions
- Improving Health outcomes

Real world Health DATA sources

Public IoT
Environmental context sensors & Apps

BIOBANKS
Samples & derived data

Smart Living
Sensors & Apps

PHR
Aggregated dataset
IP

mHealth: Sensors & Apps

?

EHR

Personal IoT
Behavioural context sensors & Apps

Ambient Assisted Living
Sensors & Apps

Fitness Wellness
Sensors & Apps

Burden of Disease Assessment Questions & Answers

Telemedicine: Medical Devices

Johan Goris – John PM Wubbe : EPPOSI.org

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5 personal datasets
raw & derived data : IP & Accessibility

- **Biobanks :**

  tissue storage (IP) / derived data (access)

- **EHR :**

  Primary/secondary/tertiary care : raw data (IP) + derived (access)

- **PHR :**

  Personal physiological measurements : raw data (IP) + derived (%IP)

- **Personal IoT :**

  Smart living : raw data (IP) + derived (%IP)

- **Personal Burden of Disease Assessment**

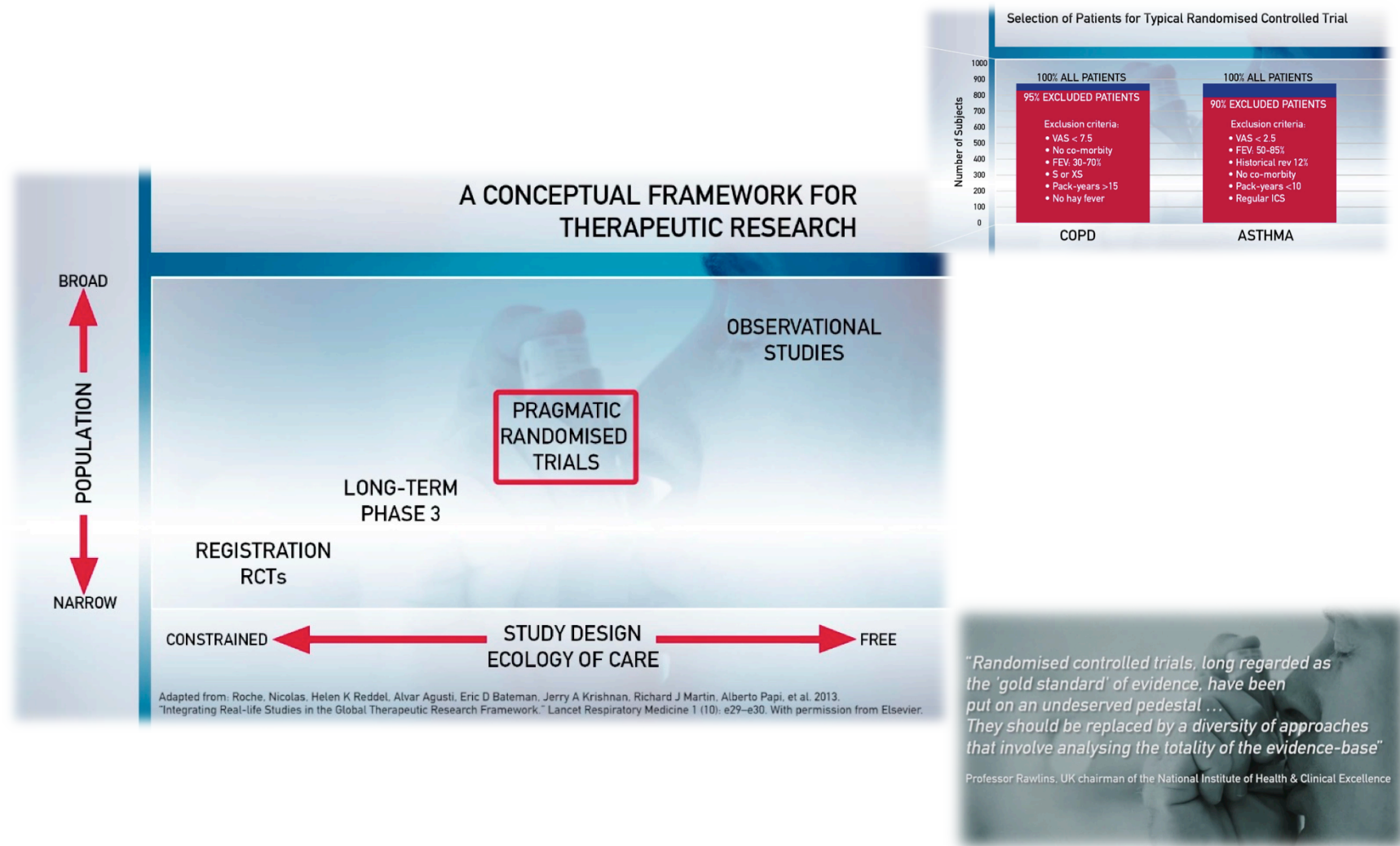 raw data (IP = questions + answers) + derived data(%IP)

(+ **Public IoT** data)

  Aggregation => Personal Environmental Context

Johan Goris – John PM Wubbe : EPPOSI.org

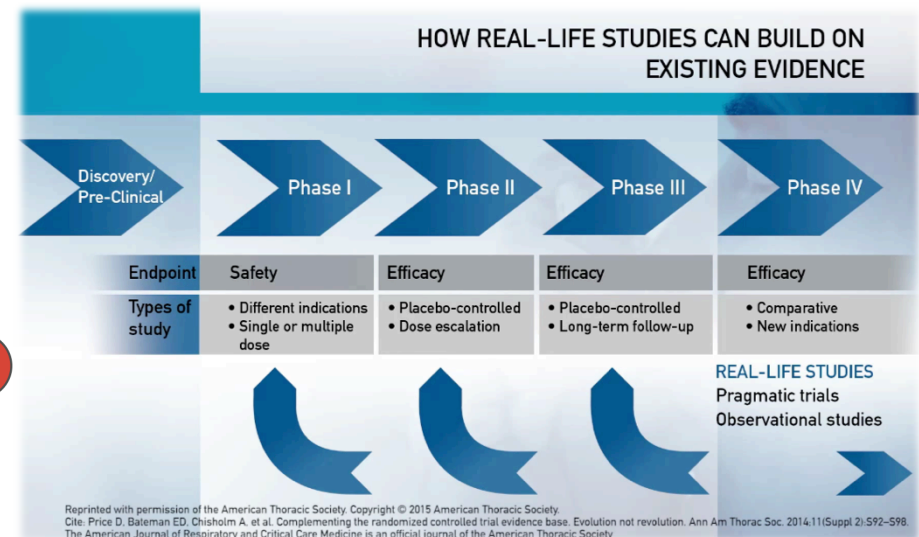# Methodology of Clinical Investigations across Products Lifecycle
The patient perspective

Clinical evaluation & investigation:
Parallels from a patient perspective

- Product : lifecycle stages / study design
  - Medtech : Diagnostic / Therapeutic
  - Drugs
  - IV-Diagnostic
  - Biotech
  - Combinations
    - Closed Loop delivery
    - Companion diagnostics
    - …

HOW REAL-LIFE STUDIES CAN BUILD ON EXISTING EVIDENCE

	Discovery/ Pre-Clinical	Phase I	Phase II	Phase III	Phase IV
Endpoint		Safety	Efficacy	Efficacy	Efficacy
Types of study		• Different indications • Single or multiple dose	• Placebo-controlled • Dose escalation	• Placebo-controlled • Long-term follow-up	• Comparative • New indications

REAL-LIFE STUDIES
Pragmatic trials
Observational studies

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Cite: Price D. Bateman ED. Chisholm A. et al. Complementing the randomized controlled trial evidence base. Evolution not revolution. Ann Am Thorac Soc. 2014.11(Suppl 2):S92–S98.
The American Journal of Respiratory and Critical Care Medicine is an official journal of the American Thoracic Society.

Patient involvement opportunities at all stages

- Real world 24/7 **quality** patient generated health data
- Digital peer patient recruitment
- …

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rapid HTA = EPPOSI's Multi Stakeholder methodology
Patient expert included step-up advise for evidence generation

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Innovation :
- Pharma
- IV Diagnostic
- MedTech
- Digital Health
- **+ combinatory**…

Re-imbursement access threshold
- evidence
- Appraisal
- HTA
- HIA
- …

BENEFIT

Regulatory access threshold
- Clinical evaluation
- Clinical investigation
- Certification
- …

Successful design & development thresholds
- Usability
- Desirability
- Intended use
- …

?

UNCERTAINTY

?

Funding & development thresholds
- Funding triage
- Expectations
- Claims
- …

RISK

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rHTA
Dragon round
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Partnering for Healthcare solutions
Improving Health outcomes

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