ONCOVALUE - Generating real world effectiveness data

Johanna Mattson and Wim H. van Harten

ONCOVALUE - Implementing value-based oncology care at European cancer hospitals
This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101095245

Consortium of cancer centers & technology companies

THE ONCOVALUE CONSORTIUM

HUS Helsinki University Hospital

NETHERLANDS CANCER INSTITUTE ANTONI VAN LEEUWENHOEK

REGION H Rigshospitalet

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THIRD PARTY PARTNERS

Rijnstate

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5 clinical partners

3 technology partners

3 dissemination partners

Project duration:
1.12.2022 –
30.11.2026
7 M€ total budget

HORIZON-HLTH-2022-TOOL-11-02: New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment

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Oncovalue Mission Statement

- The efficacy of new therapies is often **based on** small studies with **relatively little evidence for true value *(outcomes, quality of life, cost-effectiveness)***.

- To achieve value-based assessment of novel cancer therapies, ONCOVALUE will enable **the inclusion of high-quality real-world data (RWD) in regulatory and reimbursement decision-making**.

- This will support the development of effective medicines, reduce spending on drugs that yield little benefit and **enable oncologists to promote value-based cancer care.**

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ONCOVALUE will

A. enable and guide **cancer hospitals to collect**, **harmonize** and **analyze** high quality RWD in **real-time**
   - *How to organize and maintain data collection as part of standard clinical routines?*

B. empower and train **health regulatory** and health technology assessment **(HTA) bodies** to **adopt** RWD-driven methodologies **in their decision-making on cost-effectiveness of novel cancer therapies**.

C. Develop and test next generation **AI-based tools supporting the effective use of unstructured data**
   - *Text analytics to extract and structure clinical information (oncologist's evaluation of treatment response and adverse events) from free text.*
   - *Detection and analysis of response to treatment (disease progression vs. clinical benefit) from CT scans of the metastatic target lesions.*
   - *Methods that can be systematically harnessed to help in utilizing large amounts of RWD.*

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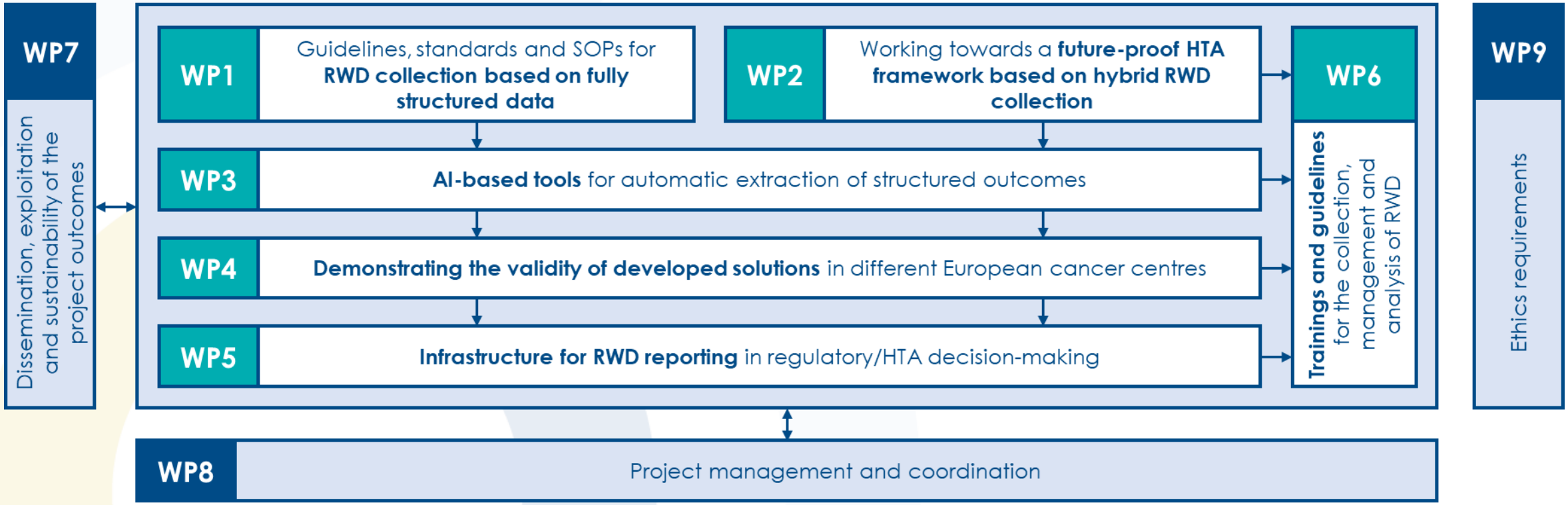
Work packages (WP)



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Real world hospital data for better Health Technology Assessments

Prof. Wim H. van Harten MD PhD

NKI-team:

Prof. Valesca Retèl PhD, Nora Franzen PhD, Kevin Tittel MSc, Zainab Al-Khayat MSc

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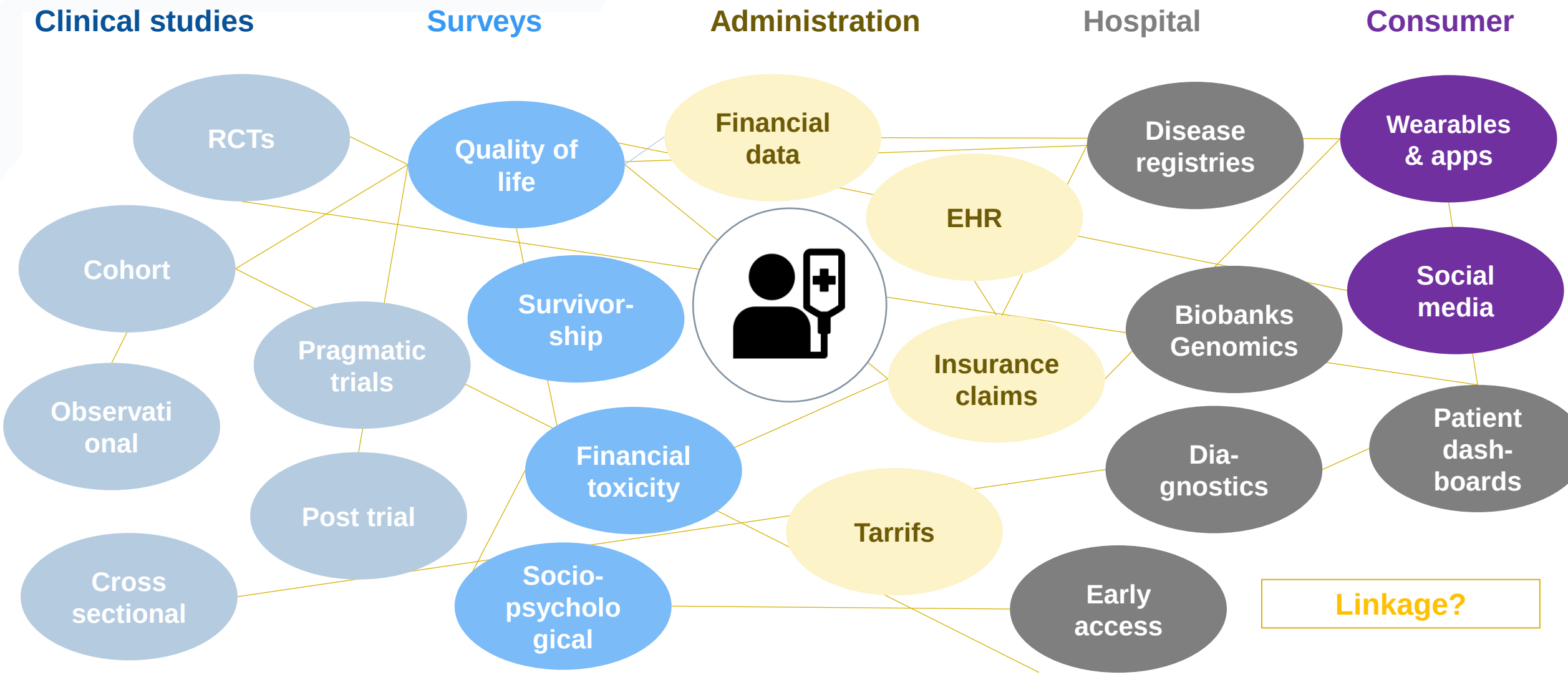
RWD-based “future-proof” Health Technology Assessments

Objective Oncovalue HTA

To develop guidelines for collection and processing RWD-based “future-proof” Health Technology Assessments based on structured and unstructured data across Europe.

1. To explore requirements for RWD-HTA of EU HTA bodies and the related status of data infrastructure and –generation in European cancer centers.
2. To define the data scope and domain for RWD-HTA in oncology.
3. To develop a hybrid framework to feed “future-proof” RWD-HTA across Europe.
4. To perform pilots and use cases, relevant to HTA ,to test administrative access, feasibility of data generation and fit with BI software.

Real world data sources



RWE – where are we now?

Increasing uncertainty in current regulatory decisions

Randomized, Interventional Study		Nonrandomized, Interventional Study	Nonrandomized, Noninterventional Study
Traditional randomized trial using RWD in planning	**Trial in clinical practice settings, with pragmatic elements**	**Externally controlled trial**	**Observational study**
RWD used to assess enrollment criteria and trial feasibility RWD used to support selection of trial sites	Selected outcomes identified using, e.g., health records data, claims data, or data from digital health technologies RCT conducted using, e.g., electronic case report forms for health records data or claims data	Single-group trial with external control group derived from RWD	Cohort study Case–control study Case–crossover study

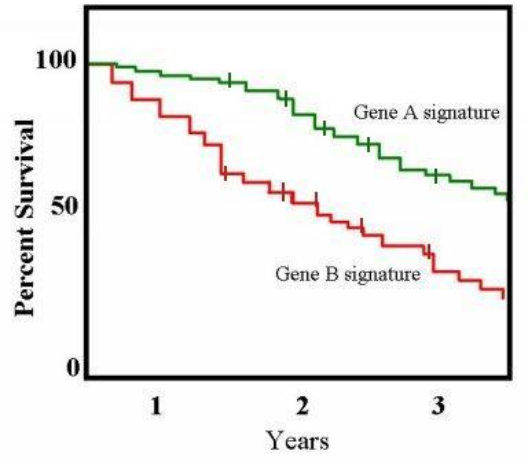
Generation of RWE

Increasing reliance on RWD

Source: Concato J, Corrigan-Curay J. Real-World Evidence - Where Are We Now? N Engl J Med. 2022

Elements of an HTA

- What is the **real long-term effectiveness**?
- How **generalizable** are the effects?



Survival

Quality of life

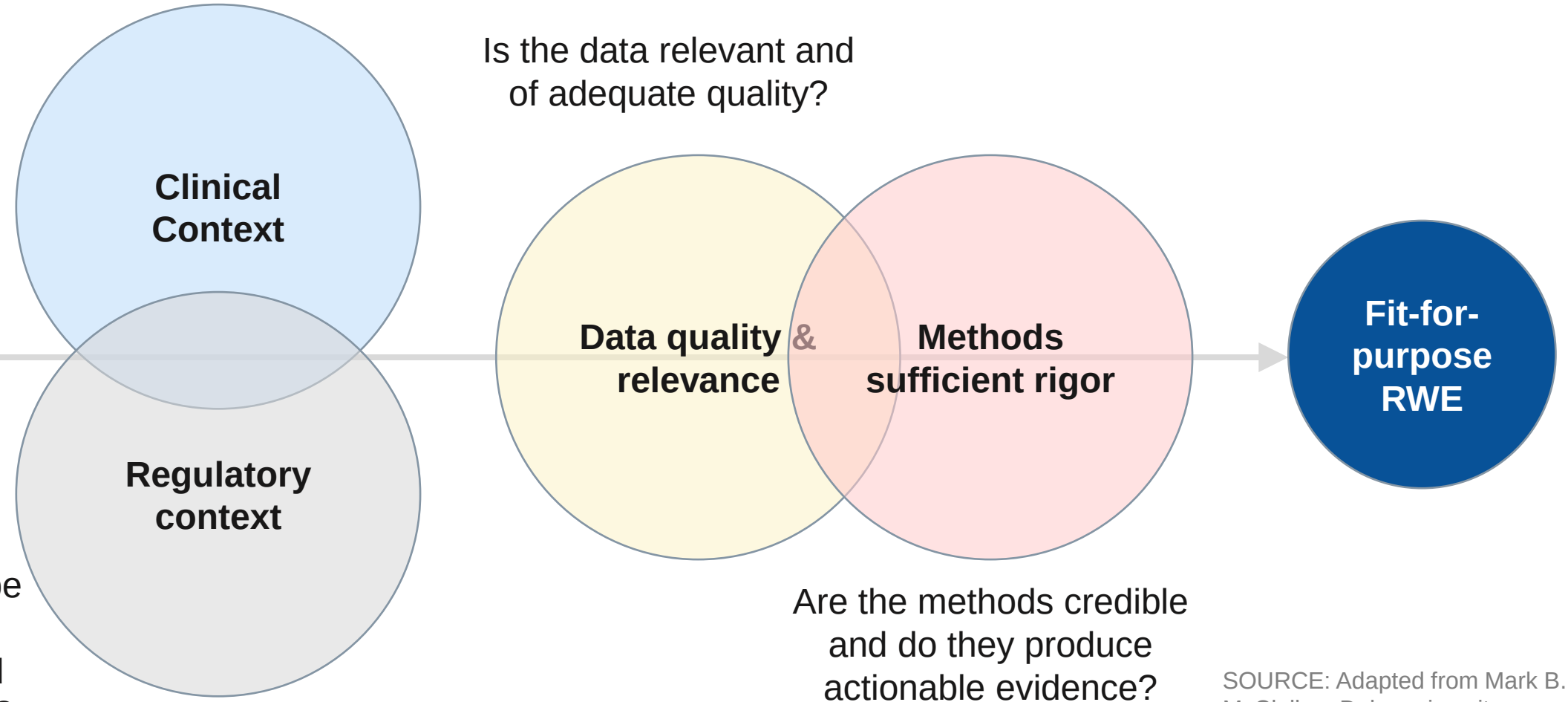
- Do tariffs **reflect the real cost**?
- What are the real cost of **patented medicines**?

Cost

- **When and how** is quality of life measured along the clinical pathway?
- Are the measurements **complete**?

Generating RWE fit for regulation

What are relevant regulatory (EMA/HTA) questions?



Is the data relevant and of adequate quality?

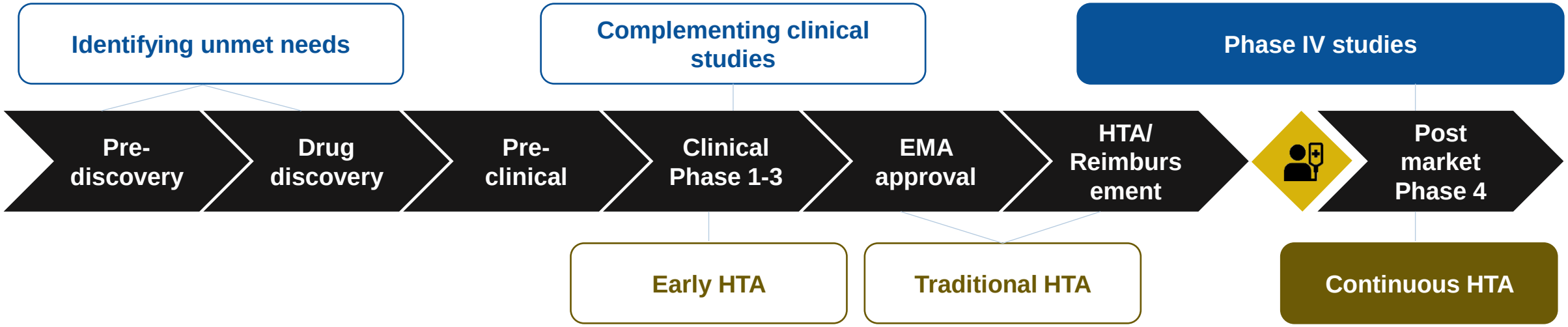
Can the clinical question be reliably addressed with RWE?

Are the methods credible and do they produce actionable evidence?

SOURCE: Adapted from Mark B. McClellan. Duke university. Presentation at GetReal conference 2023

RWE along the value chain

Clinical RWE applications



HTA RWE applications

- Real cost
- Real effects
- Real QoL

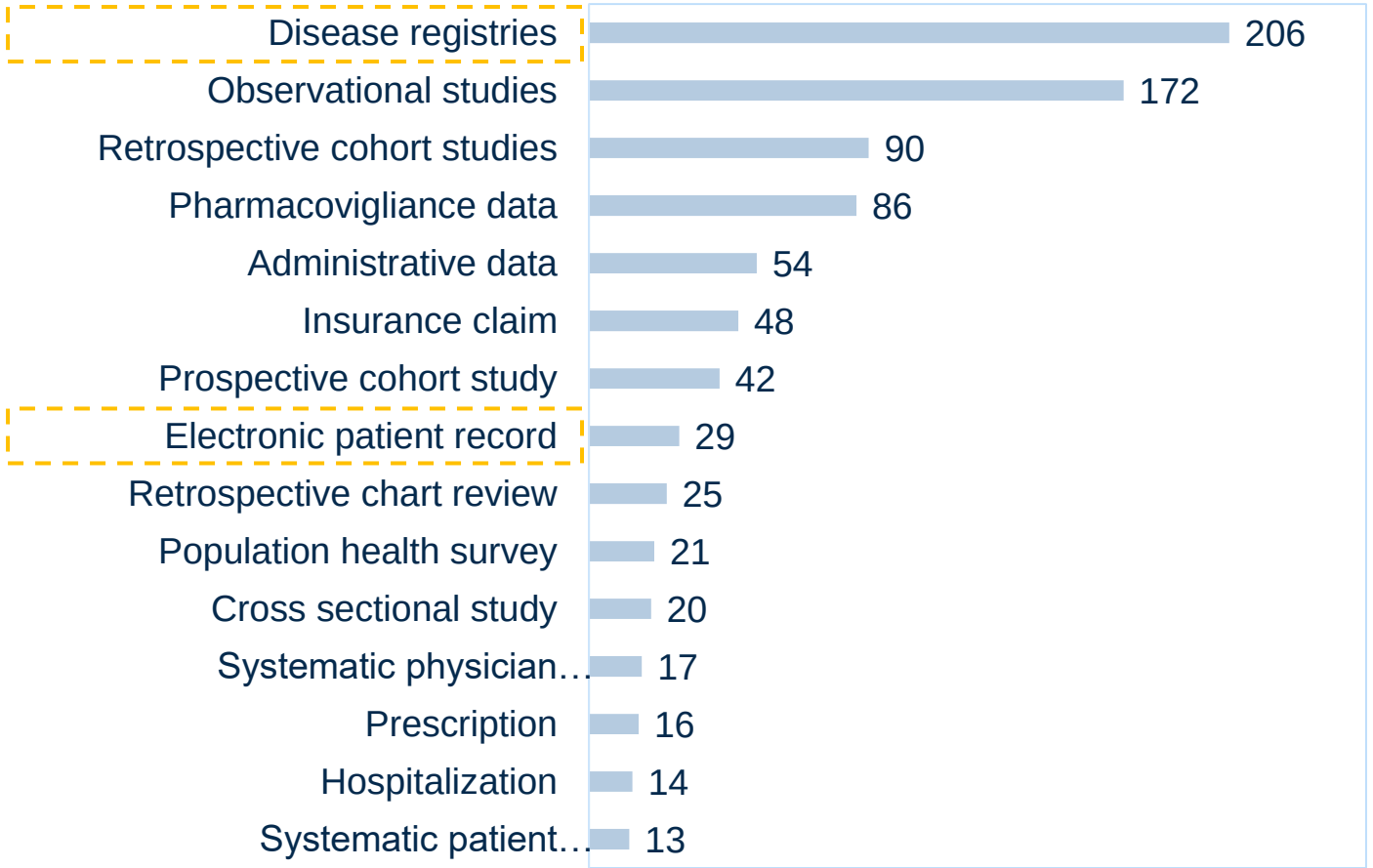
- Learning healthcare systems
- Risk based pricing
- Longterm cost effectiveness
- Adding/replacing RCT

Adapted from: National Academies of Sciences, Engineering, and Medicine. Real-World Evidence Generation and Evaluation of Therapeutics: Proceedings of a Workshop. Washington (DC). 2017.

Hospitals are a valuable and underused source for RWE-HTA

Sources of RWD in accepted HTA submissions

USA, Europe, Japan 2017-2021



SOURCE: IQVIA. Use of Real World Evidence to Support Health Technology assessments in United States, Europe, and Japan – a brief analysis. ISPOR Europe 2022.

- Primary source for disease registries
- Rich data sets
- Decisive for data quality & validity
- Strong existing international networks

Methods needed to link structured and unstructured data

ONCOVALUE activities – WP2 status: feasibility study (M6 of 48)

Objective: To investigate the **feasibility** to generate data fit for **Health Technology Assessment,** comparing **neo-adjuvant treatment modalities for breast cancer**, based on **real world data** from hospital databases and business intelligence systems.

- **Clinical question:** What is the real-world cost-effectiveness of neo-adjuvant treatment modalities in breast cancer patients (from time of diagnosis until 1st CT scan result after surgery)?
- **Technical question:** What are the technical steps to extract the relevant data points? Is the data fit-for-purpose? Numbers, missing data, follow up length, et‘., etc.

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