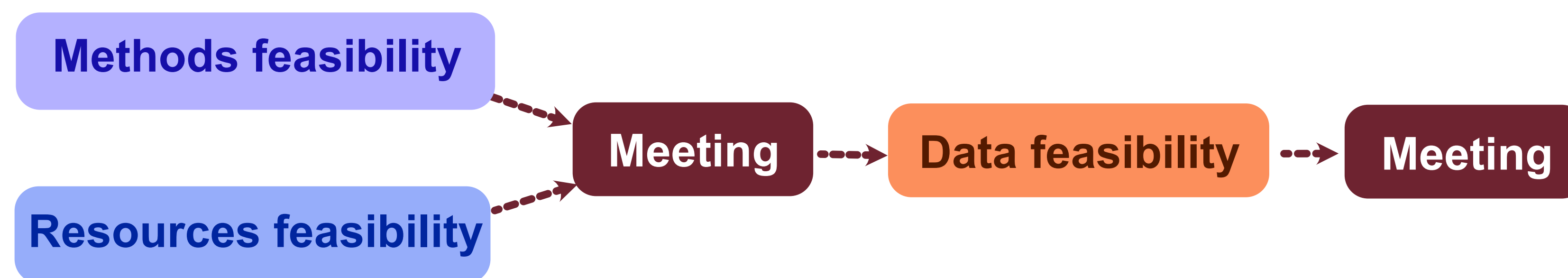


# 29 institutions from various sectors propose a standardised approach to assess whether conducting a particular study using RWD is feasible

## Standardising feasibility assessments: a proposal from the IHI-GREG project

**Background:** A feasibility assessment aims to **determine whether an RWE study can be conducted** producing robust, timely, decision-grade results **given available data, methods, and resources**. **Currently, no standard approach exists.** The IHI-GREG project—a five-year public-private partnership of 29 organisations from academia, industry, regulators, HTA bodies, and patient groups—aims to create practical, evidence-based guidance and tools to improve the planning and use of RWE. As part of this effort, we propose a standardised feasibility-assessment framework to **support transparent and reproducible assessment of RWE research questions and selection of real-world data sources**.

### Three dimensions to be assessed using a standard reporting template



#### Methods feasibility

- Is the **study design** suitable?
- Is this research question **answerable with RWD** or needs data collected prospectively?
- Are the **analytical methods** proposed suitable and consider the state of the art?
- Are there **standard analytical packages** available?

#### Resources feasibility

- **Staff resources** available
- **Number of data partners** required
- **Need for new mapping, vocabularies, new standard analytics...**

#### Data feasibility

**Is the available data suitable, in terms of relevant data domains, sufficient patient counts, particular population representation, and readily available?**

5-phase process with multiple touch points:

- **Exploration:** preliminary assessment of available data sources for healthcare setting, temporal, and geographical suitability and required data domains presence > *Potential Data Partners Landscaping* looking for pre-calculated **concept-level counts** and other metrics > *Shortlisted Data Partners for feasibility* + reasoning
- **Initiation:** data partners contracting
- **Implementation:** preliminary phenotypes and standard R code
- **Execution:** data partners run code
- **Dissemination:** report using **standard template** to ensure transparency and reproducibility, including *Shortlisted Data Partners for the study* + reasoning

Data partner	Compliance	Granularity	Timing
DP1			
DP2			
DP3			
DP4			
DP5			
DP6			
DP7			
DP8			
DP9			
DP10			

## Methods

The feasibility assessment framework is being **co-designed** with academic, industry, regulatory, and HTA contributors to **ensure broad applicability across Europe**. The development process is **iterative**: prototyping, piloting with diverse real-world use cases, gathering stakeholder feedback, and refining in successive cycles. A **continuous learning plan** based on performance indicators, internal review, version control, and a lessons-learned repository supports ongoing improvement. An **R package** is being developed to standardise the analytics.



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