IMDRF International Medical Device Regulators Forum

Evolving Landscape of Real-World Evidence Research Practice and Policy

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Presentation Topics

Current Global Regulatory Landscape for Real-World Evidence Policies

Rapid Evolution of Real-World Evidence Research

- Real World Data
- Analytical Methods
- Research Practices
- Interpretation and Analysis

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Current Global Regulatory Landscape for Real-World Evidence Policies

Insights from EU IHI Public Private Partnership

IDERHA
integrating health data

Integration of Heterogeneous Data and Evidence towards Regulatory and HTA Acceptance

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innovative health initiative

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union

IDERHA Consortium Partners

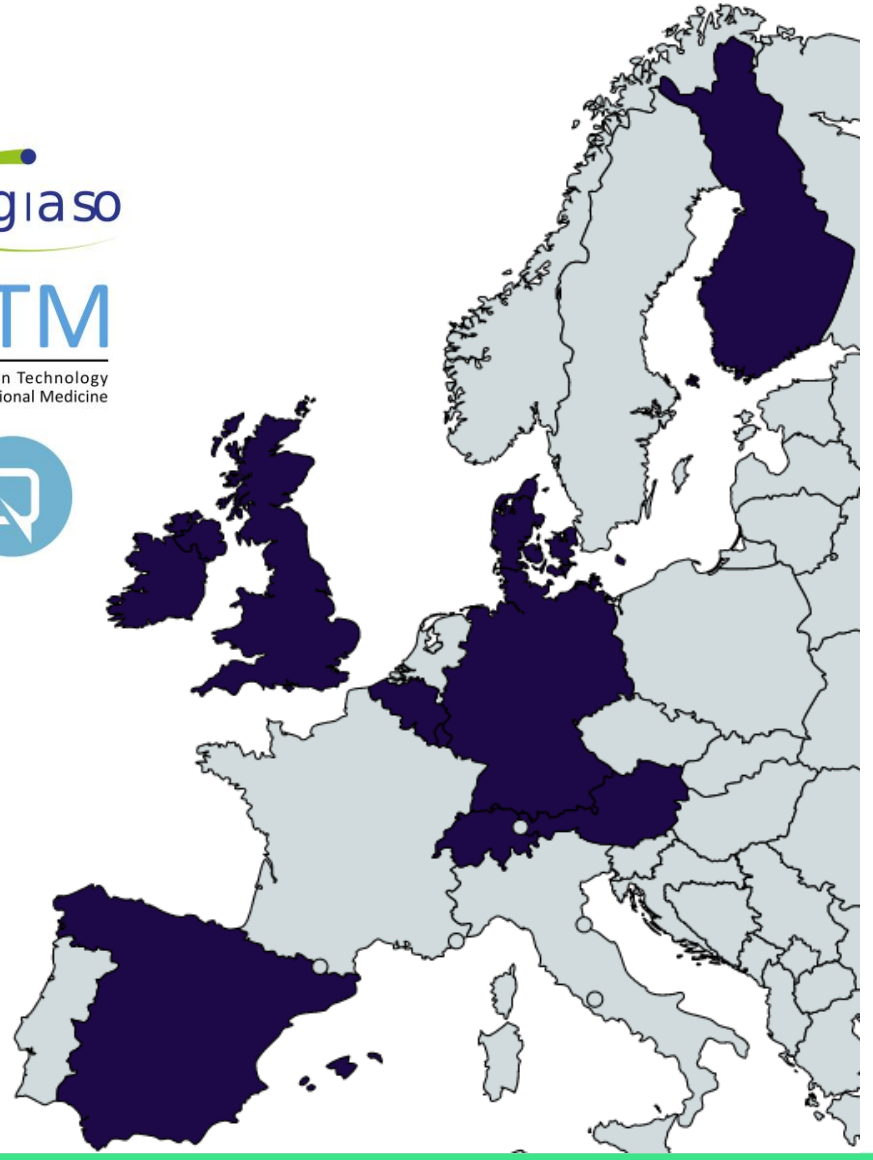
industry

academia

data / clinical

public

SME



https://www.iderha.org/

IDERHA integrating health data

Advancing Harmonized RWE Policies

Project Goal

Provide well-researched and consensus-driven recommendations to ***Inform*** and ***Accelerate*** harmonized Real-World Evidence policy development

Landscape of RWD/RWE Specific Policies

- Global scope
- Policies for:
  - Regulatory & HTA organizations
  - Medicines and Medical Devices
- 2017 to January 2024
- English text only or translations

Overview of analysed documents

Definitions of key terms (e.g., RWD/RWE)

Uses of RWD and RWE

Guidance on study design and conduct

Data collection, curation, & characterization

Data quality assessment

Ethics, governance, trust, and transparency

Intersection of RWD/RWE and AI

Link to Landscape Review https://www.iderha.org/landscape-analysis

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Global Landscape Review

Regulatory
EMA (EU)
MHRA (UK)
Swissmedic (CH)

HTA
HAS (FR)
IQWiG (DE)
EUNetHTA (EU)
NICE (UK)
ZIN(NL)

3rd party
IMI (EU)

Regulatory
US FDA
Health Canada

HTA
CADTH (CAN)
ICER (US)

3rd party
NESTcc (US)

Regulatory
NMPA (CN)
PSEHB & PMDA (JP)
NIFDSE & MFDS (KR)

HTA
REALISE working group (mixed)

Regulatory
ANVISA (Brazil)

Regulatory
TGA (AUS)

International 3rd party

- ICH
- IMDRF
- HTAi
- ISPOR
- ISPE
- OHE

Findings of RWE Policies Landscape Review

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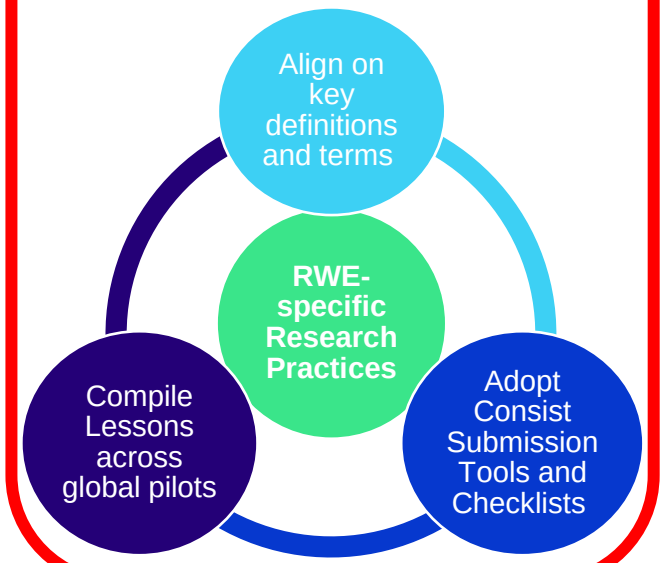
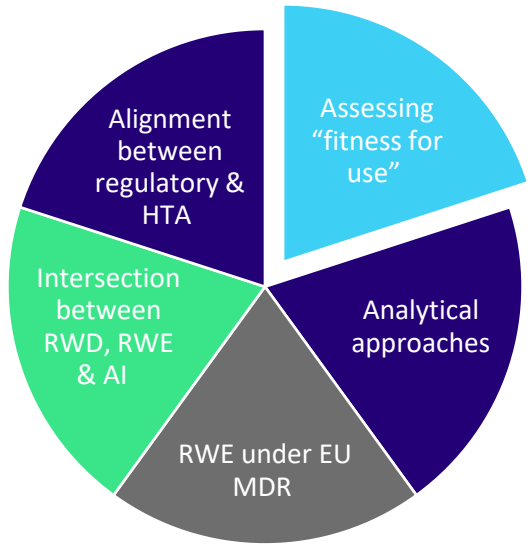
Evolving Organizational Perspectives
Policy & programmatic changes are needed to ensure high-quality and transparent research to build trust.

Emerging Best Practices



Policy Gaps



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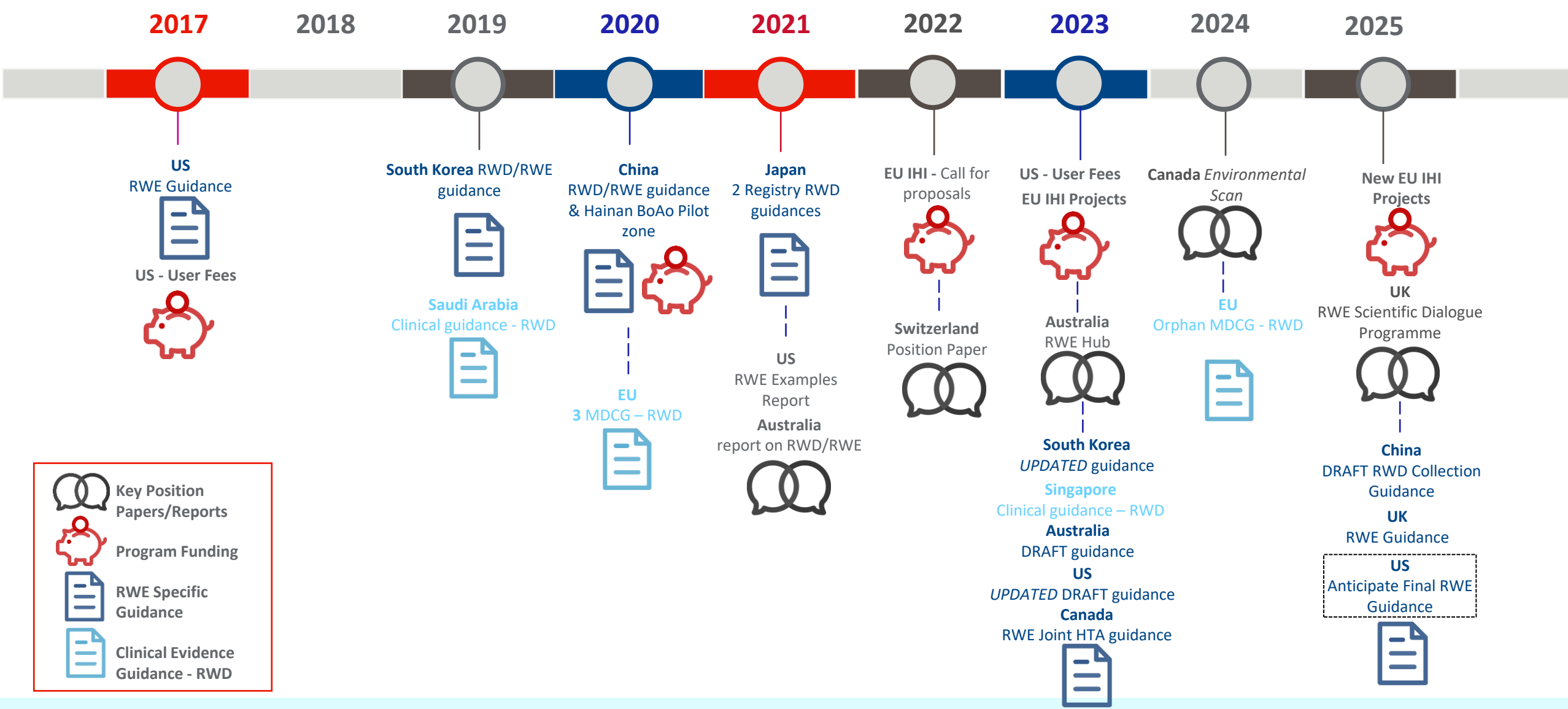
Medical Device RWE Activities & Guidances



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Rapid Evolution of Real-World Evidence Research

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Components of Real-World Evidence Policy Guidance

Ethics and Transparency

- Posting/registering protocol
- Interactions between sponsor and authority
- Documenting data provenance
- Process for protocol changes
- Criteria for submitting an IDE or similar requirements

Uses of RWD/RWE

- Pre, Post market
- Submission types (e.g., High to Low Risk, implantables, humanitarian/rare/orphan, pediatrics)
- Accepted uses (e.g., supplemental, primary clinical evidence)

Data Quality

Data Provenance/Traceability

- Allowable data sources
- Data set characterization
- Extraction, curation practices
- Data governance/ethics (e.g., consent)
- Define relevance and/or reliability

Study Design

- Research question guidance
- Data methods (e.g., Common Data Model, data dictionary requirements, linkages between different sources)
- Analytical methodology (e.g., weighting, bias)

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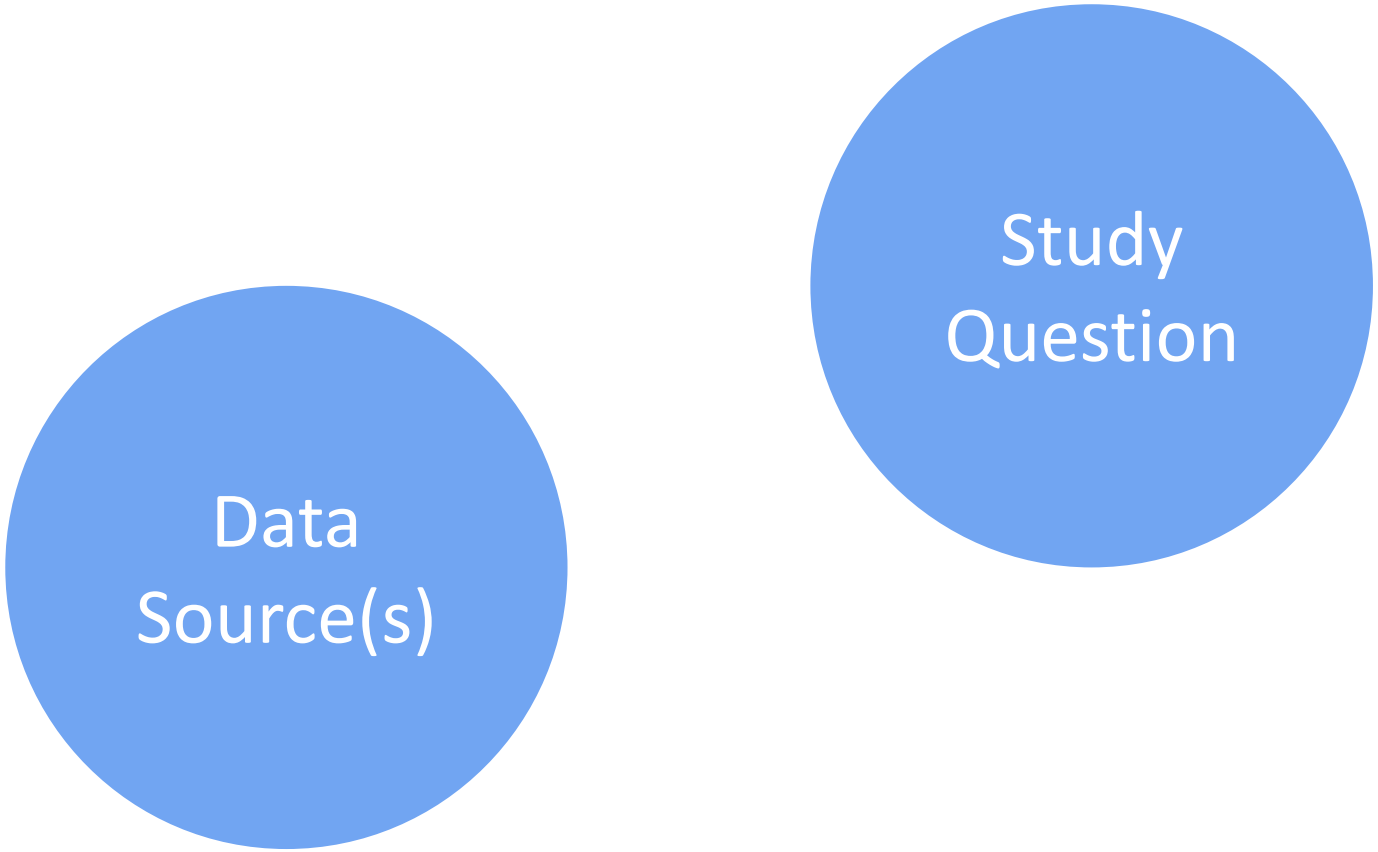
Assessing the RWE Fit for Purpose to the Study Question

Inter-relationship between the Study Question, Data Sources and Research Methods



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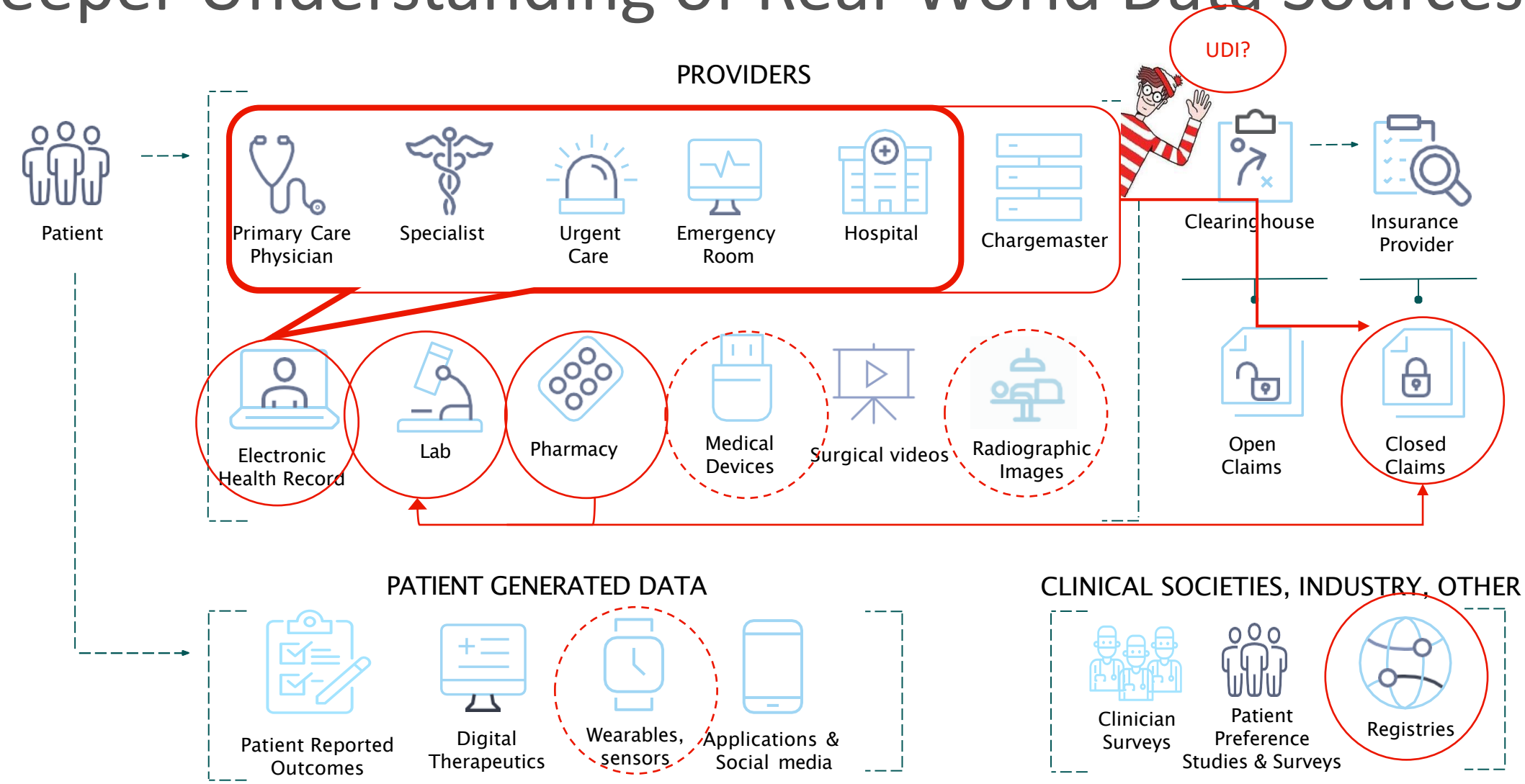
Deeper Understanding of Real-World Data Sources



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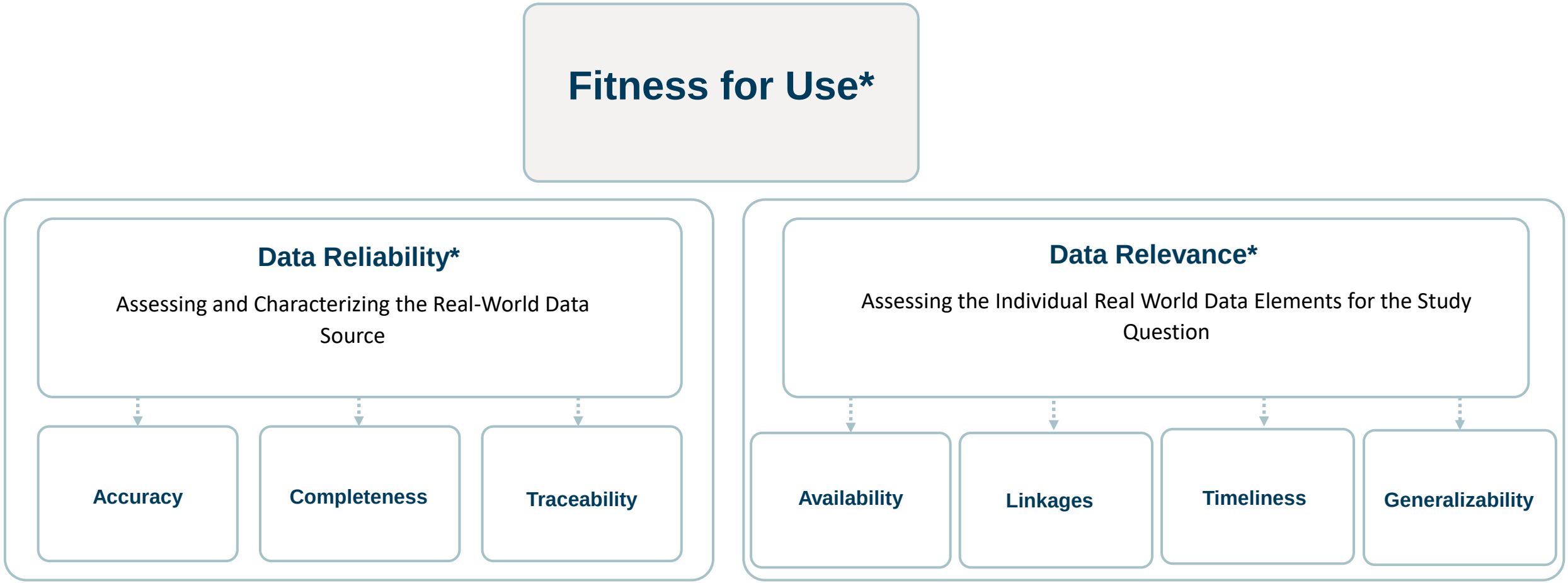
Advances in Evaluating Fit-for-Use of RWD



*Sources:

- DRAFT Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices guidance. FDA 2023. Available at: https://www.fda.gov/media/99447/download; https://www.fda.gov/media/174819/download
- Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products; Draft Guidance for Industry. FDA 2021.

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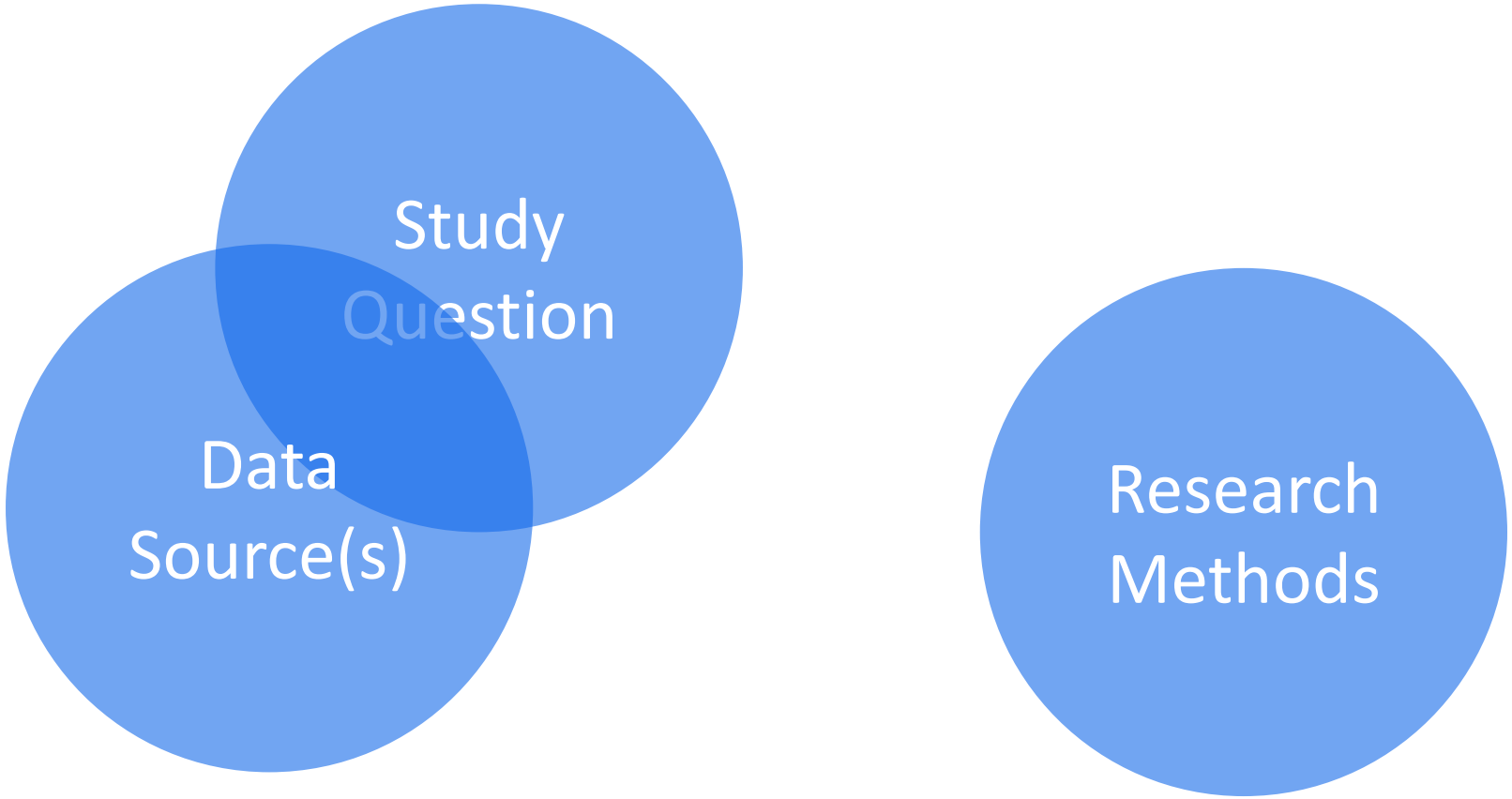

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Advancements in Methods

Data Linkage & Standardization

Bias & Confounding

Research Standardization

Research Transparency

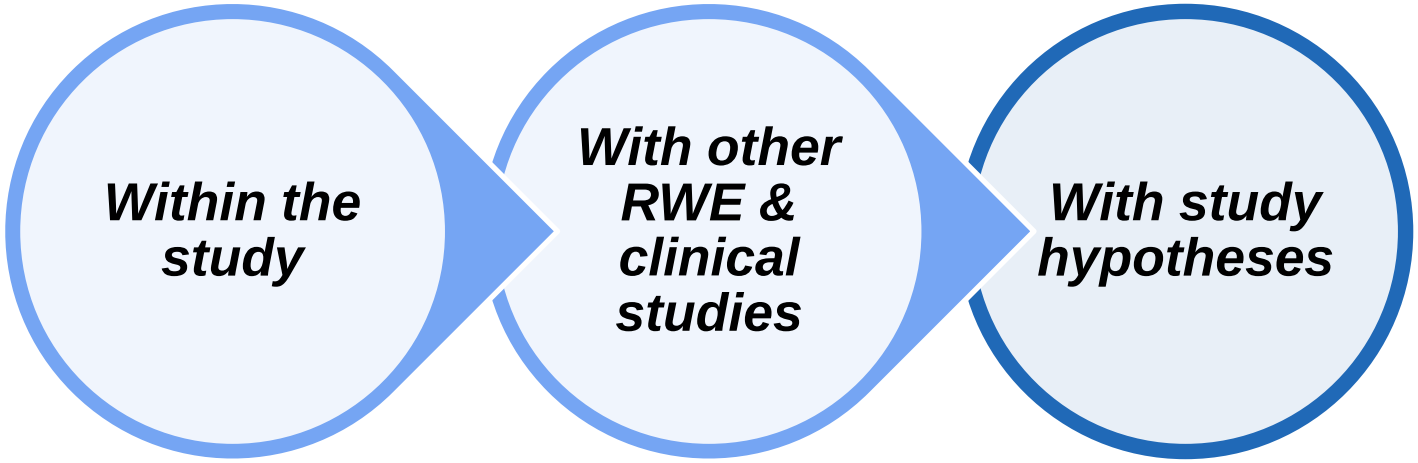
Procedural Guidance

Interpretation of Study Results

Study Strengths and Limitations

- Assess study results in the context of data, study design, and data analysis
  - Sample size and statistical power
  - Potential residual confounding and biases
  - Generalizability

Consistency of Study Results



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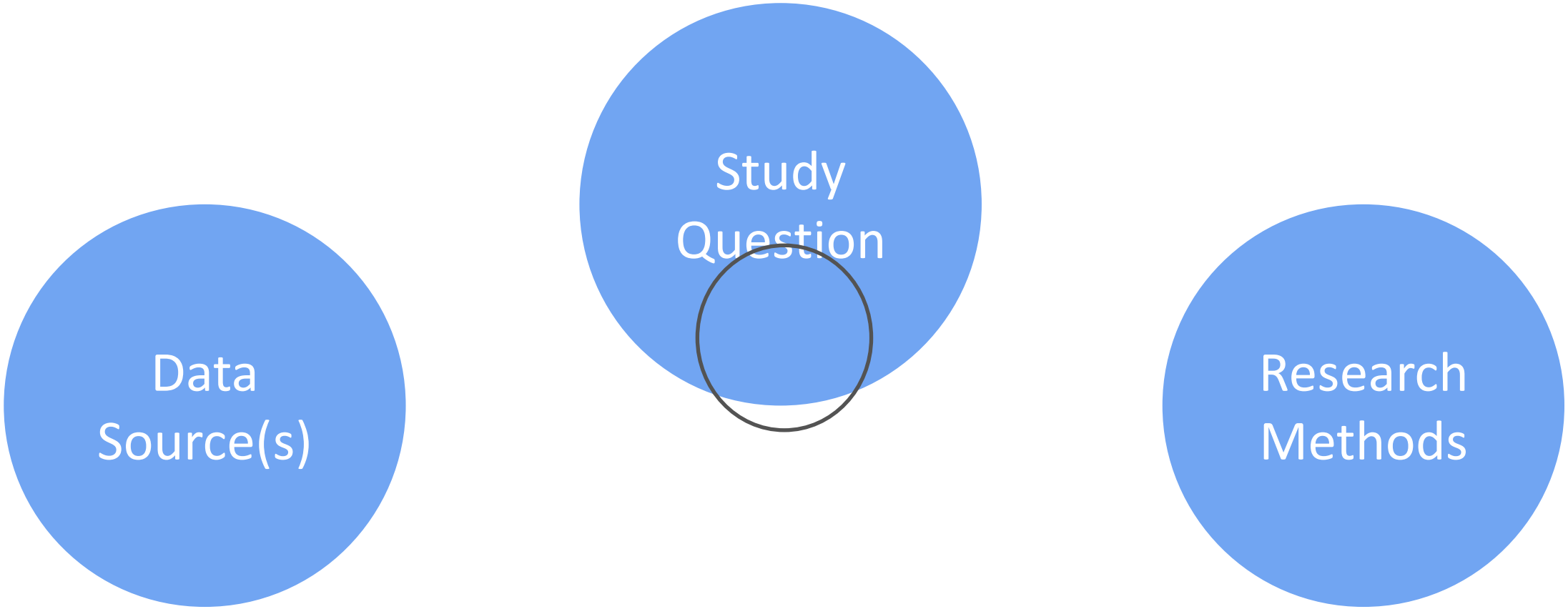

Transparency in Research Practices

Consistent and shared expectations

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Growing Need for Evidence

Evolution of Medical Products

Expanding Sources of Clinical Data & Evidence

Emerging Needs of Decision Makers