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FROM DATA TO IMPACT

TURNING REAL-WORLD DATA INTO REAL-WORLD EVIDENCE

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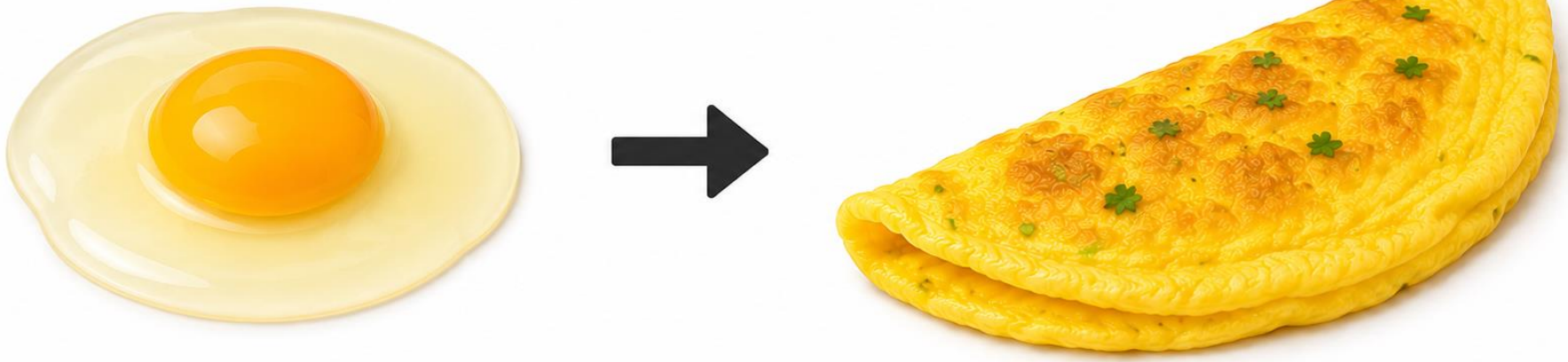
Disclaimer

The content of this presentation reflects solely my own insights and viewpoints and does not necessarily represent the vision, position, or policies of my current employer.



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TURNING REAL-WORLD DATA INTO REAL-WORLD EVIDENCE

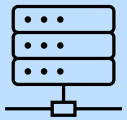
REAL-WORLD DATA

REAL-WORLD EVIDENCE

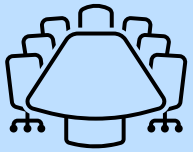
HOW CAN WE TURN REAL-WORLD DATA INTO REAL-WORLD EVIDENCE?

REAL-WORLD DATA IS EVERYWHERE

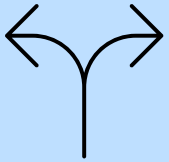
Rapid growth of real-world data sources across industry



Increasing expectations for real-world evidence



Used for decision-making: regulatory, scientific, business



Risk: confusing *data availability* with *evidence generation*

➡ **HAVING DATA IS NOT THE SAME AS HAVING EVIDENCE**

TRANSFORMING REAL-WORLD DATA INTO REAL-WORLD EVIDENCE TO MAKE IMPACT

Data Quality

Appropriate statistical methods

Stakeholder alignment and engagement

Clear narrative around the research questions

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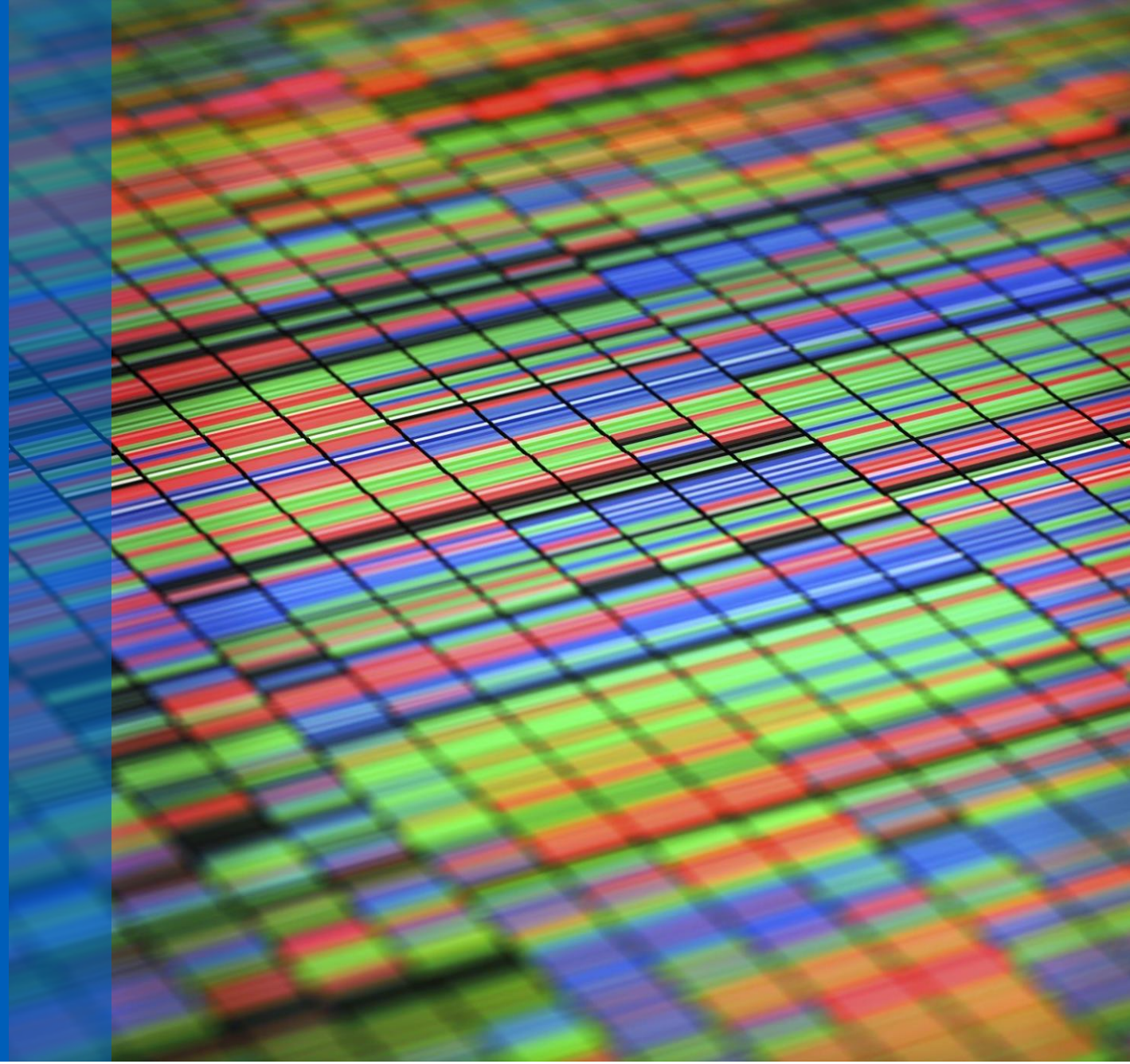
DATA QUALITY



CLINICAL TRIAL DATA

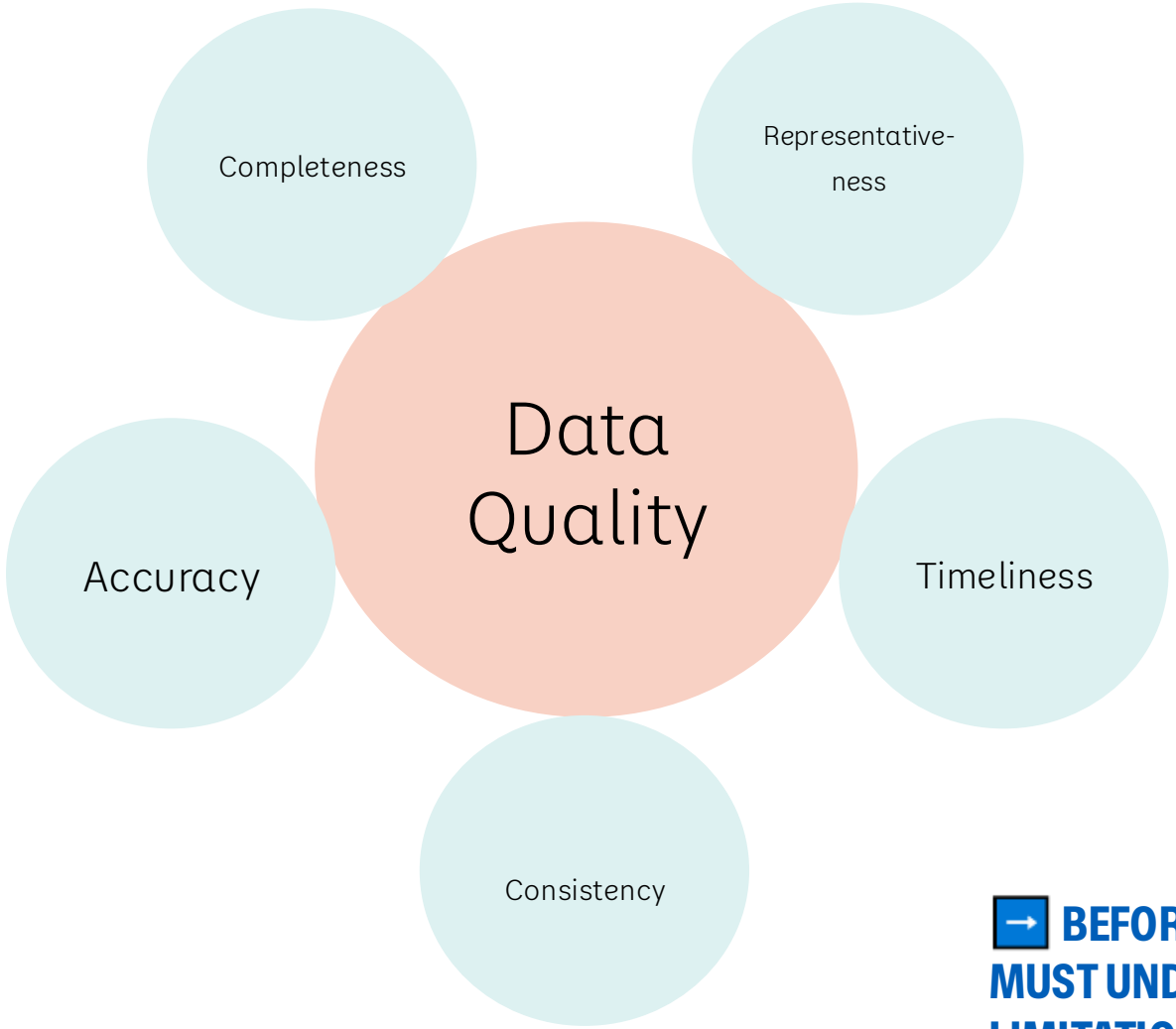
- ✓ Standardized protocols
- ✓ Scheduled measurements
- ✓ Controlled collection
- ✓ High completeness

REAL-WORLD DATA

- ✓ Routine clinical practice
- ✓ Irregular measurements
- ✓ Multiple data sources
- ✓ Missingness common

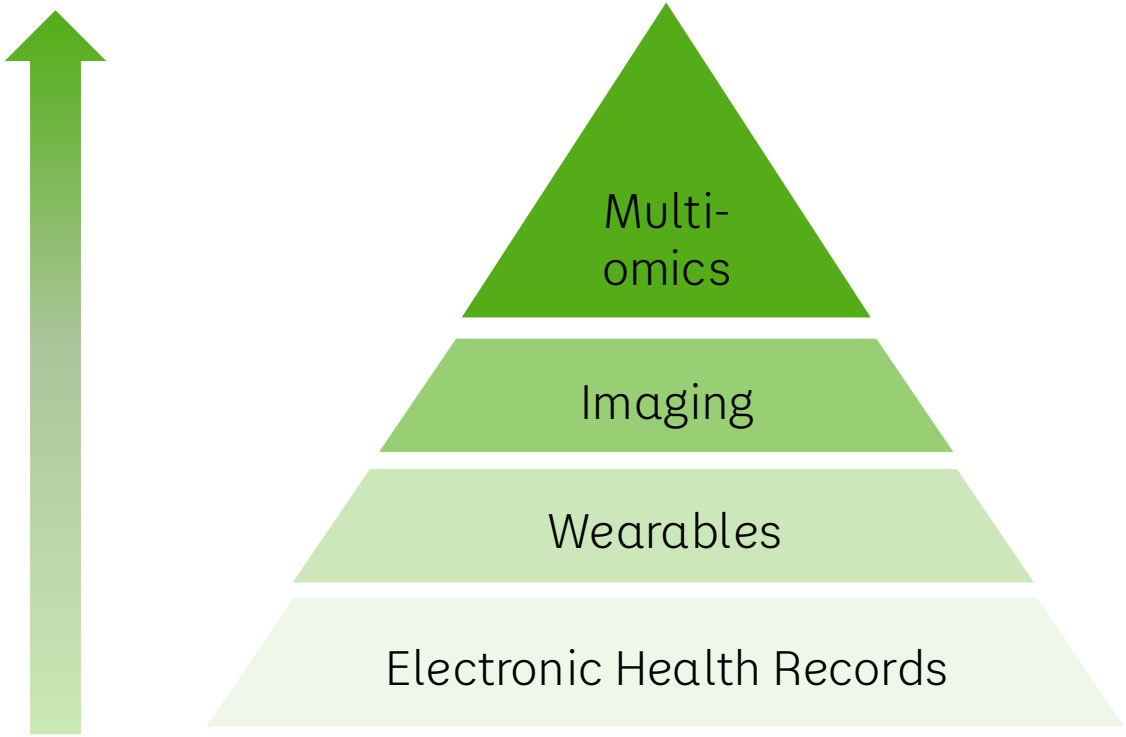
➡ **REAL-WORLD EVIDENCE CAN ONLY BE AS RELIABLE AS THE UNDERLYING REAL-WORLD DATA.**

ASSESSING DATA QUALITY



➡ **BEFORE ANALYZING OUTCOMES, WE MUST UNDERSTAND THE STRENGTHS AND LIMITATIONS OF THE DATA-GENERATING PROCESS.**

Data Volume
Complexity
Processing requirements



➡ **ADVANCED DATA SOURCES OFFER UNPRECEDENTED OPPORTUNITIES, BUT ONLY IF DATA QUALITY AND PREPROCESSING ARE HANDLED RIGOROUSLY.**

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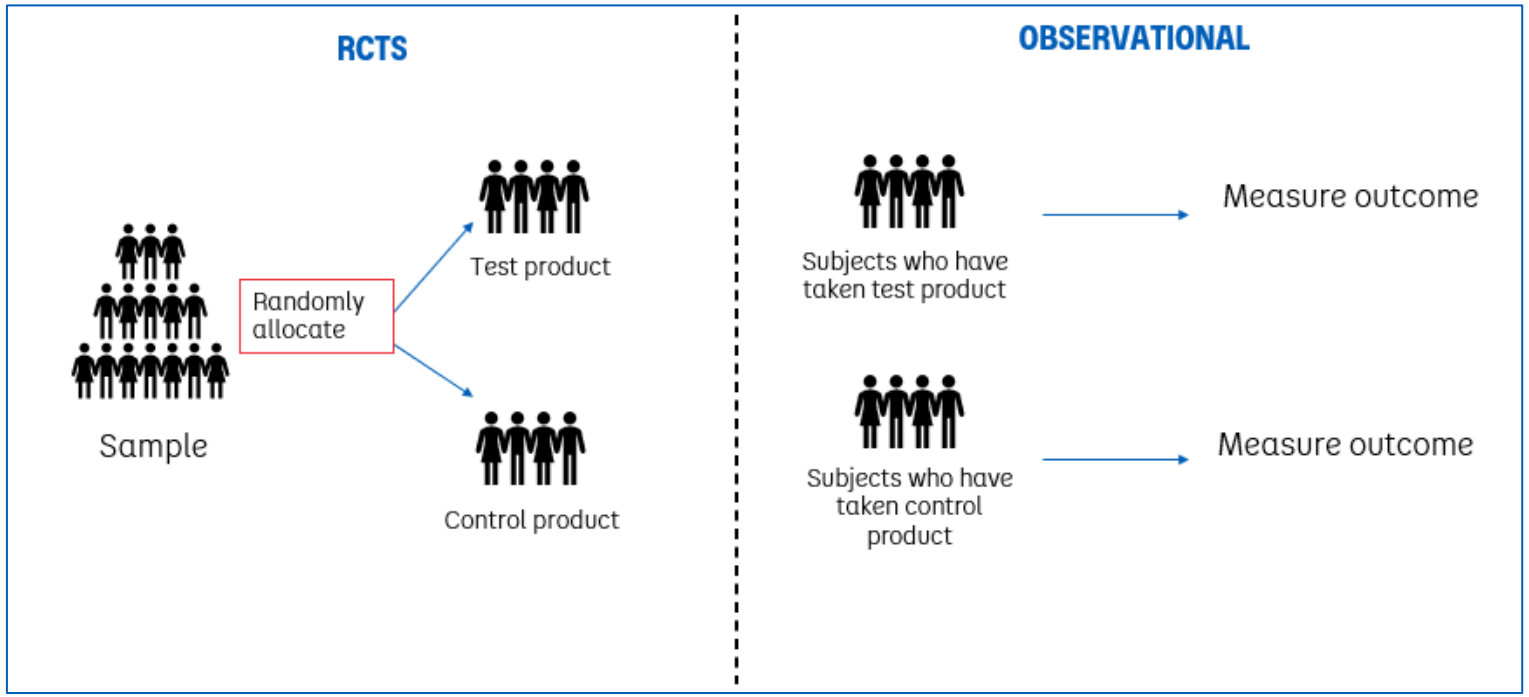
APPROPRIATE STATISTICAL METHODS

RISK OF CONFOUNDING



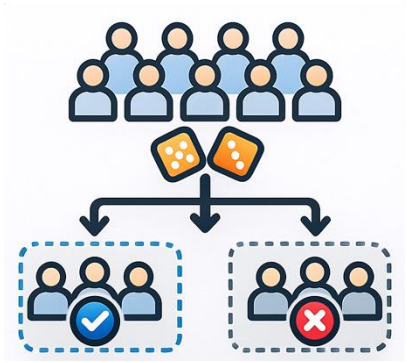
REAL-WORLD EVIDENCE

- Obtained from real-world data
- Real-World Data → Observational
- Risk of confounding bias

TARGET TRIAL EMULATION

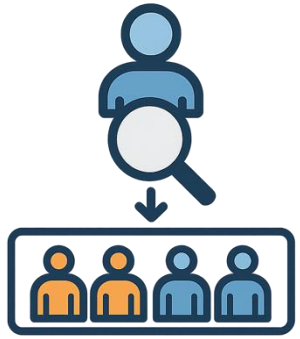
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA U.S. FOOD & DRUG ADMINISTRATION



Randomized controlled trial

Emulate



Observational study

Emulate ideal RCT with observational data

Target Trial Emulation Framework

Define the ideal RCT

Specify population, interventions, outcomes, and follow-up.

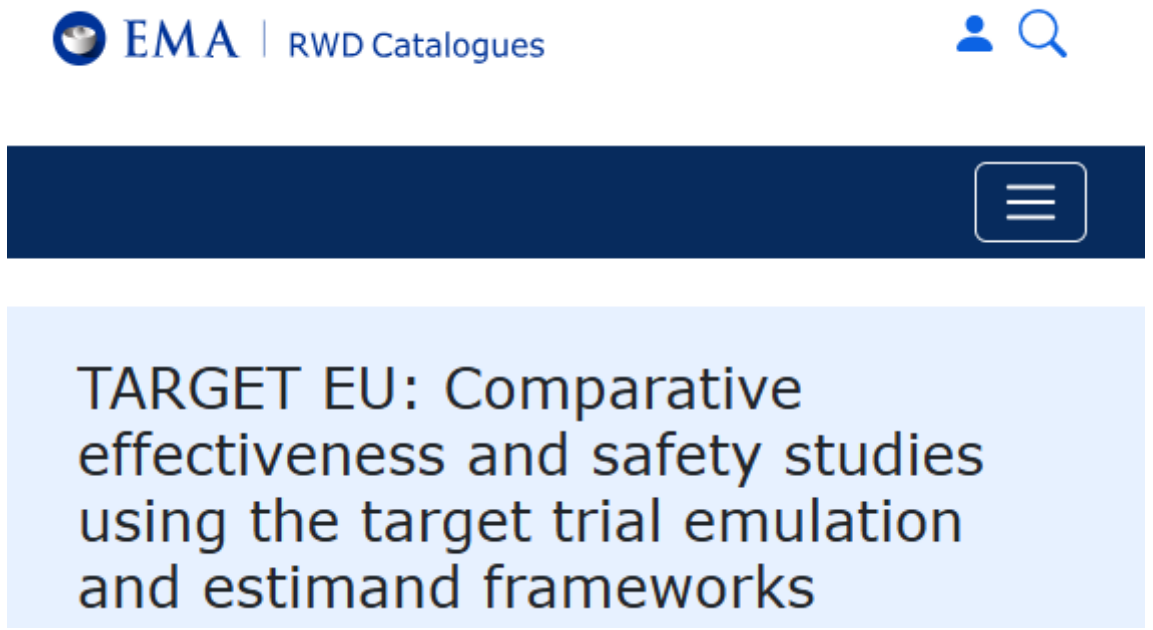
Replicate with non-randomized data

Align conditions and procedures to the target trial.

Apply causal inference methods

Estimate intervention effects and address biases.

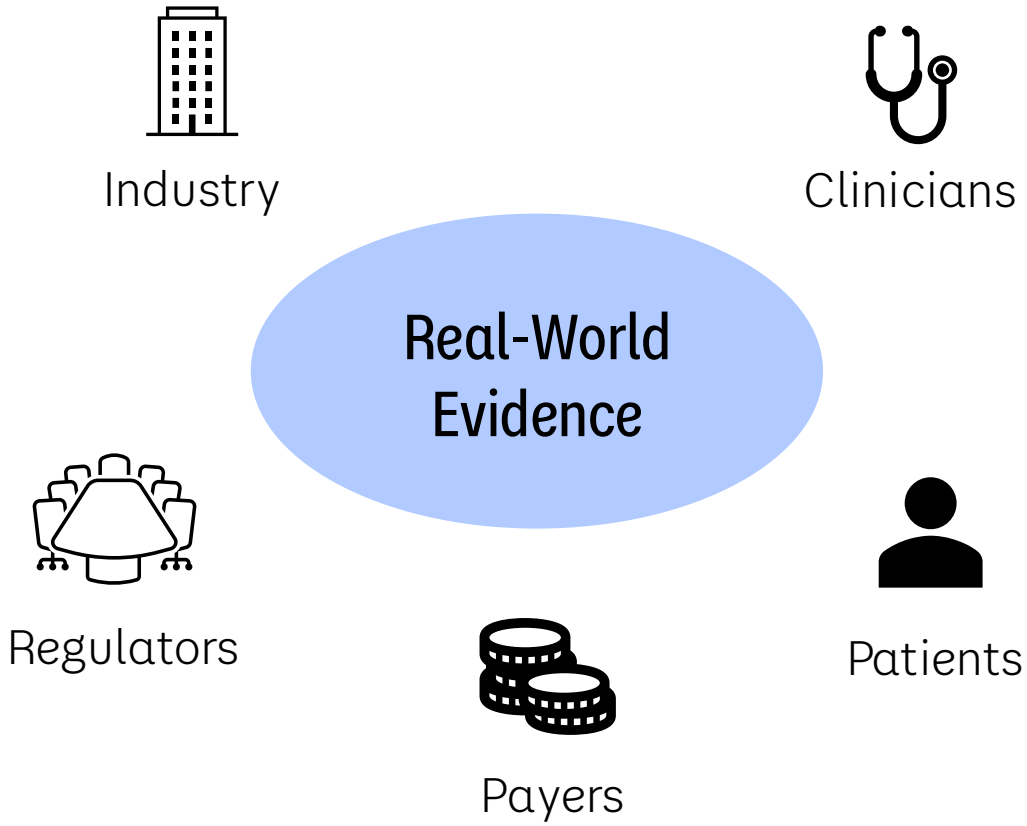
- **EMA flagship on target trial emulation (TTE)**
  - Embedded in DARWIN EU to test TTE in regulatory settings
  - Moves TTE from concept → real-world regulatory use
- **Bridges RCTs and RWE**
  - Applies when randomized trials are not feasible
  - Positions RWE as a causal alternative
- **Focus on regulatory use cases**
  - External comparator studies
  - Directly relevant for approvals and lifecycle decisions
- **Defines regulatory-grade standards**
  - Integrates TTE + Estimands + reporting guidance
  - Builds credibility and acceptance of RWE



STAKEHOLDER ALIGNMENT & ENGAGEMENT

IF WE WANT TO MAKE IMPACT, WE MUST DEFINE FOR WHOM AND IN WHAT CONTEXT WE WANT TO MAKE IMPACT

Generating evidence that stakeholders care about



➡ **DIFFERENT STAKEHOLDERS ASK DIFFERENT QUESTIONS, BUT ALL RELY ON THE SAME EVIDENCE.**

STAKEHOLDER ALIGNMENT DRIVES SCIENTIFIC AND BUSINESS VALUE

SCIENTIFIC VALUE

- ✓ More relevant research questions
- ✓ Better interpretation of results
- ✓ Greater likelihood of influencing practice

BUSINESS VALUE

- ✓ Reduces risk of generating evidence that nobody uses
- ✓ Supports market access discussions
- ✓ Accelerates evidence generation for strategic decisions

→ **WITHOUT STAKEHOLDER ALIGNMENT, ORGANIZATIONS RISK PRODUCING HIGH-QUALITY EVIDENCE WITH LIMITED REAL-WORLD IMPACT**

JUST BECAUSE THERE'S A LOT OF DATA TO GENERATE EVIDENCE FROM, DOESN'T MEAN WE ALWAYS SHOULD

NARRATIVE AROUND RESEARCH QUESTION

START WITH THE QUESTION, NOT THE DATA

CLINICAL TRIALS

- ✓ Research question defined first
- ✓ Data collection specifically to answer that question
- ✓ Measurements planned prospectively

REAL-WORLD DATA

- ✓ Data already available
- ✓ Multiple possible analyses
- ✓ Risk of “fishing” for interesting findings

→ **CLINICAL TRIALS ARE DESIGNED AROUND A RESEARCH QUESTION. REAL-WORLD DATA ALREADY EXIST, MAKING IT TEMPTING TO START WITH THE DATA INSTEAD.**

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BEGIN WITH THE END IN MIND

📊 Dataset

📈 Analysis

📄 Results

❓ Why does it matter?

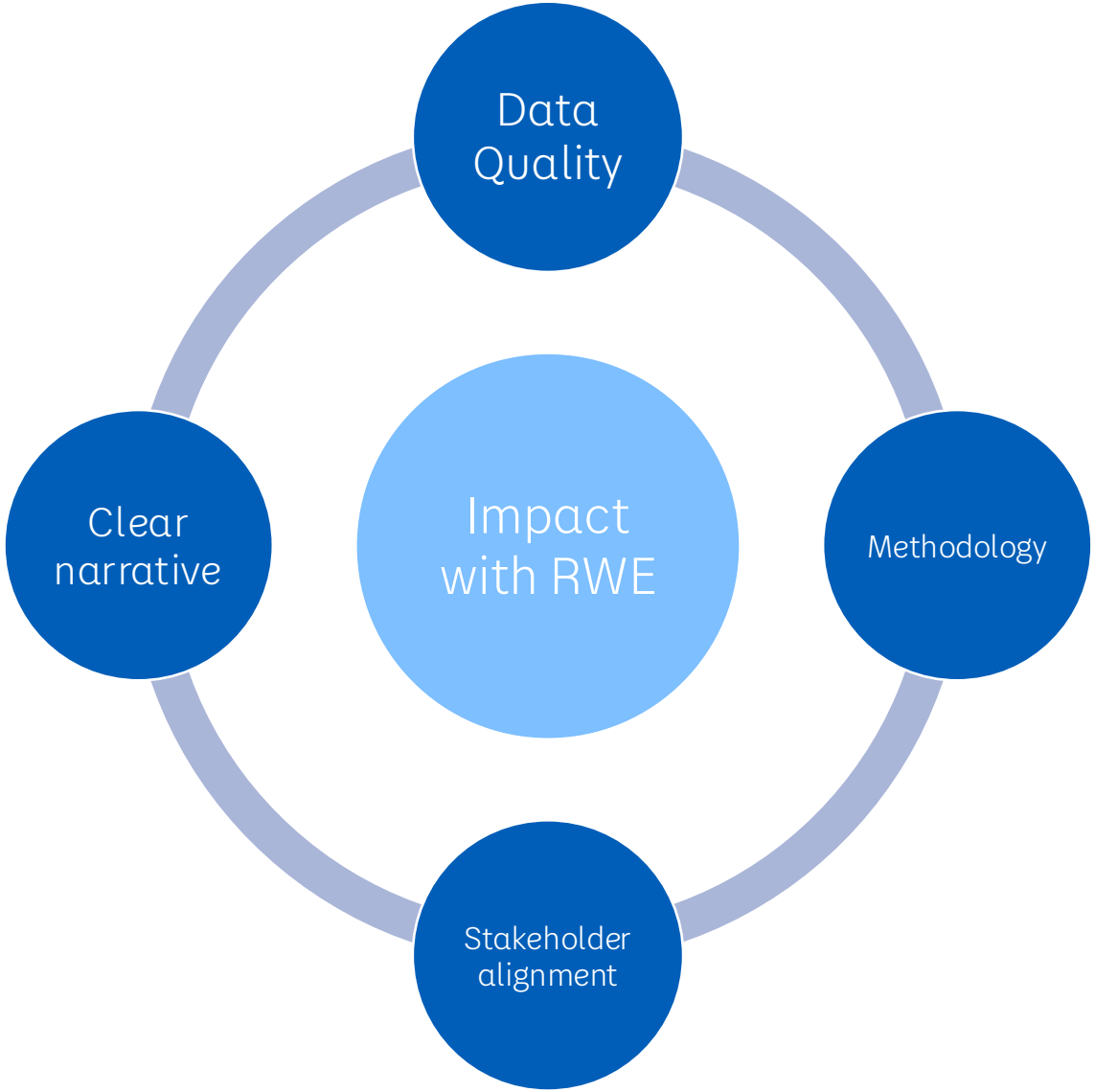
👥 Who does it affect?

🎯 What decision does it inform?

➡️ Impact

THE GOAL OF RWE IS NOT TO TELL A STORY ABOUT THE DATA. IT IS TO USE DATA TO TELL A STORY ABOUT THE REAL WORLD.

IN SUMMARY


Data Quality
Clear narrative
Impact with RWE
Methodology
Stakeholder alignment

IMPACT DOES NOT COME FROM DATA

IMPACT COMES FROM TRANSFORMING HIGH-QUALITY DATA INTO EVIDENCE THAT INFORMS REAL-WORLD DECISIONS.

THANK YOU

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