



RWE & The Global Research Landscape

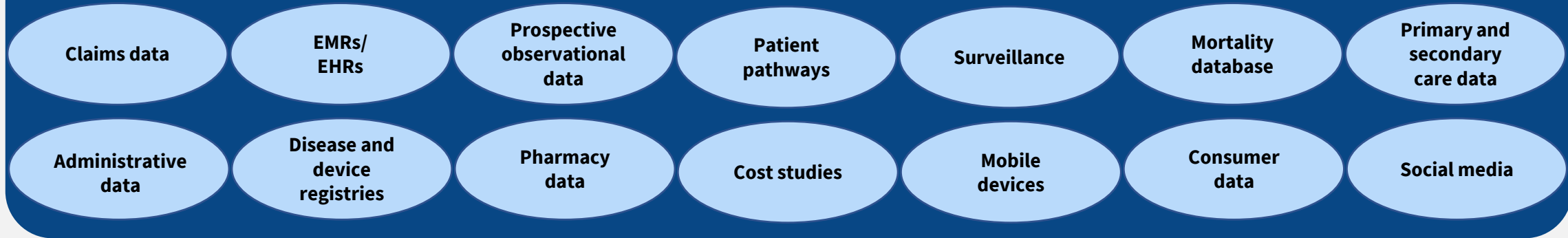
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Our Future Health

Get Real Institute
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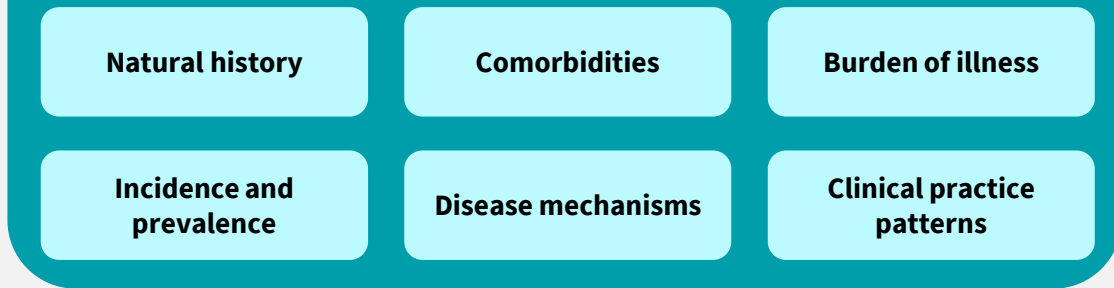


What is and why do we use RWE in healthcare?

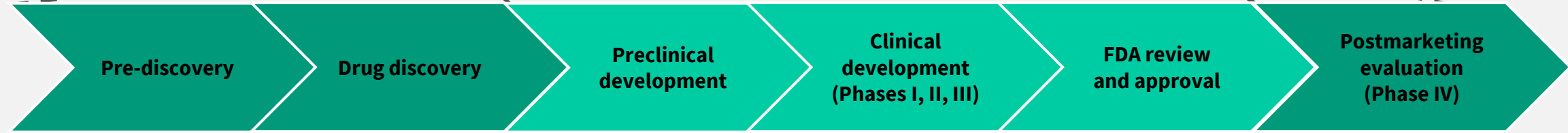
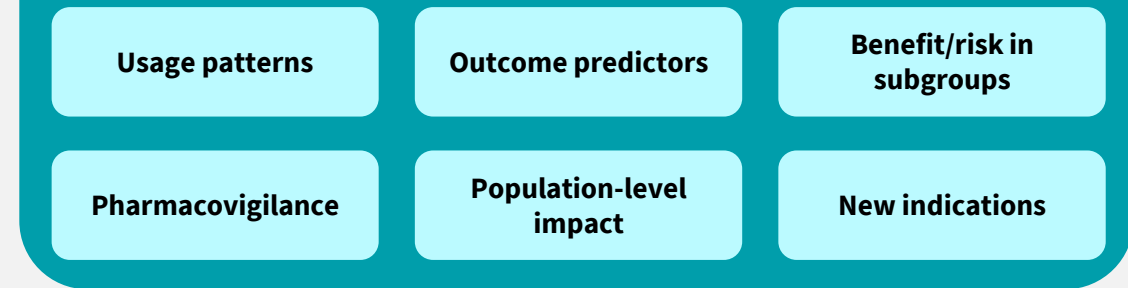
Real-world data sources



Real-world evidence Identifying unmet needs



Real-world evidence Informing clinical and policy decisions



EHR, electronic health record; EMR, electronic medical record; FDA, Food and Drugs Administration.
Adapted from National Academies of Sciences (2017). Real-World Evidence Generation and Evaluation of Therapeutics: Proceedings of a Workshop.
National Academies Press: Washington DC.

Who is using RWE?

Manufacturers

From identifying unmet needs to clinical trials optimization to market access and pharmacovigilance, the industry actors are high "consumers" of RWE.



Healthcare providers

They gain the ability to "augment" their intelligence on patient profiles, diagnosis, treatment pathway and potential adverse events. They are able to leverage more efficient clinical decisions through evidence-based methodologies and systems.



Patients

As an integral participant to their own healthcare, patients will benefit from more data openness and availability enabling next-generation healthcare such as "personalized medicine."

Regulators

FDA and EMA use the data traditionally for post-market safety and benefit/risk studies. FDA with the 21st Century Act clearly puts RWE as a key enabler for regulatory decisions and market approvals.



Payers

They can manage cost of care and good usage. RWE also enables insights and decisions for personalized reimbursement models based on usage, value and outcome.



Has RWE achieved its promise?

In the past 10 + years there have been many advances

- Guidelines

- Large Scale Demonstration Projects

- Use of RWE in “novel” situations and novel commercial deals

- Greater acceptability and use among payers compared to regulators

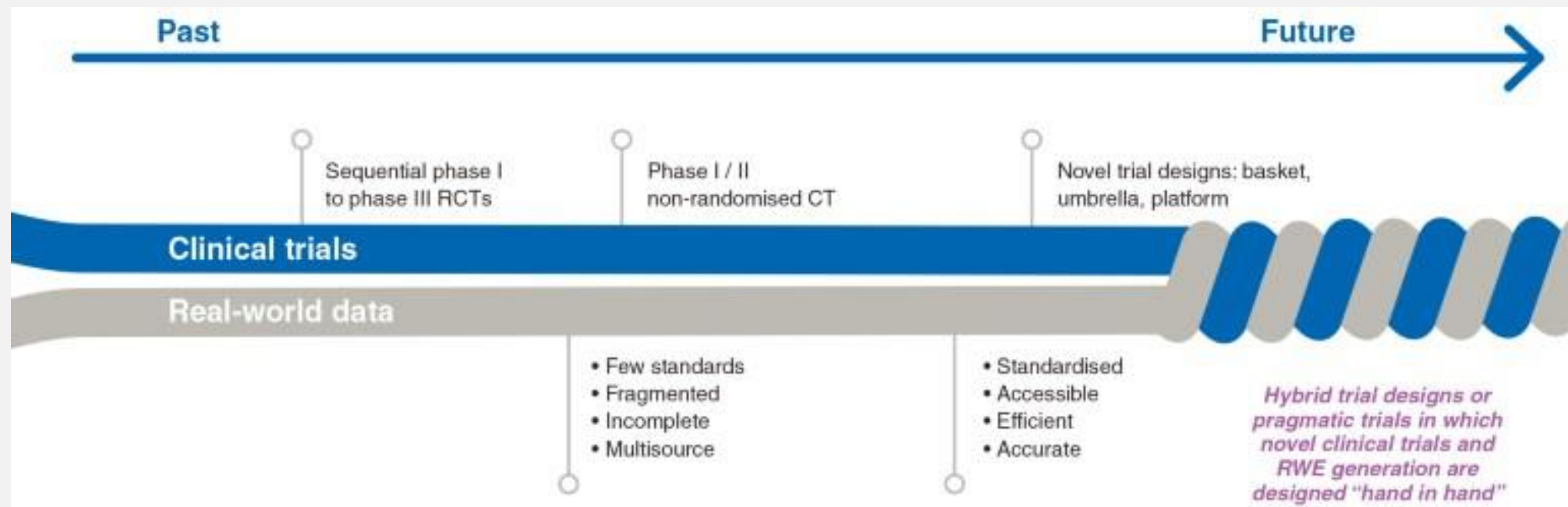
However

- Demonstrable improvement to healthcare has been slow

- Considerable variation across geographies

- Generalisability remains a challenge

An ever evolving evidence generation process



What are the priorities for the future?

