

Advancing the Use of Registry Data to Improve Health Technology Assessment and Payer Evidence


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**Climbing the
mountain: tackling
challenges with
real-life cases**

**Base camp:
understanding
registries and
traditional uses**

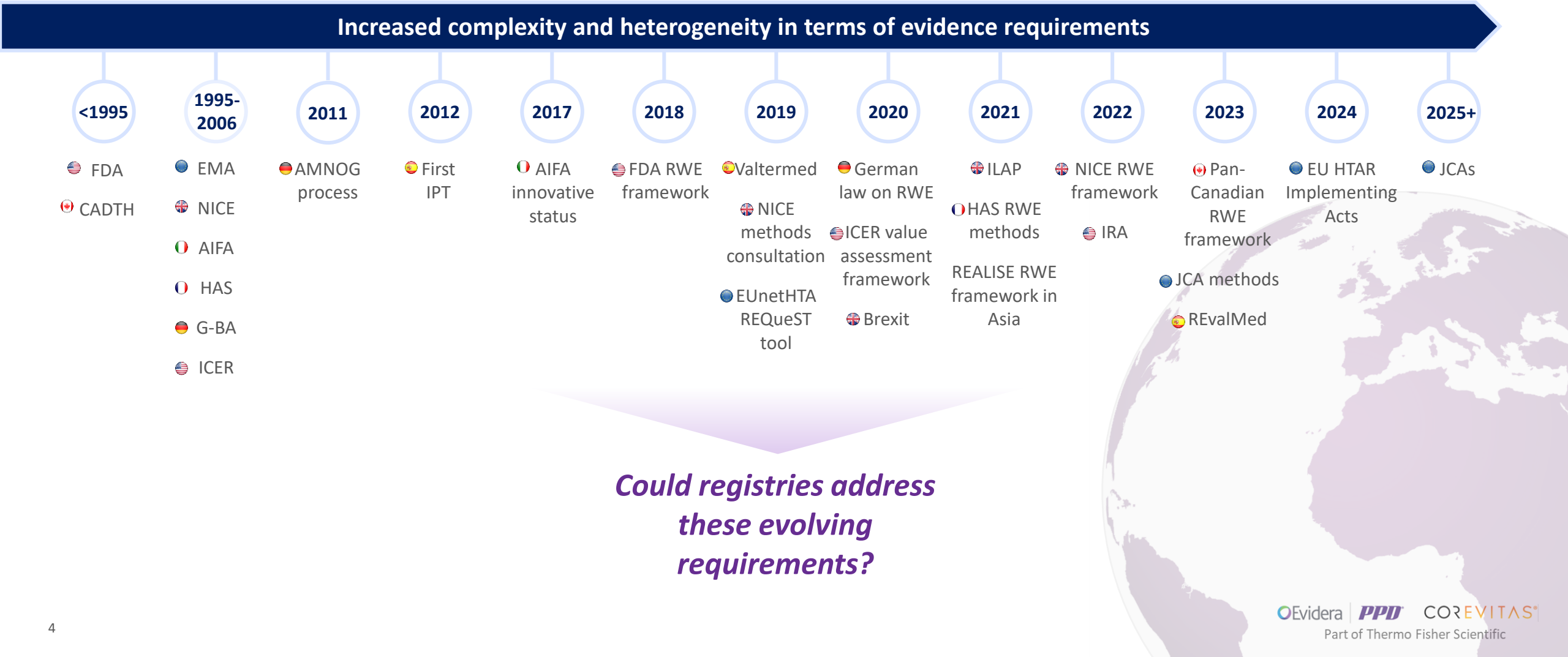
**Our journey's end:
recommendations
for strategic uses**



Base camp: understanding registries and traditional uses

Why are we here today? Evidence requirements have evolved, which prompts a fresh look at the ability of registries to solve them

Key global events



Let's take a step back for now – what are registries and how have they been traditionally used for data generation?

Organized systems that prospectively collect clinical and other data in a standardized format, at regular intervals, for an open cohort of subjects that may be defined by a particular disease, disorder, condition, risk factor, genomic feature, or exposure

FOCUS



TRADITIONAL USES & OBJECTIVES

Natural history of disease

Treatment patterns and outcomes

Factors influencing prognosis & QOL

Care patterns (disparities, appropriateness of care)

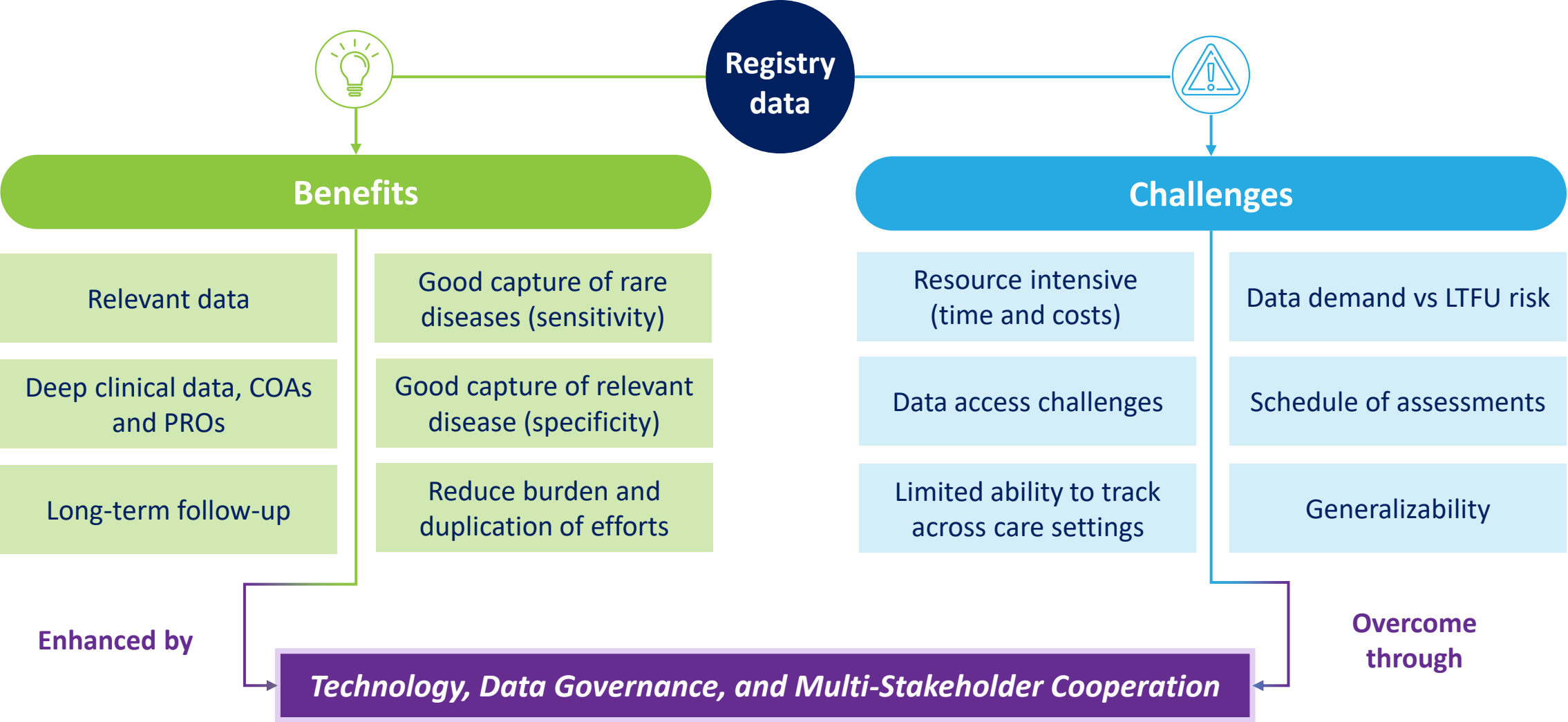
Product effectiveness (current vs new indications)

Safety

Label extension / support approvals

Defend / broaden patient access to product

Use of registry data comes with benefits and challenges, both addressable via technology advances, new data governance policies and multi-stakeholder cooperation





Climbing the mountain: tackling challenges with real-life cases

We have seen a shift in how registry data are used, especially for innovative health technologies, to address uncertainties in the evidence and support patient access

Increased use of registry data by HTA and payer bodies

Strengthening evidence for HTAs

Use of registry data to describe symptoms and financial concerns
(idecabtagene vicleucel)



Use of registries to define outcomes with SOC and build indirect comparator arm
(valoctocogene roxaparvovec-rvox)



Managed Entry Agreements

Performance-based agreements based on registries to allow for early access
(tisagenlecleucel)



Establishment of more robust registry systems to allow for these agreements
(Valtermed)



Addressing uncertainties in future

Use real-world evidence to inform long-term safety of a novel type of asset
(voretigene neparvovec-rzyl)



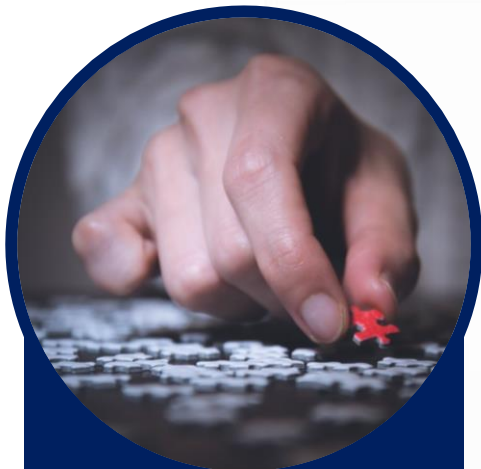
Use of real-world evidence from registries to address initial uncertainties
(lisocabtagene maraleucel)



Innovative health technologies (e.g., ATMPs) have benefited from the use of registry data to enhance patient access despite uncertainties in the data package

NOTE: Information above represent illustrative examples and is not intended to be an exhaustive exhibit of all relevant uses of registry data to support HTA/payer evidence needs

Real-life case study in Rheumatoid Arthritis that illustrates how the use of registries has evolved



Situation

- *Need for robust evidence on safety benefits and cost offsets for lower disease activity states*

Solution

CorEvitas RA Registry
(formerly Corrona)



Medicare
admin & claims data

Population:

Physician-confirmed RA

(Time-varying)

Exposure:

Disease activity measured by CDAI

Outcomes:

- Hospitalizations
- Composite hospitalization or ED visit
- All-cause mortality
- HCRU and costs

Main covariates synthetized into 4 distinct comorbidity groups leveraging combined data from both sources

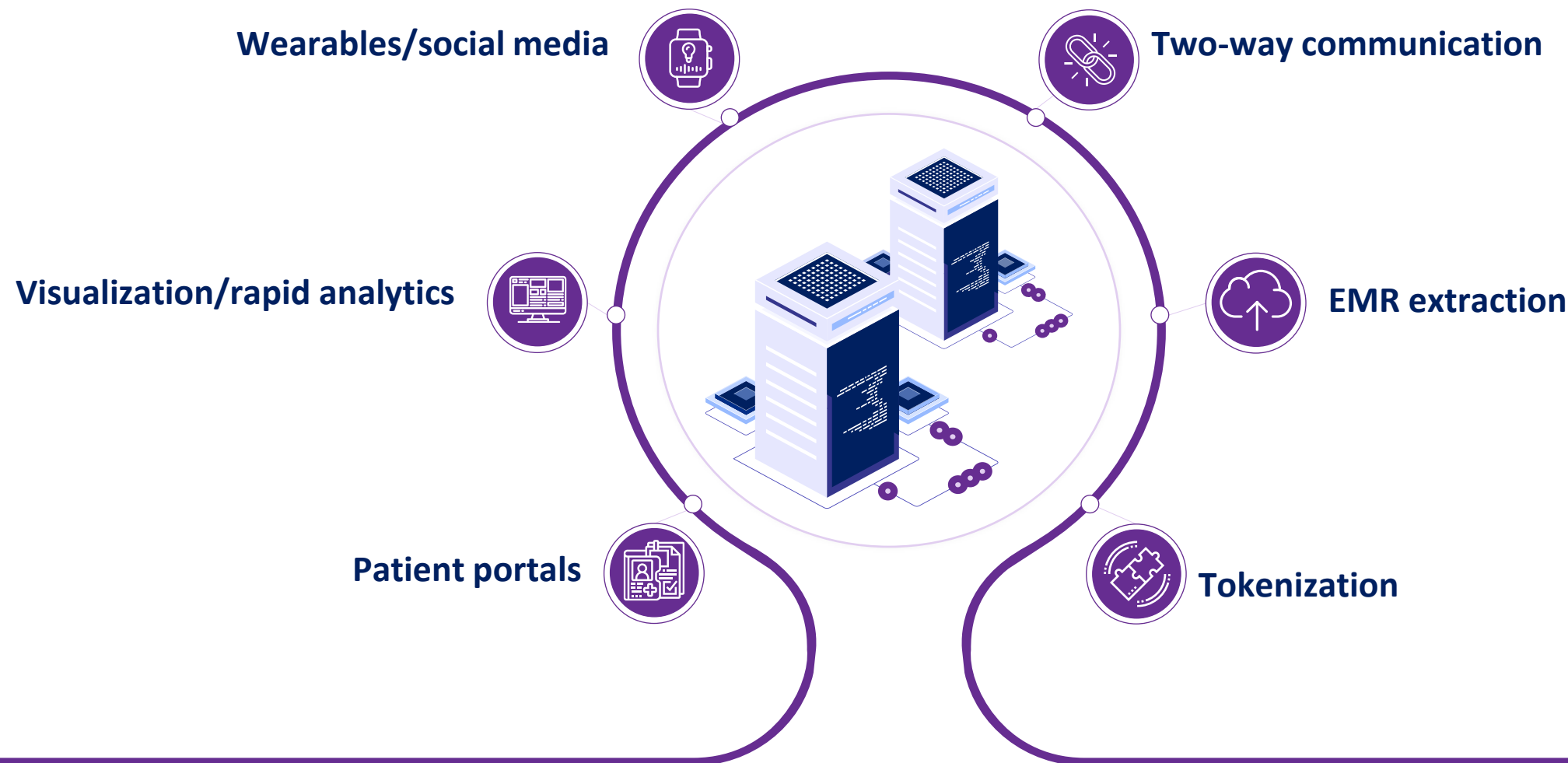
Data science methods to create analytical files followed by regression models

Impact

- *Established relationship between disease activity and incidence of hospitalizations, ED visits, mortality, & direct costs*
- *Incremental cost savings offset cost of additional therapy*



As technology has advanced, so have registry capabilities and the breadth of insights obtainable





Our journey's end: recommendations for strategic uses

So, how can registries help “scale” the HTA/Payer evidence mountain?*

Translate Efficacy into Financial Terms

- Tokenization
- “Map” measures of efficacy to direct/indirect costs to facilitate cost-effectiveness assessments

Indirect & Societal Costs

- Family/caregiver impacts
- Country- & disease-specific

Long-term Effectiveness

- Demonstrate long-term benefit(s)
- Include “patient voice”

Unmet Need/Burden

- Establish need for new tx
- Collect hard-to-obtain info

Expand Indications

- Country-specific solution
- Arguments for new indications

Registry

Registry

Registry

Registry

Registry

However, climbing mountains isn't the easiest thing to do in the world...



Start early

- Earlier plan = faster data generation
- Determine strategic focus
- Initial vs subsequent activities

Buy, build or partner?

- Registries can be expensive, important to plan approach
- If partnering, relationships are key
- Consider automated EMR extraction

Consider tokenization

- Expand registry reach and ability to address relevant questions
- Facilitate data collection (including long-term)
- Currently primarily US-focused, but things are changing

Have a plan

- Consider registries in your integrated evidence generation plan
- Vet with relevant stakeholders (e.g., scientific advice)
- Ensure maximally relevant and impactful data from day one



Any questions?

FAQ

Thank you for your time today



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