CHILMARK RESEARCH

GETTING REAL WITH HEALTHCARE DATA

REAL WORLD DATA AND EVIDENCE ENABLING NEW MODELS OF RESEARCH AND CARE DELIVERY

About Chilmark Research

Helping healthcare leaders make the best decisions for the populations they serve.

Founded in 2007, **Chilmark Research** is a preeminent global research and advisory firm focused exclusively on tracking the market evolution of healthcare information technologies (health IT) and use cases.

Our team is united by the belief that new health IT tools are critical for improving the quality and efficiency of care in a modern world. It is therefore our mission to foster the effective adoption, deployment, and use of these new solutions (and enabled services) through objective, high-quality research into those technologies with the greatest potential to impact care delivery.

This laser-sharp focus allows us to provide our community with the most in-depth, future-forward research on the critical technology and adoption trends occurring throughout the healthcare sector.

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Introduction

What are Real-World Data & Real-World Evidence?

Real-world data (RWD) are data collected from a variety of sources that reflect patient health status and/or the delivery of healthcare in real-world settings. RWD is different from data collected in clinical trials, which is typically collected in a controlled environment and may not reflect real-world treatment patterns and outcomes.

RWD can be collected from various sources, including electronic medical records (EMR), medical claims, product or disease registries, and other sources. EMRs contain patient health information that is entered by healthcare providers during clinical visits, while medical claims data provide information on the medical services and treatments that patients receive and the associated costs. Product or disease registries are databases that track patients with specific medical conditions or who are receiving specific treatments.

What is Real World Evidence?

Real-world evidence (RWE) is clinical evidence that is derived from real-world data (RWD) and provides insights into the usage and potential benefits or risks of a medical product in real-world settings. RWE is different from evidence generated from randomized controlled trials (RCTs), which are typically conducted in a controlled environment and may not reflect real-world treatment patterns and outcomes.

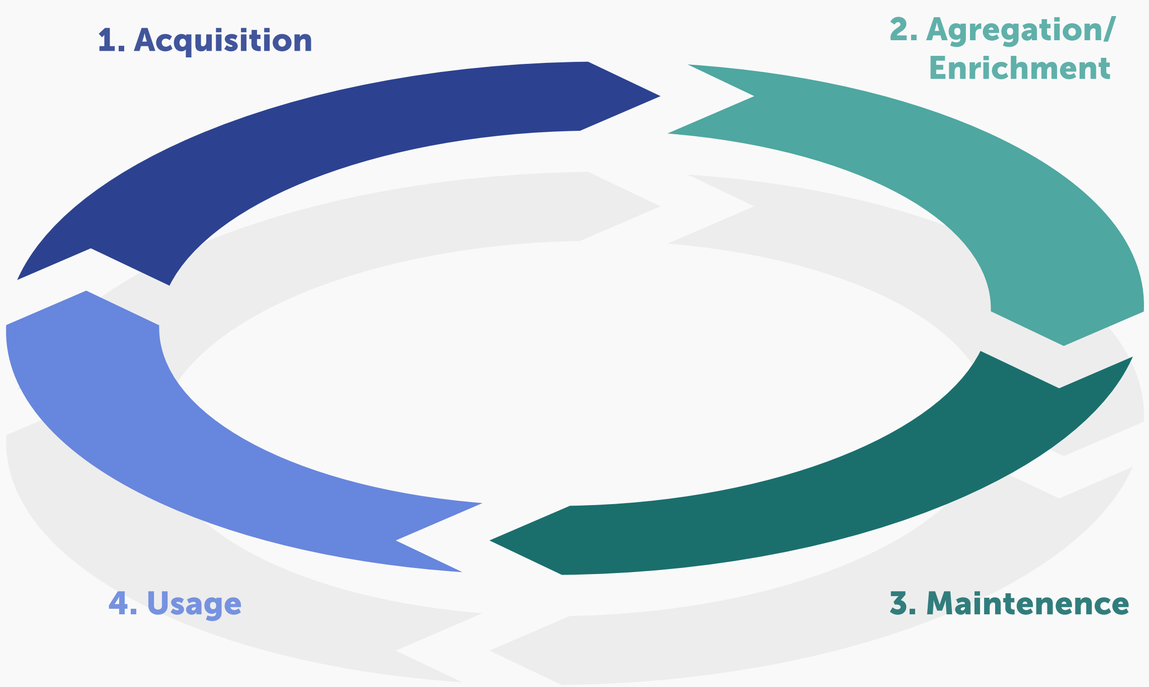
RWE can be generated from various sources of RWD, including electronic medical records, medical claims, product or disease registries, and other sources. By analyzing RWD, researchers can generate RWE that provides insights into how medical products/clinical treatments perform in real-world settings, including the effectiveness and safety of medical products/clinical treatments as well as their patterns of use in different patient populations.

Real World Data and Real-World Evidence Market

Tools and Services for Aggregating, Processing, & Managing RWD and for Generating RWE Insights

Data Sources

- Electronic healthcare records
- Claims and reimbursements
- Observational databases
- Patient or disease registries
- Molecular and "-omics" data
- Patient-derived or medical wearables



Processing Steps

- Linkage of sources
- Abstraction of structured data
- Harmonization to standards
- Transformation
- Unstructured data handling
- Quality assurance
- Integration and mismatch handling

Return Value

- Datasets for observational research
- Datasets for virtual trials
- Analytics and insights for clinical and operational pathways
- Direct insights for patients
- Population health management

Storage Platform

- Partitioning of data
- Distributed computing systems
- On-going quality assurance
- Data security and privacy
- Data access rules

Zhang J, Symons J, Agapow P, Teo JT, Paxton CA, et al. (2022) Best practices in the real-world data life cycle. PLOS Digital Health 1(1): e0000003

Data Sources And Management

Clinical Data: Digitized Health Records

Structured versus Unstructured Data

The HITECH (Health Information Technology for Economic and Clinical Health) Act of 2009, was a part of the American Recovery and Reinvestment Act (ARRA) signed into law by President Obama. The purpose of HITECH was to promote the adoption and meaningful use of electronic health records (EHRs) in healthcare organizations by providing financial incentives to eligible providers. Prior to the HITECH Act, many healthcare organizations relied on paper-based records, which are difficult to manage, prone to errors, and challenging to share between providers. The incentives provided by HITECH encouraged healthcare organizations to invest in EHR systems, which are digital versions of patient health records that can be easily accessed and shared between providers.

As a result of these financial incentives, the adoption of EHRs has increased significantly over the past decade. This has led to a substantial increase in the amount of digitalized health data available, including patient demographics, medical histories, diagnoses, and treatment plans. This availability of digitalized health data has been a key driver of the growth of the Real-World Evidence (RWE) market. Overall, the widespread adoption of electronic medical records has played a crucial role in increasing the availability of digitalized health data and enabling the growth of the RWE market.

However approximately 80% of this data are in unstructured forms and neither easily normalized nor aggregated, limiting the usefulness of the data collected. Examples of unstructured data in healthcare include free-text clinical notes, medical imaging, audio and video recordings, and social media posts related to health.

Data sources

EMR/EHR Data

Digital versions of a patient's medical history, containing information on diagnosis, medications, allergies, immunizations, lab results, and other clinical information. EMRs/EHRs are typically maintained by healthcare providers such as hospitals and clinics, and are designed to support clinical decision-making, improve patient care coordination, and enhance population health management.

EMRs/EHRs offer several advantages, including improved accuracy and completeness of patient data, faster access to patient information, and enhanced patient safety with clinical decision support tools. They also support the efficient exchange of health information between different healthcare providers and care settings, enabling better care coordination and improved patient outcomes.

Drawbacks for EMR/HER data is the large amount of unstructured data (e.g., notes or images). There can also be limited representation of populations as smaller health systems have a limited catchment area.

Data sources

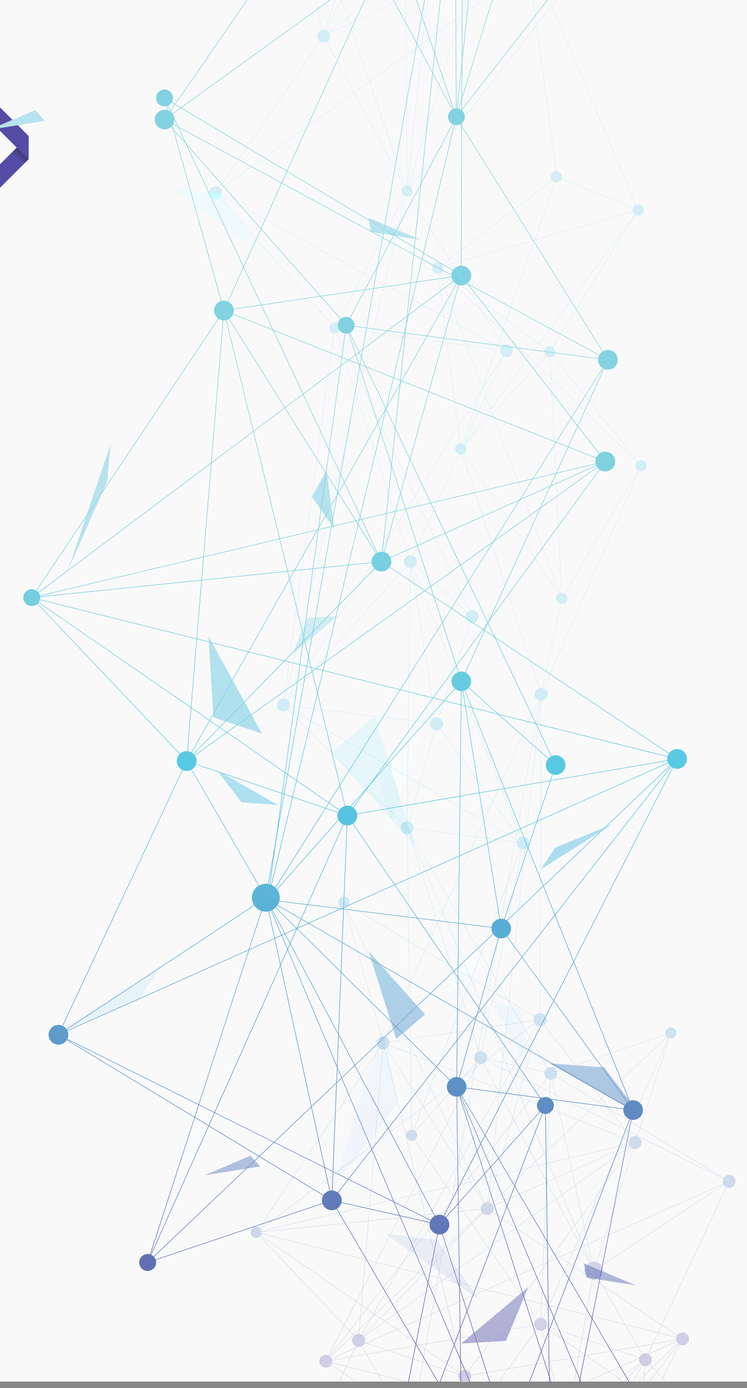
Claims data

Claims data contains detailed information on the services provided, including diagnosis codes, procedure codes, and medication codes, as well as demographic information on the patient. This data can be used to analyze patterns of healthcare utilization, cost, and quality of care, and can provide valuable insights into population health.

Claims data is a rich source of real-world data (RWD) that can be used for a variety of research and healthcare purposes. For example, claims data can be used to identify patient populations with specific health conditions, track healthcare utilization and costs over time, evaluate the effectiveness of treatments and interventions, and support population health initiatives.

Claims data can also be linked with other sources of data, such as EMR/EHR or patient-generated health data (PGHD), to provide a more comprehensive picture of patient health and outcomes.

However, there are limitations that need to be considered when using claims as a source of RWD. The data does not capture all aspects of a patient's health or healthcare utilization, particularly for services that are not reimbursed through insurance or for patients who are uninsured. Claims data also may not capture important clinical details or context that are necessary for some research questions, such as patient preferences or treatment adherence.



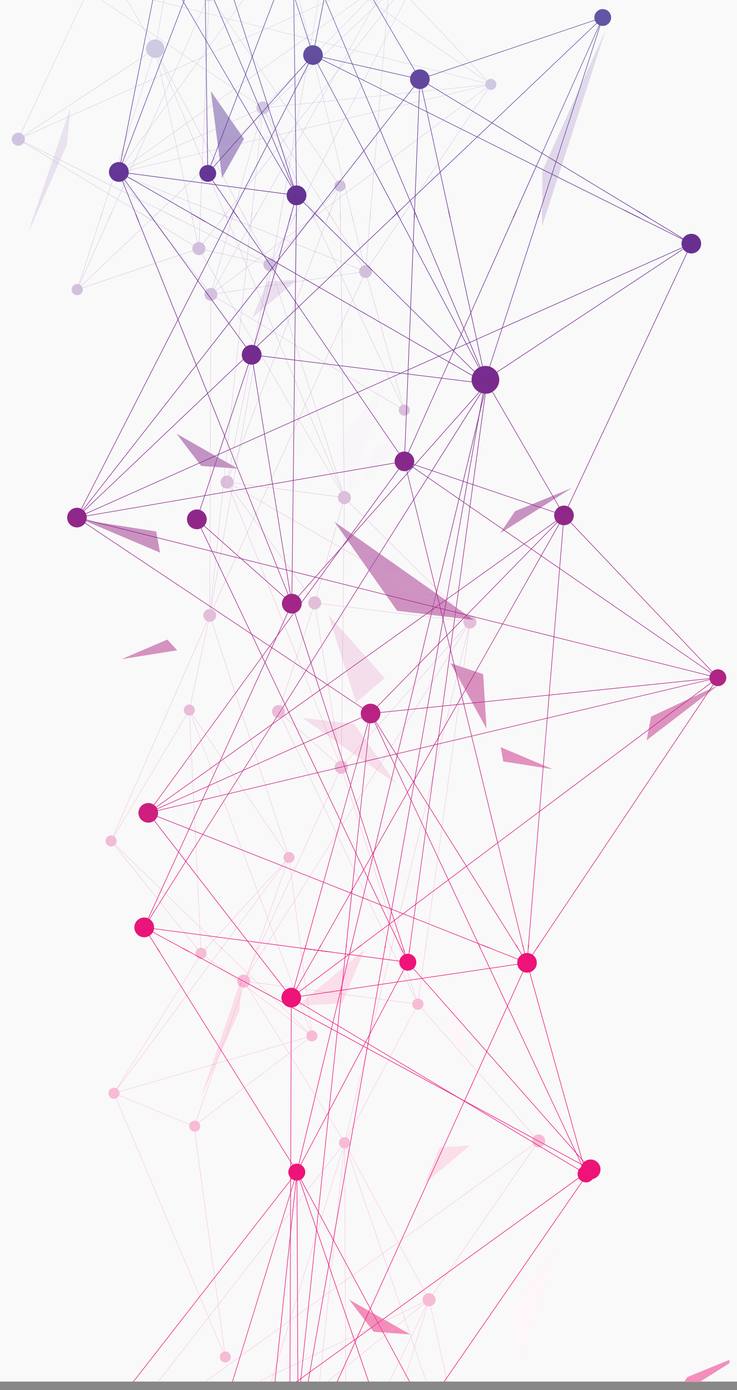
Data sources

Patient Generated Data

Patient generated data can include a wide range of data types, such as self-reported symptoms, biometric data (e.g. blood pressure or heart rate), and information from wearable devices such as fitness trackers or smartwatches.

Patient generated data is an increasingly important source of real-world data (RWD) in healthcare, as it can provide valuable insights into patient behavior, preferences, and outcomes. Collecting data directly from patients can help to fill gaps in traditional healthcare data sources, such as EMRS/EHRs or claims data, and provide a more comprehensive view of patient health and wellbeing. It can also support patient engagement and empowerment by giving patients greater control over their health data and enabling them to take an active role in their care.

However, there are also challenges associated with using it as a source of RWD. These include concerns around data quality and accuracy, as well as the need to ensure that patients are able to access and use the technology needed to generate and share their health data. Additionally, there are important ethical and privacy considerations that need to be addressed when collecting and using patient generated data. Despite these challenges, this type of data are likely to play an increasingly important role in the future of healthcare.



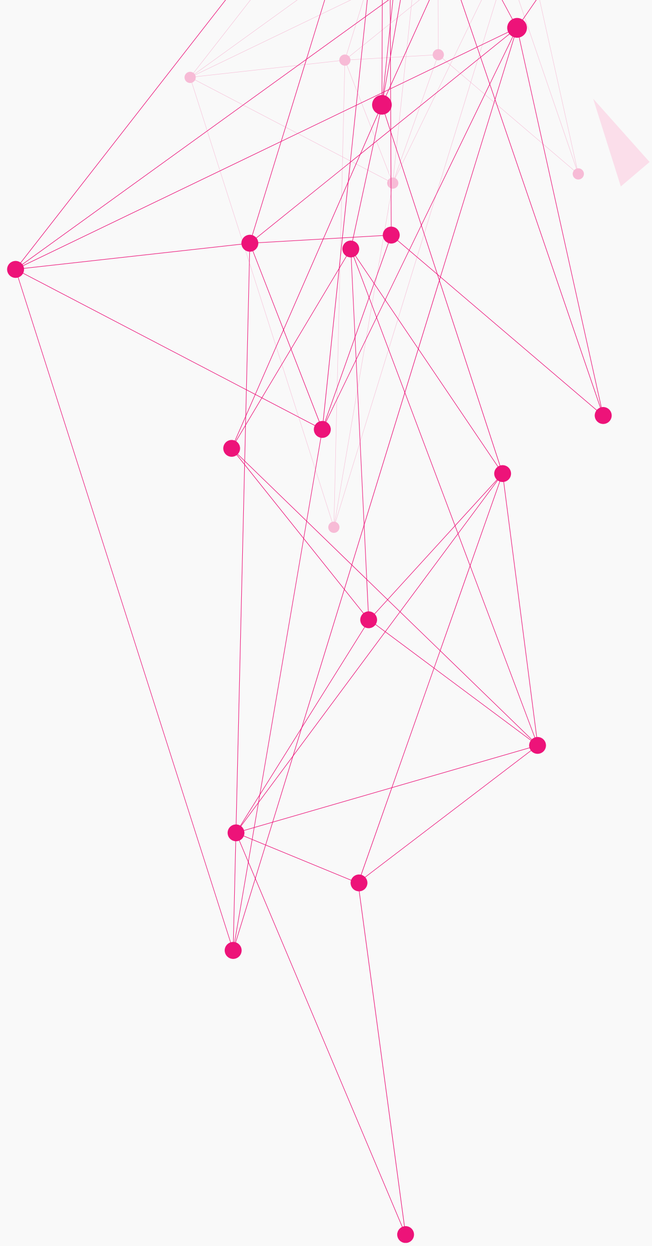
Data sources

Registries data

Registries are specialized databases that collect information on specific diseases, medical devices, or treatments. These databases are often created and maintained by professional medical societies or advocacy groups, and may contain detailed clinical and demographic information on patients with a particular condition or who have undergone a specific treatment.

Registry data can be particularly valuable for RWE studies, as they often provide a rich source of longitudinal data on patient outcomes, including both clinical and patient-reported outcomes. Additionally, registry data can help researchers identify patients who may be eligible for clinical trials or other research studies, and can provide insight into how specific patient populations respond to different treatments. Registry data can be a valuable tool for researchers looking to study specific patient populations or conditions, and can help provide a more complete understanding of how different treatments and interventions impact patient outcomes in the real world. Examples of registry databases include SEER data from the National Cancer Institute or the American College of Cardiology's National Cardiovascular Data Registry.

Drawbacks of these data are that it is collected for a specific purpose or population, and may not be representative of the broader patient population. Also, there is some selection bias, as patients who choose to participate may differ in important ways from those who do not participate. Both of these drawbacks can lead to results that are not generalizable to the general population.



Data sources

Clinical Trials

Clinical trials provide a controlled environment for collecting data on the safety and efficacy of new treatments or interventions, and can help to establish a baseline for comparison with real-world outcomes. One benefit of using clinical trial data as RWE is that it can help to address some of the limitations of observational studies, such as confounding by indication or selection bias. By collecting detailed data on patient characteristics and outcomes in a controlled environment, clinical trials can help to control for some of the factors that may influence treatment outcomes in the real world.

However, there are also some limitations to using clinical trial data as RWE. First, clinical trials may not be representative of the broader patient population, as they often have strict inclusion and exclusion criteria and may only enroll a small subset of the patient population. This can limit the generalizability of study results and make it difficult to draw broader conclusions about the effectiveness of treatments or interventions in the real world.

Additionally, clinical trial data may not reflect real-world treatment patterns or outcomes, as patients in clinical trials may receive more intensive monitoring or follow-up than patients in routine clinical practice. This can limit the external validity of study results and make it difficult to draw conclusions about the effectiveness of treatments or interventions in the real world.

Finally, clinical trial data may be subject to publication bias, as studies with positive results are more likely to be published than studies with negative results. This can limit the generalizability of study results and make it difficult to draw conclusions about the overall effectiveness of treatments or interventions.

Why Real World Data and Real World Evidence?

Why Real World Data and Real World Evidence?

Drug Development/Life Sciences

Real-world data (RWD) and real-world evidence (RWE) have become increasingly important in the healthcare industry in recent years. Companies can benefit from using RWD and RWE in a number of ways:

Supporting drug development: RWD and RWE can provide valuable insights into patient populations, disease patterns, and treatment outcomes that can inform drug development and improve the efficiency of clinical trials.

Identifying patient populations

RWD can help identify patient populations for clinical trials. For example, to identify patients with a certain condition or a specific genetic profile, which can help target patient recruitment efforts for clinical trials.

Improving trial efficiency

RWE can be used to inform the design of clinical trials and improve their efficiency. For example, it can be used to identify endpoints relevant to patients and can help reduce the number of patients needed for a trial by identifying patient subgroups that are most likely to benefit from a treatment.

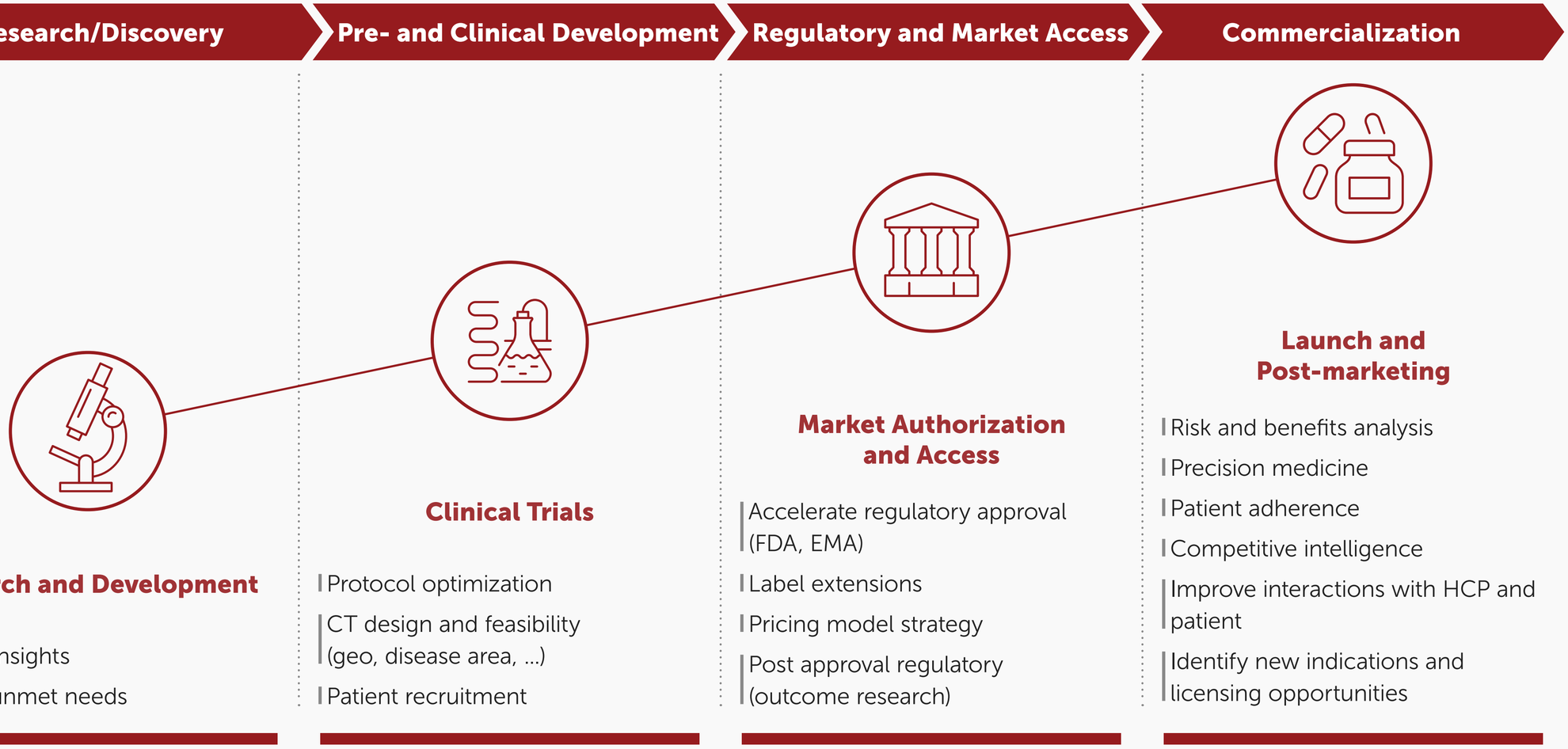
Supporting regulatory submissions

RWE can be used to support regulatory submissions by providing evidence of the real-world effectiveness and safety of a treatment, supporting drug approval and labeling decisions.

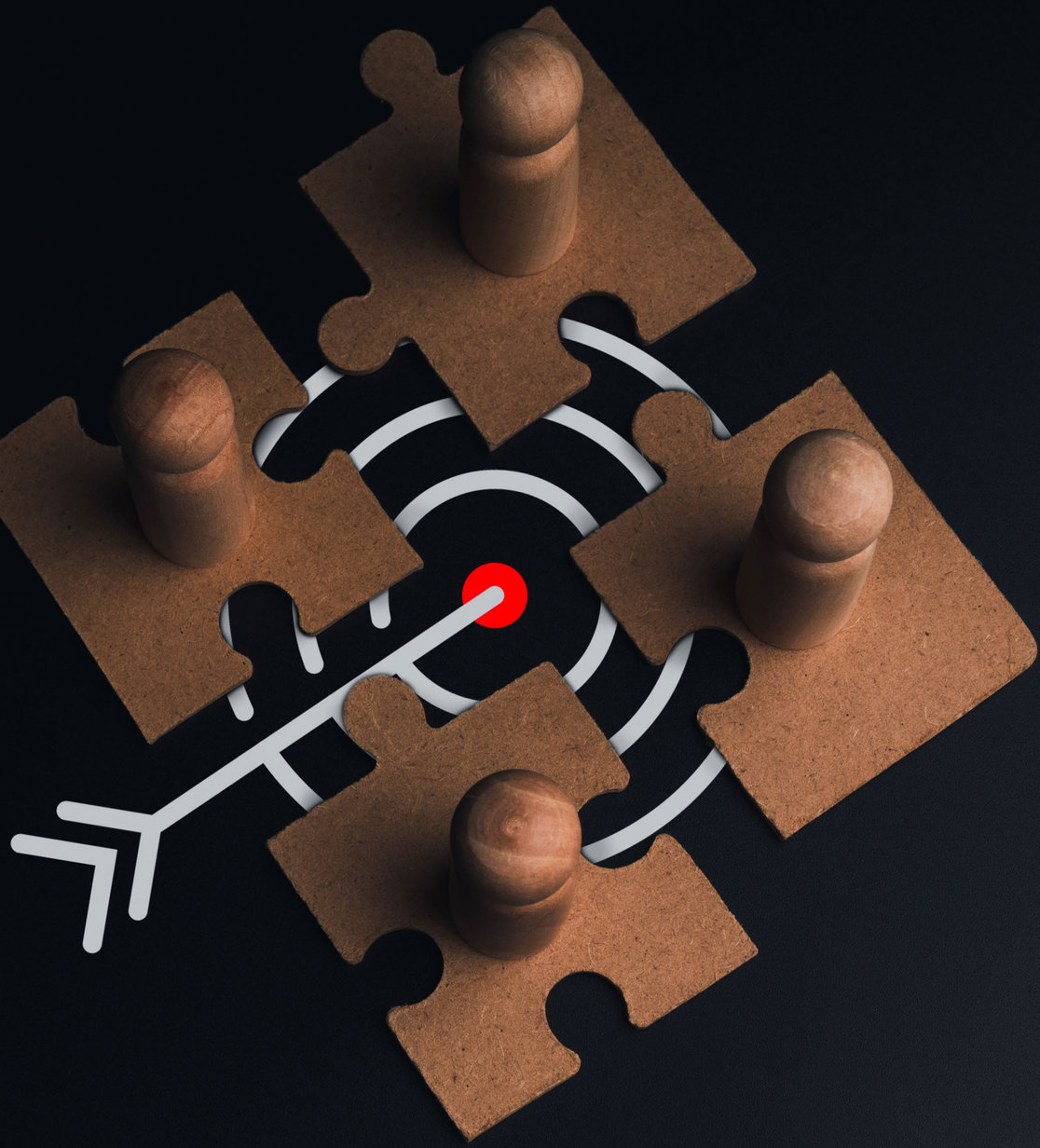
Facilitating post-marketing studies

RWE can be used to facilitate post-marketing studies that can help identify new uses for a drug, evaluate its long-term safety and effectiveness, and inform clinical practice.

Life Sciences Use Cases Are Relatively More Established and Extend From Discovery Through Commercialization Efforts



Stakeholders Driving Growth



Market Challenges

Adopting RWD/RWE in Care and Clinical Trials

Vendor Categories

Approaches to Market

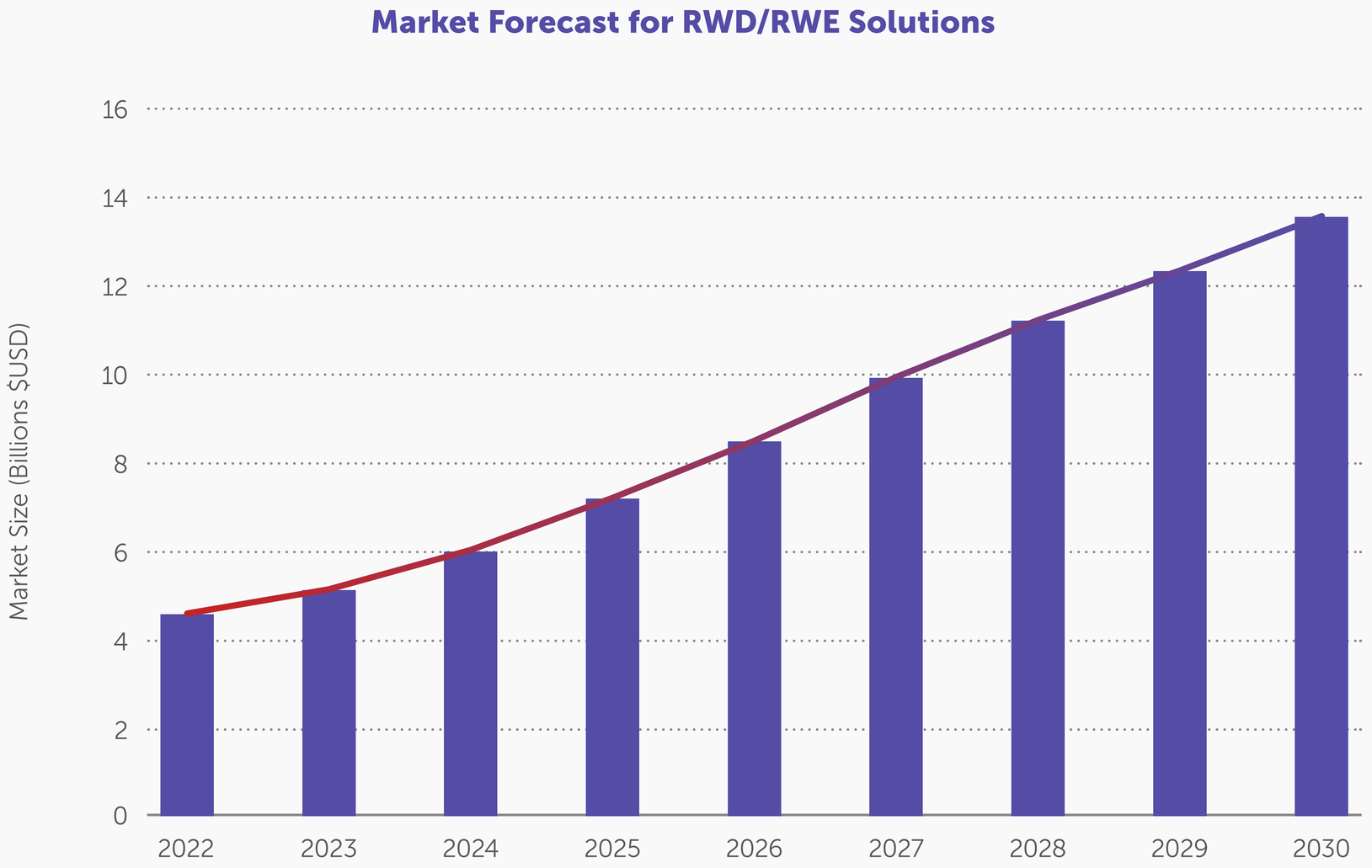
Example Products and Companies

Market Size

Market forecast

Growth Drivers

- Info blocking enforcement goes into effect, liberating new data assets
- Growing number of FDA filings approved utilizing RWE (View Invitae/Ciitizen example)
- New use cases emerge for HCO benchmarking & care pathways research
- Public health research and growing demand to address health equity
- **Forecasted CAGR: 14.57%†**



†Forecast calculation for CAGR goes through 2030. Forward-looking statements based on current trends are no guarantee this is how the market develops.

Product Capabilities and Features

Buyers' Guide Preview

2023 RWD / RWE Buyers' Guide Solution Vendors*

Notable Offerings (full profiles)

Clinical Use (Analytics, Operations, Care Pathways)

- Arcadia
- Clarify Health
- Epic (Cosmos)
- Optum
- Syapse
- Tempus

Clinical Research

- Cerner Enviza
- Evidation
- Flatiron Health (Roche)
- IQVIA
- TrinetX
- Verana Health
- PointClickCare

Stakeholder-agnostic Data Purveyor

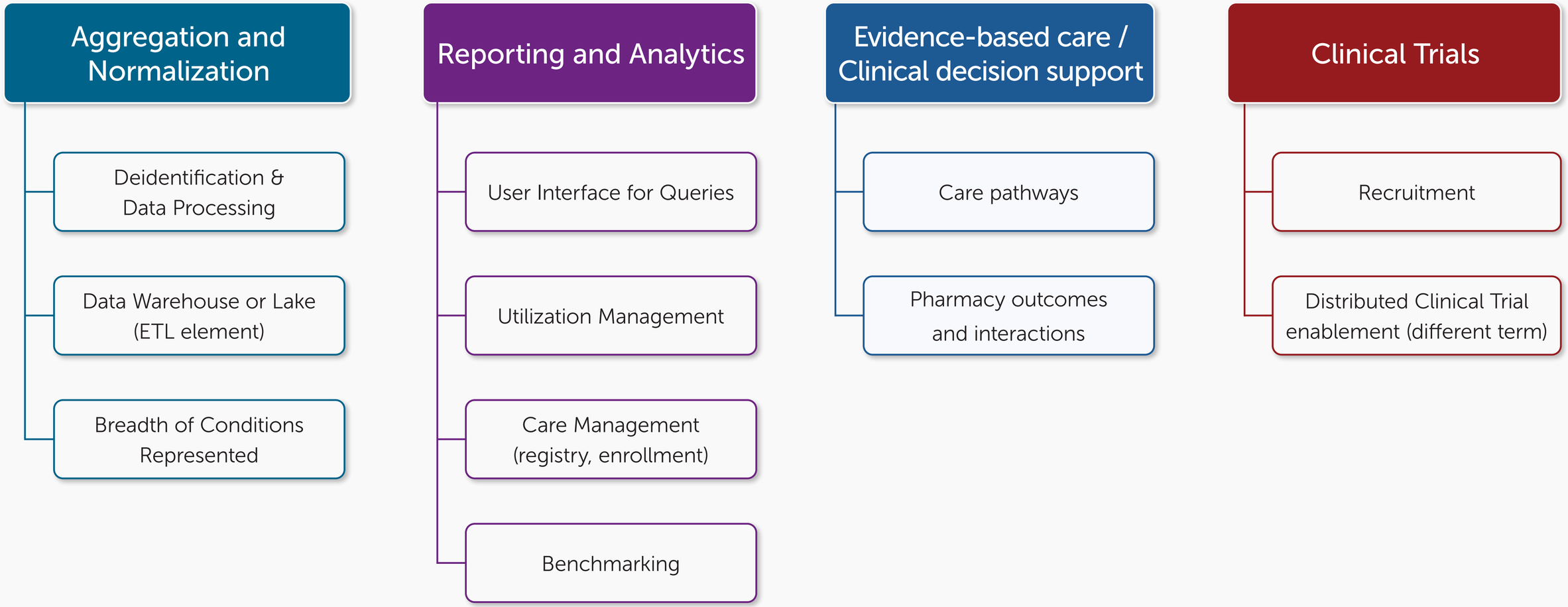
- Aetion
- Inovalon
- Komodo Health
- Truveta
- Veradigm

Vendors to watch (lite profiles)

- Blue Health Intelligence
- Carevive
- Cegedim Health Data
- Invitae (Ciitizen)
- Clarivate
- Eversana
- OM1
- Particle Health
- Picnic Health
- Pluto Health
- Quantiphi
- Verantos
- ThermoFisher

† Tentative list. Chilmark Research reserves the right to change the final cohort of solutions evaluated at any time.

Capabilities and Features



About the Analyst Team

Joshua McHale

Consulting Analyst

Joshua joins Chilmark Research as a consulting analyst for this research effort. He previously led the Analytics team at Southcoast Health in Massachusetts, and then at Evolent Health helping ACOs understand how to best manage patient populations. Josh is a believer that impartial science combined with ideas from traditional and unexpected sources can deliver solutions to help solve real world problems.

John Moore III

Managing Partner

After 12 years with the company in just about every role, John Moore III now leads Chilmark Research. His interests lie in the many ways that health data is collected, packaged, used, and repurposed – and the social implications of these practices. This RWD/RWE research project brings together both his early career experience in life sciences and his more recent work in the health IT sector.

Fatma Niang

Research Analyst

Fatma Niang graduated Purdue University with a degree in Public Health. As Chilmark Research's analyst covering interoperability, the RWD/RWE project was naturally aligned with her ongoing research around data liquidity. With a genuine passion for healthcare improvement, Fatma remains dedicated to making a meaningful difference in the field.

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