



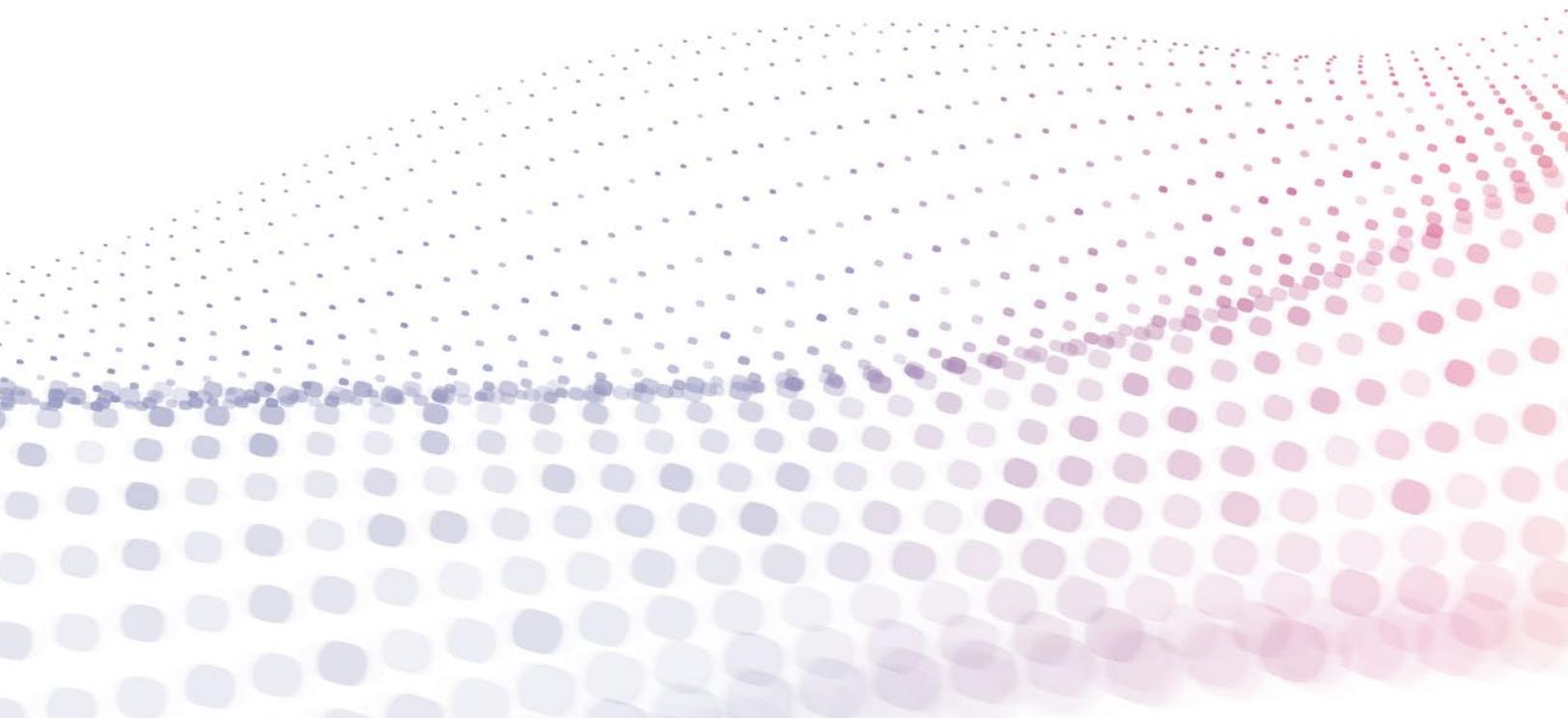
# Accelerate Real World Evidence Development in Just Ten Weeks

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QUICK START GUIDE · JUNE 2018

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The MarkLogic Real World Evidence Quick Start Service is designed to get you up and running in gathering insight from your real world data—in a fraction of the time. Our service solution leverages the MarkLogic database platform to reduce time to insight via secure and simplified processes for data integration, data governance, and powerful search that reveals hidden data relationships.



# Accelerate Development of Real World Evidence

To improve and protect public health, the Food and Drug Administration (FDA) strives to increase its understanding of the value, safety, and efficacy of regulated products in order to make regulatory decisions regarding the use of drugs and medical devices. Available evidence for pharmaceutical and medical device products has historically come from randomized controlled trials (RCTs) and is delivered to the FDA by the product's sponsor.

Today, however, with increasing insight into the limitations of RCTs in predicting a product's safety and efficacy on larger, unstudied populations, the FDA and equivalent international regulatory bodies recognize that an abundance of product data is available—and collected routinely—via doctor visits, insurance claims, device registries, wearable technology, and even social media channels. And though this real world data may not have the same data quality and bias controls as data collected in an RCT, high-quality real world data sources can be used to help our understanding of the benefits and risks of a product over its lifecycle—and across larger populations.

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***“ We need to close the evidence gap between the information we use to make FDA's decisions and the evidence increasingly used by the medical community, by payers, and by others charged with making healthcare decisions.”***

- Scott Gottlieb, FDA Commissioner

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For Life Sciences companies, real world evidence (RWE) initiatives present a lucrative opportunity to demonstrate the clinical and economic value of their drugs and medical devices—and to get those products to market faster. However, the success of real world evidence development efforts hinges upon the organization's ability to effectively leverage real world healthcare data to generate insights in a comprehensive yet efficient manner. The ability to extract more value from real world data sets in less time can provide life sciences companies with decisive competitive advantages.

That's why MarkLogic's consulting team has built a Quick Start Service for real world evidence insight and cohort building. Designed specifically to set your company on an accelerated track to RWE delivery, our service solution utilizes the operational and transactional MarkLogic® database as the foundation for an agile, scalable data platform that solves the critical limitations and inefficiencies inherent to point-to-point systems when it comes to multi-structured data integration, data governance, and search and discovery.

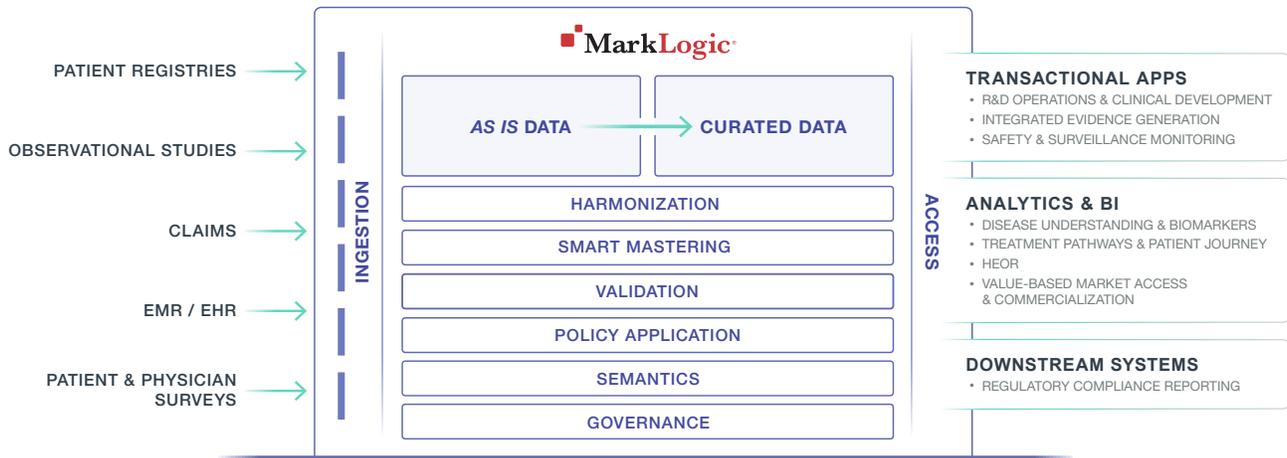


Figure 1: An operational data hub for real world evidence development

## RWE Quick Start Service

MarkLogic’s Quick Start Service for real world evidence will enable you to achieve faster time to insight with your disparate real world data sets. Our expert consulting team will quickly get you up and running with the major capabilities and processes required for RWE program success, including:

- Rapid integration and harmonization of disparate real world data sets
- Data governance, privacy, and quality assurance
- Enhanced analysis and discovery of data relationships

## What We Will Help You Do

### 1. Integrate Disparate Data Silos and Metadata

MarkLogic’s consulting team will work with you to load RWE data in common formats from any source as is. And, the flexibility of storage options supports adding new metadata, such as ICD or MedDRA codes, to your content. This metadata helps ensure that your data scientists can query data to find the information they seek. Accordingly, real world datasets should include accurate metadata that describes when, how, and by whom the data was created. Using shared vocabularies and publicly available medical taxonomies, we will show you how to leverage MarkLogic’s semantics capabilities to harmonize, link, and query across all of your data, and metadata, to find deeper context, hidden connections—and potentially dramatic new insights.

## SEMANTIC SEARCH

Can return relevant documents even if none of the search terms are actually in it

🔍 Radiology procedure for a cancer near a kidney

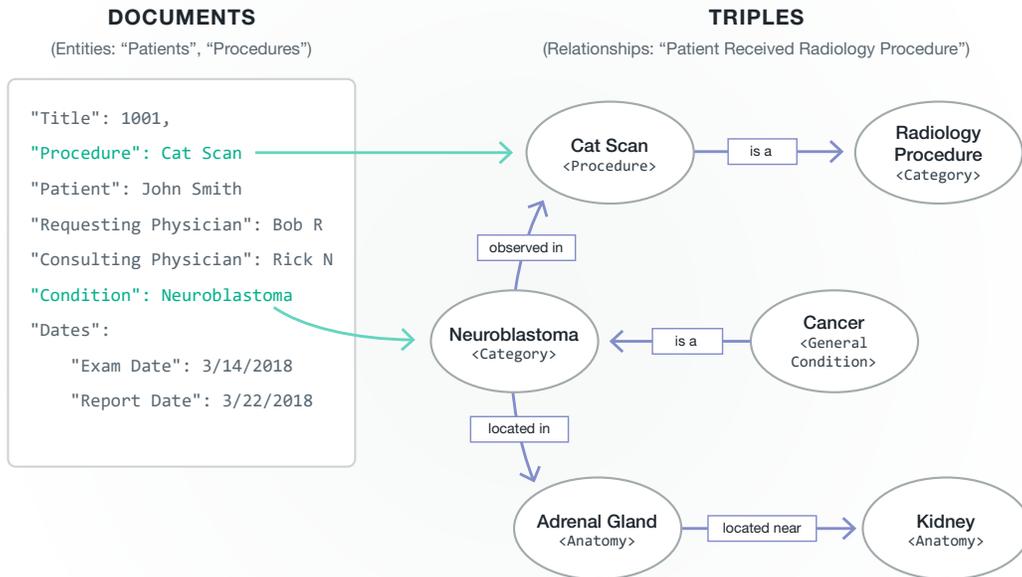


Figure 2: Advanced semantics capabilities enable rapid discovery of hidden data relationships

## 2. Comply With Data Governance Requirements Today – and Tomorrow

MarkLogic provides features that were designed specifically to help healthcare and life sciences organizations meet regulatory requirements for data governance and security. Our team will work with and advise you on best practices and optimal configurations for platform features and capabilities, such as bitemporality, redaction, and element-level security—all while ensuring your real world data platform is extensible in preparation for changes in the shifting regulatory landscape.

## 3. Discover Data Relationships to Enhance Analysis and Insight

Using shared vocabularies and publicly available medical taxonomies, we will show you how to leverage MarkLogic's semantics capabilities to harmonize, link, and query across all of your data, and metadata, to find deeper context, hidden connections—and potentially dramatic new insights in real time (e.g., "Which dataset is most appropriate for my study?"). MarkLogic enables a 360 view of data that can reveal previously unknown but critical data relationships and patterns, enabling co-occurrence analysis that could show "heat density" or "popping" activity. This ability to "connect the dots" will inform and enhance your RWE decision-making for "go or no" conclusions on clinical trials, patient selection, on-boarding, competitive intelligence, and global regulatory compliance initiatives.

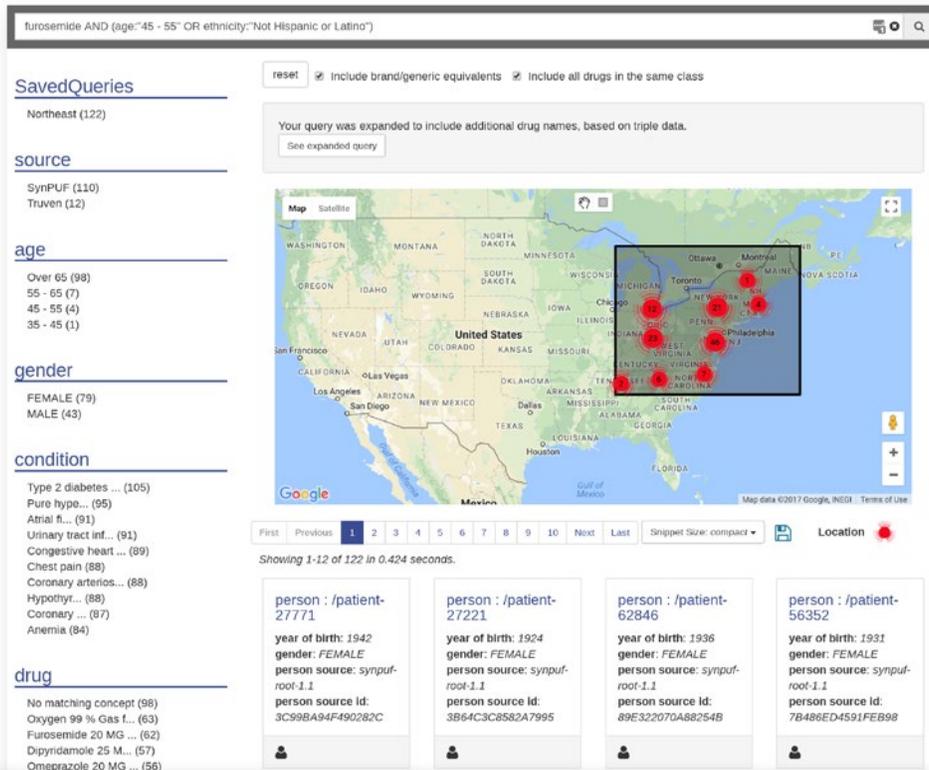


Figure 3: MarkLogic enables real-time search and analytics across many variables

## Key Factors for Your Success

We have worked with many healthcare and life sciences institutions—satisfying their requirements for agile, secure, and rapid integration of multi-structured data. When you partner with us, you won't need a large team to build the platform, nor a lot of upfront "data janitoring" work to get started. Experience has shown us that the most decisive factors in determining the success of enterprise data projects include the following:

- **Understanding your scope** – You need to already have a good idea of how your business intends to use RWE, and the specific requirements to achieve these goals. We can build an appropriate framework to satisfy this.
- **Selecting success criteria** – Choose success criteria that fit the project scope and meet business needs. This may include the ability to define a cohort across datasets from different providers, displaying population level statistics for a given query, tracking attrition for a series of cohort criteria, exposing or exporting cohorts and results for downstream applications or analysis.
- **A strong integrated team** – The people who know and run your business must be part of your core team, so that information and validation are available at the point of need.
- **Data** – We don't require a full data model, but we do need sufficient data in order to provide representative results for analysis and cohort definition. MarkLogic will work with your team to identify the data sources that will initially deliver value for your first phase. For a quick turnaround, this may at first be limited to two to four sources while we work with your team to scope additional data onboarding.

## How We Work

If the above elements are already in place or underway—you're ready to partner with MarkLogic's consulting team to quick start your RWE projects. Within the first 30 days of partnering, we expect to achieve the following objectives:

- Develop a solution architecture and project roadmap so that you can see what we will be building and when it will be delivered.
- Define and implement processes and communication structures to ensure that we can work with your business analyst, test, and other teams most efficiently.
- Define a specification for your infrastructure, cluster and database topology to ensure performance and interoperability with existing systems.
- Develop endpoints for MarkLogic Server to allow data from upstream sources to be pushed into the operational data hub.
- Build out a framework tailored to your organization to allow support for downstream analytics and real-time cohort generation.

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“ *As the demand for RWE increases, companies are turning to new technologies to compress the workflow and improve time to insight.*”

- Deloitte RWE Benchmark Survey

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## Life Sciences Companies Trust MarkLogic

The ability to access, analyze, and manage vast volumes of multi-structured real world data is critical to RWE objectives for process improvement, clinical insights, brand protection, and competitive intelligence. MarkLogic's consulting team can help eliminate many of the challenges you're likely to encounter when integrating real world data sets from a variety of sources and formats. A multi-model database provides the features and functions required for an efficient RWE development platform (including JSON, XML, semantics, bitemporal, search, etc.) and simplifies the polyglot persistence challenges of other architectures. With all of these options available in a single, unified platform, MarkLogic provides unrivaled capabilities in data ingestion, data linking, search, and application development time.

AT YOUR SERVICE

## A Team of Dedicated Consultants

The MarkLogic Consulting Services team is comprised of service experts with vast experience in high-volume, multi-structured data integration. This experienced team has honed their skills in working on some of the world's most complex data integration projects—e.g., the health insurance marketplace for Healthcare.gov—leveraging an agile delivery methodology that encourages stakeholder feedback, enterprise adoption, and the skill acquisition required to ensure successful implementation of your project. Dedicated to building strong partnerships with our customers, our Consulting Services team is committed to continuous improvement in its methodologies and best practices, and goes to work with an attitude of “whatever it takes” to ensure you deliver agile, powerful, and trusted applications to market faster than ever before.

Contact us at [consulting@marklogic.com](mailto:consulting@marklogic.com).

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