Extending Open Source OHDSI Analytics Applications to Enable Automated Data Characterization of Clinical Trials Data

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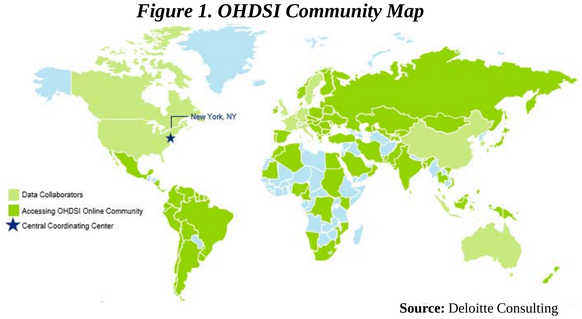
Introduction

Clinical trials make up a large part of the intellectual property that life science companies invest in to launch a product. When a trial closes, the insight gleaned from the trial often resides siloed in local data sets across an organization. Even after implementing a data catalog tool, users still need an application to perform rapid data characterization specific to this type of data set.

About Observational Health Data Science and Informatics

The Observational Health Data Sciences and Informatics (OHDSI) collaborative is comprised of over 140 community members/collaborators from 16 countries. OHDSI focuses on building open-source software tools designed to run against the OMOP common data model (CDM). ConvergeHEALTH by Deloitte collaborates within the OHDSI community due to a shared goal to leverage novel analytics to facilitate high-quality evidence generation.

Figure 1. OHDSI Community Map



Source: Deloitte Consulting

Open Source OHDSI Analytics Application: ACHILLES

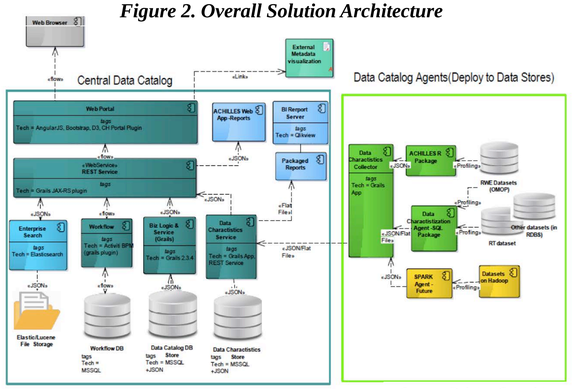
Automated Characterization of Health Information at Large-scale Longitudinal Evidence Systems (ACHILLES) is a platform which enables the characterization, quality assessment and visualization of observational health databases. ACHILLES provides users with an interactive, exploratory framework to assess patient demographics, the prevalence of conditions, drugs and procedures, and to evaluate the distribution of values for clinical observations.

The Problem with ACHILLES and Non-OMOP Data

To leverage OHDSI analytics applications an organization must transform the structure of its data from its native format to the OMOP CDM. This can be a substantial investment for an organization and has some limitations:

- The OMOP CDM is optimized for observational data sets. As such, it is only partially suited to absorb clinical trial data attributes (i.e. adverse events, drug exposures).
- The OMOP CDM can retain the relationship between facts stored as records in a table called FACT_RELATIONSHIP. Detailing all of the relationships captured in study metadata requires shoehorning and stretching the OMOP vocabulary to adapt to the nuances of clinical trials data.
- The visualizations deployed in ACHILLES are not optimized for experimental data. An out of the box deployment of ACHILLES lacks a report to characterize key clinical trials data such as specimens and biomarker data.

Figure 2. Overall Solution Architecture

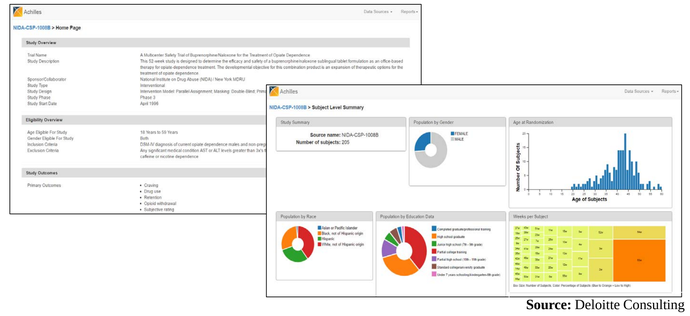


Source: Deloitte Consulting

Our Solution

We designed and implemented a series of extensions to the ACHILLES infrastructure to enable data characterization specifically for clinical trials data. Our approach extends the OMOP CDM to allow clinical trials data to reside in its native format by leveraging our technology, Research Trust. This decouples ACHILLES from its CDM dependency, retains the native attributes of the clinical trial data and allows the tools to accommodate additional ways to characterize these data. We then curated a new package of queries to address nuances of clinical trials data such as information on protocol design, adherence, inclusion and exclusion criteria, enrollment retention and observed adverse events.

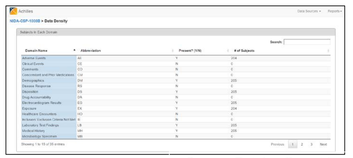
Figures 2 & 3. ACHILLES for Clinical Trials Data – Protocol & Subject-Level Summary



Source: Deloitte Consulting

The resulting JavaScript Object Notation (JSON) files are rendered in an HTML5 / JavaScript website with a series of interactive reports that integrate seamlessly into the existing ACHILLES web site. Our solution directly addresses the limitations of ACHILLES and non-OMOP data, specifically around ingesting and visualizing clinical trials data.

Figures 4 & 5. Data Density – Viewing SDTM Domain Completeness



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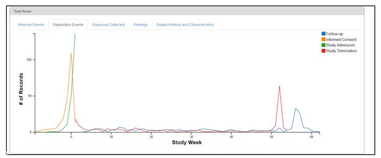
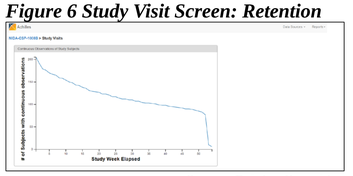


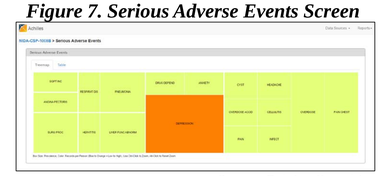
Source: Deloitte Consulting

Figure 6 Study Visit Screen: Retention



Source: Deloitte Consulting

Figure 7. Serious Adverse Events Screen



Source: Deloitte Consulting

Conclusion

We have designed a framework to expand OHDSI analytics applications to address additional use cases to rapidly characterize clinical trials data. We continue to leverage the robustness of the OHDSI collaborative to perfect this highly-configurable solution so that we can help life sciences companies better leverage their data assets and ultimately drive faster time-to-innovation.