




Extending ACHILLES to Enable Automated Data Characterization of Clinical Trials Data

May 17, 2016

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Kristin Feeney

Bio | OHDSI Publications



Kristin Feeney, MPH
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Kristin is a Consultant for the ConvergeHEALTH by Deloitte division of Deloitte Consulting. She specializes in computational epidemiology for real world evidence generation and translational research.

Kristin is currently a collaborator with the symposium organizing committee working group in OHDSI and regularly attends community calls. Her Deloitte team is actively exploring ways to expand the use cases that OHDSI applications address.

Kristin holds a Bachelor's degree in Exercise Science from Elon University and a Master's in Public Health in Epidemiology from Boston University School of Public Health.

Prior to joining Deloitte, Kristin ran more than a dozen Phase 1-4 NIH, industry and physician-led cardiovascular clinical trials at a Harvard Medical School affiliated Academic Medical Center. Following her research tenure, she completed a post-graduate rotation with a Nationwide Accountable Care Act Medicare Demonstration Project mining real world health plan payer and provider data to improve Medicare Risk Adjustment program management.

Collaborator page: <http://www.ohdsi.org/who-we-are/collaborators/kristin-feeney/>

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- 9 of the 10 Largest Health care Systems (Mdrn Hthcre)
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- 10 of the 10 Largest Catholic Healthcare Systems (Modern Healthcare)
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Track 7 – Clinical Research & Translational Informatics Luncheon Presentation II: Accelerating Insights in Translational Research: Self-Service Analytics and Visualizations at Amgen

*George Seegan, Ph.D., Research & Development
Informatics, Amgen*
*David Hardison, Ph.D., Vice President, Health Sciences,
ConvergeHEALTH by Deloitte*

**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 (OHDSI) Collaborative
The Observational Health Data Science and Informatics (OHDSI) collaborative is comprised of over 140 community members/laboratories from 16 countries. OHDSI focuses on building open-source software tools designed to run against the OHDSI 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



The Problem with Achilles and Non-OMOP Data
To leverage OHDSI analytics application 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. Decoupling all of the relationships captured in study monitors requires shuffling and restructuring 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 trial data such as specimens and biomarker data.

Figure 2. Overall Solution Architecture



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 created a new package of queries to address nuances of clinical trial data such as information on protocol design, adherence, inclusion and exclusion criteria, enrollment retention and observed adverse events.

Figure 3. Data Diversity - Flipping SFDM Domain Compliance




Figure 4. Study Risk Score - Retention


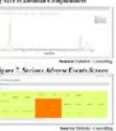
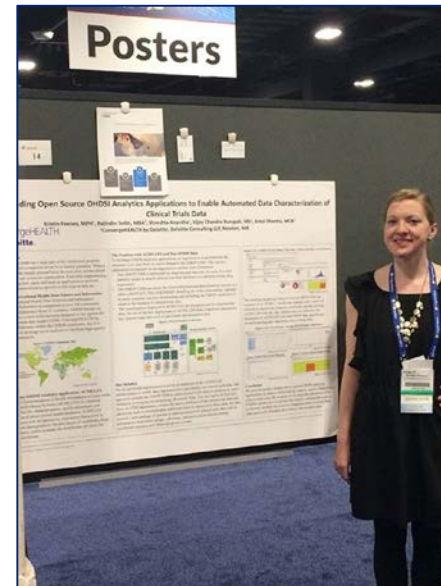


Figure 5. Serious Adverse Events Screen



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.



Track 11 – Open Source Innovations, Poster

Why Extend ACHILLES?

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- 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.

Demo