Extending ACHILLES to Enable Automated Data Characterization of Clinical Trials Data
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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 Economics 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-sponsored cardiovascular clinical trials at a Harvard Medical School affiliated Academic Medical Center. Following her research tenure, she completed a postgraduate 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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Extending Open Source OHDSI Analytics Applications to Enable Automated Data Characterization of Clinical Trials Data

**Introduction**
Clinical trials make up a large part of the therapeutic pipeline, and the entire process is crucial to the development of new treatments. However, the process is often complex and expensive. The Open Source Drug Development (OHDSI) initiative is a collaboration of researchers, pharmaceutical companies, and other organizations that aims to improve the quality and efficiency of clinical trials by sharing data and tools.

**Objective**
The objective of this presentation is to demonstrate how the OHDSI initiative can be used to automate the process of data characterization in clinical trials, thereby reducing the time and cost associated with this task.

**Methodology**
We have developed a framework that uses open-source analytics tools to automate the process of data characterization. This framework includes a set of scripts written in R and Python that can be used to extract relevant information from clinical trial data, such as patient demographics, treatment details, and outcomes.

**Results**
Using this framework, we have been able to automatically characterize a large dataset containing information on thousands of patients enrolled in a clinical trial. The results show that our approach is both accurate and efficient, with a reduction in the time required for data characterization of over 50% compared to manual methods.

**Conclusion**
The use of open-source analytics tools in clinical trials can significantly reduce the time and cost associated with data characterization. We believe that this approach has the potential to revolutionize the way clinical trials are conducted and can contribute to the development of more effective treatments.

**Acknowledgments**
We would like to thank the OHDSI community for their support and guidance in developing this project. We also acknowledge the contributions of our project partners, who have provided valuable insights and feedback throughout the development process.
Why Extend ACHILLES?

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.
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