OHDSI Clinical Trials Working Group February 8, 2019

*All members can edit the text.*

Roll Call

* Thomas Falconer (NYC)
* Ziran “Ryan” Li (NYC)
* Vojtech Huser (missing due to meeting)
* Greg Klebanov (Philadelphia, PA)
* Rupa Makadia (SF, California)
* Andy Williams (Maine!)
* Qi Yang
* Ayesha Kang (TBD) – not sure if Ayesha Kang joined correctly with no audio, or was a mistake

Thomas Falconer: Columbia; OHDSI Studies; helps engage Columbia in all OHDSI network studies; FDA ‘Best’ Project (sic); Thomas came to OHDSI from clinical studies background; applied mathematics and statistics background.

Greg Klebanov: CTO of Odysseus Data Services. A service company, work on model, vocabularies, tools all of the OHDSI ‘stack’. Been in the community for long time.

Rupa Makadia: Janssen staff member in Patrick Ryan’s group. Current role looks at how we can operationalize clinical trials via OHDSI; can create index population; has poster(s) at symposia; over 100 clinical studies; typically used in conjunction with other data that may not sit in OHDSI; feasibility. Interest in seeing how this could be leveraged also outside of Janssen/ greater good. Could there be a framework to recruit patients to a clinical trial; gets better medicines to patients. Usually claims data, less E.H.R.

Andy Williams: faculty Tufts Institute for Health Policy Studies; health services research and infrastructure for years, started at Kaiser, clinical background. New-er to clinical trials. Cohort identification for trials, NCATS Trial Innovation network. Can trials and studies complement each other. Biostatistician also!

Qi Yang: IQVIA staffer; was at the Hadoop Hackathon that IQVIA hosted in 2017; does E.H.R. and claims conversion into database(s). Not clinical trial expert. Has biomedical sciences education. Also developer. Now an analyst.

Housekeeping; will be recorded by default; meeting no every 2 weeks; logs will be posted; pref for time (T.F. Friday good; not 11am; FDA 11-12 Tue and Thur); (Greg 10am, 11am fine Fri; Mon and Thur bad); (Rupa; Friday) (AW Friday 10)(QY has conflict at 10am; Sonya is not in E.H.R.) – seems like 10am US EST is good.

Comments made on prospective process of the group (including keywords below due to lack of typist’s skill); **use cases breadth**; use cases depth; leading to changes, improvements in the OHDI stack; **data analysis side**, and how can RWE work with clin trials; conversation about the status of RWE data vs clin trial data, discussions happening now about the **potential contributions of RWE as a class to clin trials**; complementarity vs either/ or; heuristics for how to use them when—and data and analytic requirements of doing both; status of evidence; also practical stuff about running trials where usage of OHDSI comes in; TF—needs to go; heuristics; Rupa coincides with Andrew re larger conversation on how you use RWE in world of trials; need to cover larger aspects more so than operational day to day; can OHDSI make clinical trials run faster; feasibility; data power; Qi on board with AW; RM; FDA released framework on use of RWE, a trend building here; can OHDSI be used to support regulatory decisions; AW was a reviewer on the draft guidance (FDA), FDA will produce related guidance on status of observational/ RWE (data curation was important to them). Can you emulate a trial, can you make a distinction between possible treatments; signal detection; all RWE is lumped together in this dialogue, which is sub-optimal; can heuristics be used to help with some of these; **what islands of data** are more functional. Scholarly that would situation RWE in the broader context of clinical evidence vs actual usage.