Principles of the YODA Project

- Promote sharing of clinical research data to advance science and improve public health and healthcare
- Promote responsible conduct of research
- Ensure good stewardship of clinical research data by external investigators
- Protect rights of research participants

Project Metrics

- 341 clinical trials currently available
  - Over 70% of trials have been requested so far
- 129 data requests received
- 26 projects have been published in peer-reviewed journals, more at conferences
  - 3 additional manuscripts are under review

Data Requests Submitted, No.

Data Requests: Status

- Manuscript Submitted for Publication
- Incomplete with Preliminary Results
- Incomplete without Results
- Data Access Enabled
- DUA/Data Preparation in Progress
- Under Review/Revisions Requested
- Withdrawn/Closed

Data Requests: Purpose

- New Question
- Validation
- Meta-Analysis
- Statistical Methods
- Clinical Prediction, Risk Prediction
- Other
- Comparison Group

Experience to Date

- Completed projects have generated evidence to inform policies and guidelines (e.g. HTAs, WHO)
- Majority of requests have been to conduct meta-analyses and answer new research questions on treatment effectiveness or safety
- Validation studies have supported – not undermined – the primary publication
- Direct collaborations with original study teams (at company) have been facilitated
- No instances of serious safety concerns or privacy breaches, nor of reports disseminating spurious safety findings that received unwarranted attention or disrupted patient care