Lilly Clinical Trial Data Sharing

Pandurang Kulkarni PhD
Chief Analytics Officer and VP – Biometrics
Eli Lilly & Company

Recent Lilly History of Data Sharing

- 1/2014 - Implemented a company website for research requests
- 6/2014 - Joined ClinicalStudyDataRequest.com with SAS environment
- 7/2019 – Lilly joined Vivli.org - Pharma, Funders, Aca Inst, non-profits

Cost to date

- >US $3 million on research environment and data anonymization
- > 3 FTE resources/yr – moving to Vivli allowed Lilly to reduce FTE needs
- All costs except researcher time and effort have been paid for by Lilly

What does Lilly proactively share?

- Lilly will list Lilly-sponsored interventional clinical studies from approved medicines and indications in the United States (US) and European Union (EU) in the following categories

  - Phase 2, 3 or 4 studies used as part of a regulatory approval submitted to the US FDA on or after 1999.

  - Phase 2, 3, or 4 global studies in indications approved in both the US and EU with a first patient visit after 1 January 2007.

  - Phase 2, 3, or 4 regional/local studies in indications approved in both the US and EU with a first patient visit after 1 January 2014.

What does Lilly proactively share?

- Studies are listed 6 months after the studied medicine and indication have been approved by regulators in the US and EU and after the primary manuscript describing the results has been accepted for publication, whichever is later.

Current Request Process

- Researcher
  - Comes to data sharing site and searches for Lilly studies
  - Submits hypothesis testing proposal with the list of studies included
- Clarification may be requested by Vivli, Lilly ensures data are available to answer the question
- Completed proposal is reviewed by IRP managed by WellcomeTrust
- Data sharing agreement is signed
- Data are provided in secure research environment
- Analyses performed by researchers
- Results are published in appropriate manner

Lilly Data Sharing Metrics

- >350 trials are listed as available to request
- 78 proposals received since 2014
  - 40 -only Lilly data, 38 - combining Lilly data with other sponsors' data
  - Average of 6.6 Lilly trials per proposal
  - 90% proposals for data from neuroscience or oncology trials
- 50 - approved and data access provided
  - Other proposals are either in process, withdrawn, or rejected by the IRP
- 12 proposals have resulted in publications
  - 8 - Lilly only data, and 4 - combining data with other sponsors

What is the future?

- Data sharing will continue – the commitment is in place and this is the normal process of conducting clinical trials for Lilly
- Data sharing initiatives will increase
  - Lilly currently participates also in
    - Project Data Sphere
    - TransCelerate Placebo and Standard of Care Data Sharing
  - Disease Research Foundations
    - Lupus
    - Alzheimer's
    - Duchenne Muscular Dystrophy

Questions?

Why control access?

- Why is access to the data controlled?
  - Protect the privacy of trial participants
    - Data are anonymized but risk of reidentification decreases with secure research environment and data sharing agreement
  - Protect the innovation
    - Research should be focused on hypothesis testing and not data fishing
  - Maintain the cost
    - Full data sets can be provided if utilizing a secure environment which limits the resources required to provide custom data sets for each request
- The biggest risk to continued data sharing is the reidentification of a patient causing harm to the patient or the trial sponsor