Use of Existing Data to Inform and Speed Development of Personalized Medicine for CNS Disorders

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Use of Existing Data to Inform Personalized CNS Pharmacotherapy

- What we Have
- What we Need
- Who Does and Who Might Undertake Efforts

What we Have: Relevant Datasets

- Data From Clinical Trials and Drug Utilization in Computerized Files
  - FDA approved drugs - Several Data Mining Studies
  - Prescription Use Data either from private or public (CDMS) databases
  - NIH Data Repositories – Limited Use to Date
  - EU Repositories (e.g. IMI and subsequent programs) – Past & Current Studies Company trial data held at individual companies for drugs that did not advance beyond Phase 2 or failed in Phase 3 –Publications of Primary Group Outcome and some Subgroup Analyses
  - Shared company data mainly with regard to placebo response especially from Alzheimer's drug trials that failed – Role of Critical Path Institute
  - Processes to Facilitate Data Mining for Future Studies?

What We Need: More Data and Better Data Sharing Mechanisms

- Most repositories of data do not yet include the 10's of thousands of subjects which are needed to address certain levels of inquiry such as polygenic risk scores and consistency of relationships between emerging individual level biomarkers and clinical response
- The effort to share data requires not only willingness but also dedicated and sustainable resources that are only in place for efforts such as ADNI and genetic consortia
- Beyond willingness at decision maker levels: legal, proprietary, confidentiality and technical challenges around homology of data elements and simply accessing these need to addressed
- Different Barriers to Sharing across Geographies (e.g. US vs EU)

Current and Potential Structures for Sharing

- The ADNI and AMP model: pre-competitive partnerships to generate and share data that does not involve specific interventions
- IMI Model: EU based Sharing of Clinical Trial Data of Marketed Drugs with limits that prevent sharing of how one compound compares with another
- Critical Path Institute Model
- NIH Repositories which are open but are not curated or managed in a manner to be user friendly or deal with questions around commonality of data elements
- Varying FDA approaches
- Potential Foundation of the National Institute of Health role which might emerge from alignment from academia, industry and advocacy groups including organizations such as ISCTM