DEVELOPMENT OF THERAPEUTIC AREA-SPECIFIC DATA STANDARDS FOR BRAIN DISEASES

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AFFILIATIONS:

1 – Critical Path Institute, Tucson, AZ
2 – Clinical Data Interchange Standards Consortium, Austin, TX
3 – Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT
4 – Piramal Pharma Inc, Boston, MA
5 – Quanterix, Lexington, MA
6 – Johns Hopkins University School of Medicine, Baltimore, MD
7 – Ixico, London, UK
8 – Takeda Pharmaceuticals U.S.A., Inc., Deerfield, IL
9 – Institute for Neurodegenerative Disorders, New Haven, CT
10 – J&J PRD, Titusville, NJ
11 – Banner Alzheimer’s Institute, Phoenix, AZ
12 – National Institute for Neurological Disorders and Stroke
13 – Mount Sinai Medical Center, New York, NY
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OBJECTIVE:

To improve the quality, efficiency and cost-effectiveness of clinical trials by developing brain disease-specific open data standards.

BACKGROUND:

Implementation of consensus-based clinical data standards serves two main purposes: integration of existing data, and consistency in prospective data collection. Critical Path Institute (C-Path), working with the Clinical Data Interchange Standards Consortium (CDISC), has played a leadership role in the development of data standards for neurodegenerative diseases, as well as in precompetitive data sharing for multiple disease areas. These therapeutic area-specific standards represent the preferred format of regulatory agencies for submitting new drug applications.

DESIGN/METHODS:

Industry members, regulatory agencies, academics, and patient groups collectively developed data