DEVELOPMENT OF THERAPEUTIC AREA-SPECIFIC DATA STANDARDS FOR BRAIN DISEASES

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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