IMPACT OF THERAPEUTIC AREA-SPECIFIC DATA STANDARDS FOR PARKINSON’S DISEASE

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Background and Objectives

Critical Path Institute (C-Path) has played a leadership role in developing consensus data standards and fostering prescriptive data sharing for multiple diseases. These actions are key to the success of future clinical trials, The Coalition Against Major Diseases (CAMD), one of C-Path’s consortia, in partnership with the Clinical Data Interchange Standards Consortium (CDISC), and the National Institute of Neurological Disorders and Stroke (NNINDS), has successfully developed consensus data standards for Parkinson’s disease (PD). These therapeutic area-specific standards represent the preferred format by regulatory agencies for submitting new drug applications. Standards are key to data integration, pooling and analyses of diverse data sources (Kush and Goldman, 2014), and have contributed significantly to platforms that have advanced Alzheimer’s disease (Neville et al., 2015).

Methods

A coalition of academic experts, NNINDS, industry members, regulatory agencies, and patient advocacy groups collectively developed standards in partnership with C-Path. With input from clinical subject matter experts (CMMEs) and NNINDS, working groups of data standards experts mapped clinical concepts relevant to PD to the CDISC Study Data Tabulation Model (SDTM) and developed controlled terminology to support the construction of standardized databases for research and regulatory submission in PD clinical trials. C-Path SDS therapeutic area user guide www.cdisc.org/therapeutics.

Results

A CDISC therapeutic area standards user guide was developed for PD based on the CDISC SDTM foundational standards, recognized by the FDA. The PD Therapeutic Area User Guide (TAU) comprised of the comprehensive common data elements (CDEs) developed by the PD Common Data Elements (CDE) Work Group (www.commontools.org/standards/pd/pd-pstext-pstools-cde).

Conclusions

The use of consensus data standards maximizes efficiency in regulatory review and facilitates analyses across diverse studies. Importantly, CDISC standards will be required by FDA for regulatory submission as early as fiscal year 2017. These standards foster the collection of clinical trial data and the integration and analysis of existing or anticipated data across various stakeholders’ systems independent of the particular platform. The CDISC TAU is readily available to sponsors, data scientists and researchers for implementation (http://www.cdisc.org/therapeutics/ TAU= Therapeutic area user guide.

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Figure 1. Examples of CDEs from the PD domain. Standards development projects make use of existing domains where possible, and develop new domains to represent types of data not previously covered. There are currently more than 40 published SDTM domains.

Table 1: Concepts new to CDISC SDTM that were identified as part of Parkinson’s v5 development. Concepts are organized by the SDTM domain in which these types of data are represented.

References

CDISC Therapeutic Area User Guide. www.cdisc.org/therapeutics


