A coalition of academic experts, NINDS, industry members, regulatory agencies, and patient advocacy groups collectively developed data standards in partnership with CDISC. With input from the clinical subject matter experts (SMEs) and NINDS, 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. CDISC PD Therapeutic area user guide: https://www.cdisc.org/therapeutic.

Methods

A coalition of academic experts, NINDS, industry members, regulatory agencies, and patient advocacy groups collectively developed data standards in partnership with CDISC. With input from the clinical subject matter experts (SMEs) and NINDS, 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. CDISC PD Therapeutic area user guide: https://www.cdisc.org/therapeutic.

Results

A CDISC therapeutic-area data standards user guide was developed for PD based on the CDISC SDTM foundational standards, recognized by the FDA. The PD Therapeutic Area User Guide (TAUG) originated from the comprehensive data elements (CDEs) developed by the PD Common Data Elements (CDE) Work Group (http://www.commondataelements.ninds.nih.gov/pd/taug/Data_Standards).

Conclusions

The use of consistent 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 of 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 PD CDISC TAUG is readily available to sponsors, data scientists and researchers for wide implementation (http://www.cdisc.org/therapeutic/). TAUG = therapeutic area user guide.