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Associazione Farmaceutici Industria
Società Scientifica

TITOLO (maiuscolo)

IMPLEMENTATION OF CLINICAL DATA INTERCHANGE STANDARD CONSORTIUM (CDISC) STANDARDS TO REAL-WORLD DATA: CHALLENGES AND STRATEGIES IN THE SETTING OF OBSERVATIONAL STUDIES

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Riassunto

Carattere: ARIAL
Corpo: 10
Interlinea: 1

Background:
In the world of clinical trials, conducted with the intent of submitting a new medical product or intervention to regulatory authorities for marketing authorization approval, a set of global data standards has been adopted and is being required by an increasing number of national and regional regulatory agencies. In this context, CDISC (Clinical Data Interchange Standard Consortium) standards were generated for regulatory submissions of clinical trials data in support of approval to market medical products. However, recent expansion of CDISC standards through therapeutic area user guide development has led to an increase in CDISC visibility and to the recognition of the value of data standards in other areas of medical research as well, such as observational research. Observational studies differ from randomized controlled trials under several aspects, i.e. regarding study goals, study design, subject populations, clinical settings, regulatory/study oversight requirements, and data collection/data management practices.
The aim of this work is to describe the challenges faced in the application of CDISC SDTM (Study Data Tabulation Model) standard to map data from observational studies before the issue on 28-02-2024 on CIDSC website (*https://www.cdisc.org/standards/real-world-data*) of the new document "*Considerations for SDTM Implementation in Observational Studies and Real-World Data*" v1.0 (Final).

Methods: As starting point of the SDTM mapping process, the reasons of application of CDISC standards within the pharmaceutical company are investigated (regulatory, standardization for pooled analyses, etc). Then, sources to be taken as reference during SDTM mapping are clearly defined and the need for adaptations of CDISC standards due to the observational nature of the study is discussed. Starting from agreed sources, technical specifications are defined. For SDTM mapping, Pinnacle 21 is used to meet conformance rules even if not mandatory (because a submission to regulatory authority is not foreseen).

Results: The application of the CDISC standards in observational studies has been evaluated both when a medication to treat the disease under study is defined in the study protocol and also when it is not.
The implementation of the CDISC standards gives the opportunity to generate a ready-to-use database from the observational study to allow for data review or possible pooled analyses. Eighty-six SDTM data sets from 3 observational studies were considered, 82 of which were included in the standard SDTM domains. It was not always possible to create some typical SDTM domains such as Exposure as expected (EX) or Trial Elements (TE) because the study did not foresee the administration of a protocol-defined intervention treatment. Moreover, it was necessary to develop custom domains in order to map all collected data. Issues were generated by the validation program both at dataset and variable level; they were managed and discussed with Sponsor on a case-by-case basis.

Conclusion: The newly released CDISC document "*Considerations for SDTM Implementation in Observational Studies and Real-World Data*" confirms the issues and challenges which we already experienced since the last 5 years in our CDISC implementation activities. It is a valid support because it also provides possible solutions to challenges which are typical of the observational study design and speeds up the evaluation of automatic alerts from validation softwares (e.g. Pinnacle).

IMPORTANTE: inviare il testo in formato (word o pdf) editabile e NON in formato immagine.

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