Clinical Trial Data Sharing – De-identification Standards

Clinical Trial Data Sharing Commitment

Teva is committed to sharing both patient-level and study-level clinical trial data from clinical trials using Teva Specialty Branded products approved in the United States (US) and European Union (EU) after January 2014, to conduct legitimate research. Teva considers the scientific merit of the proposed research, the protection of clinical trial participant information, the publication plan for results, and the protection of commercially confidential information before deciding whether to share clinical trial data.

Teva will redact, delete, or replace personal identifiers to protect personal information in clinical documents and/or data sets before sharing them with qualified researchers. Commercially confidential information will be redacted in clinical documents before being shared with researchers per industry standards.

1. Purpose

The purpose of this document is to identify the steps Teva will take to prepare data transfers related to Study Data Tabulation Model (SDTM) datasets / Analysis Data Model (ADaM) datasets when sharing individual patient-level data to meet data sharing commitments. Data sharing requests granted to qualified researchers require a data sharing agreement and minimum process requirements to protect personally identifiable information and commercially confidential information per industry standards.

This guideline covers the de-identification of personal information to protect the privacy of the trial participants, clinical trial site, sponsor, and vendor staff.

2. Scope

This guideline is applicable to Teva-sponsored clinical trials using approved Specialty Branded products for indications approved in the United States and the European Union after 01January2014. Clinical trials conducted using products or indications that are not approved, generic products and biosimilar products are out of scope.

The decision to share de-identified data for a particular trial depends on many factors including Teva's Transparency & Disclosure Policy, the feasibility of de-identification, the content of informed consent form, and Teva's publication plan.

3. Overview of the Process

When Teva receives a request from a qualified researcher for patient-level data or study-level data, the request will be evaluated and either approved or not approved. If the request is approved, Teva will de-identify the data and provide data sets to the researcher through the secure file sharing tool.

4. Process Details

4.1 Only de-identified data that has been requested will be shared.

4.2.1 De-identification is the removal of personally identifiable information from each dataset and supporting documentation according to the description below (unless otherwise specified). Clinical trial data from participants who do not agree to share data when explicitly required to provide consent for external data sharing requests per country or local requirements will be removed before sharing data with external researchers.

a. Subject identification numbers will be replaced with a different identification number in the de-identified data set. The algorithm to translate subject identification numbers from the original number to the de-identified number will not be saved per industry standards.

b. Personal identifiers such as names, initials, phone numbers, email addresses, social security numbers, addresses, countries, account/records numbers, vehicle identification or license plate numbers, certificate or license numbers, health plan numbers, and fax numbers will be deleted.

c. Screening Number will be deleted.

d. Age will be retained as reported unless the subject is older than 89 years old. When the subject is older than 89 years old, the age field should be set to "higher than 89".

e. The date of birth will be deleted for all subjects. Only age or age category will be included as per above. The other dates (date of visit, date of death, AE stop/end dates, study drug start/stop dates, etc.) will be removed. Original relative days (XXDY) will be retained.

f. Subject initials will be deleted from the database, and the field left blank.

g. Medication or device indicators reported with the exposure data, such as bulk patch identifier, lot numbers, or serial numbers, will be deleted from the database.

h. Investigator name, study staff, or other names will be deleted from the database. Site numbers will be recoded for data utility purposes. Other geographic information (e.g., zip codes, addresses) will be deleted.

i. Medical dictionary coded term values should remain and be populated, while investigator-reported verbatim terms (e.g., Adverse Event investigator term, Medical History investigator term, Medication investigator term) will be deleted.

j. Genetic data, biometric data, photographs, imaging data (e.g., MRIs, X-rays) will be deleted.

k. Any “comments” data sets will not be provided.

l. Any free text variables will be deleted.

m. Other unique identifiers such as internet protocol (IP) addresses or web universal resource locators (URLs) will be deleted.