

Mitsubishi Tanabe Pharma Clinical Trial Data Transparency

Introduction

Protecting the privacy of patients or participants (hereinafter referred to as participants) who contribute their data to clinical trials is an important obligation of sponsors who conduct clinical trials. Mitsubishi Tanabe Pharma will take appropriate measures, including anonymization of data, to ensure that participant privacy is safeguarded. This document describes the approach taken by Mitsubishi Tanabe Pharma to prepare participant-level clinical trial datasets for sharing with qualified external researchers in response to requests for such information via www.vivli.org. This approach minimizes the risks to the privacy and confidentiality of research participants and ensures compliance with data privacy legal requirements. We seek to comply with all applicable laws and regulations, such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States and European Union regulations on processing and protection of personal data including the General Data Protection Regulation (EU) 2016/679 (GDPR).

General Principles

- a. For each approved data sharing project, Mitsubishi Tanabe Pharma will maintain the integrity between the datasets to allow reliable analyses.
- b. Mitsubishi Tanabe Pharma will share the anonymized participant-level data in the same format that was used for the original statistical analysis.
- c. The extent and approach to anonymization is modified based on multiple factors such as the study population, disease prevalence, data sensitivity, system controls, and others.

Process Overview

The following steps will be performed when de-identifying clinical trial data for external research in an anonymous format:

1. Removal of personally identifiable information (PII) from each dataset.
2. Internal quality control (QC) review and approval of the anonymized dataset.
3. Destruction of intermediate anonymized outputs and storage of the anonymized dataset.