

1 . About

Mitsubishi Tanabe Pharma contributes to the progress of medical science and medical treatment by increasing transparency in clinical trial information, clinical trial results, and clinical trial data, from clinical trials conducted by the MTPC group in a timely and appropriate manner. The purpose of sharing clinical study data is to benefit patients and fosters scientific discovery in ways that maintain patients' privacy and preserve the integrity of Mitsubishi Tanabe Pharma research.

2 . Studies Listed for Sharing

Mitsubishi Tanabe Pharma will share Phase 2, Phase 3 and Phase 4 Mitsubishi Tanabe Pharma group sponsored interventional clinical studies conducted in patients that form part of the submission package for products and indications approved in all regions of the United States (U.S.), the European Union (EU)* and Japan (JP) where approval is sought, in and after January 2018. Except for studies in healthy subjects other than vaccine studies.

* including European Economic Area; EEA

3 . Exceptions

- Studies where there is reasonable likelihood that patients' anonymity cannot be maintained. For example, in very rare diseases, studies with very small patient numbers or studies performed at a single center.
- When necessary to restrict information to protect commercially confidential information and intellectual property rights on occasion.
- Data collected subject to legal, contractual or consent provisions that prevent further sharing of clinical data will be excluded.
- A data request proposal competes with, and/or conflicts with our publication plan for the research.
- Studies where agreement to disclose clinical data is not gained with a co-development/research/marketing/promotion partner for a compound/product.
- Studies where clinical trial data and/or supporting documents are not in English.

4 . Additional Conditions for Access

Access may be declined on occasions where, for example, there is a potential conflict of interest between Mitsubishi Tanabe Pharma and the requesting party, or an actual or potential competitive risk.

The external research request must not extend beyond the limitation of participants' informed consent.

5. 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. 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.