Overview of ICF Common Template

1. Background and Purpose for Preparing ICF Common Template

Informed Consent Forms (ICFs) used in clinical trials differ among sponsors. In addition, a specific format or template is commonly specified in each study site. For this reason, inconsistency of information provided to study participants even among study sites of the same clinical trial has been an issue. There is a great burden on both the study sites and the sponsor in preparation and review of ICFs as well, which is one of the factors for inefficiency of clinical trials in Japan.

Purpose of ICF Common Template

Consistency of information provided to study participants

- The information received by participants of the same study should be consistent so that they can decide the participation in the study using the same information.

Burden reduction for personnel in charge of preparation, review, or explanation

- The time and effort to replace the template can be eliminated, thereby resulting in reduction of the time and effort required in the preparation for the conduct of the clinical trial and streamlining IRB reviews.
- The description of general matters related to the clinical trial can be standardized, thereby reducing burdens on those who give explanation.

Improvement of study environment

- Consolidation of IRBs and introduction of eConsent can be facilitated.

The ICF Common Template was prepared in June, 2024 by Clinical Evaluation Expert Committee, Drug Evaluation Committee of Japan Pharmaceutical Manufacturers Association based on the Common ICF template (Ver. 1.1) issued by R&D Head Club*, reflecting opinions of medical institutions, patient groups, and lawyers. Also, the Ministry of Health, Labour and Welfare recommends active use of the ICF Common Template#.

*R&D Head Club (https://rdhead-club.com) is a voluntary group mainly consisting of R&D division heads of Japanese pharmaceutical companies. The group discusses issues related to development and approval of new drugs, and proposes and encourages various areas to take appropriate measures or establish new policies as needed. The R&D Head Club took initiative to conduct a survey regarding ICFs in 2021, and then the Common ICF template (Ver. 1) was issued in October, 2022.

HPB/RDD Notification No. 0704-1, PMSB/ELD Notification No. 0704-2, dated July 4, 2024 "Utilization of standard forms for patient information sheets and informed consent forms in clinical trials": https://www.mhlw.go.jp/hourei/doc/tsuchi/T240708I0020.pdf

2. Features of ICF Common Template

Features of ICF Common Template

- In the past, study-specific descriptions and general descriptions about clinical trials were mixed as a whole, but dividing the descriptions into each section will streamline the preparation of ICFs specific to the study site. Furthermore, **it will be easier to give explanations according to the levels of participants' experiences and understanding of clinical trials**.
- The most parts (in black) of **Sections B and D are unmodifiable as they are common parts of all clinical trials**. Therefore, they don't need to be reviewed again for each study.

[Reference link]

- Informed Consent Form (ICF) Common Template | List of deliverables of the Drug Evaluation Committee | Japan Pharmaceutical Manufacturers Association (jpma.or.jp): https://www.jpma.or.jp/information/evaluation/results/allotment/CL_202406_material.html
- ICF Survey 2021 (R&D Head Club): https://rdhead-club.com/struct/wp-content/uploads/ICH-2021-Dec.pdf

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Special Project 3 (TP-3)

Prepared in August, 2024

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3. Structure of ICF Common Template

The ICF Common Template consists of 5 sections A to E and a consent form.

- Table of Contents -

ICF Common Template
(JPMA Website)

Sections	Contents/Features
A. Summary of the clinical trial <To be prepared for each clinical trial>	A brief summary of the study should be provided. • Contents of the study should be listed to allow the study participants to confirm them.
B. Participation in the clinical trial <Common to all clinical trials (**unmodifiable**)>	This is a common explanation section given regardless of the study site, sponsor, or study. • This section aims to improve participants' general understanding of "What is a clinical trial?". • This section allows the study staff to effectively give explanations according to the participants' levels of experiences and understanding of clinical trials.
C. Description of this clinical trial <To be prepared for each clinical trial>	This section should be prepared by authors with reference to the preparation guide and sample sentences and include the study-specific information (e.g., study drug details, study procedures, expected benefits/disadvantages). • This section allows the study participants to properly confirm contents of the clinical trial. • The authors can focus on preparation of this section.
D. General description about clinical trials <Common to all clinical trials (**unmodifiable**)>	This is a common explanation section given regardless of the study site, sponsor, or study. • This section allows the study staff to effectively give explanations according to the participants' levels of experiences and understanding of clinical trials. • The authors do not need to prepare this section separately. However, any necessary study-specific additions or supplements should use "E. Additional or detailed information."
E. Additional or detailed information <To be prepared for each clinical trial>	As opposed to "D. General description about clinical trials," this part should provide the information specific to the study site, the sponsor, or the study (e.g., summary of the compensation system, handling of personal information, matters related to pharmacogenomics).

Please understand the purpose for using the common ICF template in Japan. Your cooperation to diffusion of the ICF Common Template will be highly appreciated.

JPMA ICF Common Template

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