

Kit Labeling

- CRF

Diagram illustrating the structure of the CRF (Conditional Random Field) model. The diagram shows three rows of boxes representing different components or layers. The top row consists of a 4-box box followed by a 24-box box labeled "CRF". The middle row consists of a 12-box box followed by an 8-box box. The bottom row consists of a 12-box box.

[illegible]

項目	概要	CRF項目
性別	性別	性別
年齢	年齢	年齢
職業	職業 職業	職業 職業
婚姻状況	婚姻状況	婚姻状況 婚姻状況
収入	収入	収入 EDC 収入 収入
健康状態	健康状態	健康状態
治療	治療 —— GCP	治療 —— 治療 治療

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 CRF

□ CRF

ICH-GCP E6 R3 GCP

CRF

- [illegible]

- 10256" CRF

CRF

ALCOA+ Reconciliation

IWRS CRF

- / "IWRS CRF "
- "CRF IWRS "

EDC CRF

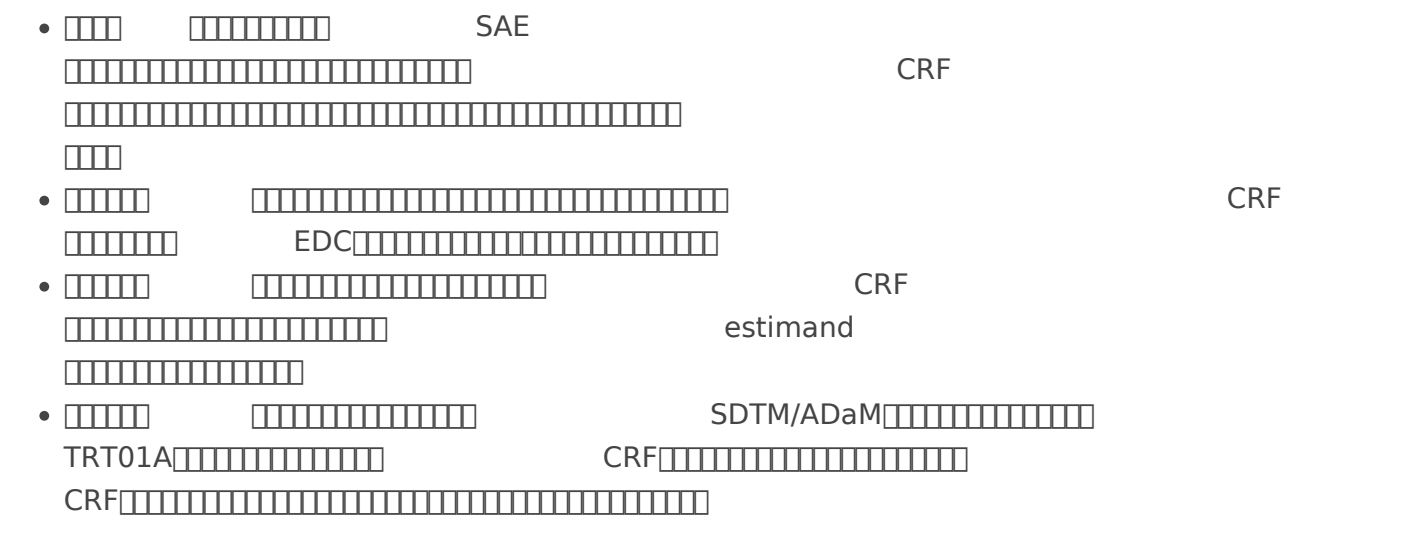
- " CRF " —
- = — / × 100% CRF PPS

CRF

CFDI EDC CRF

CRF " " CRF EDC IWRS

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“ ” ” CRF ”
”
CRF
GCP
”
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[1] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). **ICH E6(R3): Guideline for Good Clinical Practice** — Principles and Annex 1. Step 4, 06 January 2025; Annex 2 adopted 03 June 2026. Available at: <https://www.ich.org/page/efficacy-guidelines>

[2] , . 2020 57 . 2020 4 23 , 2020 7 1 .

[3] CFDI .
2026 . 2026 8 31 , 2026 9 1 .

[4] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). **ICH E9(R1): Addendum on Estimands and Sensitivity Analysis in Clinical Trials** to the Guideline on Statistical Principles for Clinical Trials. Step 4, November 2019; legal effective date 30 July 2020. Available at: <https://www.ich.org/page/efficacy-guidelines>

[5] Clinical Data Interchange Standards Consortium (CDISC). **Study Data Tabulation Model (SDTM) & Analysis Data Model (ADaM)**. Available at: <https://www.cdisc.org/standards>

[6] World Health Organization (WHO). **Guidance on Good Data and Record Management Practices**. WHO Technical Report Series, No. 996, Annex 5, 2016. □ ALCOA+□□□□□□□□