

Diagram illustrating a CRF (Conditional Random Field) model structure. The input layer (10 nodes) is connected to the hidden layer (10 nodes), which is connected to the output layer (10 nodes). The output layer is labeled "CRF".

項目	概要	CRF項目
性別	性別	性別
年齢	年齢	年齢
体重	体重 単位	体重 単位
身長	身長	身長 単位
血圧	血圧	EDC 血圧 単位
心拍数	心拍数	心拍数
体温	体温	体温
呼吸数	呼吸数	呼吸数
酸素飽和度	酸素飽和度	酸素飽和度

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 CRF

CRF

ICH-GCP E6 R3 GCP CRF

- [illegible]

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[illegible]

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?????CRF??????????

[illegible]

[illegible]

The diagram illustrates four different data structures for a clinical trial, each represented by a horizontal bar divided into segments. The segments are labeled with data types: SAE, CRF, EDC, estimand, SDTM/ADaM, and CRF. The diagram shows how these data types are organized and linked across different time points or events.

- Structure 1:** A single bar with segments labeled SAE, CRF, and CRF.
- Structure 2:** A bar with segments labeled EDC, CRF, and estimand.
- Structure 3:** A bar with segments labeled SDTM/ADaM, CRF, and CRF.
- Structure 4:** A bar with segments labeled TRT01A, CRF, and CRF.

[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+□□□□□□

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