

## 13 Points to consider when designing case report form

**Outlining a case report form (CRF) is crucial in a clinical trial as it helps in surveying the wellbeing and adequacy of the therapeutic item precisely. Some of the points that need to be considered while designing a CRF are:**

- 1)** The CRF booklet should use consistent format, font style and font sizes.
- 2)** The questions and instructions should be clear.
- 3)** Visual cues should be provided which can help in recording of the clinical data.
- 4)** Checkboxes should be used as much as possible in the CRF booklet.
- 5)** Instructions should be provided to distinguish the essential components to be filled in from the optional ones.
- 6)** Separate lines or boxes should be provided in the CRF booklet. This would inform the data recorder where to enter the information in the CRF booklet.
- 7)** Columns in the CRF booklet should be separated using thick lines.
- 8)** Important instructions should be provided in bold or Italicized form.
- 9)** Page numbering in the CRF booklet should be consistent.
- 10)** All units of measurement should be specified.
- 11)** The number of decimal places to be recorded should be indicated.
- 12)** The standard date format (dd/mm/yyyy) should be used in the CRF booklet.
- 13)** Use of precoded answers such as yes/no, male/female should be provided.

## References:

1. Nahm M, Shepherd J, Buzenberg A, Rostami R, Corcoran A, McCall J, et al. Design and implementation of an institutional case report form library. Clin Trials. 2011;8:94–102.
2. ICH Guidance E6: Good Clinical Practice: Consolidated guideline. US HHS, US FDA, CDER, CBER.1996. [Last accessed on 2013 Jun 11]. No authors listed. Available from
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4. <https://ichgcp.net/5-sponsor>

**Note:** This checklist was compiled by [Kalpataru Mukherjee](#).