

## Regulations Affecting All CRFs

A number of sections in the ICH GCP guidelines refer to the collection of trial data. In addition, there are some Food and Drug Administration (FDA) regulations that are relevant to CRF design for trials to be conducted in the USA (in particular, parts f (2) and f (3) of 21 CFR 314.50). National requirements in some countries may also affect CRF design and approval.

The ICH GCP guidelines require that:

- ✓ “All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification”. [section 2.10](#)
- ✓ “The sponsor should utilize qualified individuals (e.g. biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and CRFs and planning the analyses to analyzing and preparing interim and final clinical trial reports”. [section 5.4.1](#)
- ✓ Sponsors should “ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)”. [section 5.1.1](#)