OCS Life Sciences

DO IT YOURSELF: CASE REPORT FORM (CRF) ANNOTATION

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Case Report Form (CRF) Annotation

There is more than one way to skin a cat; and there is also more than one way to annotate a Case Report Form (CRF).
As the regulatory authorities and CDISC have guidelines to deal with metadata submission, we do have a roadmap to create an annotated CRF. However, some of these guidelines contradict each other, and what do you do when your CRF cannot adhere to all the guidelines?

As a CRO we annotate CRFs ourselves, but we also work with CRFs annotated by our clients and we do see differences regarding the annotations, but also in the required bookmarking.

These different approaches are not wrong, but to be consistent it is useful to always try to annotate CRFs following the FDA Technical Specifications Document and CDISC Metadata Submission Guidelines.
The CDISC guidelines have updated in march 2021, and we wanted to take a closer look at how we think we can best annotate a CRF.
Furthermore, bookmarking a CRF can be a lengthy task, but by automating this to a great extent we can speed up this process considerably.