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A Best Practice Guide to CRF Design

Introduction to case report forms

Case report forms (CRFs) play a crucial role in helping to assess the safety and efficacy of clinical products.

Insufficient or inaccurate data collection can prove costly when it comes to data analysis. It could require lots of unpicking to identify gaps and resolve terminology inconsistencies before submission.

Therefore, it follows that CRF design should be based on standardized practices with the end-user in mind.

In this best practice guide to CRF design, we'll tackle the most common CRF design issues we see, and the best practice solutions that will save you time, resources and money, so you can focus on getting life-saving and lifeenhancing treatments to those in need, faster.

What makes a good CRF?

CRFs or electronic CRFs (eCRFs) are documents designed to record all patient information required by the sponsor during a clinical trial.

An eCRF can be stored in cloud-based systems such as Electronic Data Capture (EDC) systems. The terms 'CRF' and 'eCRF' tend to be used interchangeably, and they're also referred to simply as forms.

Designing the perfect CRF is about striking a balance. The aim is to collect data that answers the study premise with sufficient detail, without gathering irrelevant, ambiguous or duplicated data.

Forms should:

- Be well planned with meticulous attention to detail
- Comply with regulatory requirements, such as those defined by the US Food and Drug Administration (FDA)
- Gather high-quality, complete and accurate data
- Be easy to use in order to avoid end-user errors
- Be designed to collect the key safety and efficacy information required by the study protocol
- Collect data in accordance with controlled terminology, for easier interpretation and analysis
- Be reusable

With lots of stakeholders, version control requirements, and complex approvals processes to deal with, achieving the perfect CRF design is often easier said than done!

Common design challenges and best practice solutions

Challenge #1: The need to recreate the wheel with every study

Designing your CRFs from scratch for every study means a lot of repetitive, intricate and time-consuming work. This manual process increases the risk of admin errors and makes consistency difficult to achieve.

If you do have some old content to base your new forms on, it can be difficult to find the most up-to-date version. You might find that different teams are using different versions and have these saved in different locations. They might be tracking changes in a spreadsheet, in email conversations with stakeholders, or not at all. This can mean you are wasting lots of time trying to find the content you need.

All of this can also lead to problems after the study is live. How will you report on why edits where made? How will you know the impact on related content of any changes you make? How different is the standard form from the study version? And how will you learn lessons for your next study?

Solution #1: Maintain standardized forms you can reuse

While it is possible to standardize CRFs in text files, you might find you're having to keep track of changes in a separate document, or that different teams within your organization are still using different versions.

The best solution is to switch to standardized, electronic CRFs stored in a centralized location. Using eCRFs through an EDC system enables easier standardization and reuse; eCRFs are stored in a central repository and any edits can be made quickly and tracked easily.

Challenge #2: Complex approval cycles

Different stakeholders need different views of metadata in different formats. You might find yourself going back and forth between teams, making changes and rebuilding your forms until all approvers are happy and have the required file formats.

And if you're creating forms in text documents, there's no easy way to keep track of all these changes. Getting CRFs approved can be a lot of work and is a common cause of delays in study build.

Solution #2: Do proper planning early in the study

This should be done by a team of people that includes data managers, biostatisticians, and clinicians – anyone who will have a final say in the CRF design. Define clear objectives and stick to them.

With this many people involved, you'll probably need to undertake several rounds of edits. It will help to use an electronic, version-controlled form that's stored within a centralized location such as an EDC system. This will allow you to easily edit while tracking changes to your forms. Avoid storing feedback or edits in spreadsheets or long email chains to avoid the headache of trying to decipher changes down the line.

Challenge #3: Data entry errors and collection of unnecessary data

If a form isn't planned and designed well, the collected data will likely have errors or be inconsistent. You may end up collecting data that is incomplete or unusable. In the worst case, you might discover that you haven't collected all the data you need, and you now can't get that information. To rerun the trial would mean considerably more resources, time and money.

On the other hand, having excess data can be messy. It wastes the time of the user, the patient, and the data management personnel who will have to pick through what has been collected to determine what is and isn't relevant.

Solution #3: Use a simple design, provide clear guidance and listen to user feedback

Simple and consistent CRF design is crucial as it reduces the chance of mistakes being made in data entry. You should avoid duplicated questions, ambiguity in approved answers, and redundant data collection, for example calculated fields or derivable data.

You should also provide completion guidelines to minimize errors in data capture and entry. These guidelines might provide visual clues for how an answer should be formatted, such as the date format or number of decimal places. See examples below.

Poorly designed CRF	Well designed CRF
Unclear guidance on how to fill the required field	Clear guidance on how to fill the required field
Date of visit MM/DD/YYYY ? DD/MM/YY ? _____ DD/MM/YYY ?	Date of visit __ __ /__ __ / __ __ DD/MM/YYYY
Single line field doesn't define how the answers should be formatted	Clear guidance on how the Systolic Blood Pressure answer should be formatted
BP Systolic _____	BP Systolic |_|_|_| mmHg

Finally, build a user feedback process into the CRF design and maintenance stages. This way, you can hear straight from the end user about any problems or ambiguity in the form and correct any problems before they happen.

By only asking for what you actually need, providing guidance for the investigators, and gathering user feedback, you'll make it easier for users to fill in forms correctly and ensure that data is accurately captured for analysis.

We have created this editable design checklist containing some dos and don'ts to help you create a well-designed form that meets the requirements of your study.

Get the design checklist

Clinical Data Acquisition Standards Harmonization (CDASH)

According to CDISC: "CDASH establishes a standard way to collect data consistently across studies and sponsors so that data collection formats and structures provide clear traceability of submission data into the Study Data Tabulation Model (SDTM), delivering more transparency to regulators and others who conduct data review."

In 2015, we collaborated with CDISC, the global clinical research data standards development organization. We created and enabled access to a portal of free, ready-to-use, CDASH-compliant, electronic case report forms. CDISC used our all-in-one cloud-based clinical metadata repository (CMDR) to design these templates.

Certara has you covered

Our Pinnacle 21 **CRF Creator** software makes aligning with best practice much easier. Now you can design and build full studies for leading EDC systems, in one central platform.

- Standardize and reuse forms, visits, visit schedules, edit checks, Controlled Terminology, annotations & more from your central, global repository
- Visualize how forms will look for leading EDCs (including Rave & Veeva)
- Build full EDC studies from the CRF Creator platform
- Validate against EDC specific rules
- Maintain version history & audit trail
- Analyze the impact of potential changes

- Shorter review-approval cycles
- Faster, more efficient study setup
- Less manual work & human error
- Reduced risk
- Increased data quality & consistency
- Greater opportunity for compliant, timely submissions
- Potential to launch drugs to market sooner

What you've learned

- The background to case report forms
- The difference between CRFs and eCRFs
- Common CRF design challenges
- Best practice solutions
- The checklist to follow when designing a form
- The platform that can make CRF design, approval and use easier!

> "Thanks to the team, we were able to gain efficiencies by adopting new standardized case report forms. We no longer have to recreate the wheel with every clinical trial."
>
> Coretta Robinson, Program Manager

Design, standardize and reuse CRFs from a centralized repository and maximize efficiencies in study setup with **Pinnacle 21 CRF Creator** software.

Book a free no-obligation demo

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Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,400 biopharmaceutical companies, academic institutions and regulatory agencies across 70 countries.

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