Five Guidelines for EDC Study Design

Whether you are an EDC newbie or pro, it is easy to loose sight of key tenants that help ensure successful EDC-powered studies. While each study protocol is different and carries its own unique challenges, the following guidelines will help you maintain your focus on proven elements for success.

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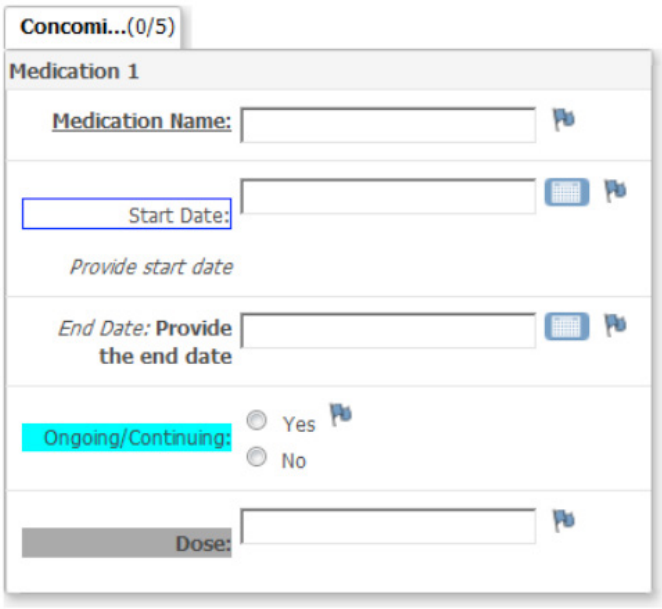
Guideline #1: **Consider your users.**

As you build your study, keep in mind that you're building a system that others will be using. Putting yourself in the mindset of your stakeholders will help you optimize the EDC experience for those who will be using it.

- Remember to balance the needs of the site users with the needs of the sponsor. An EDC study may seem to flow seamlessly from the viewpoint of a data manager, while the same study, from the viewpoint of a research coordinator could appear repetitive or illogical, making it difficult to achieve efficiency and data quality goals. For example, the data manager who configured the study may have defined the eCRFs and events needed to collect the right data according to the protocol, but the site may have its own worklows which dictate data collection in a different order.
- Avoid misintrepretations by employing brevity and clarity. Consider having reviewers outside of the main project team evaluate your study to ensure eCRF questions are clear, rules and error warnings cannot be misconstrued, and the visit workflow is logical and intuitive for each type of end user. Often, designers are too close to the build process to see where questions or edit checks might be misconstrued by end-users. Precise questions, explicit edit checks and error messages lead to more efficient responses and reduced data collection times.
- Ensure users have all the data they need at the time of data entry. Sounds simple, right? It is all too common to design an eCRF requiring a data point that may not actually be available at the time of data entry. For example, drawing a patient's blood may be part of a particular event definition, suggesting it might be appropriate to request data from the sample's analysis at this point in the EDC system. However, in reality, lab analysis results may not be available until a future visit. Users may become confused and frustrated if they repeatedly encounter validation checks or rules requiring information that it is not available to them.
- Conversely, an expected data field that is missing can lead to misrepresentation of the overall form or event status, or even provide an incorrect indication of the patient's actual status in the study. In most EDC systems, for instance, the missing lab result from the example above would prevent the baseline visit from reaching a completed status. In this setting it would be difficult to determine which subject baseline visits were incomplete from the missing lab result and which were truly incomplete due to additional missing data.

Guideline #2: **Simplicity.**

- Keep formatting simple. Remember that a system doesn't have to be aesthetically complex in order to achieve the goal of quality data collection. While fancy fonts, colors, and custom HTML may make the designer feel like a graphic arts pro, these things typically do not add much value and can negatively impact usability. The goal is to build a logical and user-friendly interface for your users.



In this figure, what is the most important item on the CRF? Good question!

- Beware of over-engineering. EDC systems have evolved to include sophisticated feature sets, with complex workflows, dynamic logic, and other bells and whistles. Know when to use and when not to use these tools. For example, it may be easier to manually enter simple data (one or two data points per subject) rather than going through the trouble of generating custom import files. Similarly, you may also be able to avoid using an excessive amount of dynamic show/hide questions by simply setting certain data items as required or optional. An over-engineered study increases testing and training time, and can complicate inevitable downstream study changes.

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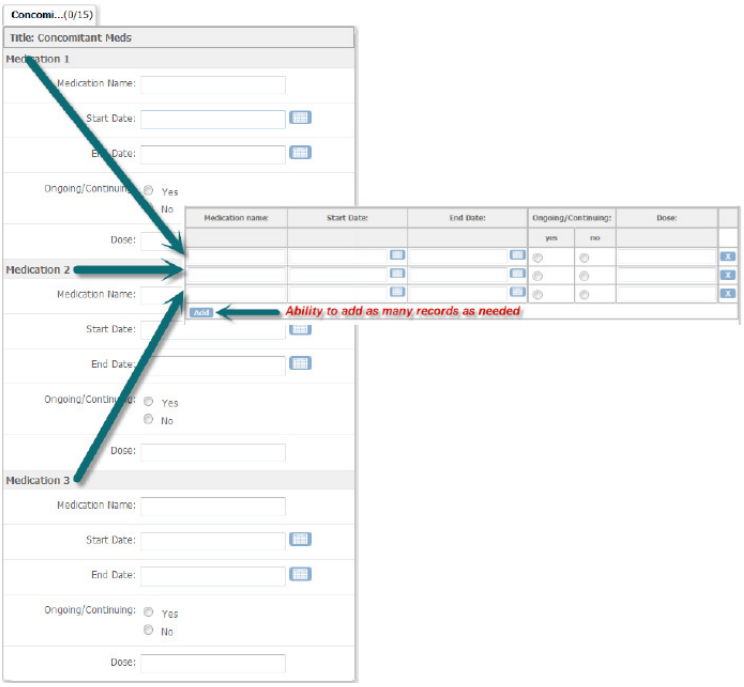
Guideline #3: **Right-size your eCRFs.**

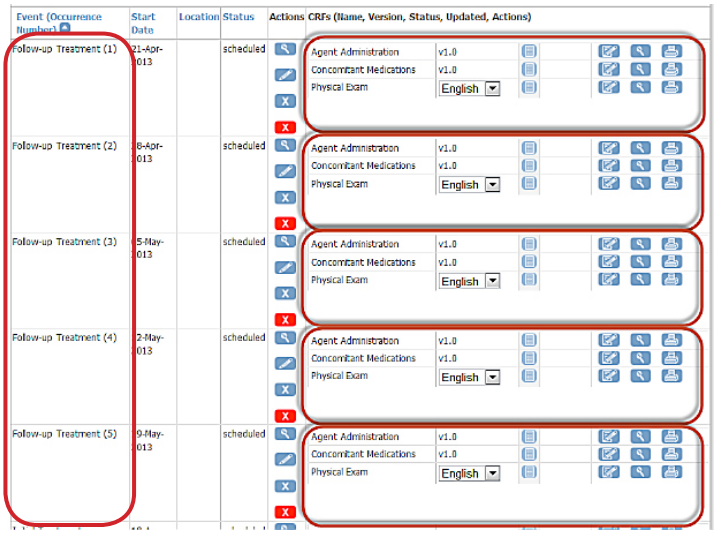
The eCRF is the centerpiece of your EDC study. Maximize usability of your eCRFs and take steps to ensure they don't inadvertently act as a barrier to quality data and efficient process.

- Use a form length that is appropriate for the web. When designing eCRFs, it is important to keep your forms and their pages/sections short. Long forms can function as hurdles to data entry, and where scrolling is required (either horizontally or vertically), you run the risk of the user not seeing everything on the page. Conversely, form sections that are too short can be frustrating to use, lacking sufficient context, and requiring unnecessary clicks.
- Judiciously use edit checks. There is a widespread tendency in EDC to make excessive use of edit checks that fire "in-line" with data entry. Although an undeniable advantage of EDC is the ability to have edit checks that fire as data are entered, if these checks are too numerous (especially on a single item or form) users may users may feel inundated.

  Hard edit checks, or edit checks that prevent the user from moving forward or saving data unless specified criteria are met, are often misused. For example, if the user enters a value that falls outside a designated range, a hard edit check would block the user from continuing data entry. In this situation, a frustrated user might even feel forced to enter a false value in order to continue. Consider using "soft" edit checks that allow the user to proceed after they explain themselves via a comment/annotation.



Using repeating item groups versus creating areas for multiple entries can help make forms more usable and scalable



Appropriate use of a repeating events feature leverages existing forms for reuse. In this example you can see that the Follow-up visit is a repeating occurrence. The same forms are reused in each occurrence of this event.

Guideline #4: **Make optimal use of system functionality.**

The only way to truly maximize the benefit of your EDC system is to fully understand its capabilities. This will allow you to make informed decisions about how best to utilize the technology for various situations. Here are some tips based on commonly available EDC software features:

- Use required item functionality to denote questions as required or optional. When the data property "required" can be utilized, you can avoid unnecessary effort associated with writing and validating multiple rules, conditionals or complex dynamics.
- Leverage repeating sections and repeating visits instead of creating multiple copies of the same question or set of forms.

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Guideline #4: **Make optimal use of system functionality** (continued).

- Carry forward (via auto inserts or data mapping) data that is reused, rather than require users to re-enter the same data in multiple places. For example, if Body Mass Index (BMI) is calculated at every visit, your EDC system should be able to carry forward the value for height instead of having the height entered as a new data point in each visit. It is also common to use this functionality for Date of Visit if you want the assessment date to appear on assessment forms.
- Users should not be forced to conduct their own calculations just to have their calculation confirmed by a validation check. If your EDC system supports auto-calculations, you can use this feature to minimize user effort and increase data accuracy. But make sure any system calculated data point is set as read-only/ non-editable to prevent any accidental updates.
- Make use of email notifications, which will email messages to relevant parties when pre-defined criteria are met, such as a serious adverse event. This can deliver critical information faster and save you from having to constantly run extracts or reports.
- Utilize email alias/distribution lists rather than an individual person's email addresses. As people come and go, so do their email addresses, but email aliases can be permanent and "repointed" as needed. Using email aliases can save you form having to update the EDC system when an employee is no longer on the project.

Guideline #5: **Build for the Future.**

It is rare that an organization only conducts a single clinical study. Most EDC technology offers the ability to easily reuse eCRFs, edits checks, and other assets for new studies. Consider adopting standards that facilitate this reuse and help "future-proof" your investment. Standards may be as simple as a vitals signs or demographic form commonly used within your department or a specific naming convention for your data variables and rules. Adopting libraries and independent, widely accepted open standards, such those promulgated by CDISC[1], facilitate interoperability and can reduce overall study build time. As users become familiar with core standardized forms they will require less training, deliver more consistent data, and speed data collection time.

When building a study in your EDC system you are configuring a dynamic software application. Completely and accurately visualizing every detail of the application up front, and in a way that accounts for every stakeholder's perspective, is not realistic. You should assume that changes will need to be made before the final product is ready. Adopting an iterative approach to building studies can be a good way to accommodate change at various points in the process.

Summary:

As designers of eclinical studies, our attention is often commandeered by tight timelines, frequent requests for fixes, and revisions. We are challenged to create unique solutions for often complicated requirements and optimize system functionality to achieve our fullest potential. A thorough understanding of your EDC technology, a sound process, and thorough planning with stakeholders are essential ingredients to help maximize the benefits of EDC.

[1] CDISC: Clinical Data Interchange Standards Consortium. CDISC is a non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. See http://www.cdisc.org.

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