Moving from Paper to EDC

An overview of key considerations and common pitfalls when migrating from paper to a clinical research electronic data capture (EDC) system.

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Adoption of electronic data capture (EDC) technology continues to grow as the advantages of this technology are now widely understood (faster data collection, cleaner data, real-time data access, and reduced cost). While a significant and growing number of clinical research studies utilize EDC, there are still many people who are considering using EDC for the first time.

Re-orienting Your Perspective

Successfully transitioning from paper to EDC is not simply a matter of copying existing Case Report Forms (CRFs) verbatim into the EDC system. Users interact differently with web content than they do with paper. When placed online, CRFs must take into account functionality optimized for a computer screen, keyboard and trackpad/mouse. For example, the experience of browsing articles on a news website is considerably different from reading a physical newspaper. Online, the user must scroll in order to view the entire webpage and possibly click tabs and links to see additional story content. With a newspaper, the reader is physically turning pages and manually scanning the entire newspaper to locate stories of interest. Although both may have the same content, physical newspapers and their online counterparts are presented differently in order to take advantage of both the limitations and opportunities inherent in the different form factors. Similarly, in clinical research, successfully moving from paper to EDC requires re-envisioning paper forms in the context of the opportunities, expectations, and constraints in the digital world.

From Paper to the Web

Web-based EDC introduces interactivity to traditional paper CRFs (pCRFs). With electronic case report forms (eCRFs) inherent in EDC, users are no longer simply recording data, but interacting with a dynamic system that responds to their actions in real time. For instance, when a validation check is programmed on an eCRF field, the user receives feedback as soon as the data is saved, giving the user the option to immediately update their response before moving forward. The output of this EDC feature reduces manual queries and allows for cleaner data to be captured at initial entry, saving time downstream in comparison with a paper-based process.

Another characteristic of most EDC systems is the ability to use dynamic workflows. They can be used to enhance quality and productivity over paper. EDC systems can be configured to show questions or sections based upon certain criteria. For example, pregnancy questions may be programmed such that they are only available to females. This prevents pregnancy data from erroneously being entered for male subjects. Dynamics may also be used to present specific sections for certain groups of subjects, e.g., demographics, where a smoking history section might only appear for smokers, or a treatment section might only appear for subjects receiving the study drug.

Figure 1: Questions 1b and 3b are dynamically generated, based upon response to questions 1 and 3 respectively.

There are also some important considerations when it comes to CRF layout when comparing paper with EDC. For instance, header and footer areas are often automatically added to electronic CRFs (eCRFs) and populated with subject enrollment data such as subject number, subject initials, date of birth, study name, and event name. Unlike paper, page numbers are not typically relevant in an electronic system. Instead, eCRFs are often organized into multiple manageable sections with convenient navigation. This can help improve the users focus by minimizing distractions. Notwithstanding, users may still miss data fields that sit outside of the immediately viewable area, or "folds," of the web page. When designing your eCRFs, knowing where the page folds will likely sit on the screen will allow you to minimize unnecessary scrolling (both top-to-bottom and left-to-right).

Paper and EDC Comparison

Paper	EDC
Records kept in binders; must manually create links between forms and subject documents	Records easily accessed and status known at a glance • Electronic forms indexed by subject and by visit • Subjects easily searchable • Icons show subject, visit, form status for high-level review
Accepts any data	Only accepts data that meets pre-defined logic and validation checks with a clear workflow, to resolve data discrepancies
All data fields available for all subjects	Sections and data fields not shown unless appropriate criteria met
Can choose more responses than required	Enforces appropriate response quantity
Little control over question response format	Built-in data types increase data quality and ease of analysis
Responses may be illegible, dates may be illogical	All data responses are typed or selected. Ability to limit responses to dates, numbers, decimals or alphanumeric as designed.
Users must follow manual skip pattern instructions	Skip patterns can be automatic, removing guesswork, lending to cleaner data
Pagination to divide content	Sections or tabs to break up content
Manual calculations and manual scoring	Auto calculations and scoring assessments
Pages and pages of reference materials	Hyperlinks to reference documents and more information
Cumbersome Data Clarification Form (DCF) process	EDC Query Management allows instant review and automated resolution of queries
Audit trail manually managed, or non-existent	Audit trail automated and runs in background. System can force user to supply a reason for changing any data item.

Figure 2: Examples of questions from a pCRF rendered in an eCRF.

Thinking about Data Structure

Even in the paper world, clinical research data is entered into a database, and this database has defined data structures. When using EDC, you will need to define response types and response values for each question on your eCRFs.

For example, the inclusion question, "Is the subject at least 18 years of age? Yes (1) or No (0)," Yes and No are predefined, single select response types with response values set to 1 and 0 respectively. In EDC, responses will also be associated with a data type such as text, integer, decimal, date, file, etc. Every piece of data is assigned one of these data types, which defines the most basic structure or syntax the question response will accept.

A beneficial feature of EDC is that data type can help define the user's response. A field defined as an integer data type will neither accept alphanumeric characters nor values containing decimal points. A date field will only accept a valid date, often assisting the user with a calendar widget.

When you think about putting your paper CRFs into electronic form, you'll need to anticipate which type of input to use for each question. For instance, questions that offer the user a predefined set of responses from which to choose, could be manifest as a single select (i.e., drop down list), multi-select, checkboxes, or radio buttons. Your choice may ultimately impact form layout as well as whether the user can physically choose one or multiple options from the list. You may also set a limit to the number of characters allowed in a textbox, number of digits in an integer, or number of decimals allowed in a real number. For example, a text field may be limited to 255 characters (a common limit), or a height field may only allow up to three numeric digits.
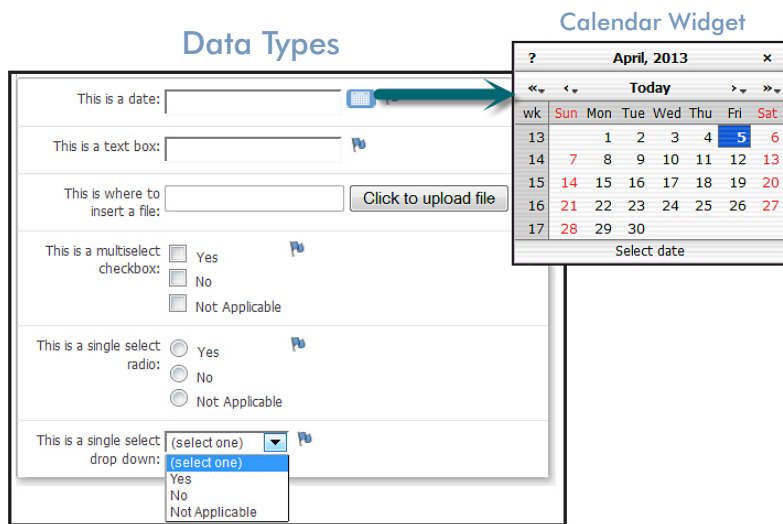
Data Types

Calendar Widget

Figure 3: Examples of common EDC response and data types.

The ability to enforce whether the response to a question is required or optional is another basic characteristic of EDC that sets it apart from paper. A required question means that the user must provide a response before moving forward in the system.

In addition to validating data against pre-defined data structures, EDC also introduces additional, more sophisticated ways of validating your data via edit checks and rules.

Understanding Edit Checks and Rules

A major benefit of moving from paper to EDC is ability to utilize edit checks and rules. Edit checks (also known as validation checks) are predefined actions that the EDC system performs on the data, forms or visits. Some examples are:

■ Ensure data falls within a specific range, is of a particular syntax, or equals a pre-defined value. If a data point provided does not meet the requirements of the edit check, an error message might appear and/or email notification might be sent. Edit checks might be used to verify the range of blood pressure, height or drug dose. More complex checks can validate across forms and visits such as ensuring an assessment date occurs after an informed consent date or within a specific visit window.

■ Make a question or sections appear (show) or disappear (hide), based upon certain criteria. For example, if the outcome of an adverse event is death, a rule could populate questions regarding the summary and date of death while subjects whose outcome is not death will never see the death-related questions. This type of rule has the ability to alter study workflow.

■ Insert/pre-populate a data point with a specific value or map a value from an item within the system. For example, if the assessment date should be repopulated with the current date, you could use an insert rule to pre-fill the item with the system date, or map the date to this item from a Date of Visit form.

■ Automatically calculate and insert a value into a field. Examples include body mass index (BMI) or determining the score for a Quality of Life assessment.

Edit checks and rules can be run in-line with data entry where they can be defined as "hard" (the user cannot proceed unless they satisfy the requirements of the edit check) or "soft" (the system displays an alert when the edit check fires but does not prevent the user from proceeding). Edit checks can also be run in batch mode after data is collected.

When used wisely, edit checks and rules can help deliver higher quality data and reduce downstream data management effort. However, excessive, poorly designed, or inadequately tested edit checks can become a source of user frustration, creating an undue burden on research sites. It is therefore important to carefully and clearly define each edit check, and the edit checks you would like to use should be well understood early in your study configuration process.

However, despite best efforts, it is rare to define all your edit checks up front. Although you may have a finalized edit check and rule plan prior to CRF build, you will often uncover additional edit checks and rules you would like to include during the design and review process. This is especially true when you are first acquainting yourself with your EDC system's functionality. Ensure your study build plan allows time to make these improvements to your system. If need be, edit checks can also be added after the study is live and run on the data in batch form.

Common Edit Checks and Rules

Edit Checks and Rules	Type
Inclusion /Exclusion Form: If any Exclusion Criteria are yes, then error message that Subject should not participate.	Edit Check
Physical Exam Form: If a body system is selected as Abnormal, a reason must be provided.	Edit Check
Assessment date is after Date of Informed Consent and not a future date.	Edit Check
End date is not before Start Date.	Edit Check
Demography Form: Weight is less than xxx.x kg.	Edit Check
Demography Form: Age is >18 and < 85	Edit Check
Adverse Event Form: If an Adverse Event is severe, send email to the safety team.	Email
Adverse Event Form: If Adverse Event is serious, Serious Adverse event form appears and is required to be completed.	Dynamic
Demography Form: Subject is female, pregnancy questions appear.	Dynamic
Labs Form: Date of assessment pre-populates on lab form.	Insert
Physical Exam Form: Calculate BMI.	Calculation
Adverse Event Form: Auto generate Adverse Event Sequence Number.	Calculation

Ready, Set, Design!

As you can see, moving from paper to EDC requires some significant changes in how you think about your study. Keys to EDC success include having a thorough understanding of your EDC system's capabilities and functionality, a clear definition for your data specifications, and the ability to visualize how to apply validation checks, rules, and desired workflows. All of these components come together to create a complete EDC study, which can deliver superior results over paper studies. Over time, organizations running their studies in an EDC system will develop a reusable library of forms, edit checks, rules, and other assets that make deploying future EDC studies more and more efficient.

For additional tips on designing studies for EDC, refer to white paper, Building Successful EDC Studies.

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