
CRF Printing and Vendor Selection

May 2007

Abstract

Planning for the printing of a study's case report forms (CRFs) is essential to the study's conduct. This chapter provides insight and guidance for this critical component. Guidelines for the evaluation and selection of CRF printing vendors are provided. The chapter also covers the process by which a clinical data manager plans for the production of printed CRFs and their timely delivery to sites, with both tasks completed by a third-party vendor. Guidelines for the CRF binder, the paper used for printing, and tabs banks are discussed in regard to the specifications that should be provided to the printing vendor. Recommendations are made for binding, packaging, and shipping the CRFs, with an emphasis on the importance of timetables. Guidelines for the evaluation and selection of CRF printing vendors are provided. An example of a CRF printing specifications checklist is included.

Introduction

The case report form (CRF) is a critical document for capturing relevant data in a clinical trial. The development of a study's CRFs is addressed in the Data Acquisition chapter. However, the production aspects of the CRF, including printing CRFs and ensuring their delivery to sites, must also be addressed. The selection of a vendor for these tasks should also be carefully considered.

Scope

This chapter will review considerations for outsourcing the printing of CRFs. Use of the following guidelines will help ensure the same quality and service from the contracted print vendor that the Clinical Data Manager expects to receive.

Minimum Standards

- Establish specifications outlining CRF printing and distribution requirements. These specifications should include:
 - ☐ the complete list of items in the CRF binder
 - ☐ the total number of each item to be printed
 - ☐ the type of paper
 - ☐ the type of binding
 - ☐ the collation order
 - ☐ the type and number of tab banks
 - ☐ the number of tabs per bank
 - ☐ the images to be printed
 - ☐ the instructions for printing
- Provide packaging instructions to the printer.
- Submit new printing specifications (including printing and shipping timetables) to the printers whenever significant modifications are made to the CRF or to any item outlined in the specifications.
- Obtain approval by appropriate team members of the final print-ready CRF, the CRF printing specifications, and the shipping/distribution timetable prior to the submission of the final printing specifications to the printer.

Best Practices

- Use a vendor qualification program to select a vendor.
- Ensure that other study materials such as pocket cards, study schedule posters, pre-printed return envelopes, and study contact information are printed to compliment the CRF and associated materials and are distributed simultaneously.

- Obtain a prototype of the CRF book from the printing vendor for review and approval before the final print run. The prototype should include all pages, tabs, spine label, and cover.
- Use a vendor evaluation program throughout the vendor relationship.

CRF Binder

Prior to submitting the final printing specifications to the printer, the final print-ready CRF, printing specifications, and shipping/distribution timetable should be approved by appropriate project team members. CRF binder specifications should include all of the information the vendor needs to produce the CRF binder and associated materials.

To determine the total number of CRFs, diaries or other required pages to be printed, consider the number of evaluable patients required per the protocol, the expected drop-out/replacement rate, and the possible need for a back-up supply. The back-up supply should be 10–15% of the total number of patients enrolled. If materials are distributed in packages, overage estimates should take into account the extra items that are in the pack. For example, if SAE forms are printed on a pad of 100 forms, they will be distributed in allotments of 100. Generally, a site that requires 101 pages will actually use 200 printed forms.

Also estimate the number of CRF papers with a breakdown of the number of no-carbon-required (NCR) pages, non-NCR pages, and other pages (e.g., diary or quality of life pages).

Paper

Specify the paper to be used for printing the CRFs. Include information on the type of paper, color, page weight, hole-punch, perforation, and gum for each page or section. For example, conventional three-part, NCR paper comes in many colors and weights. Many organizations use a white, yellow, pink combination or a white, yellow, heavy card stock combination. The type and number of NCR pages required depend on the workflow and system used. Traditionally, white is the original copy, yellow is the working data management copy, and pink is the site copy. Scanning or fax-based systems

may require only two copies (the original white copy for scanning and the site copy).

There are other special considerations with the use of NCR paper. Printer specifications should include a piece of cardboard or other provision for the site to protect unused pages while completing a CRF page. When using a new vendor or a new paper supplier, it is advisable to test the NCR paper. The copy quality on the second or third ply is dependent on the quality of NCR paper. The weight of the paper should also be specified depending on your workflow. Paper of certain weights has been known to work more efficiently when faxed or scanned. If evaluating the paper supplied by a vendor, test the paper's quality when used to fax or scan printed material.

Consideration for collection of adverse events (AEs) and concomitant medications must be taken. If AEs and medications are collected at each visit and then harvested at every monitor visit, a pull-page system may be used. For example, a clinical data manager (CDM) may use four-part NCR paper in which the fourth page is harvested first (a pull page), thereby enabling the data to be collected earlier. In an alternative approach, the fourth copy could be non-NCR so the next copy of the document reflects only the changes to the data.

Tab Banks

Tab banks are very helpful to the sites in navigating the CRF during the clinical trial. Specify the number of tab banks and number of tabs per bank. Organizing the printing specifications by tabs can effectively communicate the collation order to the printer. Also, specify the paperweight of the tabs (usually card stock), the type and color of Mylar dip or other laminate on the tabs, and the text to be printed on each tab or tab page.

Binding, Packaging, and Shipments

Specify the type of binding, binder color, width, number of inside pockets, cover text or art, and spine label.

Specify the packaging instructions and include a packing list of the items that each site should receive. For example, special forms such as drug accountability logs, screening logs, SAE forms, subject diaries, and

questionnaires may be bound separately in books or pads. Special forms may also be conveniently shrink-wrapped in appropriate numbers for each site.

If the printer is shipping materials to sites, provide shipping instructions. Specify the number of sites and the number of items per site, the shipping company, and the shipping method (e.g., ground or air). When finalizing timelines, the location of sites should be considered. Shipping to international sites may require additional time. With the shipping timetable, provide process instructions for tracking the shipment, checking the inventory of the shipment, and notifying the sponsor of the shipment's status.

Information Commonly Provided With Printing Specifications

If applicable, the following information should be provided to the printer in addition to the printing specifications:

- The final camera-ready artwork of the CRF, the diary, and other pages in electronic files. The format of any electronic files should be discussed and agreed upon with the printing vendor.
- The specifications for CRF layout (e.g., layout of the CRF identifying location of tabs, instructions on the back of tabs, collation of pages, etc.).
- A list of tabs, including the breakdown by bank and color.
- The camera-ready artwork of instructions to be printed on the tab backs.
- The company logo and text for the spine label.
- If the printer is shipping to the sites, a list of sites and their mailing addresses. Moreover, shipping instructions should include details on how the printer will know when the site is approved to receive study materials.
- The priorities and specifications for printing the barcode, if applicable.
- The tentative timetable for sending the final-master copy to the printer, for reviewing the materials prior to the final printing run, and the deadline for the arrival of the shipments at the sites.

The printer should provide a complete prototype of the CRF book for review and approval before the final print run. The prototype should include all of the book's pages and tabs, the spine label of the book, and the cover of the book.

New printing specifications (including printing and shipping timetables) should be submitted to the printers each time significant modifications are made to the CRF or to any item outlined in the specifications. An example of a CRF printing specifications checklist appears in Appendix A.

Selection & Evaluation of CRF Printing Vendors

Print vendors should be qualified. Select print vendors who specialize in CRF printing and have an understanding of the clinical trial process and CRF design. The print vendor should understand the importance of maintaining timelines in the printing and shipping of CRFs before the first patient is enrolled at each site. The printer should be knowledgeable regarding time-to-ship internationally and customs regulations.

Evaluation criteria should include the following: accuracy of printing, quality of service, turnaround time (turnaround time on initial print job and additional requests for extra pages), pricing, CRF design experience, digital or rotary printing, bar-coding capabilities, changes for re-setup, and storage charges. Other criteria to consider is whether the printer out-sources parts of each job such as printing Mylar tabs, separate charges for printing on tab backs, volume discounts, international shipping capabilities, and turnaround times.

Recommended Standard Operating Procedures

- CRF Design
- CRF Production Guidelines
- CRF Printing Specifications
- Vendor Selection

References

N/A

Further Reading

N/A

Chapter Revision History

| Publication Date | Comments |
|-------------------------|--|
| January 2002 | Initial publication. |
| May 2007 | Revised for style, grammar, and clarity. Substance of chapter content unchanged. |

Appendix A: Sample CRF Printing Specifications Checklist

Total # of CRF binders to be printed _____
Total # of diaries to be printed _____
Total # of CRF pages per binder _____
 # of NCR pages per binder _____
 # of non-NCR pages per binder _____
 # of diary pages per binder _____

Page formats: 2-part NCR with 2nd part cardstock, or specify other (The first part NCR should be white paper of weight 26):

Specify page format for diary pages and diary covers (ex. Tri-fold):

Tabs: specify # of banks, # tabs/bank, #tabs with printed instructions on back, mylar-laminated or not and Mylar color:

Does printer need to add page numbers? : Y N

Binders (specify):

| | | | |
|-------------------|-------|----------------------|--------------------------|
| Color: | _____ | Attach spine label | <input type="checkbox"/> |
| Width: | _____ | | |
| # inside pockets: | _____ | Attach cover artwork | <input type="checkbox"/> |

Timetable:

| | |
|--|----------------|
| Final master copy to printer: | ____/____/____ |
| Prototype to XXX/XXX for review & approval | ____/____/____ |
| Shipment to arrive on site or at XXX/XXX | ____/____/____ |

Packaging instructions:

Shipping Instructions: # of CRFs to be shipped per site: _____

of diaries to be shipped per site _____

Will printer store backup supply? Y N

Specify ground or air and # of days to arrive: _____

Attach bar code specifics ☐

Attach list of sites, addresses, and shipping priorities ☐

Attach final camera ready artwork for the CRF, tab back instructions, diary ☐

Attach specifications of layout

Additional comments: _____