

***ACE* DATAFAX INSTRUCTIONS**

Contents

1. DataFax Questions & Answers

- 1.1 What is it?
- 1.2 Do study centers need any special equipment?
- 1.3 Why are we using DataFax for the ACE study?
- 1.4 How does it work?
- 1.5 Who keeps the original CRFs?

2. Completing CRFs.

3. Faxing CRFs.

4. Quality Control Reports.

1. DataFax Questions & Answers

1.1 What is it?

DataFax is a data management system which integrates fax and computer technologies. It provides a clinical trial coordinating center with tools which facilitate the collection, review, correction and tracking of study case report forms (CRFs).

1.2 Do study centers need any special equipment?

Just a standard office fax machine. Completed CRFs are faxed from the clinical centers participating in a study to the coordinating center over ordinary phone lines using ordinary fax machines. The coordinating center receives the faxes through fax modems connected to a computer(s) running the DataFax software.

1.3 Why are we using DataFax for the ACE study?

Because it automates much of the clerical work involved in managing and tracking patient CRFs, DataFax will substantially increase efficiency and reduce costs at the study coordinating center. DataFax also has a number of important advantages which stem from its ability to increase the timeliness of CRF collection, review and quality control. The typical delays in clinical trial data collection and processing make it difficult to keep on top of problems and implement corrections. This ultimately effects the completeness and quality of the study database. Delays in data collection also make it difficult to monitor the progress of the trial and to produce accurate status reports. Long delays reduce the effectiveness of statistical stopping rules and thus can affect study duration, cost and time to publication of results. Also, in studies, like ACE, where centers are paid for each completed case, speedier data processing results in speedier payments to centers.

While DataFax provides the technology needed to solve these problems the ultimate benefit depends, as always, on the people who use it. The participating centers must fax completed CRFs as soon as possible after each patient assessment and attend to requests for CRF clarifications and corrections in a timely manner. And the study coordinating center must keep up with the review of incoming faxes and reliably fax back quality control reports on schedule.

1.4 How does it work?

When a fax arrives at the coordinating center DataFax breaks it into pages and proceeds to process each page. It corrects any misalignment problems, flips pages faxed upside down, identifies which study each page belongs to, reads the data from each page, enters the data into the study database, and stores all pages from the fax on disc. Data management staff then use the DataFax split-screen Validation tool to review all pages received, complete data entry and flag any problems they identify (e.g. missing data) with quality control notes. On a regular basis, usually once a week, DataFax will generate and fax a Quality Control report back to each participating clinical center. These reports show the follow-up status of all

patients enrolled at the center and identify any problems flagged during the central review. Study centers are asked to correct any problems identified on these QC reports and re-fax the corrected CRF pages to the coordinating center. When received these pages are identified as re-faxes by DataFax so that the data management staff can review them and resolve the data clarification requests, or if necessary reissue them.

1.5 Who keeps the original CRFs?

The original paper CRFs will remain on file at each participating center. At the ACE coordinating center the faxed CRFs and corresponding data records can be reviewed simultaneously, on-screen, any time during the trial, thus eliminating the need to print, file and track paper CRFs. This effectively eliminates the “paper shuffle” in the data management office. However, it also means that we will be counting on you to re-fax any form that you modify. If we have requested the modification on a quality control report DataFax will keep track of whether or not it has been made. But we have no way of knowing that you modified a form on your own unless you re-fax it to us. Although we do not intend to collect all CRFs, as an extra quality control step we will ask each center to return a random selection of forms so that we can verify that forms have not been changed after they were faxed in to the coordinating center.

2. Completing CRFs

- Use a black ball point pen. The optical character recognition software included in DataFax attempts to read numerical data written in boxes and to identify which boxes have been marked with an X. It is tolerant of other ways of filling check boxes but it is only successful on numbers if they are written entirely inside of the boxes. For this reason avoid using wide tipped pens and try to keep each digit entirely inside its bounding box. A pen which produces crisp dark characters is best.
- To maximize OCR accuracy please print numbers *inside* the boxes as shown below:

- Print all text (drug names, symptoms, adverse events, etc.) as clearly as possible. Handwriting is often difficult to decipher and can be even more difficult to read at standard fax resolution.
- For check boxes a simple **X** inside the box is adequate. You do not need to shade them in.
- The standard set of CRFs have been pre-numbered, but event reports (stroke, myocardial infarction and death) are completely blank. Please remember to enter the Patient ID Number at the top of each page on these event reports.

- If data is not available print “NA” **beside** the boxes.
- Do not erase or “white out” errors. If you make a mistake and need to correct a number or check box put a single line through the error and print the correct number above the box, or put an **X** in the correct box. If you think it is important do not hesitate to print explanatory notes in blank areas of the forms, but avoid printing over data boxes or check boxes.
- All corrections should be initialed and dated.
- Fax data in as soon as possible after each clinic visit by a study patient. If data forms pile up faxing will become a chore and it may become difficult to answer queries from the coordinating center as time passes and memory fades.

3. Some General Faxing Instructions

DataFax runs continuously, thus the cost of faxing can be substantially reduced by using the delayed transmission feature available on most fax machines, but this is entirely up to you. Whether using immediate or delayed transmission it is important to verify that the fax has been properly read into the sending fax machine, and successfully transmitted. Here are some guidelines:

1. Your fax machine should be setup to transmit a standard 8.5 by 11 inch page. Legal size documents are not supported by DataFax.
2. Make sure the adjustable paper guides are snug against the pages in the input tray. Some machines use the position of these guides to determine how large the pages are and will resize the fax, shrinking it, if the guides are not snug against the pages.
3. Do not overload your fax machine. The paper feed mechanism will misbehave (e.g. pull in 2 pages at a time, or jam) if the input tray is overloaded. There is also a limit on how many pages a fax machine can store in memory at one time (typically 30-40 pages). Each machine is different so you will have to learn the limits of the one you are using.
4. Check the number of pages in your fax against the number your fax machine reports having read in. If it has read fewer pages than were in the input tray it has probably pulled in 2 pages at a time. If this happens abort the fax and read it in again. If you think the problem was due to an overloaded input tray you might want to break the fax in half and send it in 2 transmissions.
5. Most fax machines print out a transmission receipt which can be checked to determine whether the fax was sent successfully. The receipt will include the date and time of transmission, the receiving phone number and the number of pages successfully transmitted. Check this receipt against the fax log and check off each entry as successful or not.

4. DataFax Quality Control Reports

A DataFax Quality Control (QC) Report will be faxed to each active center once a week usually on Wednesday nights. For purposes of QC Reports active centers are those which are currently following one or more patients.

A QC Report has 3 parts. Part 1, the Patient Status Report, shows the follow-up status of all patients enrolled in the study from your center. Part 2, the Refax List, shows problems which require that you correct and refax data forms. It also shows any pages which are missing or visits which are overdue. Part 3, the Question & Answer List, shows any other questions which we have about patients or data forms, and provides a space below each question for you to respond. An example of each of these 3 parts of the QC Report is shown below.

PART 1: THE PATIENT STATUS REPORT

The first part of the DataFax Quality Control Report shows patient scheduling information including the date each patient was entered into the trial, the last follow-up, and the next scheduled follow-up. The ACE assessment numbers which prefix these dates include: 1 for entry, 2 for surgery, 3 for hospital discharge, 4 for the 30 day follow-up and 5 for the 90 day follow-up. The status report also shows whether there are any outstanding problems with each patients CRFs.

Here is a fictitious example. It shows the status of the first 4 patients entered from center 202 (Chedoke Hospital, Hamilton), as of May 11, 1994. The first patient (202501) entered the trial on January 5, 1994 and had his last follow-up (visit number 5) on April 5th. All pages of the CRF have been received and reviewed and there are no outstanding problems. The second patient (202502), who entered the trial on February 20th, also has no problems and is coming due for his final follow-up on May 18th. The third patient (202503) who entered the trial on March 3rd died following the 30 day follow-up and thus is shown as done following assessment number 4. The the last patient, 202504, who entered the trial on April 2nd, is now overdue for the 30 day follow-up. Both of these last 2 patients have outstanding CRF problems which need to be resolved. The specific problems will appear in the Refax List and Question and Answer List which follow the Patient Status Report.

QUALITY CONTROL REPORT # 125-940724-01 (Chedoke Hospital, Hamilton)

PATIENT STATUS SUMMARY

PATIENT	ENTRY	LAST FOLLOW-UP	NEXT FOLLOW-UP	CASE REPORT FORMS
202501	1: 01/05/94	5: 04/05/94	done	done
202502	1: 02/20/94	4: 03/18/94	5:05/18/94	complete to date
202503	1: 03/03/94	4: 04/03/94	done	outstanding problems
202504	1: 04/02/94	3: 04/16/94	4: 05/01/94	outstanding problems

PART 2: THE REFAX LIST

The second part of the standard DataFax Quality Control Report identifies problems which need to be resolved by either faxing in something which was never received or correcting a page and faxing it in again. The example below shows the outstanding problems for patients 202503 and 202504, which were noted on the Patient Status Report. For patient 202503, pages 1.2 and 1.3 from the baseline assessment are missing and pages 1.4 and 1.6 need to be corrected and refaxed. For patient 202504, the 30 day follow-up is overdue and pages 1.7 and 2.1 need to be corrected and refaxed. For the ACE study DataFax has been configured to consider assessments overdue if they do arrive within 7 days following the assessments scheduled protocol target date.

FAX/REFAX LIST (Please locate/correct and then fax the following pages of the CRF)

BE SURE TO INITIAL AND DATE ALL CHANGES.

PATIENT	Form Number	PROBLEM		
202503	Form 1.2	Missing Page.		
202503	Form 1.3	Missing Page.		
202503	Form 1.4	Total dose per day #2	=	(Missing Value)
202503	Form 1.6	Gait Abnormality	= checked	(Other Problem)
		Please describe gait abnormality.		
202504	Form 1.7	3. Comprehen. of language	=	(FAX Noise)
202504	Form 2.1	Was the C.E. completed?	=	(Missing Value)
202504		30 Day Follow-Up(Overdue)		

Each problem is identified by Patient ID number, CRF form number, and data field. This is followed by the current value read from the fax (after the = sign) and the problem type (in brackets).

Problem types include:

- *missing* - indicates that required information was not recorded
- *illegal* - indicates an impossible value (e.g. an impossible date, or physical value)
- *inconsistent* - indicates that the recorded value is inconsistent with some other piece of information
- *illegible* - could not read your hand writing
- *fax noise* - fax transmission noise has made the field unreadable
- *other* - anything else (such problems will be explained with a comment)

If the nature of the problem is clear from the above problem type label no further explanation will be provided. But if needed, the ACE data management staff will add a note to clarify the nature of each problem. For example, for patient 202503, “Total dose per day #2” on form 1.4 was found to be missing. The investigator needs to correct the CRF by either entering the appropriate value or by indicating that it is unavailable by printing “NA” beside the field. The next problem on form 1.6 includes a short explanatory note which appears directly below it.

PART 3: THE QUESTION & ANSWER LIST

The third and final part of the standard DataFax Quality Control Report is optional. It will only be included if we have questions which do not require refaxing CRF pages. In such cases the question is listed using the same format as on the refax list, and space is provided directly below the question for your reply. Please print your reply clearly in the space provided and then fax in the page. Here's an example.

QUESTION & ANSWER LIST (Print your answer below each question and fax back this page)

PATIENT	Form Number	PROBLEM
202503	Form 9.1	Autopsy performed = (Other Problem) The autopsy report has not yet arrived. Has it been sent?

PATIENT	Form Number	PROBLEM
202507	Form 1.0	Patient No. = 202507 (Other Problem) No CRFs have been received for patient 202507. Please explain. Patient medication and CRFs are to be used in order from each ACE study kit.