

Entering data within the correct Form and Due Date

The Data Collection screen contains a list of forms to be entered into the web and the projected due date for each form type. If a form is submitted at varying frequencies throughout the length of the trial, attention to the due data is important for accurate submission of data. If a form is listed within the *Data Collection* table, the form is designated as due. Note: Forms listed within the *Data Collection* table for web entry are listed in order of expected submission by date.

For example, the IA and IS forms are submitted at baseline, 12 months and at 24 months. As each IA and IS are expected to be submitted yearly, the form due dates are distinguished by the month, day and year, i.e. 09-17-2004, 09-16-2005 and 09-15-2006 (due dates are case specific and calculated from the date of first imaging provided at the time of randomization).

DATA COLLECTION

Study No 6666 Institution 9999 - Test Institution
Case No 132 Patient Name L.,F.

Form	Description	Due Date	Recvd Date
6666I1	INITIAL EVALUATION/ON-STUDY	09/17/2004	00.00.0000
6666I2	INITIAL EVALUATION SUPPLEMENTAL FORM	09/17/2004	00.00.0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/17/2004	00.00.0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/17/2004	00.00.0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/16/2005	00.00.0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/16/2005	00.00.0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/15/2006	00.00.0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/15/2006	00.00.0000

baseline
12 months
24 months

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Once a form is completed and the final submit button (*Complete Form Submission*) is depressed, the *View Patient Calendar* is updated with a received date for the form submitted and the submitted form is removed from the Data Collection table.

For example, (1) the I1 is accessed and all modules are completed, prior to final submission, (2) a *Summary Form Preview* screen is generated. While the *Summary Form Preview* screen is active, the submitted form may be printed, corrected or deleted. (3) When the *Complete Form Submission* button is depressed, the form is no longer available through the web and (4) an e-mail confirmation of receipt is sent to the individual who accessed the web for data entry.

DATA COLLECTION

Study No 6666 Institution 9999 - Test Institution
Case No 132 Patient Name L.,F.

(1)

Form	Description	Due Date	Recvd Date
6666I1	INITIAL EVALUATION/ON-STUDY	09/17/2004	00.00.0000
6666I2	INITIAL EVALUATION SUPPLEMENTAL FORM	09/17/2004	00.00.0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/17/2004	00.00.0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/17/2004	00.00.0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/16/2005	00.00.0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/16/2005	00.00.0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/15/2006	00.00.0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/15/2006	00.00.0000

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The *Summary Form Preview* should be reviewed for accuracy of data entry (transcription accuracy). The Summary may be viewed in two versions, short or long. The short version will allow review of data fields completed, the long version allows review of the form in entirety, i.e. all data fields (populated or skipped). Depressing the (2a) *Preview Entire Form* button converts the summary preview to the long version.

acrin 6666I1 - INITIAL EVALUATION/ON-STUDY

Summary Form Preview

(2)

I1 - INITIAL EVALUATION/ON-STUDY		STUDY # : 6666 CASE # : 132
INSTITUTION : Test Institution		INSTITUTION # : 9999
PATIENT'S NAME : L.,F.		PATIENT'S ID # : 123456
QNO	DESCRIPTION	RESP & DESC
1	DATE OF BIRTH	09/01/1960
2	PRIOR MAMMOGRAM	2 Yes
3	MONTH/YEAR OF LAST MAMMOGRAM (MM/YYYY)	08/2003
4	FACILITY WHERE MAMMOGRAM WAS DONE	unknown
5	3. Have you had a prior breast ultrasound?	1 No
12	4. Have you had a prior MRI of the breast(s) with contrast?	1 No
17	5. Age at first menstrual period (if unknown, code "99")	99
18	6. How long ago was your last menstrual period?	1 Within the last month
128	15a. Genetic testing has been performed to evaluate possible familial risk of breast cancer?	1 No
143	18. Prior radiation treatment to the chest, axilla, and/or mediastinum not for breast cancer.	1 No
153	LIFETIME RISK FOR BREAST CANCER BY GAIL MODEL	25
154	LIFETIME RISK FOR BREAST CANCER BY CLAU MODEL	25
155	Comments:	
156	Signature of person responsible for data	ss
157	Date form completed (mm/dd/yyyy)	09/21/2004
158	Signature of person entering data onto the web	ss

(2a)

Depressing the *Complete Form Submission* button, is the final step for data to be transmitted to the ACR.

acrin DATA COLLECTION

(3)

Study No 6666 Institution 9999 - Test Institution
Case No 132 Patient Name L.,F.

The I1 Form is no longer accessible within the Data Collection Table once the *Complete Form Submission* button is depressed.

Form	Description	Due Date	Recvd Date
6666I2	INITIAL EVALUATION SUPPLEMENTAL FORM	09/17/2004	00:00:0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/17/2004	00:00:0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/17/2004	00:00:0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/16/2005	00:00:0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/16/2005	00:00:0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/15/2006	00:00:0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/15/2006	00:00:0000

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To confirm receipt of the data entry at the DMC, the received date for the submitted form is updated within the case specific (5) *View Patient Calendar*. The View calendar may be accessed through the *Main Menu* link and then the *View Patient Calendar* link. The View Patient Calendar identifies all case specific items required for submission. The required items may be data forms (web and paper submitted), images, reports, image and or data form related query forms generated from the data management or the imaging center. All items on the View Patient Calendar are linked to a due date for submission calculated from the date of first imaging (date is provided at the time of randomization). Note: As indicated within the *Data Collection Table*, all data (form, imaging, reports, queries) for submission are listed within the *View Patient Calendar* in order of due date submission.

VIEW PATIENT CALENDAR

Study No 6666 Institution 9999 - Test Institution
Case No 132 Patient Name L.,F.

(5)

Form	Description	Due Date	Recvd Date
6666A0	*HQ*CONFIRMATION	09/02/2004	09/02/2004
6666C4	Mammography Images	09/17/2004	00/00/0000
6666H1	Ultrasound Images	09/17/2004	00/00/0000
6666I1	INITIAL EVALUATION/ON-STUDY	09/17/2004	09/21/2004
6666I2	INITIAL EVALUATION SUPPLEMENTAL FORM	09/17/2004	00/00/0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/17/2004	00/00/0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/17/2004	00/00/0000
6666F1	FOLLOW-UP ASSESSMENT FORM	09/02/2005	00/00/0000
6666C4	Mammography Images	09/16/2005	00/00/0000
6666H1	Ultrasound Images	09/16/2005	00/00/0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/16/2005	00/00/0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/16/2005	00/00/0000
6666F1	FOLLOW-UP ASSESSMENT FORM	09/01/2006	00/00/0000
6666C4	Mammography Images	09/15/2006	00/00/0000
6666H1	Ultrasound Images	09/15/2006	00/00/0000
6666IA	MAMMOGRAPHY INTERPRETATION FORM	09/15/2006	00/00/0000
6666IS	ANNUAL ULTRASOUND INTERPRETATION FORM	09/15/2006	00/00/0000
6666F1	FOLLOW-UP ASSESSMENT FORM	08/31/2007	00/00/0000

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As the *View Calendar* is updated to confirm of the completed form, an e-mail confirmation of the web entered form is sent to the individual who accessed the web and entered the form. The e-mail contains two versions of the form, a short version, containing a list of only those data fields entered or a long version, a list of all data fields within the form, entered or skipped. A copy of the html form should be maintained as part of the case specific file either in hard copy or as a password protected electronic copy.

ACR Case Form Data Registration for Case No - 132 and Form Cd 6666I1 - Message (Plain Text)

From: CONFIRMATION [CONFIRMATION@acrin.org] Sent: None
To:
Cc:
Subject: ACR Case Form Data Registration for Case No - 132 and Form Cd 6666I1

c:\FormData\ c:\FormData\
132FORM6666I1.132FORM6666I1

Hello,

The Confirmation of Form Data listing for the American College Of Radiology :
Study 6666 Case # 132 and Form 6666I1. Please find the attached Form Data HTML File.

Thanks,
ACR

Note:
This information E-mail is Auto generated by the server silver2 and the database ACRINPILOT at Tue Sep 21 08:28:00 EDT 2004 (Eastern Standard Time). Replies will not be checked on this server, So please send your Queries to HQ directly for prompt response.