ACRIN 6702

Diffusion Weighted Imaging for Detection and Diagnosis of Breast Cancer

CRF Set

Subject: **Subject**

Page: **CT Image Transmittal Worksheet**

Date of imaging ...

Date of imaging submission ...

Mode of image submission

- TRIAD
- sFTP
- Disk
- Hard Drive

#	PET data sets submitted	Select all that apply	Comments
1	...		

Add a new Log line

COMMENTS

Name of Technologist

Technologist phone number

Technologist email

Printable Version Icon Key

CRF Draft 2781 - Page Generated: 16 Mar 2015 17:18:51 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**
Page: **DCE-MRI Assessment**

IMPORTANT REQUIREMENT:This form must be signed by the Radiologist to confirm that DCE-MRI was reviewed before DWI

Date of MRI scan ...

Reader Name

Total number of BI-RADS 3,4 and 5 MRI-detected lesions that were not previously biopsied. ...

#	Lesion number	Breast	Quadrant	Clock position	Distance from the nipple from nipple:	MRI finding type	ML Size	SI Size	AP Size	Shape	Margin	Internal enhancement	NME Distribution	Internal enhancement patterns	T2 Signal	Initial kinetics	Delayed kinetics	Was Computer Added Detection (CAD) software used to assess kinetics?	BI-RADS	Recommendation	Type of additional imaging recommended
1	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data

Add a new Log line

Count Rows

Count Rows 6

Count rows 7

Printable Version Icon Key
CRF Draft 2781 - Page Generated: 16 Mar 2015 16:50:03 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**
Page: **Demography**

FORM_OID

Patient Initials (LFM)

Patient's Date of Birth ... ▼

Ethnicity ... ▼

Gender of a Person ... ▼

Country of Residence ... ▼

ZIP Code

Method of Payment ... ▼

#	Race
1	... ▼

Add a new Log line

Printable Version Icon Key

CRF Draft 2781 - Page Generated: 16 Mar 2015 16:49:35 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**
Page: **DWI Central Assessment**

Date of MRI scan ... ▼

Total number of MRI-detected lesions that are BI-RADS 3, 4, or 5 based on DCE-MRI:

DWI quality score:

In which breast was normal fibroglandular tissue measured?

- Right
- Left
- None

Reason normal fibroglandular tissue was not measured?

- Patient has fatty breasts; not sufficient fibroglandular tissue
- Suspicious enhancement throughout; no normal tissue identified
- Patient has had prior mastectomy
- Image artifact in normal tissue regions
- Other

Provide the normal tissue ADC values

Normal ADC b=0,100,600,800:

Normal ADC b=0,800:

Normal ADC b=0,600:

Normal ADC b=0,100:

Normal ADC b=100,600,800:

Normal ADC b=100, 600:

Normal ADC b=100, 800:

Enter one log line for each study lesion with suspicion level of BI-RADS 3, 4 or 5 based on DCE-MRI

#	Lesion number	Breast	Quadrant	Clock position	Is the lesion visible on DWI?	ADC b=0,100,600,800:	ADC b=0,800:	ADC b=0,600:	ADC b=0,100:	ADC b=100,600,800:	ADC b=100,600:	ADC b=100,800:	
1	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	

Add a new Log line

Printable Version Icon Key

CRF Draft 2781 - Page Generated: 16 Mar 2015 17:01:49 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**
Page: **DWI Local Assessment**

Was ADC map calculated with all b-values?

- No
- Yes

Provide the b-value combination used to calculate ADC map?

- ADC b=0,600
- ADC b=0,800
- ADC b=100,600,800
- Other

Enter one log line for each previously unbiopsied lesion with suspicion level of BI-RADS 3, 4 or 5 based on DCE-MRI

#	Lesion Number	Breast	Quadrant	Clock position	Is the lesion visible on DWI?	ADC	Did reviewing DWI cause a change in BI-RADS or recommendation for this lesion?	What is the post DWI BIRADS assessment?	What is the post DWI recommendation?	Post DWI type of additional imaging recommended
1	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data

Add a new Log line

Printable Version Icon Key

CRF Draft 2781 - Page Generated: 16 Mar 2015 17:00:53 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**
Page: **Eligibility Checklist**

FORM_OID

Date the informed consent was signed

Was the informed consent obtained from the patient?

Has the participant received chemotherapy in the last 6 months?

Does the patient have at least one MRI-detected lesion, which has not been previously biopsied, categorized as either BI-RADS 3, 4, or 5 based on DCE-MRI only (without reference to DWI)?

Did the participant complete a breast MRI examination with DWI that meets protocol criteria?

Is the participant scheduled to begin neoadjuvant chemotherapy before pathologic confirmation of lesion outcome?

Printable Version Icon Key
CRF Draft 2781 - Page Generated: 16 Mar 2015 16:48:14 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**
Page: **End of Study**

Date of disposition ... ▼

Provide reason for study disposition by selecting one of the following

- Protocol defined follow up completed
- Participant lost to follow up
- Participant refused follow up/withdrew
- Death
- Adverse Event/Side Effects/Complications
- Disease progression
- Study terminated by sponsor
- Protocol violation-did not meet eligibility
- Protocol violation-technical problems
- Protocol violation-related to study visits
- Protocol violation-related to imaging
- Protocol violation-related to randomization
- Other, specify

Date of Death ... ▼

Cause of Death

- Disease progression
- Other, specify

Printable Version Icon Key

CRF Draft 2781 - Page Generated: 16 Mar 2015 17:06:11 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**
Page: **Follow up-Imaging**

Was imaging of the breast performed since last study visit or follow-up time point?

- No
- Yes

Select the reason imaging was not done

- Not indicated
- Participant missed appointment
- Participant unable to be located
- Participant refused
- Referring physician's choice
- Participant's death
- Other

Enter one log line for each lesion described for each imaging procedure done since last study visit.

#	Lesion number	Breast	Quadrant	Clock position	Date of imaging	Type of imaging performed	BI-RADS Assessment	Follow up recommendation	Type of additional imaging recommended
1	Data	Data	Data	Data	Data	Data	Data	Data	Data

Add a new Log line

27 Days ...

33 Days ...

155 Days ...

211 Days ...

338 Days ...

394 Days ...

Printable Version Icon Key
CRF Draft 2781 - Page Generated: 16 Mar 2015 17:03:23 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**
Page: **Follow up-Lesion Diagnosis**

INSTRUCTIONS: Complete one log line for each lesion reported on the DCE-MRI form. For lesions that underwent pathological sampling, add a separate log line for each procedure, repeating the lesion number.

#	Lesion number	Breast	Quadrant	Clock position	Distance from the nipple	Was a biopsy or surgery performed on this lesion that has not previously been reported to ACRIN?	Reason tissue sampling was not done?	Date of sampling	Type of procedure	Type of image guidance used for tissue sampling	Procedure findings
1	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data

Add a new Log line

27 Days

33 Days

155 Days

211 Days

338 Days

394 Days

Printable Version Icon Key
CRF Draft 2781 - Page Generated: 16 Mar 2015 17:02:49 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**
Page: **Follow up-Participant Status**

Was follow-up information obtained for this time-point? ○ No ○ Yes

Reason follow-up information was not obtained:

- Unable to contact participant's treating physician
- Unable to contact participant's family member or participant proxy
- Unable to review participant's medical record
- Unable to contact the participant

Source of information used to obtain participant data for this form:

- Site physician
- Outside physician/hospital
- Family
- Medical record
- Cancer registry
- Participant

What was the method of contact? ○ Office visit ○ Telephone ○ Mail

Date the data was obtained ... ▼

Participant vital status ○ Alive ○ Dead ○ Unknown ○ Unspecified

Date participant last known to be alive ... ▼

Date of death	...			
27 Days	...			
33 Days	...			
155 Days	...			
211 Days	...			
228 Days	...			
394 Days	...			

Printable Version Icon Key

CRF Draft 2781 - Page Generated: 16 Mar 2015 17:02:20 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**
Page: **Lost to Follow-Up**

FORM_OID

Patient Lost to Follow-Up

Was the study participant unable to be contacted for follow-up per defined criteria?

- No
- Yes

Date of last contact

...

#	Methods of Contact	Date of most recent attempt
1	Data	Data

Add a new Log line

Study Participant Found

Was a study participant previously deemed lost to follow-up able to be contacted?

- No
- Yes

Date most recent contact

...

Lost to Follow-Up Internal Review

Study participant lost to follow-up approved?

- No
- Yes

Date of Approval

...

Printable Version Icon Key
CRF Draft 2781 - Page Generated: 16 Mar 2015 17:08:57 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**

Page: **Mammography Image Transmittal Worksheet**

Date of imaging ...

Date of imaging submission ...

Mode of image submission

- TRIAD
- sFTP
- Disk
- Hard Drive

#	Mammogram data sets submitted	Select all that apply	Comments
1	...		

Add a new Log line

COMMENTS

Name of Technologist

Technologist phone number

Technologist email

Printable Version Icon Key

CRF Draft 2781 - Page Generated: 16 Mar 2015 17:12:18 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**
Page: **MRI Clinical Indication**

Clinical indication for MRI (Check all that apply):

- Evaluate extent of disease for known breast cancer
- Further evaluation of lesion detected on other imaging
- Further evaluation of palpable lesion
- Short interval follow-up MRI
- Screening due to personal history of breast cancer
- Screening due to genetic risk or family history of breast cancer
- Evaluate implant integrity
- Known malignant axillary adenopathy, unknown primary
- Other
  - Specify Indication

Printable Version Icon Key
CRF Draft 2781 - Page Generated: 16 Mar 2015 16:56:14 Greenwich Standard Time

Save Cancel
Close Preview

Subject: **Subject**

Page: **Other Image Transmittal Worksheet**

Type of Other Imaging

Date of imaging

Date of imaging submission

Mode of image submission

- TRIAD
- sFTP
- Disk
- Hard Drive

#	Data sets submitted	Select all that apply	Comments
1			

Add a new Log line

COMMENTS

Name of Technologist

Technologist phone number

Technologist email

Printable Version Icon Key

CRF Draft 2781 - Page Generated: 16 Mar 2015 17:21:50 Greenwich Standard Time

Save Cancel

Close Preview

Subject: **Subject**

Page: **PET Image Transmittal Worksheet**

Date of imaging ...

Date of imaging submission ...

Mode of image submission

- TRIAD
- sFTP
- Disk
- Hard Drive

#	PET data sets submitted	Select all that apply	Comments
1	...		

Add a new Log line

COMMENTS

Name of Technologist

Technologist phone number

Technologist email

Printable Version Icon Key

CRF Draft 2781 - Page Generated: 16 Mar 2015 17:20:28 Greenwich Standard Time

Save Cancel

Close Preview