AKT1 E17K Activating Mutation in Human Breast Cancer

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STUDY OBJECTIVES

In a multi-center, retrospective and controlled study we plan to describe the clinicopathological features, response to standard therapies and outcome of ER + MBC patients, found to be *AKT1* E17K mutant (mt) on tumor sequencing vs those found to be *AKT1* E17K wild type (wt).

- *Primary Endpoint:* Overall Survival (OS) from date of metastatic diagnosis
- *Secondary Endpoints:*
    1. Duration on Therapy (DOT) for the first line of therapy used after metastatic diagnosis. This analysis will be repeated for the second line metastatic therapy and additional lines of therapy as sample size permits.
    2. Given the potential association of AKT mutation with response to rapalogs such as everolimus and temsirolimus, we plan to look specifically at DOT with mTOR inhibitor containing therapy across all lines of therapy in the AKT mt and wt cohorts.

STUDY INFORMATION

Overall PIs

- David Hyman, MSK
- Lillian Smyth, MSK
- Phillipe Bedard, UHN

Participating Centers

Center	PI/Contact	Data Abstractor(s)	Data Manager
Dana-Farber Cancer Institute (DFC)	Michael Hassett, MD Deb Schrag, MD	Sindy Ortiz Pimentel	Eva Lepisto
GRR	Fabrice Andre, MD Monica Ardenos, MD	Semih Dogan	
HOP	Ben Park, MD	Ben Park, MD	Christopher Gocke, MD
MDA	Funda Meric-Bernstam, MD	Chetna Wathoo Walter Kinyua	Kenna Shaw
MSK	David Hyman, MD Lillian Smyth, MD	Odette Hauke Sarah Lendore	Natalie Blauvelt
NKI	Hugo Horlings, MD	Tessa Steenbruggen, MD Jan Hudecek	
PMH	Phillipe Bedard, MD	Lailah Ahmed Geeta Krishna	Celeste Yu
VDB	Mia Levy, MD Christine Micheel, PhD	Michele LeNoue-Newton Lucy Wang	Christine Micheel

Data Abstraction Information

REDCap URL: https://redcap.mskcc.org/

BaseCamp URL: https://basecamp.com/2944763/projects/13104837/

Process for Asking Questions During Data Collection:

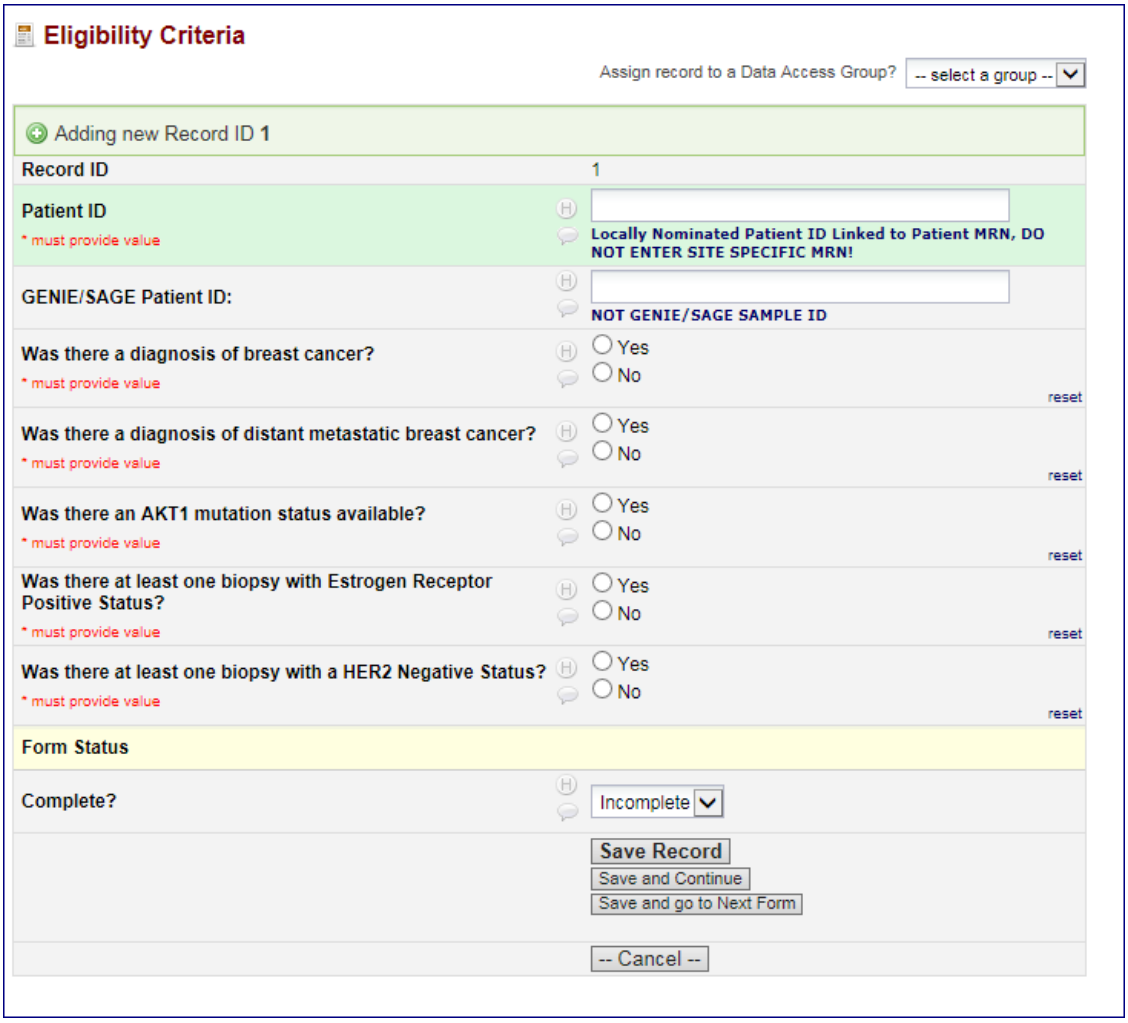
1. Ask Center PI
2. Post BaseCamp Question to Group
3. Lillian will answer the question
4. Celeste will update Data Abstraction Guide to reflect answer

ELIGIBILITY CRITERIA SECTION

General Abstracting Notes:

1. In this section, patient data will be entered to determine whether the patient is eligible for continued data collection in the study. In order for a patient to be included in the study, the patient must meet the following criteria:
    - Invasive breast cancer
    - Distant metastatic site of breast cancer
    - AKT1 genomic mutation status (mutant or wildtype)
    - Estrogen Receptor (ER) status is positive (at least one)
    - HER2 status is negative (at least one)

2. In the eligibility form, information on each of these criteria will be recorded.
3. Prior to data entry, assign the record to a Data Access Group based on your center, using one of the following:
    - DFC
    - GTR
    - HOP
    - MDA
    - MSK
    - NKI
    - PMH
    - VDB



Field Label	Patient ID
REDCap Variable Name	patient_id
Field Type	text
Directives	Locally Nominated Patient ID This identifier should be maintained at the site linked to the center's MRN in a separate place accessible only to the center's study staff. The patients actual MRN should not be used.
Identifier?	Y
Required Field?	Y
Field Label	**GENIE/SAGE Patient ID**
REDCap Variable Name	genie_patient_id
Field Type	text
Directives	Record the existing ***GENIE/SAGE ID***, if the patient's genomic data was submitted to in the September 2016 data submission. This identifier is maintained at each center and is linked to the patient's MRN. For more details and access to the ***GENIE/SAGE ID***, ask

	the Center Site PI for this project. If there is no existing GENIE ID, leave this field blank OR create a new GENIE ID that will continue to be used in reference to this case for future GENIE data submissions.
Identifier?	Y
Required Field?	N
Field Label	**Was there a diagnosis of breast cancer?**
REDCap Variable Name	eligible_breastca_yn
Field Type	yesno
Directives	Record whether the patient has had a diagnosis of breast cancer.
Identifier?	N
Required Field?	Y
Field Label	**Was there a diagnosis of distant metastatic breast cancer?**
REDCap Variable Name	eligibile_metsdx_yn
Field Type	yesno
Directives	Linked to ***Was there a diagnosis of breast cancer?*** Record 'Yes' if the patient has a distant site of breast cancer that is proven either by imaging or pathology. Record 'No' if there is no indication in the EMR that the patient has experienced a distant site of metastasis of breast cancer. This data field is one of five that establishes the eligibility of the patient for the AKT1 project.
Identifier?	N
Required Field?	Y
Field Label	**Was there an AKT1 mutation status available?**
REDCap Variable Name	elgibile_akt1_yn
Field Type	yesno
Directives	Linked to ***Was there a diagnosis of breast cancer?*** Record 'Yes' if the patient has an AKT1 mutation status associated with the breast cancer. Record 'No' if there is no indication that the patient's breast cancer an associated either an AKT1 mutation or AKT1 wildtype status. This data field is one of five that establishes the eligibility of the patient for the AKT1 project.
Identifier?	N
Required Field?	Y

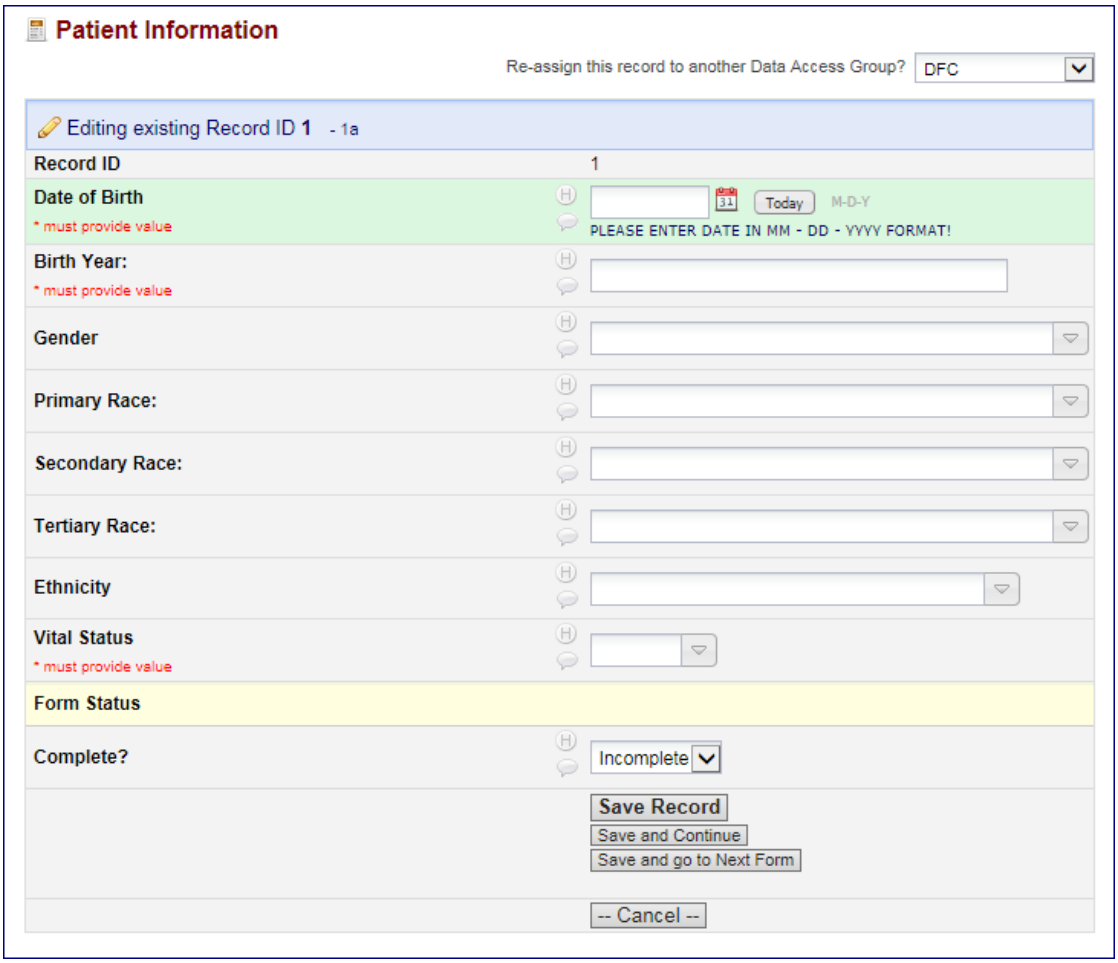
Field Label	Was there at least one biopsy with an Estrogen Receptor Positive Status?
REDCap Variable Name	elgibile_estrogen_yn
Field Type	yesno
Directives	Linked to ***Was there a diagnosis of breast cancer?*** Record 'Yes' if the patient's breast cancer has ever had a pathology report stating that the breast cancer was estrogen receptor positive. The report could pertain to a biopsy or surgical procedure associated with initial diagnosis, recurrence, or distant metastasis. Record 'No' if there is no indication that the patient's breast cancer was ever estrogen receptor positive. This data field is one of five that establishes the eligibility of the patient for the AKT1 project.
Identifier?	N
Required Field?	Y
Field Label	**Was there at least one biopsy with a HER2 Negative Status?**
REDCap Variable Name	elgibile_her2
Field Type	yesno
Directives	Linked to ***Was there a diagnosis of breast cancer?*** Record 'Yes' if the has ever had a pathology report stating that the breast cancer was HER2 negative. The pathology report could pertain to a biopsy or surgical procedure associated with initial diagnosis, recurrence, or distant metastasis. Record 'No' if there is no indication that the patient's breast cancer was ever HER2 negative. This data field is one of five that establishes the eligibility of the patient for the AKT1 project.
Identifier?	N
Required Field?	Y
Field Label	**Eligibility Calculation - Automated**
REDCap Variable Name	elg_warning
Field Type	Calculated: [eligible_breastca_yn] = '0' or [eligibile_metsdx_yn] = '0' or [elgibile_akt1_yn] = '0' or [elgibile_estrogen_yn] = '0' or [elgibile_her2] = '0'
Directives	If any of the questions in the eligibility section were answered with a 'No' the patient is not be eligible for the AKT1 study.
Identifier?	N
Required Field?	Coded
Field Label	**Form Status: Complete?**

REDCap Variable Name	
Field Type	Dropdown
Choice List	Incomplete | Unverified | Complete
Directives	Record 'Complete' once all of the data fields in this section have been entered and the eligibility calculation has been performed. This field will be used during data quality review. 'Incomplete' is the default choice; patients with any indication of 'Incomplete' or 'Unverified' sections are not eligible for data analysis.
Identifier?	N
Required Field?	N

PATIENT INFORMATION SECTION

Abstracting Notes:

1. In order to record data in this section, the patient must be eligible for the study; meaning, the patient has passed the calculated eligibility field found in the Eligibility section.
1. Much of the data fields found in this section should be provided by Sage through a download of each center's GENIE data submission.
2. For data fields that are not pre-populated by Sage, please record the appropriate data.
3. For patients who are not found in the Genie data submission, please adhere to the NAACCR method for coding the data as applicable.



Field Label	Patient's Date of Birth
REDCap Variable Name	dob_date
Field Type	Text
Valid Field	mm-dd-yyyy
Directives	Enter the patient's date of birth using the following convention: mm-dd-yyyy. Please note that all components of the date must be entered.

	If the full date is not known, estimate the date on using the components that are known. • If month and year of the date is known, and the day of the month is not known, record 15 for the day. • If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day. • If the year is known, and the seasons are noted rather than the month and day, use the following: o For winter use January (1) o For spring use April (4) o For summer use July (7) o For autumn/fall use October (10) Do not leave blank.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	Y
Field Label	**Patient's Birth Year**
REDCap Variable Name	birth_year
Field Type	text
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor. Linked to the ***Patient's Date of Birth.*** If the data is not pre-populated, record the 4-digit year associated with the ***Patient's Date of Birth*** recorded in the previous data field. Use the ***Patient's Date of Birth*** to compare the ***Patient's Birth Year*** with this data field; the two years should be the same. Do not leave blank.
Identifier?	N
Required Field?	Y
Field Label	**Patient's Gender**
REDCap Variable Name	naaccr_sex_code
Field Type	dropdown
Choice List	1, Male | 2, Female | 3, Other (intersex, disorders of sexual development/DSD) | 4, Transsexual, NOS | 5, Transsexual, natal male | 6, Transsexual, natal female | 99, Not stated/Unknown
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor. Record the sex of the patient using the NAACCR sex codes.

	Do not leave blank.
Identifier?	N
Required Field?	Y
Field Label	**Patient's Primary Race**
REDCap Variable Name	naaccr_race_code_primary
Field Type	dropdown
Choice List	1, White | 2, Black | 3, American Indian, Aleutian, or Eskimo (includes all indigenous populations of the Western hemisphere) | 4, Chinese | 5, Japanese | 6, Filipino | 7, Hawaiian | 8, Korean | 10, Vietnamese | 11, Laotian | 12, Hmong | 13, Kampuchean (Cambodian) | 14, Thai | 15, Asian Indian or Pakistani, NOS (code 09 prior to Version 12) | 16, Asian Indian | 17, Pakistani | 20, Micronesian, NOS | 21, Chamorro/Chamoru | 22, Guamanian, NOS | 25, Polynesian, NOS | 26, Tahitian | 27, Samoan | 28, Tongan | 30, Melanesian, NOS | 31, Fiji Islander | 32, New Guinean | 88, No further race documented | 96, Other Asian, including Asian, NOS and Oriental, NOS | 97, Pacific Islander, NOS | 98, Other | 99, Unknown
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor. **FOR US and Canadian Centers:** Record the first mentioned race of the patient using the code used for the NAACCR Primary Race field for the GENIE clinical data submission, if applicable. **FOR European Centers**: Record '99, Unknown.' Do not leave blank.
Identifier?	N
Required Field?	Y
Field Label	**Patient's Secondary Race**
REDCap Variable Name	naaccr_race_code_primary
Field Type	dropdown
Choice List	1, White | 2, Black | 3, American Indian, Aleutian, or Eskimo (includes all indigenous populations of the Western hemisphere) | 4, Chinese | 5, Japanese | 6, Filipino | 7, Hawaiian | 8, Korean | 10, Vietnamese | 11, Laotian | 12, Hmong | 13, Kampuchean (Cambodian) | 14, Thai | 15, Asian Indian or Pakistani, NOS (code 09 prior to Version 12) | 16, Asian Indian | 17, Pakistani | 20, Micronesian, NOS | 21, Chamorro/Chamoru | 22, Guamanian, NOS | 25, Polynesian, NOS | 26, Tahitian | 27, Samoan | 28, Tongan | 30, Melanesian, NOS | 31, Fiji Islander | 32, New Guinean | 88, No further race documented | 96, Other Asian, including Asian, NOS and Oriental, NOS | 97, Pacific Islander, NOS | 98, Other | 99, Unknown
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor. **FOR US and Canadian Centers:** Record the second mentioned race of the patient using the code used for the NAACCR Secondary Race field for the GENIE clinical data

	submission, if applicable. If the patient does not have a secondary race, enter 'No further race documented'. **FOR European Centers**: Record '99, Unknown.' Do not leave blank.
Identifier?	N
Required Field?	Y
Field Label	**Patient's Tertiary Race**
REDCap Variable Name	naaccr_race_code_primary
Field Type	dropdown
Choice List	1, White | 2, Black | 3, American Indian, Aleutian, or Eskimo (includes all indigenous populations of the Western hemisphere) | 4, Chinese | 5, Japanese | 6, Filipino | 7, Hawaiian | 8, Korean | 10, Vietnamese | 11, Laotian | 12, Hmong | 13, Kampuchean (Cambodian) | 14, Thai | 15, Asian Indian or Pakistani, NOS (code 09 prior to Version 12) | 16, Asian Indian | 17, Pakistani | 20, Micronesian, NOS | 21, Chamorro/Chamoru | 22, Guamanian, NOS | 25, Polynesian, NOS | 26, Tahitian | 27, Samoan | 28, Tongan | 30, Melanesian, NOS | 31, Fiji Islander | 32, New Guinean | 88, No further race documented | 96, Other Asian, including Asian, NOS and Oriental, NOS | 97, Pacific Islander, NOS | 98, Other | 99, Unknown
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor. **FOR US and Canadian Centers:** Record the third mentioned race of the patient using the code used for the NAACCR Tertiary Race field for the GENIE clinical data submission, if applicable. If the patient does not have a tertiary race, enter 'No further race documented'. **FOR European Centers**: Record '99, Unknown.' Do not leave blank.
Identifier?	N
Required Field?	Y
Field Label	**Patient's Ethnicity**
REDCap Variable Name	naaccr_ethnicity_code
Field Type	dropdown
Choice List	0, Non-Spanish; non-Hispanic | 1, Mexican (includes Chicano) | 2, Puerto Rican | 3, Cuban | 4, South or Central American (except Brazil) | 5, Other specified Spanish/Hispanic origin | 6, Spanish, NOS Hispanic, NOS Latino, NOS | 7, Spanish surname only | 8, Dominican Republic | 99, Unknown whether Spanish or not
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor.**FOR US and Canadian Centers:** Record the ethnicity of the patient using the code used for the NAACCR Ethnicity field for the GENIE clinical data submission, if applicable.

	FOR European Centers: Record '99, Unknown whether Spanish or not.' Do not leave blank.
Identifier?	N
Required Field?	Y
Field Label	**Patient's Vital Status**
REDCap Variable Name	vital_status
Field Type	dropdown
Choice List	1, Alive | 2, Dead
Directives	At the time of data entry, record whether the patient is '1, Alive' or '2, Dead.' If you cannot find a definitive death date or indication that the patient has died, record '1, Alive,' and record the date that the patient was last know to be alive in ***Date of Last Follow-up***.
Identifier?	N
Required Field?	Y
Field Label	**Patient's Date of Death**
REDCap Variable Name	death_date
Field Type	text
Valid Field	mm-dd-yyyy
Directives	Linked to ***Vital Status***. If '2, Dead' is recorded in ***Vital Status***, record the date that the patient died, using the following convention: mm-dd-yyyy. Please note that all components of the date must be entered. If the full date is not known, estimate the date on using the components that are known. • If month and year of the date is known, and the day of the month is not known, record 15 for the day. • If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day. If '1, Alive' is recorded for ***Vital Status***, leave this field blank.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	**N**
Field Label	**Patient's Date of Death Interval, in Days - Automated**
REDCap Variable Name	death_date_int
Field Type	Calculated: datediff([dob_date],[death_date],'d', 'mdy', false)
Directives	Dependent upon ***Date of Death.*** If the ***Date of Death*** was entered, REDCap will calculate this field using the ***Date of***

	Birth. If the ***Date of Death*** was not entered, this data field will remain blank.
Identifier?	N
Required Field?	N
Field Label	**Patient's Date of Last Follow-up**
REDCap Variable Name	follow_up_date
Field Type	text
Valid Field	mm-dd-yyyy
Directives	Dependent upon ***Vital Status***. If '1, Alive' is recorded in Vital Status, record the date that the patient is last know to be alive. Use any data available to find this date, including: clinic notes, lab tests, procedure dates, or hospitalization dates. This date should not be approximated.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	N
Field Label	**Patient's Follow-up Date Interval, in Days - Automated**
REDCap Variable Name	follow_up_date_int
Field Type	Calculated: datediff([dob_date],[follow_up_date],'d', 'mdy', false)
Directives	Dependent upon ***Follow-up Date.*** If the ***Follow-up Date*** was entered, REDCap will calculate this field by subtracting the ***Date of Birth*** from the ***Follow-up Date***. If the ***Follow-up Date*** was not entered, this data field will remain blank.
Identifier?	N
Required Field?	N
Field Label	**Form Status: Complete?**
REDCap Variable Name	
Field Type	Dropdown
Choice List	Incomplete | Unverified | Complete
Directives	Record 'Complete' once all of the data fields in this section have been entered and the eligibility calculation has been performed. This field will be used during data quality review. 'Incomplete' is the default choice; patients with any indication of 'Incomplete' or 'Unverified' sections are not eligible for data analysis.
Identifier?	N
Required Field?	N

DIAGNOSIS INFORMATION SECTION

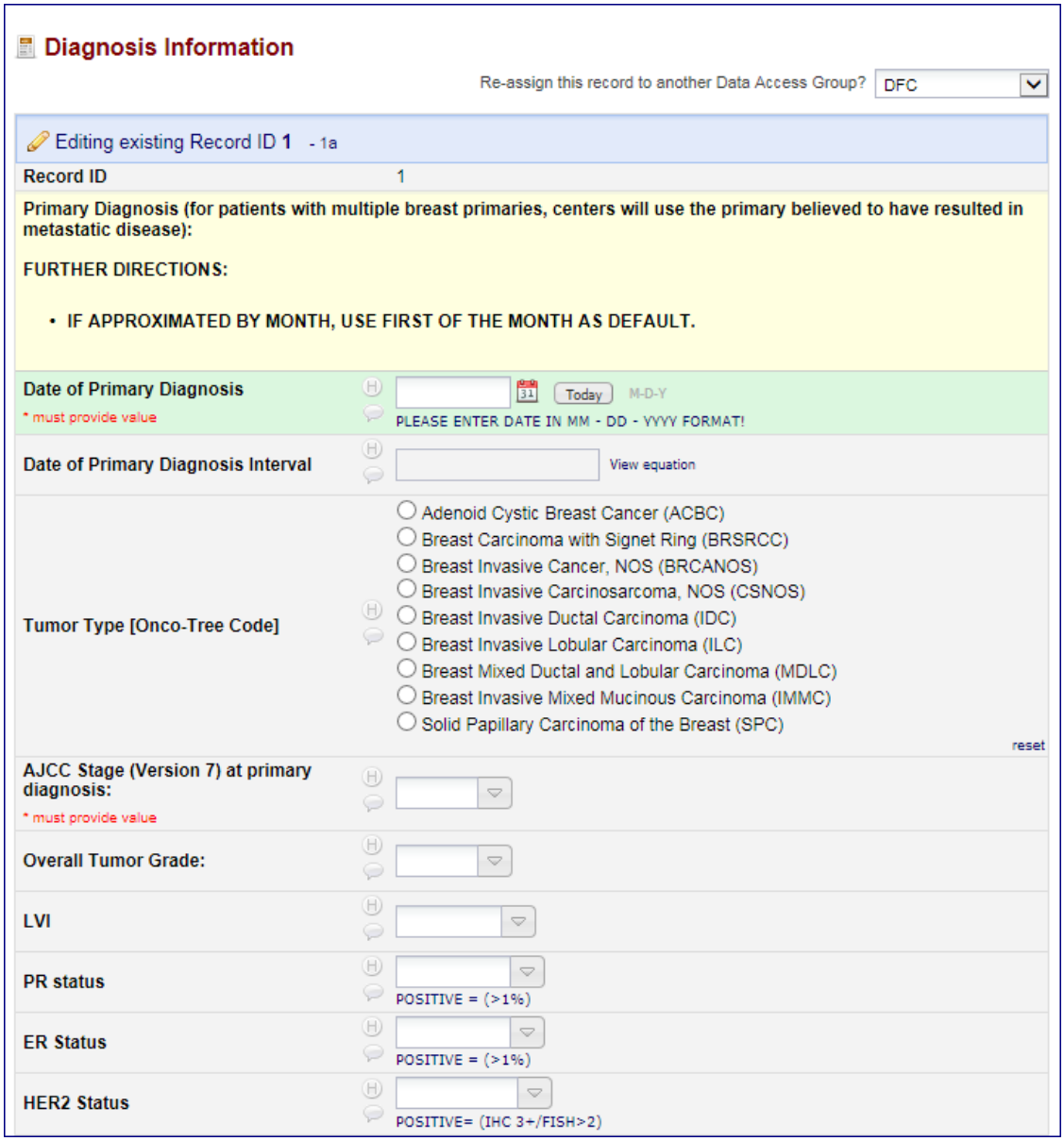
General Abstracting Notes:

1. In order to record data in this section, the patient must be eligible for the study; meaning, the patient has passed the calculated eligibility field found in the Eligibility section.
2. This section is divided into three subsections: Primary Diagnosis, Local/Regional Recurrence, and Distant Metastasis. Each section will be presented separately.
3. The best place to find the data for this section is the relevant pathology notes.

Primary Diagnosis of Breast Cancer Sub-Section

Abstracting Notes:

1. In this section, enter data pertaining to the primary breast cancer diagnosis that resulted in the metastatic site.
2. For patients with multiple breast cancer diagnoses, enter data only on the primary cancer diagnosis thought to be associated with the metastatic disease. If you have a question about which breast cancer diagnosis is appropriate, consult with your Site PI.



Field Label	Date of Primary Diagnosis
REDCap Variable Name	primary_dx_date
Field Type	Primary Diagnosis (for patients with multiple breast primaries, use the breast cancer primary believed to have resulted in metastatic disease)
Valid Field	mm-dd-yyyy
Directives	Record the date of diagnosis for the breast cancer. The date of diagnosis should correspond to the first indication of invasive cancer based on pathology. If the full date is not known, estimate the date on using the components that are known. • If month and year of the date is known, and the day of the month is not

	known, record 15 for the day. • If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day. • If the year is known, and the seasons are noted rather than the month and day, use the following: o For winter use January (1) o For spring use April (4) o For summer use July (7) o For autumn use October (10) Do not leave blank.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	Y
Field Label	**Date of Primary Diagnosis Interval, in Days - Automated**
REDCap Variable Name	primary_dx_date_int
Field Type	Calculated: datediff([dob_date],[primary_dx_date],'d', 'mdy', false)
Directives	Dependent upon ***Date of Primary Diagnosis.*** If the ***Date of Primary Diagnosis*** was entered, REDCap will calculate this field by subtracting the ***Date of Birth*** from the ***Date of Primary Diagnosis***. Since ***Date of Primary Diagnosis*** is required, this data field will be filled.
Identifier?	N
Required Field?	N
Field Label	**Tumor Type [Onco-Tree Code]**
REDCap Variable Name	oncotree_code
Field Type	radio
Choice List	ACBC, Adenoid Cystic Breast Cancer (ACBC) | BRSRCC, Breast Carcinoma with Signet Ring (BRSRCC) | BRCANOS, Breast Invasive Cancer, NOS (BRCANOS) | CSNOS, Breast Invasive Carcinosarcoma, NOS (CSNOS) | IDC, Breast Invasive Ductal Carcinoma (IDC) | ILC, Breast Invasive Lobular Carcinoma (ILC) | MDLC, Breast Mixed Ductal and Lobular Carcinoma (MDLC) | IMMC, Breast Invasive Mixed Mucinous Carcinoma (IMMC) | SPC, Solid Papillary Carcinoma of the Breast (SPC)
Directives	Record the OncoTree cancer type associated with the sequenced breast cancer specimen submitted to GENIE. Only one ***Tumor Type*** can be entered. Do not leave blank.
Identifier?	N
Required Field?	N

Field Label	AJCC Stage (Version 7) at Primary Diagnosis
REDCap Variable Name	ajcc_stage
Field Type	dropdown
Choice List	0, 0 | 1, 1 | 2, 2 | 3, 3 | 4, 4 | 99, UNK
Directives	Record the stage of the breast cancer using the 7th edition of AJCC; see Appendix One for more details. If more detail is known, record the more general code; for example, if Stage IIB is recorded in the EMR, record '2.' Do not leave blank.
Identifier?	N
Required Field?	Y
Field Label	**Overall Tumor Grade**
REDCap Variable Name	grade
Field Type	dropdown
Choice List	1, 1 | 2, 2 | 3, 3 | 99, UNK
Directives	Record the tumor grade. This information is usually found on the pathology report for either a biopsy or the definitive surgery of the primary tumor. If the grade is not found, record '99,UNK.'
Identifier?	N
Required Field?	N
Field Label	**Lymphovascular Invasion – LVI**
REDCap Variable Name	lvi
Field Type	dropdown
Choice List	1, Present | 0, Absent | 99, UNK
Directives	Record '1, Present' if the primary breast tumor is noted in the pathology report to have LVI. If the pathology reports are not available, but the treating physician records that the breast cancer is LVI positive record '1, Present.' If LVI is not noted, record '99,UNK.'
Identifier?	N
Required Field?	N
Field Label	**Progesterone Receptor – PR status**
REDCap Variable Name	pr_status
Field Type	dropdown
Choice List	1, Positive | 0, Negative | 99, UNK

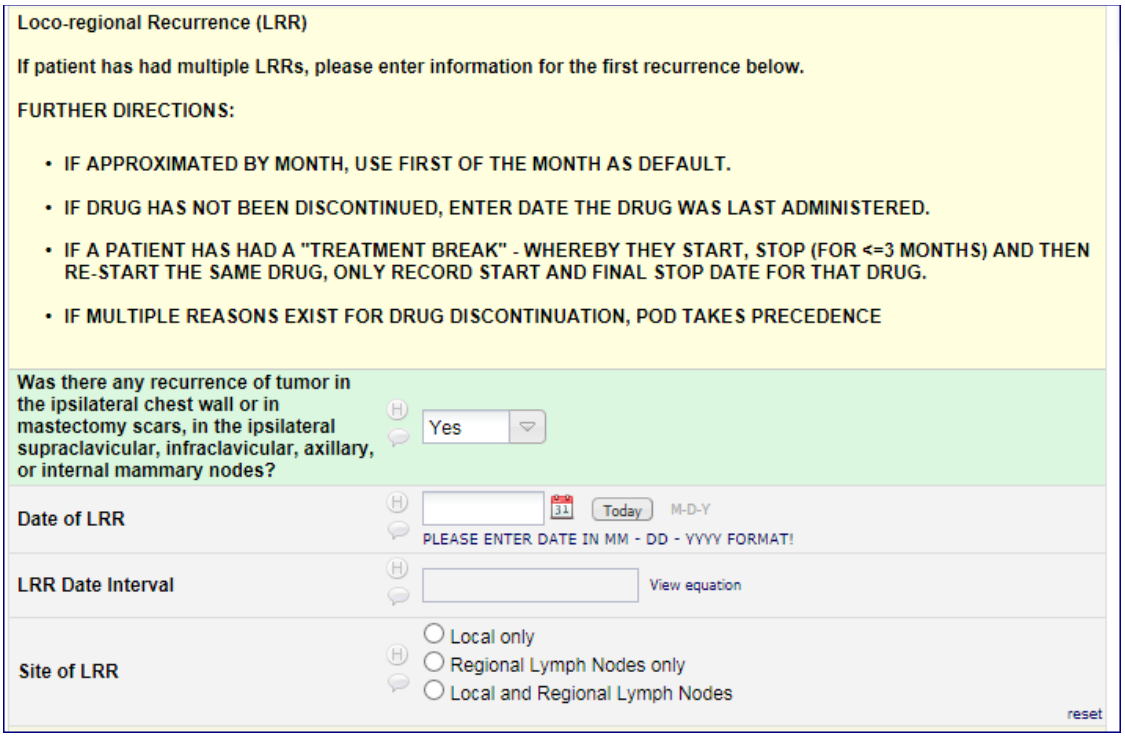
Directives	Record '1, Positive' if the primary breast tumor is noted in the pathology report to be positive for progesterone receptors. If the PR status is reported as a percentage greater than 1%, record '1, Positive.' If PR status in the pathology report is reported as negative or as less than or equal to 1%, record '2, Negative.' If the pathology reports for the biopsy and/or surgery are not available, but the treating physician records that the breast cancer is progesterone receptor positive record '1, Positive.' If PR status of the primary tumor is not noted, record '99, UNK.'
Identifier?	N
Required Field?	N
Field Label	**Estrogen Receptor – ER status**
REDCap Variable Name	er_status
Field Type	Dropdown
Choice List	1, Positive | 0, Negative | 99, UNK
Directives	Record ''1, Positive' if the primary breast tumor is noted in the pathology report to be positive for estrogen receptors. If the ER status is reported as a percentage greater than 1%, record '1, Positive.' If ER status in the pathology report is reported as negative or as less than or equal to 1%, record '2, Negative.' If the pathology reports for the biopsy and/or surgery of the primary breast cancer are not available, but the treating physician records that the breast cancer is estrogen receptor positive record '1, Positive.' If ER status of the primary tumor is not noted, record '99, UNK.'
Identifier?	N
Required Field?	N
Field Label	**HER2 Status**
REDCap Variable Name	her2_status
Field Type	Dropdown
Choice List	1, Positive | 0, Negative | 2, Equivocal| 99, UNK
Directives	Record '1, Positive' if the primary breast tumor is noted in the pathology report to be positive for HER2 by IHC at 3+ or FISH>2. If the HER2 is reported by IHC at 2+ and FISH was either not done or was done but reported as Equivocal record '2, Equivocal;' Anything else is "0, Negative", for e.g HER2 IHC 2+ but FISH is non-amplified

	If the pathology reports for the biopsy and/or surgery are not available, but the treating physician records that the breast cancer is HER2 positive record '1, Positive.' If HER2 status of the primary tumor is not noted in the pathology report or by physician report, record '99, UNK.'
Identifier?	N
Required Field?	N
Field Label	**Is the Oncotype DX Score Known?**
REDCap Variable Name	oncotype_known
Field Type	yesno
Choice List	Yes | No
Directives	If the Oncotype DX score is recorded in the EMR, record 'Yes.' If the patient's chart has no mention of Oncotype DX, record 'No.' If the patient has had Oncotype DX, but the score is not recorded, If the patient did not have Oncotype DX, record 'No.'
Identifier?	N
Required Field?	Y
Field Label	**Oncotype DX Score**
REDCap Variable Name	oncotype_score
Field Type	text
Valid Entry	0 – 100 (integer)
Directives	Linked to ***Is the Oncotype DX Score Known?*** If 'Yes' is recorded for ***Is the Oncotype DX Score Known?***, record the Oncotype DX Score; the value of which should be a integer from 0 to 100. If 'No' is recorded for ***Is the Oncotype DX Score Known?*** leave ***Oncotype DX Score*** blank.
Identifier?	N
Required Field?	N

Loco-regional Recurrence (LRR) Sub-Section

Abstracting Notes:

1. The definition of a loco-regional recurrence for the AKT1 project includes: any recurrence of breast cancer in the one or more of the following:
    - Ipsilateral chest wall
    - Mastectomy scars
    - Ipsilateral supraclavicular
    - Infraclavicular nodes
    - Axillary nodes
    - Internal mammary nodes
2. This section is intended to provide detail on patients before the development of distant metastases.
    - For patients with primary diagnoses of Stage I – III breast cancer, a LRR (if it occurs at all) should occur prior to the development of a distant metastasis to enter data. If the LRR occurs after a distant metastasis, record '0, No' to the first question.
    - For patients diagnosed with Stage IV breast cancer, record '0, No' to the first question.
3. If patient has had multiple LRRs outside the setting of distant metastases, please enter information for the first recurrence below. Information on subsequent loco-regional recurrences should not be entered into this database.



Field Label	Was there any recurrence of tumor in the ipsilateral chest wall or in mastectomy

	scars, in the ipsilateral supraclavicular, infraclavicular, axillary, or internal mammary nodes?
REDCap Variable Name	lrr_yn
Field Type	dropdown
Choice List	1, Yes | 0, No | 99, UNK
Directives	If the patient has experienced a recurrence of breast cancer that occurs after the primary diagnosis period but before the diagnosis of distant metastasis, record '1, Yes.' If the patient has not experienced a loco-regional recurrence of breast cancer after the primary diagnosis period but before the diagnosis of distant metastasis, record '2, No.' If the patient's primary breast cancer was diagnosed as Stage IV, record '2, No.' Do not leave blank.
Identifier?	N
Required Field?	Y
Field Label	**Date of LRR**
REDCap Variable Name	lrr_date
Field Type	text
Valid Field	mm-dd-yyyy

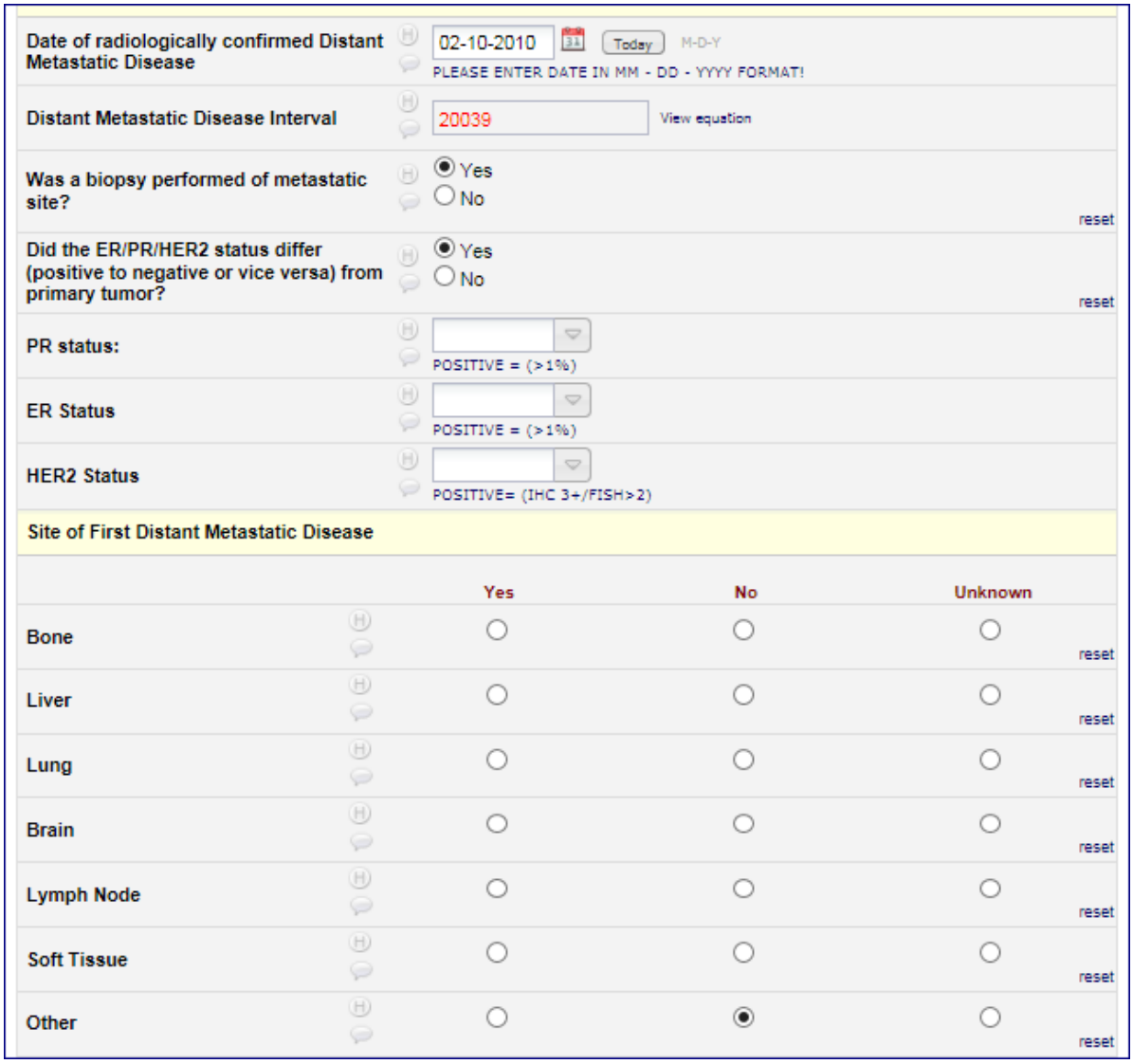
Directives	Linked to ***Was there any recurrence of tumor in the ipsilateral chest wall or in mastectomy scars, in the ipsilateral supraclavicular, infraclavicular, axillary, or internal mammary nodes?***
	
	If '1, Yes' was recorded to the LRR question, complete.
	Record the first date of loco-regional recurrence for the breast cancer. The date of loco-regional recurrence should correspond to the first indication of recurrence based on either imaging or pathology results.
	
	If the full date is not known, estimate the date on using the components that are known.
	• If month and year of the date is known, and the day of the month is not known, record 15 for the day.
	• If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day.
	• If the year is known, and the seasons are noted rather than the month and day, use the following:
	  ○ For winter use January (1)
	  ○ For spring use April (4)
	  ○ For summer use July (7)
	  ○ For autumn use October (10)

	If '0, No' was recorded to the LRR question, leave blank.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	N
Field Label	**LRR Date Interval, in Days - Automated**
REDCap Variable Name	lrr_date_int
Field Type	Calculated: datediff([dob_date],[lrr_date],'d', 'mdy', false)
Directives	Dependent upon ***LRR Date.*** If the ***Follow-up Date*** was entered, REDCap will calculate this field by subtracting the ***Date of Birth*** from the ***LRR Date***. If the ***LRR Date*** was not entered, this data field will remain blank.
Identifier?	N
Required Field?	N
Field Label	**Site of LRR**
REDCap Variable Name	lrr_site
Field Type	radio
Choice List	1, Local only| 2, Regional Lymph Nodes only| 3, Local and Regional Lymph Nodes
Directives	Linked to ***Was there any recurrence of tumor in the ipsilateral chest wall or in mastectomy scars, in the ipsilateral supraclavicular, infraclavicular, axillary, or internal mammary nodes?*** If '1, Yes' was recorded to the LRR question, complete. Record the first site of LRR. If '0, No' was recorded to the LRR question, leave blank.
Identifier?	N
Required Field?	N

Distant Metastatic Diagnosis (de novo or relapsed) Sub-Section

Abstracting Notes:

1. Use this section to record data concerning the first distant metastases. If sites are identified at the same time or within the 30 days, count them as the first distant sites.
2. Use imaging reports like CT scans or MRIs and medical oncology provider notes to identify the first distant metastatic sites. Defer to the medical oncologist's clinical assessment for an indication of metastasis.
3. Some usual sites of distant metastases for breast cancer include: bone, liver, lung, and brain.
    - If the patient's primary breast cancer diagnosis is Stage IV, record the distant metastases that were present at diagnosis.
    - If the patient's primary breast cancer diagnosis is Stage I-III, record the first distant metastases occurring after the primary diagnosis timeframe.
4. If you have any questions or concerns about the identification of distant metastases, please contact the Center PI.



Field Label	**Date of Radiologically Confirmed Distant Metastatic Disease**
REDCap Variable Name	distant_mets_disease_date
Field Type	text
Valid Field	mm-dd-yyyy
Directives	Record the first date that a distant metastatic site was identified by imaging for the breast cancer. If the full date is not known, estimate the date on using the components that are known. • If month and year of the date is known, and the day of the month is not known, record 15 for the day. • If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day.

	• If the year is known, and the seasons are noted rather than the month and day, use the following:
	  ○ For winter use January (1)
	  ○ For spring use April (4)
	  ○ For summer use July (7)
	  ○ For autumn use October (10)
	
	Do not leave blank.

Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	N
Field Label	**Distant Metastatic Disease Interval, in Days - Automated**
REDCap Variable Name	mets_disease_date_int
Field Type	Calculated: datediff([dob_date],[distant_mets_disease_date],'d', 'mdy', false)
Directives	Dependent upon ***Date of Radiologically Confirmed Distant Metastatic Disease.*** If the ***Date of Radiologically Confirmed Distant Metastatic Disease*** was entered, REDCap will calculate this field by subtracting the ***Date of Birth*** from the ***Date of Radiologically Confirmed Distant Metastatic Disease***.
Identifier?	N
Required Field?	N
Field Label	**Was a biopsy performed of metastatic site?**
REDCap Variable Name	biopsy_yn
Field Type	yesno
Directives	Record 'Yes' if a biopsy was taken from one or more of the first distant sites. Biopsies can include incisional biopsies, excisional biopsies, needle biopsies, FNAs, and aspirations. If you are unsure as to whether or not a patient had a biopsy of a metastatic site (e.g. patient could have had biopsy at outside institution), and your institution has no documentation indicating a that biopsy of a metastatic site was performed there or elsewhere, enter 'No'.
Identifier?	N
Required Field?	N
Field Label	**Did the ER/PR/HER2 status differ (positive to negative or vice versa) from primary tumor?**
REDCap Variable Name	receptor_status_change
Field Type	yesno
Directives	Linked to ***Was a biopsy performed of metastatic site?*** - if the response is 'Yes' ***Did the ER/PR/HER2 status differ (positive to negative or vice versa) from primary tumor?*** becomes active.

	Record 'Yes' if ER or PR or HER2 status changed from that which was recorded for the primary tumor. Only one of the three needs to change in order to record 'Yes.'
Identifier?	N
Required Field?	N
Field Label	**PR Status Change**
REDCap Variable Name	receptor_change_pr
Field Type	dropdown
Choice List	1, Positive | 2, Negative | 99, UNK
Directives	Linked to ***Did the ER/PR/HER2 status differ (positive to negative or vice versa) from primary tumor?*** If the response is 'Yes' ***PR Status Change*** becomes active. Record '1, Positive' if the distant site is noted in the pathology report to be positive for progesterone receptors. If the PR status is reported as a percentage greater than 1%, record '1, Positive.' If PR status is reported as less than or equal to 1%, record '2, Negative.' If the pathology report for the biopsy of the distant met is not available, but the treating physician states that the metastatic site is positive for progesterone receptors, record '1, Positive.' If the pathology report does not include PR status, report '99. UNK.'
Identifier?	N
Required Field?	N
Field Label	**ER Status Change**
REDCap Variable Name	receptor_change_er
Field Type	dropdown
Choice List	1, Positive | 2, Negative | 3, UNK
Directives	Linked to ***Did the ER/PR/HER2 status differ (positive to negative or vice versa) from primary tumor?*** If the response is 'Yes' ***ER Status Change*** becomes active. Record '1, Positive' if the distant site is noted in the pathology report to be positive for estrogen receptors. If the ER status is reported as a percentage greater than 1%, record '1, Positive.' If ER status is reported as less than or equal to 1%, record '2, Negative.' If the pathology report for the biopsy of the distant met is not available, but the treating physician states that the metastatic site is positive for estrogen receptors, record '1, Positive.' If the pathology report does not include PR status, report '99. UNK.'
Identifier?	N

Required Field?	N
Field Label	**HER2 Status Change**
REDCap Variable Name	receptor_change_her2
Field Type	dropdown
Choice List	1, Positive | 2, Negative | 99, UNK
Directives	Linked to ***Did the ER/PR/HER2 status differ (positive to negative or vice versa) from primary tumor?*** If the response is 'Yes' ***HER2 Status Change*** becomes active. Record '1, Positive' if the primary breast tumor is noted in the pathology report to be positive for HER2 by IHC at 3+ or FISH>2. If the HER2 is reported by IHC at 2+ and FISH was either not done or was done but reported as Equivocal record '2, Equivocal;' Anything else is "0, Negative", for e.g HER2 IHC 2+ but FISH is non-amplified. If the pathology reports for the biopsy of the distant met is not available, but the treating physician records that the breast cancer is HER2 positive record '1, Positive.' If the pathology report does not include PR status, report '99. UNK.'
Identifier?	N
Required Field?	N
Field Label	**Met Site: Bone**
REDCap Variable Name	bone_yn
Field Type	radio
Choice List	1, Yes | 0, No | 99, Unknown
Directives	Linked to ***Date of Radiologically Confirmed Distant Metastatic Disease.*** Use this date to determine whether metastasis to the bone is found within 30 days of the ***Date of Radiologically Confirmed Distant Metastatic Disease –*** if so, the bone is a first distant site of metastasis. If the breast cancer first metastasized to the bone, record '1, Yes.' If there is no evidence that the breast cancer metastasized to the bone at the time of the first distant metastasis, record '0, No.' If the evidence is equivocal like the imaging report states that the bone is questionable, record '99, Unknown.'
Identifier?	N
Required Field?	N
Field Label	**Met Site: Liver**
REDCap Variable Name	liver_yn
Field Type	Radio

Choice List	1, Yes | 0, No | 99, Unknown
Directives	Linked to ***Date of Radiologically Confirmed Distant Metastatic Disease.*** Use this date to determine whether metastasis to the liver is found within 30 days of the ***Date of Radiologically Confirmed Distant Metastatic Disease –*** if so, the liver is a first distant site of metastasis. If the breast cancer first metastasized to the liver, record '1, Yes.' If there is no evidence that the breast cancer metastasized to the liver at the time of the first distant metastasis, record '0, No.' If the evidence is equivocal like the imaging report states that the liver is questionable, record '99, Unknown.'
Identifier?	N
Required Field?	N
Field Label	**Met Site: Lung**
REDCap Variable Name	lung_yn
Field Type	Radio
Choice List	1, Yes | 0, No | 99, Unknown
Directives	Linked to ***Date of Radiologically Confirmed Distant Metastatic Disease.*** Use this date to determine whether metastasis to the lung is found within 30 days of the ***Date of Radiologically Confirmed Distant Metastatic Disease –*** if so, the lung is a first distant site of metastasis. If the breast cancer first metastasized to the lung, record '1, Yes.' If there is no evidence that the breast cancer metastasized to the lung at the time of the first distant metastasis, record '0, No.' If the evidence is equivocal like the imaging report states that the lung is questionable, record '99, Unknown.'
Identifier?	N
Required Field?	N
Field Label	**Met Site: Brain**
REDCap Variable Name	brain_yn
Field Type	Radio
Choice List	1, Yes | 0, No | 99, Unknown
Directives	Linked to ***Date of Radiologically Confirmed Distant Metastatic Disease.*** Use this date to determine whether metastasis to the brain is found within 30 days of the ***Date of Radiologically Confirmed Distant Metastatic Disease –*** if so, the brain is a first distant site of metastasis. If the breast cancer first metastasized to the brain, record '1, Yes.'

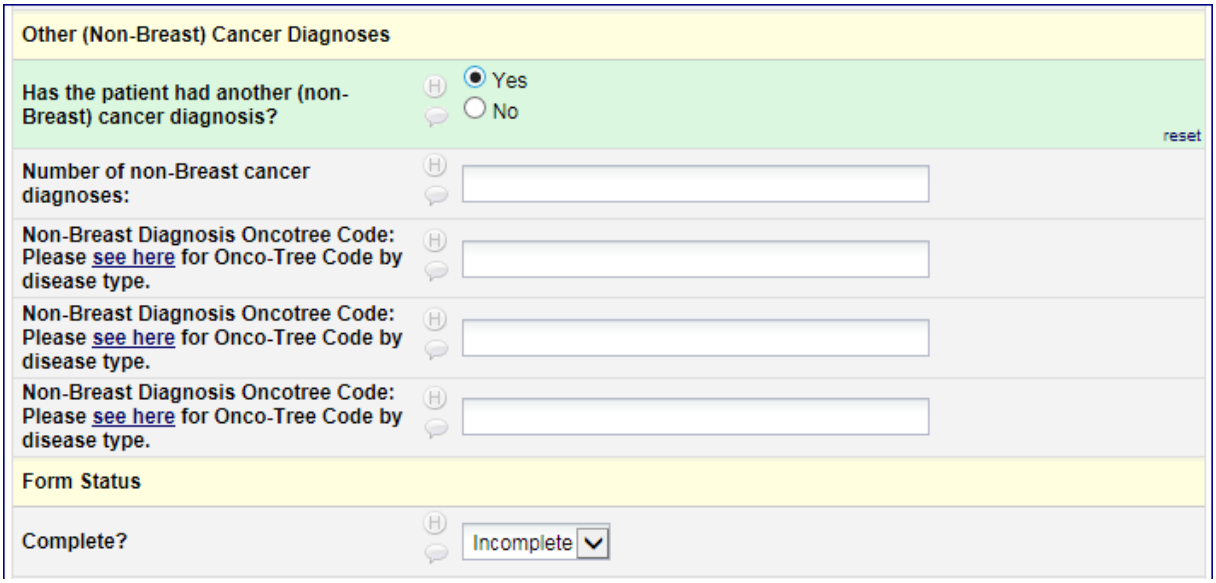
	If there is no evidence that the breast cancer metastasized to the brain at the time of the first distant metastasis, record '0, No.' If the evidence is equivocal like the imaging report states that the brain is questionable, record '99, Unknown.'
Identifier?	N
Required Field?	N
Field Label	**Met Site: Lymph Node (do not include local or regional)**
REDCap Variable Name	lymph_yn
Field Type	Radio
Choice List	1, Yes | 0, No | 99, Unknown
Directives	Linked to ***Date of Radiologically Confirmed Distant Metastatic Disease.*** Use this date to determine whether metastasis to a lymph node is found within 30 days of the ***Date of Radiologically Confirmed Distant Metastatic Disease –*** if so, the lymph node is a first distant site of metastasis. If the breast cancer first metastasized to the lymph node, record '1, Yes.' If there is no evidence that the breast cancer metastasized to the lymph node at the time of the first distant metastasis, record '0, No.' If the evidence is equivocal like the imaging report states that the lymph node is questionable, record '99, Unknown.'
Identifier?	N
Required Field?	N
Field Label	**Met Site: Soft Tissue**
REDCap Variable Name	Soft_tissue_yn
Field Type	Radio
Choice List	1, Yes | 0, No | 99, Unknown
Directives	Linked to ***Date of Radiologically Confirmed Distant Metastatic Disease.*** Use this date to determine whether metastasis to soft tissue is found within 30 days of the ***Date of Radiologically Confirmed Distant Metastatic Disease –*** if so, the soft tissue is a first distant site of metastasis. If the breast cancer first metastasized to the soft tissue, record '1, Yes.' If there is no evidence that the breast cancer metastasized to the soft tissue at the time of the first distant metastasis, record '0, No.' If the evidence is equivocal like the imaging report states that the soft tissue is questionable, record '99, Unknown.'
Identifier?	N
Required Field?	N

Field Label	Met Site: Other Site
REDCap Variable Name	other_yn
Field Type	Radio
Choice List	1, Yes | 0, No | 99, Unknown
Directives	Linked to ***Date of Radiologically Confirmed Distant Metastatic Disease.*** Use this date to determine whether metastasis to a site that is not listed is found within 30 days of the ***Date of Radiologically Confirmed Distant Metastatic Disease –*** if so, this other site is a first distant site of metastasis. If the breast cancer first metastasized to a site that is not listed, record '1, Yes.' If there is no evidence that the breast cancer metastasized to another at the time of the first distant metastasis, record '0, No.' If the evidence is equivocal like the imaging report states that the other site is questionable, record '99, Unknown.'
Identifier?	N
Required Field?	N
Field Label	**Met Site: Which Site?**
REDCap Variable Name	mets_site
Field Type	text
Directives	Linked to **Met Site: Other Site**. If the response is 'Yes,' Met Site: Which Site? becomes active. Record the other site of first distant metastasis.
Identifier?	N
Required Field?	N

Other (Non-Breast) Cancer Diagnoses Sub-Section

Abstracting Notes:

1. Other cancer diagnoses should be entered into this section; up to three diagnoses can be entered.
2. The other cancers can be diagnosed either prior to or following the breast cancer diagnosis that is eligible for this study.
3. The other cancers should be invasive.
4. Do not record pre-cancerous or non-invasive cancers.



Field Label	**Has the patient had another (non-Breast) cancer diagnosis?**
REDCap Variable Name	nonbreast_ca_dx_yn
Field Type	Yesno
Directives	If the patient has had one or more invasive cancer diagnoses, record 'Yes.' If the patient has not had another invasive cancer diagnosis, record 'No'
Identifier?	N
Required Field?	N
Field Label	**Number of non-Breast cancer diagnoses**
REDCap Variable Name	nonbreast_ca_dx_number
Field Type	Text
Valid Field	1-100
Directives	Linked to ***Has the patient had another (non-Breast) cancer diagnosis?*** If the response is 'Yes' then ***Number of non-Breast cancer diagnoses*** becomes active.

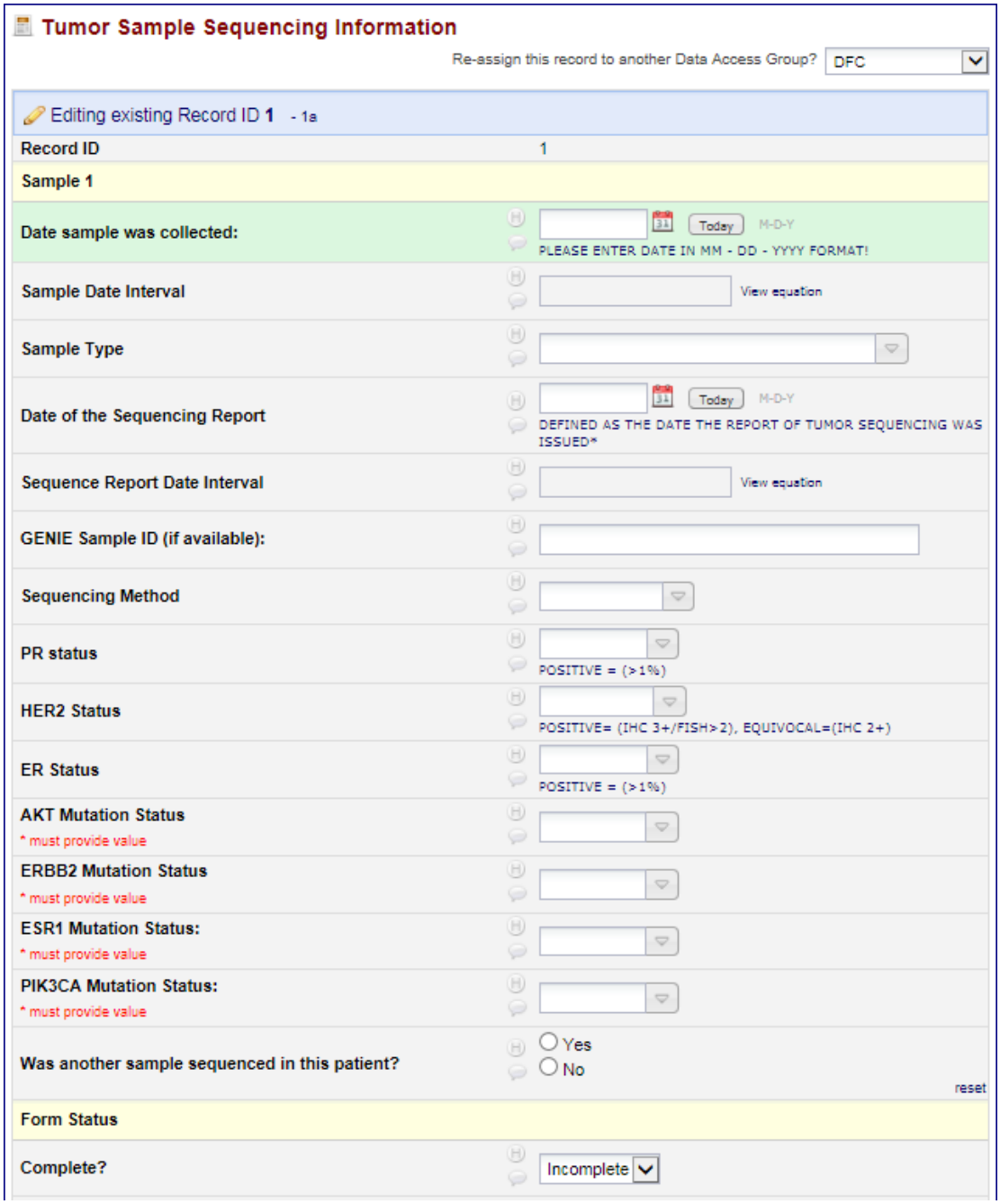
Identifier?	N
Required Field?	N
Field Label	**Non-Breast Diagnosis Oncotree Code, Number 1**
REDCap Variable Name	non_breast_oncotree_code_1
Field Type	Text
Directives	Linked to ***Has the patient had another (non-Breast) cancer diagnosis?*** If the response is 'Yes' then ***Non-Breast Diagnosis Oncotree Code*** becomes active. Please refer to http://www.cbioportal.org/oncotree/ for Onco-Tree Code by disease type.
Identifier?	N
Required Field?	N
Field Label	**Non-Breast Diagnosis Oncotree Code, Number 2**
REDCap Variable Name	non_breast_oncotree_code_2
Field Type	Text
Directives	Linked to ***Has the patient had another (non-Breast) cancer diagnosis?*** If the response is 'Yes' then ***Non-Breast Diagnosis Oncotree Code*** becomes active. Please refer to http://www.cbioportal.org/oncotree/ for Onco-Tree Code by disease type.
Identifier?	N
Required Field?	N
Field Label	**Non-Breast Diagnosis Oncotree Code, Number 3**
REDCap Variable Name	non_breast_oncotree_code_3
Field Type	Text
Directives	Linked to ***Has the patient had another (non-Breast) cancer diagnosis?*** If the response is 'Yes' then ***Non-Breast Diagnosis Oncotree Code*** becomes active. Please refer to http://www.cbioportal.org/oncotree/ for Onco-Tree Code by disease type.
Identifier?	N
Required Field?	N
Field Label	**Form Status: Complete?**
REDCap Variable Name	
Field Type	Dropdown
Choice List	Incomplete | Unverified | Complete
Directives	Record 'Complete' once all of the data fields in this section have been entered and the eligibility calculation has been performed. This field will be used during data quality review. 'Incomplete' is the default choice; patients with any indication of 'Incomplete' or

	'Unverified' sections are not eligible for data analysis.
Identifier?	N
Required Field?	N

TUMOR SAMPLE SEQUENCING INFORMATION

Abstracting Notes:

2. Some of the data fields found in this section should be provided by Sage through a download of each center's GENIE data submission.
3. The set of data elements in this section should be completed for each specimen sampled and submitted to GENIE.
    a. The last question in the set 'Was another sample sequenced in this patient?' will drive the data collection. If 'Yes' is answered, then another set of data fields will appear for the next sample.



Field Label	Date sample was collected
REDCap Variable Name	sample_date_1
Field Type	text
Valid Field	mm-dd-yyyy
Directives	Record the date that the sequenced sample was actually collected for sequencing (i.e. biopsy or surgery date). Note that the actual date of sample collection can often be years before the sample is sent for sequencing.

	If the full date is not known, estimate the date on using the components that are known. • If month and year of the date is known, and the day of the month is not known, record 15 for the day. • If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day. • If the year is known, and the seasons are noted rather than the month and day, use the following: o For winter use January (1) o For spring use April (4) o For summer use July (7) o For autumn use October (10) Do not leave blank.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	N
Field Label	**Sample Date Interval – Automated**
REDCap Variable Name	sample_date_int_1
Field Type	Calculated: datediff([dob_date],[sample_date_1],'d', 'mdy', false)
Directives	
Identifier?	N
Required Field?	N
Field Label	**Sample Type**
REDCap Variable Name	sample_type_1
Field Type	dropdown
Choice List	1, Primary tumor | 2, Lymph node metastasis | 3, Distant organ metastasis | 4, Metastasis site unspecified | 5, Local recurrence | 6, Not otherwise specified | 7, Primary, local recurrence, or metastasis
Directives	This data can be imported using the center's GENIE submission; if this is not available the data field should be entered by the data abstractor. If the data field is not pre-populated, record the sample type.
Identifier?	N
Required Field?	N
Field Label	**Date of the Sequencing Report**
REDCap Variable Name	sequence_report_date_1
Field Type	text
Valid Field	mm-dd-yyyy
Directives	This data can be imported using the center's GENIE submission; if this is not available

	the data field should be entered by the data abstractor. If the data field is not pre-populated, record the date that the sequencing report was issued. This date should be known and not be estimated. Do not leave blank.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	N
Field Label	**Sequence Report Date Interval - Automated**
REDCap Variable Name	sequence_report_date_int_1
Field Type	Calculated: datediff([dob_date],[sequence_report_date_1],'d', 'mdy', false)
Directives	
Identifier?	N
Required Field?	N
Field Label	**GENIE Sample ID (if available)**
REDCap Variable Name	genie_sample_id_1
Field Type	text
Directives	This data can be imported using the center's GENIE submission; if this is not available the data field should be entered by the data abstractor.
Identifier?	N
Required Field?	N
Field Label	**Sequencing Method**
REDCap Variable Name	sequence_method_1
Field Type	dropdown
Choice List	1, Sequenom | 2, Miseq | 3, Sanger | 98, Other
Directives	This data can be imported using the center's GENIE submission; if this is not available the data field should be entered by the data abstractor. Record the sequencing method. If the method used does not appear in the list, record '98, Other.'
Identifier?	N
Required Field?	N
Field Label	**Specify Sequence Method**
REDCap Variable Name	other_sequence_method_1

Field Type	text
Directives	This data can be imported using the center's GENIE submission; if this is not available the data field should be entered by the data abstractor. Linked to ***Sequencing Method.*** If '98, Other' is recorded for ***Sequencing Method,*** record the method used for sequencing or test name for e.g. Foundation One, local institution sequencing platform like MSK-IMPACT, etc. If this not accessible, ask the Center PI for details.
Identifier?	N
Required Field?	N
Field Label	**Progesterone Receptor – PR status of the Sequenced Sample**
REDCap Variable Name	pr_status_1
Field Type	dropdown
Choice List	1, Positive | 0, Negative | 99, UNK
Directives	Record '1, Positive' if the sequenced sample is noted in the pathology report to be positive for progesterone receptors. If the PR is reported as a percentage greater than 1%, record '1, Positive.' If PR status of the sequenced sample is not noted, record '99, UNK.'
Identifier?	N
Required Field?	N
Field Label	**HER2 Status of the Sequenced Sample**
REDCap Variable Name	her2_status
Field Type	Dropdown
Choice List	1, Positive | 0, Negative | 2, Equivocal| 99, UNK
Directives	Record '1, Positive' if the sequenced sample noted in the to be positive for HER2 by IHC at 3+ or FISH>2. If the HER2 status is reported by IHC at 2+ or 1+, record '2, Equivocal;' additionally, if the HER2 is reported as FISH 1 or 2, record '2, Equivocal.' If HER2 status of the sequenced sample is not noted in the pathology report or by physician report, record '99, UNK.'
Identifier?	N
Required Field?	N
Field Label	**Estrogen Receptor – ER status of the Sequenced Sample**
REDCap Variable Name	er_status
Field Type	Dropdown
Choice List	1, Positive | 0, Negative | 99, UNK
Directives	Record ''1, Positive' if the sequenced sample is noted to be positive for estrogen

	receptors. If the ER is reported as a percentage greater than 1%, record '1, Positive.' If ER status of the sequenced sample is not noted, record '99, UNK.'
Identifier?	N
Required Field?	N
Field Label	**AKT Mutation Status**
REDCap Variable Name	akt_mutation_status_1
Field Type	dropdown
Choice List	1, Mutant | 2, Wildtype
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor. If an AKT1 E17K mutation is identified, select '1, Mutant.' If no AKT1 E17K mutation is identified, 'select 2, Wildtype.'
Identifier?	N
Required Field?	N
Field Label	**AKT Variant 1**
REDCap Variable Name	akt_variant_1_sample_1
Field Type	text
Directives	This data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor. If the answer to "AKT Mutation Status" was "1, Mutant" (i.e. an AKT 1 E17K mutation was identified), the variant is entered here. When annotating AKT1 variants, use the cDNA nomenclature, as provided by Sage. e.g. AKT1 variant E17K should be entered as AKT1 variant **c.49G>A**
Identifier?	N
Required Field?	N
Field Label	**AKT Variant 2**
REDCap Variable Name	akt_variant_2_sample_1
Field Type	text
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor. This section is to capture if a rare patient with an AKT1 E17K mutation also has another mutation in AKT1. When annotating AKT1 variants, use the cDNA nomenclature, as provided by Sage.
Identifier?	N
Required Field?	N
Field Label	**ERBB2 Mutation Status**

REDCap Variable Name	erbb2_mutation_status_1
Field Type	dropdown
Choice List	1, Mutant | 2, Wildtype | 99, UNK
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor.
Identifier?	N
Required Field?	N
Field Label	**ERBB2 Variant**
REDCap Variable Name	erbb2_variant_1
Field Type	text
Choice List	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor.
Directives	
Identifier?	N
Required Field?	N
Field Label	**ESR1 Mutation Status**
REDCap Variable Name	esr1_mutation_status_1
Field Type	dropdown
Choice List	1, Mutant | 2, Wildtype | 99, UNK
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor.
Identifier?	N
Required Field?	N
Field Label	**ESR1 Variant**
REDCap Variable Name	esr1_variant_1
Field Type	text
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor.
Identifier?	N
Required Field?	N
Field Label	**PIK3CA Mutation Status**
REDCap Variable Name	pik3ca_mutation_status_1
Field Type	dropdown

Choice List	1, Mutant | 2, Wildtype | 99, UNK
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor.
Identifier?	N
Required Field?	N
Field Label	**PIK3CA Variant**
REDCap Variable Name	pik3ca_variant_1
Field Type	text
Directives	The data for this field may be imported using the center's GENIE submission; if this does not occur, the data should be entered by the data abstractor.
Identifier?	N
Required Field?	N
Field Label	**Was another (breast cancer) sample sequenced in this patient?**
REDCap Variable Name	sampleseq2_yn
Field Type	yesno
Directives	If the patient has another breast cancer sample sequenced, record 'Yes.' This could be the primary breast tumor or metastases from the breast cancer. A 'Yes' will activate data fields for Sample 2. If the patient has no other samples, record 'No.' If the patient has another sample with a non breast cancer OncoTree code (for e.g if the patient also has a separate lung cancer or sarcoma etc, record 'No.' Do not leave blank.
Identifier?	N
Required Field?	N

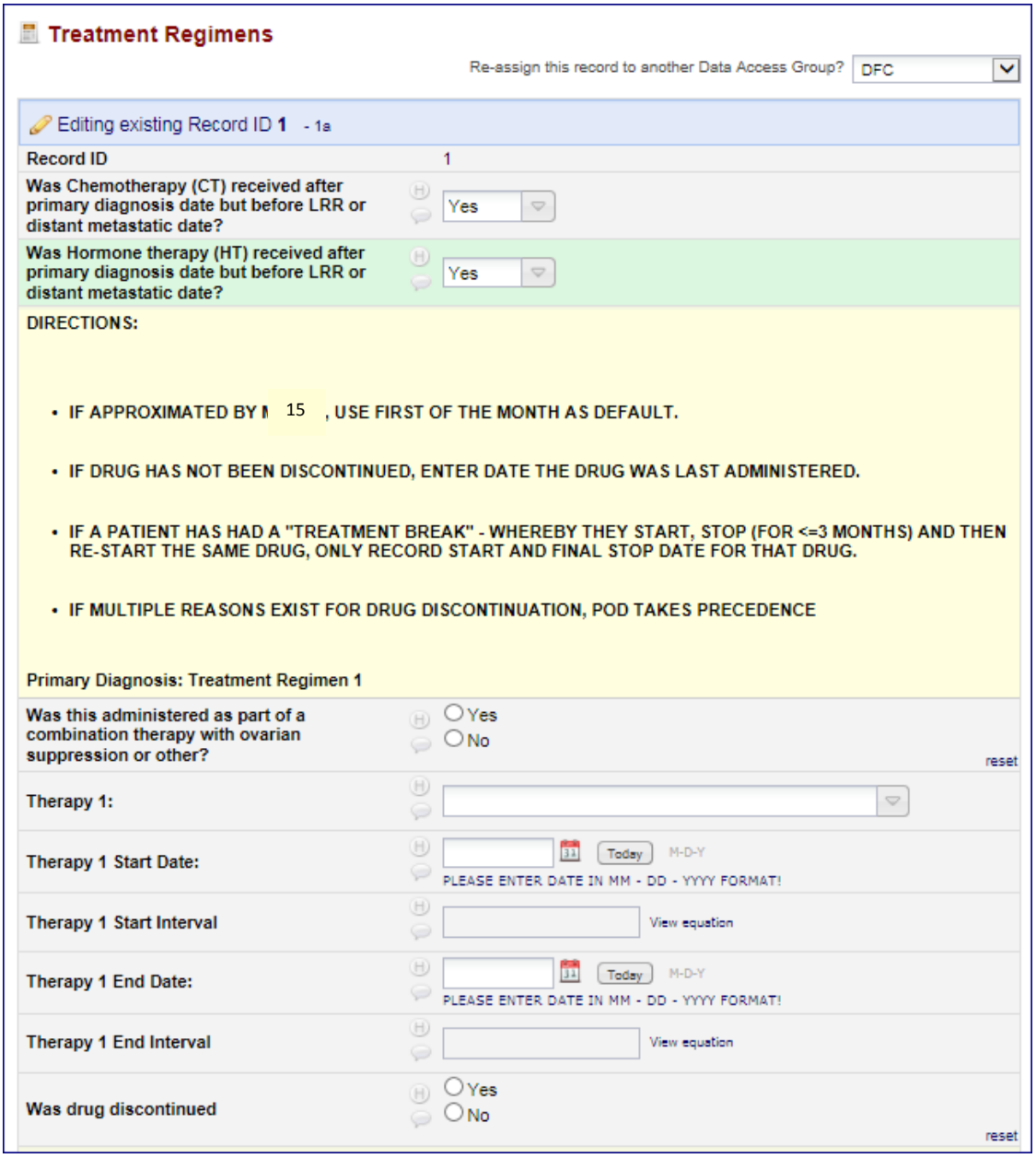
TREATMENT REGIMENS

Abstraction Notes:

1. Cancer directed drug therapies will be entered into different sections according to disease state:
    a. Primary Diagnosis Treatment with details on hormone therapy
    b. LRR Treatment with details on hormone therapy
    c. Metastatic Diagnosis Therapy with details on chemotherapy
2. Each single drug should be entered separately, even if it was administered as part of a regimen.

Primary Diagnosis: Treatment Regimen

1. Use the EMR to look for cancer-directed drug therapies; use the Medications and the provider notes to locate the details of drug therapies.
2. The receipt of chemotherapy will be recorded, but the actual chemotherapies will not be recorded.
3. The receipt of hormone therapy will be recorded, and the actual hormone therapies will be recorded; up to three drugs can be entered,
4. The data guide will provide directives for the first treatment; subsequent treatments will be similar.



Field Label	Was Chemotherapy (CT) received after primary diagnosis date but before LRR or distant metastatic date?
REDCap Variable Name	chemo_therapy_postdx
Field Type	dropdown
Choice List	1, Yes | 0, No | 99, UNK
Directives	If the patient received CT after the primary diagnosis but before LRR, record '1, Yes.' If the patient did not receive CT after the primary diagnosis but before LRR, record

	'No." In the case that a patient transfers care to your center after the primary diagnosis and it is not certain that the patient receive CT, record '99, UNK.'
Identifier?	N
Required Field?	N
Field Label	**Was Hormone therapy (HT) received after primary diagnosis date but before LRR or distant metastatic date?**
REDCap Variable Name	hormo_therapy_postdx
Field Type	dropdown
Choice List	1, Yes | 0, No | 99, UNK
Directives	If the patient received HT after the primary diagnosis but before LRR, record '1, Yes.' If the patient did not receive HT after the primary diagnosis but before LRR, record 'No." In the case that a patient transfers care to your center after the primary diagnosis and it is not certain that the patient receive HT, record '99, UNK.'
Identifier?	N
Required Field?	N
Field Label	**Was this administered as part of a combination therapy with ovarian suppression or other?**
REDCap Variable Name	combo_therapy1_yn
Field Type	yesno
Directives	Linked to ***Was Hormone therapy (HT) received after primary diagnosis date but before LRR or distant metastatic date?*** If the response is 'Yes' then ***Was this administered as part of a combination therapy with ovarian suppression or other?*** becomes active. If the hormone therapy was administered with ovarian suppression or similar, record 'Yes.' If not, record 'No.' Do not leave blank.
Identifier?	N
Required Field?	N
Field Label	**Therapy 1**
REDCap Variable Name	hormone_1
Field Type	dropdown
Choice List	1, Ovarian suppression/ablation therapyv (Leuprolide/Goserelin/ BSO) | 2, Anastrozole | 3, Letrozole | 4, Exemestane | 5, Fulvestrant | 6, Tamoxifen | 7,

	Toremifene | 8, Megestrol acetate | 9, Fluoxymesterone | 10, Ethinyl estradiol | 98, Other
Directives	Linked to ***Was Hormone therapy (HT) received after primary diagnosis date but before LRR or distant metastatic date?*** If the response is 'Yes' then ***Therapy 1*** becomes active. Choose the hormone therapy received by the patient from the drop-down list. If the hormone therapy is not listed, record '98, Other.' If the drug is not listed, record its name. In rare instances, patients may receive hormone therapy in combination with a non-hormonal agent. Do not leave blank.
Identifier?	N
Required Field?	N
Field Label	**Was this administered as part of the clinical trial?**
REDCap Variable Name	hormone1_clintrial
Field Type	yesno
Directives	Linked to ***Was Hormone therapy (HT) received after primary diagnosis date but before LRR or distant metastatic date?*** If the response is 'Yes' then ***Was this administered as part of the clinical trial?*** becomes active Record 'Yes' if the hormone therapy was administered as a part of a clinical trial. Please note that it is not necessary for the hormone therapy to be evaluated in the trial in order to record 'Yes.'
Identifier?	N
Required Field?	N
Field Label	**Therapy 1, Specify**
REDCap Variable Name	hormone1_other
Field Type	text
Directives	Linked to ***Was Hormone therapy (HT) received after primary diagnosis date but before LRR or distant metastatic date?*** If the response is 'Yes' then ***Therapy1, Specify*** becomes active. Linked to ***Therapy 1***. If the response is '98, Other' record the hormone therapy that is not listed in the drop-down list. Please make sure that the drug recorded is an actual hormone therapy.
Identifier?	N
Required Field?	N
Field Label	**Therapy 1 Start Date**
REDCap Variable Name	hormo1_start

Field Type	text
Valid Field	mm-dd-yyyy
Directives	Linked to ***Was Hormone therapy (HT) received after primary diagnosis date but before LRR or distant metastatic date?*** If the response is 'Yes' then ***Therapy 1, Start Date*** becomes active. Record the date that the drug was first administered to the patient. Note for oral medications: If the first date of administration is not known, record the date the drug was prescribed or ordered or recorded in medical notes as date of therapy initiation. If the full date is not known, estimate the date on using the components that are known. • If month and year of the date is known, and the day of the month is not known, record 15 for the day. • If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day. • If the year is known, and the seasons are noted rather than the month and day, use the following: o For winter use January (1) o For spring use April (4) o For summer use July (7) o For autumn use October (10) Do not leave blank.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	N
Field Label	**Therapy 1 Start Interval**
REDCap Variable Name	hormo1_start_int
Field Type	Calculated: datediff([dob_date],[reg2_hormo1_start],'d', 'mdy', false)
Directives	Linked to ***Was Hormone therapy (HT) received after primary diagnosis date but before LRR or distant metastatic date?*** If the response is 'Yes' then ***Therapy 1, Start Date Interval*** becomes active. Dependent upon ***Therapy1 Start Date.*** If the ***Therapy1 Start Date*** was entered, REDCap will calculate this field by subtracting the ***Date of Birth*** from the ***Therapy1 Start Date***. If the ***Therapy1 Start Date*** was not entered, this data field will remain blank.
Identifier?	N

Required Field?	N
Field Label	**Therapy 1 End Date**
REDCap Variable Name	hormo1_end
Valid Field	mm-dd-yyyy
Choice List	text

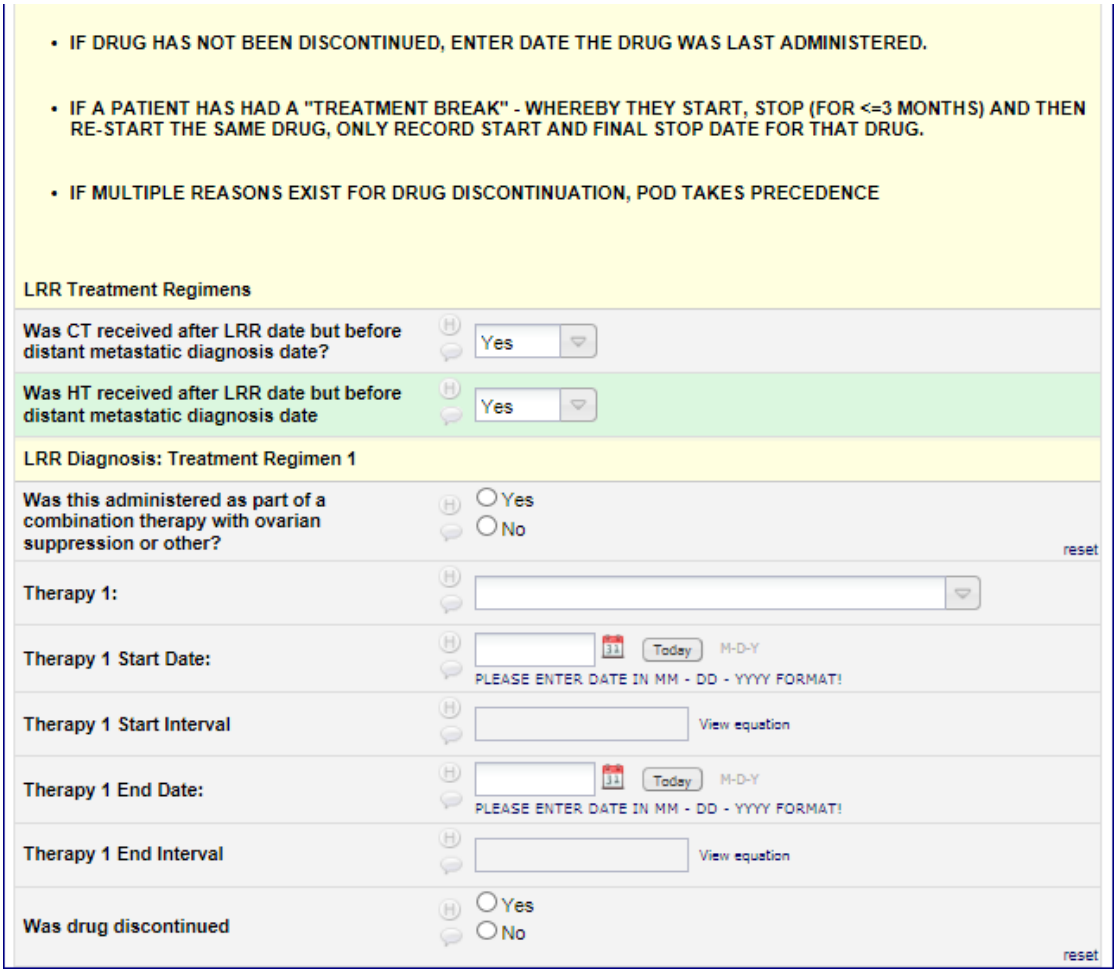
Directives	Record the last date that the patient received the medication.
	
	If the actual last date that the drug was administered is not documented, record the date that the provider stated was the last date of administration in the EMR.
	
	If a patient leaves your institutional care and you are no longer certain of when a therapy was discontinued, enter the last known date of therapy administration at your institution.
	
	If a drug has not been discontinued, enter the date that the drug was last administered at the time of data abstraction.
	
	If a patient has a treatment break or holiday, whereby she starts a hormone therapy and stops the drug for less than or equal to 3 months (90 days) and then re-starts the same medication, record the first start date for ***Therapy 1 Start Date*** and the final end date for the therapy as ***Therapy 1 End Date***.
	
	If a patient has a treatment break or holiday, whereby she starts a hormone therapy and stops the drug for greater than 3 months (90 days) and then re-starts the same medication, record the first start date and the first end date for ***Therapy 1 End Date***; record the same drug in ***Therapy 2*** with the second start date and the final end date for the therapy.
	
	If the full date is not known, estimate the date on using the components that are known.
	• If month and year of the date is known, and the day of the month is not known, record 15 for the day.
	• If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day.
	• If the year is known, and the seasons are noted rather than the month and day, use the following:
	  ○ For winter use January (1)
	  ○ For spring use April (4)
	  ○ For summer use July (7)
	  ○ For autumn use October (10)
	
	Do not leave blank.

Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	N

Field Label	Therapy 1 End Interval
REDCap Variable Name	hormo1_end_int
Field Type	Calculated: datediff([dob_date],[reg2_hormo1_start],'d', 'mdy', false)
Directives	Dependent upon ***Therapy1 End Date.*** If the ***Therapy1 End Date*** was entered, REDCap will calculate this field by subtracting the ***Date of Birth*** from the ***Therapy1 End Date***. If the ***Therapy1 End Date*** was not entered, this data field will remain blank.
Identifier?	N
Required Field?	N
Field Label	**Was drug discontinued?**
REDCap Variable Name	hormo1_discon_yn
Field Type	treatment_regimens
Choice List	Yesno
Directives	Record 'Yes' if the hormone therapy has been discontinued. If the hormone therapy has not been discontinued at the time of data abstraction, record 'No.'
Identifier?	N
Required Field?	N
Field Label	**Reason for Discontinuation**
REDCap Variable Name	hormo1_reason
Field Type	Dropdown
Choice List	0, Completion of Planned Therapy | 1, Toxicity | 2, Patient Preference | 3, Not Effective/Progression of Disease | 99, Other/UNK
Directives	Linked to ***Was drug discontinued?*** If 'Yes' record the reason that the hormone therapy was discontinued. If 'No' leave blank. If a patient leaves your institutional care and you are no longer certain of when a therapy was discontinued, enter 'Lost to follow-up'. If multiple reason exist for drug discontinuation and one of the reasons is for disease progression, record '3, Not Effective/Progression of Disease.'
Identifier?	N
Required Field?	N

LRR: Treatment Regimens

1. Use the EMR to look for cancer-directed drug therapies; use the Medications and the provider notes to locate the details of drug therapies.
2. The receipt of chemotherapy following LRR will be recorded, but the actual chemotherapies will not be recorded.
3. The receipt of hormone therapy following LRR will be recorded, and the actual hormone therapies will be recorded; up to three drugs can be entered,
4. The data guide will provide directives for the first treatment in the first regimen; subsequent treatments have similar directives.



Field Label	Was CT received after LRR date but before distant metastatic diagnosis date?
REDCap Variable Name	lrr_chemo_therapy_postdx
Field Type	Dropdown

Choice List	1, Yes | 0, No | 99, UNK
Directives	If the patient received CT following a LRR and before a diagnosis of a distant metastasis, record '1, Yes.' If the patient did not receive CT following the LRR, record 'No." In the case that a patient transfers care to your center after the LRR and it is not certain that the patient receive CT following the LRR, record '99, UNK.'
Identifier?	N
Required Field?	N
Field Label	**Was HT received after LRR date but before distant metastatic diagnosis date?**
REDCap Variable Name	lrr_hormo_therapy_postdx
Field Type	Dropdown
Choice List	1, Yes | 0, No | 99, UNK
Directives	If the patient received HT following a LRR, record '1, Yes.' If the patient did not receive HT following the LRR, record 'No." In the case that a patient transfers care to your center after the LRR and it is not certain that the patient receive HT following the LRR, record '99, UNK.'
Identifier?	N
Required Field?	N
Field Label	**Was this administered as part of a combination therapy with ovarian suppression or other?**
REDCap Variable Name	lrr_combo_therapy1_yn
Field Type	Yesno
Directives	Linked to ***Was HT received after LRR date but before distant metastatic diagnosis date?*** If the response is 'Yes' then ***Was this administered as part of a combination therapy with ovarian suppression or other?*** becomes active. If the hormone therapy was administered with ovarian suppression or similar, record 'Yes.' If not, record 'No.' Do not leave blank.
Identifier?	N
Required Field?	N
Field Label	**Therapy 1**
REDCap Variable Name	lrr_hormone_1
Field Type	Dropdown
Choice List	1, Ovarian suppression/ablation therapyv (Leuprolide/Goserelin/ BSO) | 2, Anastrozole | 3, Letrozole | 4, Exemestane | 5, Fulvestrant | 6, Tamoxifen | 7,

	Toremifene | 8, Megestrol acetate | 9, Fluoxymesterone | 10, Ethinyl estradiol | 98, Other
Directives	Linked to ***Was HT received after LRR date but before distant metastatic diagnosis date?*** If the response is 'Yes' then ***Therapy 1*** becomes active. Choose the hormone therapy received by the patient from the drop-down list. If the hormone therapy is not listed, record '98, Other.' If the drug is not listed, please make sure that it is a hormone therapy. If it is not, do not record in this field. Do not leave blank.
Identifier?	N
Required Field?	N
Field Label	**Was this administered as part of the clinical trial?**
REDCap Variable Name	lrr_hormone1_clintrial
Field Type	Yesno
Directives	Linked to ***Was HT received after LRR date but before distant metastatic diagnosis date?*** If the response is 'Yes' then ***Was this administered as part of the clinical trial?*** becomes active. Record 'Yes' if the hormone therapy was administered as a part of a clinical trial. Please note that it is not necessary for the hormone therapy to be evaluated in the trial in order to record 'Yes.'
Identifier?	N
Required Field?	N
Field Label	**Therapy 1, Specify**
REDCap Variable Name	lrr_hormone1_other
Field Type	Text
Directives	Linked to ***Was HT received after LRR date but before distant metastatic diagnosis date?*** If the response is 'Yes' then ***Therapy1, Specify*** becomes active. Linked to ***Therapy 1***. If the response is '98, Other' record the hormone therapy that is not listed in the drop-down list. Please make sure that the drug recorded is an actual hormone therapy.
Identifier?	N
Required Field?	N
Field Label	**Therapy 1 Start Date**
REDCap Variable Name	lrr_hormo1_start
Field Type	Text
Valid Field	mm-dd-yyyy
Directives	Linked to ***Was HT received after LRR date but before distant metastatic diagnosis***

	date? If the response is 'Yes' then ***Therapy 1, Start Date*** becomes active. Record the date that the drug was first administered to the patient. Note for oral medications: If the first date of administration is not known, record the date the drug was prescribed or ordered or ordered in medical notes as date of therapy initiation. If the full date is not known, estimate the date on using the components that are known. • If month and year of the date is known, and the day of the month is not known, record 15 for the day. • If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day. • If the year is known, and the seasons are noted rather than the month and day, use the following: o For winter use January (1) o For spring use April (4) o For summer use July (7) o For autumn use October (10) Do not leave blank.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	N
Field Label	**Therapy 1 Start Interval**
REDCap Variable Name	lrr_hormo1_start_int
Field Type	Calculated: datediff([dob_date],[reg2_hormo1_start],'d', 'mdy', false)
Directives	Linked to ***Was Hormone therapy (HT) received after primary diagnosis date but before LRR or distant metastatic date?*** If the response is 'Yes' then ***Therapy 1, Start Date Interval*** becomes active. Dependent upon ***Therapy1 Start Date.*** If the ***Therapy1 Start Date*** was entered, REDCap will calculate this field by subtracting the ***Date of Birth*** from the ***Therapy1 Start Date***. If the ***Therapy1 Start Date*** was not entered, this data field will remain blank.
Identifier?	N
Required Field?	N
Field Label	**Therapy 1 End Date**
REDCap Variable Name	lrr_hormo1_end
Valid Field	mm-dd-yyyy

Choice List	text

	Linked to ***Was HT received after LRR date but before distant metastatic diagnosis date?*** If the response is 'Yes' then ***Therapy 1, End Date*** becomes active.
	
	Record the last date that the patient received the medication.
	
	If the actual last date that the drug was administered is not documented, record the date that the provider stated was the last date of administration in the note.
	
	If a patient leaves your institutional care and you are no longer certain of when a therapy was discontinued, enter the last known date of therapy administration at your institution.
	
	If a drug has not been discontinued, enter the date that the drug was last administered at the time of data abstraction.
	
	If a patient has a treatment break or holiday, whereby she starts a hormone therapy and stops the drug for less than or equal to 3 months (90 days) and then re-starts the same medication, record the first start date for ***Therapy 1 Start Date*** and the final end date for the therapy as ***Therapy 1 End Date***.
	
	If a patient has a treatment break or holiday, whereby she starts a hormone therapy and stops the drug for greater than 3 months (90 days) and then re-starts the same medication, record the first start date and and the first end date for ***Therapy 1 End Date***; record the same drug in ***Therapy 2*** with the second start date and the final end date for the therapy.
	
	If the full date is not known, estimate the date on using the components that are known.
	• If month and year of the date is known, and the day of the month is not known, record 15 for the day.
	• If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day.
	• If the year is known, and the seasons are noted rather than the month and day, use the following:
	  o For winter use January (1)
	  o For spring use April (4)
	  o For summer use July (7)
	  o For autumn use October (10)

Directives	Do not leave blank.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	N
Field Label	**Therapy 1 End Interval**

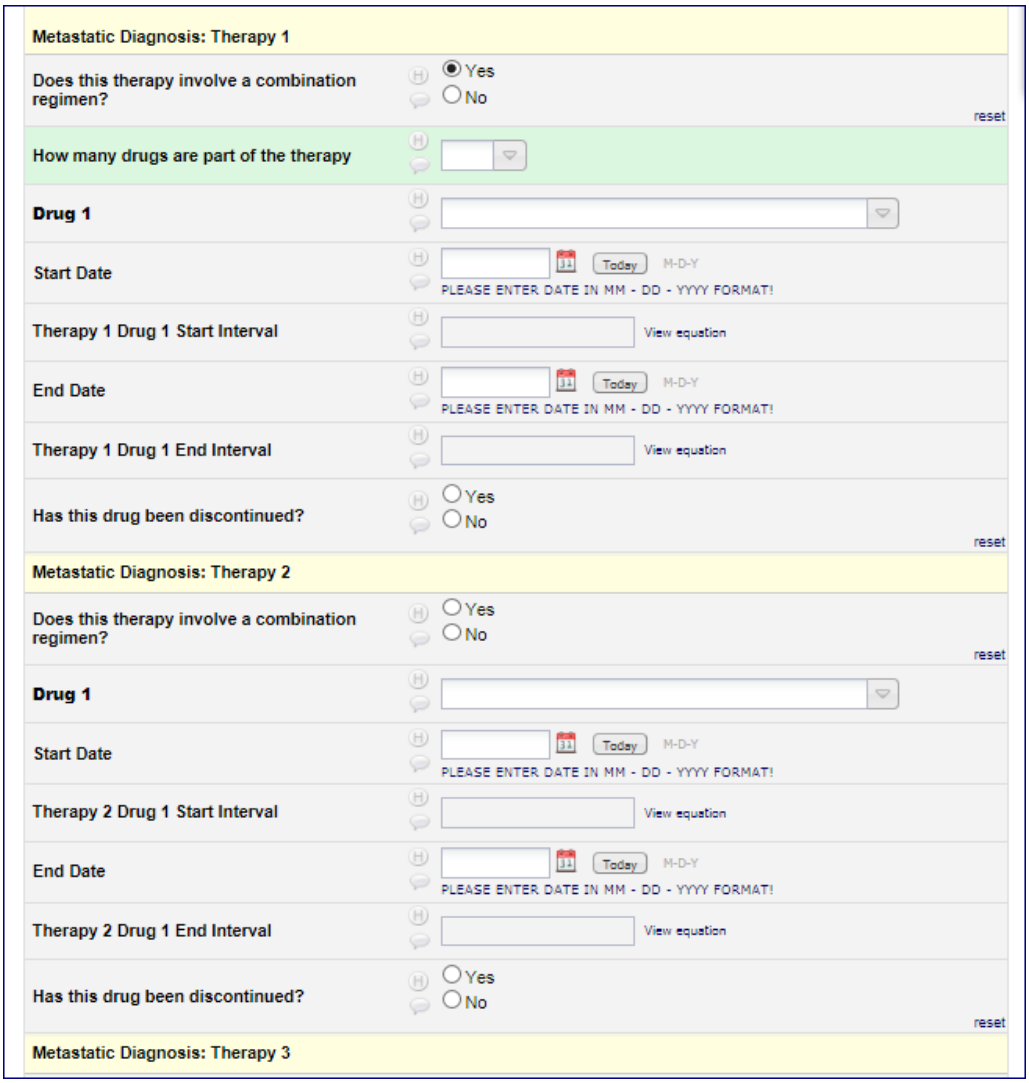
REDCap Variable Name	lrr_hormo1_end_int
Field Type	Calculated: datediff([dob_date],[reg2_hormo1_start],'d', 'mdy', false)
Directives	Linked to ***Was HT received after LRR date but before distant metastatic diagnosis date?*** If the response is 'Yes' then ***Therapy 1, End Date Interval*** becomes active. Dependent upon ***Therapy1 End Date.*** If the ***Therapy1 End Date*** was entered, REDCap will calculate this field by subtracting the ***Date of Birth*** from the ***Therapy1 End Date***. If the ***Therapy1 End Date*** was not entered, this data field will remain blank.
Identifier?	N
Required Field?	N
Field Label	**Was drug discontinued?**
REDCap Variable Name	lrr_hormo1_discon_yn
Field Type	treatment_regimens
Choice List	yesno
Directives	Linked to ***Was HT received after LRR date but before distant metastatic diagnosis date?*** If the response is 'Yes' then ***Was drug discontinued*** becomes active. Record 'Yes' if the hormone therapy has been discontinued prior to the time of data abstraction. If the hormone therapy has not been discontinued at the time of data abstraction, record 'No.'
Identifier?	N
Required Field?	N
Field Label	**Reason for Discontinuation**
REDCap Variable Name	lrr_hormo1_reason
Field Type	dropdown
Choice List	0, Completion of Planned Therapy | 1, Toxicity | 2, Patient Preference | 3, Not Effective/Progression of Disease | 99, Other/UNK
Directives	Linked to ***Was drug discontinued?*** If 'Yes' record the reason that the hormone therapy was discontinued. If 'No' leave blank. If a patient leaves your institutional care and you are no longer certain of when a therapy was discontinued, enter 'Lost to follow-up'. If multiple reason exist for drug discontinuation and one of the reasons is for disease

	progression, record '3, Not Effective/Progression of Disease.'
Identifier?	N
Required Field?	N

Metastatic Diagnosis: Therapy

Abstraction Notes:

1. Record all of the drugs given in the setting of distant metastases.
2. A portion of the data fields is provided below as an example; these types of data fields will be abstracted for each cancer-directed drug therapy received by the patient.



Data Abstraction Guide for all cancer-directed drug therapies within each combination regimens for distant metastases.

Field Label	Does this therapy involve a combination regimen?
REDCap Variable Name	therapy1_combo_yn
Field Type	yesno

Directives	Record 'Yes' two or more cancer-directed drugs are given as a regimen. If one cancer directed drug is given, record 'No.'
Identifier?	N
Required Field?	N
Field Label	**How many drugs are part of the therapy?**
REDCap Variable Name	therapy1_combo_num
Field Type	dropdown
Choice List	1, 2 | 2, 3 | 3, 4
Directives	Linked to ***Does this therapy involve a combination regimen?*** If the response is 'Yes' Record the number of cancer-directed drugs in the therapy. This data field will control the number of drugs that you can enter for the first line of therapy.
Identifier?	N
Required Field?	N
Field Label	**Drug 1**
REDCap Variable Name	therapy1_drug1
Field Type	Dropdown
Choice List	1, Doxorubicin | 2, Pegylated liposomal doxorubicin | 3, Paclitaxel | 4, Capecitabine | 5, Gemcitabine | 6, Vinorelbine | 7, Eribulin | 8, Cyclophosphamide | 9, Carboplatin | 10, Docetaxel | 11, Albumin-bound paclitaxel | 12, Cisplatin | 13, Epirubicin | 14, Ixabepilone | 15, Trastuzumab | 16, Pertuzumab | 17, Ado-trastuzumab emtansine | 18, Lapatinib | 19, Ovarian suppression/ablation therapy (Leuprolide/Goserelin/ BSO) | 20, Anastrozole | 21, Letrozole | 22, Exemestane | 23, Fulvestrant | 24, Tamoxifen | 25, Toremifene | 26, Megestrol acetate | 27, Fluoxymesterone | 38, Ethinyl estradiol | 29, Exemestane | 30, Everolimus | 31, Palbociclib | 98, Other
Directives	Choose the first drug in the therapy regimen. If the drug is not listed, record '98, Other.'
Identifier?	N
Required Field?	N
Field Label	**Was this administered as part of the clinical trial?**
REDCap Variable Name	therapy1_drug1_clintrial
Field Type	Yesno
Directives	Record 'Yes' if the drug therapy was administered as a part of a clinical trial. Please note that it is not necessary for the drug to be evaluated in the trial in order to record 'Yes.'
Identifier?	N
Required Field?	N
Field Label	**Was the drug AZD5363?**

REDCap Variable Name	therapy1_drug1_azd5363
Field Type	yesno
Directives	If ***Drug 1*** is AZD5363, record 'Yes' else record 'No.'
Identifier?	N
Required Field?	N
Field Label	**Generic name of drug**
REDCap Variable Name	therapy1_drug1_other
Field Type	Text
Directives	Linked to ***Drug .*** if '98, Other' is noted, record the generic name of the drug. If '98, Other' is not noted, leave blank.
Identifier?	N
Required Field?	N
Field Label	**Therapy 1 Start Date**
REDCap Variable Name	therapy1_drug1_start
Field Type	Text
Valid Field	mm-dd-yyyy

Directives	Linked to ***Was therapy received after primary diagnosis date but before LRR or distant metastatic date?*** If the response is 'Yes' then ***Therapy 1, Start Date*** becomes active.
	
	Record the date that the drug was first administered to the patient.
	
	<u>Note for oral medications:</u> If the first date of administration is not known, record the date the drug was prescribed or ordered or recorded in medical notes as date of therapy initiation.
	
	If the full date is not known, estimate the date on using the components that are known.
	• If month and year of the date is known, and the day of the month is not known, record 15 for the day.
	• If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day.
	• If the year is known, and the seasons are noted rather than the month and day, use the following:
	  ○ For winter use January (1)
	  ○ For spring use April (4)
	  ○ For summer use July (7)
	  ○ For autumn use October (10)
	
	Do not leave blank.

	If the full date is not known, estimate the date on using the components that are known. • If month and year of the date is known, and the day of the month is not known, record 15 for the day. • If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day. • If the year is known, and the seasons are noted rather than the month and day, use the following: o For winter use January (1) o For spring use April (4) o For summer use July (7) o For autumn use October (10) Do not leave blank.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	N
Field Label	**Therapy 1 Start Interval**
REDCap Variable Name	therapy1_drug1_start_int
Field Type	Calculated: datediff([dob_date],[reg2_hormo1_start],'d', 'mdy', false)
Directives	Linked to ***Was Hormone therapy (HT) received after primary diagnosis date but before LRR or distant metastatic date?*** If the response is 'Yes' then ***Therapy 1, Start Date Interval*** becomes active. Dependent upon ***Therapy1 Start Date.*** If the ***Therapy1 Start Date*** was entered, REDCap will calculate this field by subtracting the ***Date of Birth*** from the ***Therapy1 Start Date***. If the ***Therapy1 Start Date*** was not entered, this data field will remain blank.
Identifier?	N
Required Field?	N
Field Label	**Therapy 1 End Date**
REDCap Variable Name	therapy1_drug1_end
Valid Field	mm-dd-yyyy
Choice List	text
Directives	Record the last date that the patient received the medication. If the actual last date that the drug was administered is not documented, record the date that the provider stated was the last day of administration in the medical notes. If a patient leaves your institutional care and you are no longer certain of when a

	therapy was discontinued, enter the last known date of therapy administration at your institution. If a drug has not been discontinued, enter the date that the drug was last administered at the time of data abstraction. If a patient has a treatment break or holiday, whereby she starts a hormone therapy and stops the drug for less than or equal to 3 months (90 days) and then re-starts the same medication, record the first start date for ***Therapy 1 Start Date*** and the final end date for the therapy as ***Therapy 1 End Date***. If a patient has a treatment break or holiday, whereby she starts a hormone therapy and stops the drug for greater than 3 months (90 days) and then re-starts the same medication, record the first start date and and the first end date for ***Therapy 1*** End Date; record the same drug in ***Therapy 2*** with the second start date and the final end date for the therapy. If the full date is not known, estimate the date on using the components that are known. • If month and year of the date is known, and the day of the month is not known, record 15 for the day. • If year of the date is known, and the day and month is not known, record 6 (June) for the month and 15 for the day. • If the year is known, and the seasons are noted rather than the month and day, use the following: o For winter use January (1) o For spring use April (4) o For summer use July (7) o For autumn use October (10) Do not leave blank.
Identifier?	Y; this data element will not be shared with MSK. It will be used to calculate the interval in days.
Required Field?	N
Field Label	**Therapy 1 End Interval**
REDCap Variable Name	therapy1_drug1_end_int
Field Type	Calculated: datediff([dob_date],[reg2_hormo1_start],'d', 'mdy', false)
Directives	Dependent upon ***Therapy1 End Date.*** If the ***Therapy1 End Date*** was entered, REDCap will calculate this field by subtracting the ***Date of Birth*** from the ***Therapy1 End Date***. If the ***Therapy1 End Date*** was not entered, this data field will remain blank.
Identifier?	N
Required Field?	N

Field Label	Was drug discontinued?
REDCap Variable Name	therapy1_drug1_discon_yn
Field Type	treatment_regimens
Choice List	yesno
Directives	Record 'Yes' if the hormone therapy has been discontinued. If the hormone therapy has not been discontinued at the time of data abstraction, record 'No.'
Identifier?	N
Required Field?	N
Field Label	**Reason for Discontinuation**
REDCap Variable Name	therapy1_drug1_reason
Field Type	dropdown
Choice List	0, Completion of Planned Therapy | 1, Toxicity | 2, Patient Preference | 3, Not Effective/Progression of Disease | 99, Other/UNK
Directives	Linked to ***Was drug discontinued?*** If 'Yes' record the reason that the hormone therapy was discontinued. If 'No' leave blank. If a patient leaves your institutional care and you are no longer certain of when a therapy was discontinued, enter 'Lost to follow-up'. If multiple reason exist for drug discontinuation and one of the reasons is for disease progression, record '3, Not Effective/Progression of Disease.'
Identifier?	N
Required Field?	N
Field Label	**Form Status: Complete?**
REDCap Variable Name	
Field Type	Dropdown
Choice List	Incomplete | Unverified | Complete
Directives	Record 'Complete' once all of the data fields in this section have been entered and the eligibility calculation has been performed. This field will be used during data quality review. 'Incomplete' is the default choice; patients with any indication of 'Incomplete' or 'Unverified' sections are not eligible for data analysis.
Identifier?	N
Required Field?	N

Appendix One: AJCC 7th Edition, Staging Guidelines

The patients should be staged using the AJCC 7th Edition Guidelines. Here is a quick reference for Breast Cancer

https://cancerstaging.org/references-tools/quickreferences/Documents/BreastMedium.pdf