

Manual for the Completion of CDISC Aligned NCI Standard Case Report Form (CRF) Modules

Introduction

In 2006, members of the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) in conjunction with the cancer Data Standards Registry and Repository (caDSR) user community initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into four categories:

- **Mandatory** – A data collection variable that must be on the CRF (e.g., a regulatory requirement (if applicable)).
- **Conditional** – A data collection variable that must be collected on the CRF for specific cases that may be dictated by local or sponsor defined business rules.
- **Optional** – A data collection variable that is available for use if needed. There is no regulatory or business requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data; this is the element to include on the CRF.
- **Non-harmonized** – A data collection variable that is, by consensus, to primarily belong to a different CRF module or is not belonging to any defined module.

A template form with modules that contain questions or variables representing data to be collected and a companion electronic CRF instruction manual was developed. These CRF modules were vetted and adopted by the caDSR stakeholder community as metadata standards.

Since the original CRFs and manuals were adopted, the Food & Drug Administration (FDA) published guidelines for submission of clinical trial study data using the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) for Investigational New Drug (IND) trials starting after December 2017. In response, NCI CBIIT has aligned the NCI Standard CRF modules with the CDISC data collection standard, Clinical Data Acquisition Standards Harmonization (CDASH) where data is expected to be submitted to FDA in SDTM format.

The instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc. Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

Diagnosis Microscopic Pathology CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

This NCI Standard Template Form maps to the following domains in the CDASHIG v2.0 metadata table:

- MI – Microscopic Findings (v2.0)
- MH – Medical History (v2.0)

Mapping to the SDTM:

This NCI Standard Template Form maps to the following domains in the SDTMIG v3.3 metadata table:

- MI – Microscopic Findings (v3.3)
- MH – Medical History (v3.3)

Diagnosis Microscopic Pathology CDISC Aligned NCI Standard Template Module Template Instructions

Field Descriptions and Instructions

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Invasive Breast Carcinoma Diagnosis Type (c) 7038770 MHIBDXTP	The description of the type of invasive breast disease present. CDASH: MHTERM (6421489); SDTM: MHTERM (No CDE); Conditionality Rule: This CDE is to be included only for breast cancer trials.	CHARACTER. Use choice list.
Invasive Breast Carcinoma Diagnosis Text (c) 7038771 MHVSCOPX	The description of the type of invasive breast disease present not previously listed. CDASH: MHTERM (6421489); SDTM: MHTERM (No CDE); Conditionality Rule: This CDE is to be included only for breast cancer trials.	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Biospecimen Prostatic Intraepithelial Neoplasia Status (c) 7038772 PIN	The description of the degree of differentiation of epithelial cells of the prostate. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "PIN", MITSTDTL (6421501) = "Prostatic intraepithelial neoplasia grade"; Conditionality Rule: This is to be included only for prostate cancer patients.	CHARACTER. Use choice list.
Invasive Breast Carcinoma Glandular (Acinar)/Tubular Differentiation Outcome (c) 7038773 MIGLTBDF	The description of the percent of glandular/tubular structures in breast tissue represented using the Nottingham histologic score. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "GLDTBF", MITSTDTL (6421501) = "Glandular tubular differentiation score"; Conditionality Rule: This CDE is to be included only for breast cancer trials.	CHARACTER. Use choice list.
Invasive Breast Carcinoma Pleomorphism Score Outcome (c) 7038774 MINCPLPH	The description of the nuclei size and shape in breast tissue represented using the Nottingham histologic score. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MINCPLPH", MITSTDTL (6421501) = "Nuclear pleomorphism score"; Conditionality Rule: This CDE is to be included only for breast cancer trials.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Invasive Breast Carcinoma Mitotic Rate Score Outcome (c) 7038775 MITORT	The description of the mitotic rate of breast tissue represented using the Nottingham histologic score. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MITORT", MITSTDTL (6421501) = "Mitotic rate"; Conditionality Rule: This CDE is to be included only for breast cancer trials.	CHARACTER. Use choice list.
Invasive Breast Carcinoma Per 10 High Powered Fields Mitotic Count Value (c) 7038776 MITOHPF	The amount of mitoses per 10 high power fields in breast tissue represented using the Nottingham scoring system. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MITOHPF", MITSTDTL (6421501) = "Number of mitoses per 10 high-power fields"; Conditionality Rule: This CDE is to be included only for breast cancer trials.	NUMBER
Microscope Device Field of View Diameter Value (c) 7038777 MICFD	The diameter of the microscope field, represented as a numeric value using millimeters (mm) as the unit of measure. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MICFD", MITSTDTL (6421501) = "Diameter of microscope field"; Conditionality Rule: This CDE is to be included only for breast cancer trials.	NUMBER
Microscopic Findings Result Unit (c) 6410966 MIORRESU	The unit of the result as originally received or collected. CDASH: MIORRESU (6410966); SDTM: MIORRESU (No CDE); Conditionality Rule: This CDE is to be included only for breast cancer trials.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Invasive Breast Carcinoma Total Nottingham Score Outcome (c) 7038778 MIOVLGRD	The grade of invasive breast cancer determined by the summation of three Nottingham histologic scores. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "OVLGRD", MITSTDTL (6421501) = "Overall grade"; Conditionality Rule: This CDE is to be included only for breast cancer trials.	CHARACTER. Use choice list.
Lymphatic Invasion Present Indicator (o) 7038779	The indication of whether or not malignant cells are present within lymphatic vessels. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "LYMPHINV"	CHARACTER. Use choice list.
External Venous Invasion Present Indicator (o) 7038780 MIEXVNIN	The indication of whether or not there has been extramural invasion of the veins by malignant cells. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "EXVNIN"	CHARACTER. Use choice list.
Perineural Invasion Present Indicator (o) 7038781 MIPNLINV	The indication of whether or not there is a presence of malignant cells surrounding a nerve. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "PNLINV"	CHARACTER. Use choice list.
Pelvic Lymphadenectomy Finding Category (o) 7038782 MIPLND	The indication of whether or not there is a presence of malignant cells in pelvic lymph nodes that were removed. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "PLND"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Biospecimen Malignant Neoplasm Percentage Value (o) 7038783 MICANPCT	The percentage of malignant cells contained in a biospecimen, represented as a numeric value. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "CANPCT"	NUMBER
Microscopic Findings Result Unit (o) 6410966 MIORRESU	The unit of the result as originally received or collected. CDASH: MIORRESU (6410966); SDTM: MIORRESU (No CDE); Conditionality Rule: This CDE is to be included only for breast cancer trials.	CHARACTER. Use choice list.
Biospecimen Premalignant Change Indicator (o) 7038761 MINTPMHT	The indication of whether or not there are there are changes in cells that may become cancer and are considered premalignant or precancerous. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "NTPMHT"	CHARACTER. Use choice list.
Biospecimen Premalignant Change Type (o) 7038762 MIASPMHT	The histologic changes in a biospecimen that are associated with pre-malignant conditions. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "ASPMHT"	CHARACTER. Use choice list.
Biospecimen Premalignant Change Text (o) 7038763 MIASPMHX	The histologic changes in a biospecimen that are associated with pre-malignant conditions not previously listed. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "ASPMHT"	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Tumor Margin Configuration Present Type (o) 7038764 MITUMRBD	The tumor margin cell configuration observed at a pathologic assessment. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591)= "TUMRBD"	CHARACTER. Use choice list.
Tumor Margin Configuration Present Text (o) 7038765 MITMRBDX	The tumor margin cell configuration observed at a pathologic assessment not previously listed. CDASH: MIORRES (6421502); SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "TUMRBD"	CHARACTER

Annotated CRF: Diagnosis Microscopic Pathology CDISC Aligned NCI Standard Template

This annotated CRF is ONLY used to show CDISC mapping without consideration of the CRF layout. CDASH mapping is in **Blue**, and SDTM mapping is in **Red**.

Form Name: Diagnosis Microscopic Pathology CDISC Aligned NCI Standard Template

Conditional Questions

CRF Question	Value Domain
<p>Invasive component, breast (7038770) CDE Short Name: MHIBDXTP</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: MHTERM (6421489)</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: MHTERM (No CDE)</div>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 84 PVs</p>
<p>Invasive component, other (7038771) CDE Short Name: MHVSCOPX</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: MHTERM (6421489)</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: MHTERM (No CDE)</div>	<p>CHARACTER – Maximum Length = 200</p>
<p>Prostatic intraepithelial neoplasia (PIN) (7038772) CDE Short Name: PIN</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: MIORRES (6421502)</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "PIN", MITSTDTL (6421501) = "Prostatic intraepithelial neoplasia grade"</div>	<p>CHARACTER – Maximum Length = 20</p> <ul style="list-style-type: none"> <input type="checkbox"/> High Grade – High Grade Prostatic Intraepithelial Neoplasia <input type="checkbox"/> Low Grade – Low Grade Prostatic Intraepithelial Neoplasia <input type="checkbox"/> None – None at all <input type="checkbox"/> Not Assessed – Not Tested <input type="checkbox"/> Present NOS – Not Otherwise Specified Present

CRF Question	Value Domain
<p>Glandular tubular differentiation (7038773) CDE Short Name: MIGLTBDF</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "GLDTBF", MITSTDTL (6421501) = "Glandular tubular differentiation score"</p>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> No residual invasive carcinoma – Negation Residual Invasive Carcinoma <input type="checkbox"/> Only microinvasion present not graded – Microinvasive Breast Carcinoma Present Negation Histologic Grade <input type="checkbox"/> Score 1 – Glandular (Acinar)/Tubular Differentiation Score 1 <input type="checkbox"/> Score 2 – Glandular (Acinar)/Tubular Differentiation Score 2 <input type="checkbox"/> Score 3 – Glandular (Acinar)/Tubular Differentiation Score 3 <input type="checkbox"/> Score cannot be determined – Score Indeterminate
<p>Nuclear pleomorphism (7038774) CDE Short Name: MINCPLPH</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MINCPLPH", MITSTDTL (6421501) = "Nuclear pleomorphism score"</p>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> No residual invasive carcinoma – Negation Residual Invasive Carcinoma <input type="checkbox"/> Only microinvasion present not graded – Microinvasive Breast Carcinoma Present Negation Histologic Grade <input type="checkbox"/> Score 1 – Nuclear Pleomorphism Score 1 <input type="checkbox"/> Score 2 – Nuclear Pleomorphism Score 2 <input type="checkbox"/> Score 3 – Nuclear Pleomorphism Score 3 <input type="checkbox"/> Score cannot be determined – Score Indeterminate
<p>Mitotic rate (7038775) CDE Short Name: MITORT</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MITORT", MITSTDTL (6421501) = "Mitotic rate"</p>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> No residual invasive carcinoma – Negation Residual Invasive Carcinoma <input type="checkbox"/> Only microinvasion present not graded – Microinvasive Breast Carcinoma Present Negation Histologic Grade <input type="checkbox"/> Score 1 – Mitotic Rate Score 1 <input type="checkbox"/> Score 2 – Mitotic Rate Score 2 <input type="checkbox"/> Score 3 – Mitotic Rate Score 3 <input type="checkbox"/> Score cannot be determined – Score Indeterminate

CRF Question	Value Domain
<p>Number of mitoses per 10 high-power fields (7038776) CDE Short Name: MITOHPF</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: MIORRES (6421502)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MITOHPF", MITSTDTL (6421501) = "Number of mitoses per 10 high-power fields"</p>	<p>NUMBER – Maximum Length = 5</p>
<p>Diameter of microscope field (7038777) CDE Short Name: MICFD</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: MIORRES (6421502)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "MICFD", MITSTDTL (6421501) = "Diameter of microscope field"</p>	<p>NUMBER – Maximum Length = 5</p>
<p>Unit (6410966) CDE Short Name: MIORRESU</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: MIORRESU (6410966)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: MIORRESU (No CDE)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> mm – Millimeter</p>
<p>Overall grade (7038778) CDE Short Name: MIOVLGRD</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: MIORRES (6421502)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "OVLGRD", MITSTDTL (6421501) = "Overall grade"</p>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Grade 1 – Nottingham Grade 1 <input type="checkbox"/> Grade 2 – Nottingham Grade 2 <input type="checkbox"/> Grade 3 – Nottingham Grade 3 <input type="checkbox"/> No residual invasive carcinoma – Negation Residual Invasive Carcinoma <input type="checkbox"/> Only microinvasion present not graded – Microinvasive Breast Carcinoma Present Negation Histologic Grade <input type="checkbox"/> Score cannot be determined – Score Indeterminate

Optional Questions

CRF Question	Value Domain
<p>Lymphovascular invasion (7038779) CDE Short Name: MILYMINV</p> <p>CDASH: MIORRES (6421502);</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "LYMPHINV"</p>	<p>CHARACTER – Maximum Length = 14</p> <p><input type="checkbox"/> Indeterminate – Indeterminate</p> <p><input type="checkbox"/> No – No</p> <p><input type="checkbox"/> No Surgery – No Surgical Procedure</p> <p><input type="checkbox"/> Not Applicable – Not Applicable</p> <p><input type="checkbox"/> Unavailable – No Information Available</p> <p><input type="checkbox"/> Yes – Yes</p>
<p>Extramural venous invasion (7038780) CDE Short Name: MIEXVNIN</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "EXVNIN"</p>	<p>CHARACTER – Maximum Length = 14</p> <p><input type="checkbox"/> Indeterminate – Indeterminate</p> <p><input type="checkbox"/> No – No</p> <p><input type="checkbox"/> No Surgery – No Surgical Procedure</p> <p><input type="checkbox"/> Not Applicable – Not Applicable</p> <p><input type="checkbox"/> Unavailable – No Information Available</p> <p><input type="checkbox"/> Yes – Yes</p>
<p>Perineural invasion (7038781) CDE Short Name: MIPNLINV</p> <p>CDASH: MIORRES (6421502);</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "PNLINV"</p>	<p>CHARACTER – Maximum Length = 14</p> <p><input type="checkbox"/> Indeterminate – Indeterminate</p> <p><input type="checkbox"/> No – No</p> <p><input type="checkbox"/> No Surgery – No Surgical Procedure</p> <p><input type="checkbox"/> Not Applicable – Not Applicable</p> <p><input type="checkbox"/> Unavailable – No Information Available</p> <p><input type="checkbox"/> Yes – Yes</p>
<p>Pelvic lymph node dissection (PLND) (7038782) CDE Short Name: MIPLND</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "PLND"</p>	<p>CHARACTER – Maximum Length = 10</p> <p><input type="checkbox"/> Negative – Negative Finding</p> <p><input type="checkbox"/> Not Done – Not Done</p> <p><input type="checkbox"/> Positive – Positive Finding</p>

CRF Question	Value Domain
<p>Percent of cancer in specimen (7038783) CDE Short Name: MICANPCT</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "CANPCT"</p>	<p>NUMBER – Maximum Length = 5</p>
<p>Unit (6410966) CDE Short Name: MIORRESU</p> <p>CDASH: MIORRESU (6410966)</p> <p>SDTM: MIORRESU (No CDE)</p>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> % – Percentage</p>
<p>Non-tumor premalignant histology (7038761) CDE Short Name: MINTPMHT</p> <p>CDASH: MIORRES (6421502)</p> <p>SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "NTPMHT"</p>	<p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No</p> <p><input type="checkbox"/> NA – Not Applicable</p> <p><input type="checkbox"/> U – Unknown</p> <p><input type="checkbox"/> Y – Yes</p>

CRF Question	Value Domain
<p>Associated pre-malignant histologic changes (7038762) CDE Short Name: MIASPMHT</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: MIORRES (6421502)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "ASPMHT"</p>	<p>CHARACTER – Maximum Length = 100</p> <ul style="list-style-type: none"> <input type="checkbox"/> Basal cell hyperplasia – Basal Cell Hyperplasia <input type="checkbox"/> Basal cell hyperplasia with angiogenic squamous dysplasia changes – Basal Cell Hyperplasia with Angiogenic Squamous Dysplasia changes <input type="checkbox"/> Carcinoma in situ – Carcinoma in Situ <input type="checkbox"/> Mild dysplasia – Mild Dysplasia <input type="checkbox"/> Mild dysplasia with angiogenic squamous dysplasia changes – Mild Dysplasia with Angiogenic Squamous Dysplasia changes <input type="checkbox"/> Moderate dysplasia – Moderate Dysplasia <input type="checkbox"/> Moderate dysplasia with angiogenic squamous dysplasia changes – Moderate Dysplasia with Angiogenic Squamous Dysplasia changes <input type="checkbox"/> None – None at all <input type="checkbox"/> Other, specify – Other, specify <input type="checkbox"/> Severe dysplasia – Severe Dysplasia <input type="checkbox"/> Severe dysplasia with angiogenic squamous dysplasia changes – Severe Dysplasia with Angiogenic Squamous Dysplasia changes <input type="checkbox"/> Squamous metaplasia – Squamous Metaplasia <input type="checkbox"/> Squamous metaplasia with angiogenic squamous dysplasia changes – Squamous Metaplasia with Angiogenic Squamous Dysplasia changes
<p>Associated pre-malignant histologic changes, other (7038763) CDE Short Name: MIASPMHX</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: MIORRES (6421502)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "ASPMHT"</p>	<p>CHARACTER – Maximum Length = 200</p>

CRF Question	Value Domain
<p>Description of tumor border configuration (7038764) CDE Short Name: MITUMRBD</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: MIORRES (6421502)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: MIORRES (No CDE) where MITESTCD (6620591)= "TUMRBD"</p>	<p>CHARACTER – Maximum Length = 100</p> <ul style="list-style-type: none"> <input type="checkbox"/> Indeterminate – Indeterminate <input type="checkbox"/> Infiltrating – Infiltrative Tumor Margin <input type="checkbox"/> Other – Other <input type="checkbox"/> Pushing – Pushing Tumor Margin
<p>Description of tumor border configuration, other (7038765) CDE Short Name: MITMRBDX</p> <p style="border: 1px solid blue; padding: 2px;">CDASH: MIORRES (6421502)</p> <p style="border: 1px solid red; padding: 2px;">SDTM: MIORRES (No CDE) where MITESTCD (6620591) = "TUMRBD"</p>	<p>CHARACTER – Maximum Length = 200</p>