

The below data dictionary is for the EA1141 analysis dataset: “ea1141\_year0\_tomolesions\_outcome.sas7bdat”.

This dataset contains one record per reported lesion for participants with a positive Year 0 Tomo screen, and is unique by SUBJECT\_DE and TOMO\_LESIONNUM\_YR0. **Participants without a Year 0 Tomo screen or with a negative Year 0 Tomo screen (Final BIRADS 1-2) DO NOT appear in this data set.** There are a total of **72** variables contained in this dataset.

Variable name	Variable definition	Code Table/Values
		‘Num’ signifies numeric variable  ‘Char’ signifies character/text variable  Otherwise, variables are numeric with coded values as indicated
<b>Year 0 Tomo lesion-specific variables and recommendation variables [15 variables]</b>		
SUBJECT_DE	De-identified case number ( <u>numeric</u> ).	Num
TOMO_LESIONNUM_YR0	Year 0 Tomo lesion number [taken from LES_NUM from the Tomosynthesis YR-0 Lesions form, and the corresponding lesion number element in the Final Management, Needle Biopsy Pathology, Surgical Biopsy Pathology and BIRADS 3 6-month FUP forms] ( <u>character</u> ).	Char (\$400.)  Possible values are:  “T0-1” “T0-2” “T0-3”
TOMO_LESIONBREAST_YR0	Breast of reported lesion [taken from BRST from the Tomosynthesis YR-0 Lesions form] ( <u>numeric, code table</u> ).	.M=Missing
		1=Right breast
		2=Left breast
TOMO_LESIONVIEWSSEEN_YR0	What views was lesion seen on? [taken from LES_SEEN_VIEWS from the Tomosynthesis YR-0 Lesions form] ( <u>numeric, code table</u> ).	.M=Missing
		1=2D
		2=Tomosynthesis
		3=Both 2D and Tomosynthesis
TOMO_LESIONSEENUS_YR0	Was lesion seen on ultrasound? [taken from LES_SEEN_ULTRA from the Tomosynthesis YR-0 Lesions form] ( <u>numeric, code table</u> ).	.M=Missing
		0=No
		1=Yes
		2=Ultrasound not performed for this lesion
TOMO_LESIONLOCATION_YR0	Location of lesion [taken from LES_LOC_1 from the Tomosynthesis YR-0 Lesions form] ( <u>numeric, code table</u> ).	.M=Missing
		1=Quadrant axillary tail
		2=Central/Subareolar region
		3=Lower-inner quadrant
		4=Lower-outer quadrant

		5=Upper-inner quadrant 6=Upper-outer quadrant 7=Subareolar
TOMO_LESIONCLOCK_YR0	Clock position of lesion [taken from CLOCK_POS from the Tomosynthesis YR-0 Lesions form] ( <u>numeric</u> ).	1-12  .M=Missing
TOMO_LESIONDISTNIPPLE_YR0	Distance of lesion from nipple [taken from DIST_NIPPL from the Tomosynthesis YR-0 Lesions form] ( <u>numeric, code table</u> ).	.M=Missing 1=Anterior 1/3 2=Middle 1/3 3=Posterior 1/3
TOMO_LESIONFINDINGTYPE_YR0	Finding type [taken from TP_FINDING from the Tomosynthesis YR-0 Lesions form] ( <u>numeric, code table</u> ).	.M=Missing 1=Architectural distortion 2=Calcification(s) 3=Mass 4=Asymmetry/Focal asymmetry 5=Mass and calcifications 6=Distortion and calcifications
TOMO_LESIONMAXDIAM_YR0	Greatest diameter of lesion (cm) [taken from MAX_DIAM_1 from the Tomosynthesis YR-0 Lesions form] ( <u>numeric</u> ).	Num  .M=Missing
TOMO_LESIONBIRADS_YR0	Lesion BIRADS [taken from BIRADS-3_5 from the Tomosynthesis YR-0 Lesions form] ( <u>numeric, code table</u> ).	3=3:Probably Benign 4=4:Suspicious Abnormality 5=5:Highly Suggestive of Malignancy
TOMO_LESIONREPORTEDMRI_YR0	Was the lesion also reported as BIRADS 3, 4, or 5 on the MRI blinded reading? [taken from LES_RP_MRI_READ_YN from the Final Management – Tomo Lesions form located in the Visit 1 folder] ( <u>numeric, code table</u> ).	0=No 1=Yes
TOMO_LESIONREPORTEDMRI_NUM_YR0	Corresponding Year 0 MRI lesion number [taken from LES_NUM_MR from the Final Management – Tomo Lesions form located in the Visit 1 folder] ( <u>character</u> ).  <b>NOTE: This variable is only populated if TOMO_LESIONREPORTEDMRI_YR0=1. Otherwise, it is .N.</b>	Char (\$400.)  .N=N/A  Possible values are: “M0-1” “M0-2” “M0-3” “M0-4”

TOMO_LESIONREC_YR0	Recommendation for lesion [taken from REC_DBT from the Final Management – Tomo Lesions form located in the Visit 1 folder] ( <u>numeric, code table</u> ).	1=Stereotactic-guided core biopsy
		2=Ultrasound-guided core biopsy
		3=MR-guided core biopsy
		4=Surgical biopsy
		5=6-month follow-up
		99=Other
TOMO_LESIONREC_OTHERSPEC_YR0	Recommendation for lesion, other specify [taken from REC_DBT from the Final Management – Tomo Lesions form located in the Visit 1 folder] ( <u>character</u> ).  <i><b>NOTE: This variable is only populated if TOMO_LESIONREC_YR0=99. Otherwise, it is .N.</b></i>	Char (\$400.)  .N=N/A
<b>Year 0 Tomo BIRADS 3 6-month FUP variables [7 variables]</b>		
TOMO_LESION6MONTHFUP_YR0	Was 6-month FUP imaging performed? [taken from _6_MTH_FU_IMAG_YN_V2 from the BIRADS 3 Follow-up form located in the Visit 1 folder] ( <u>numeric, code table</u> ).	.N=N/A (6-month FUP imaging was not recommended for the lesion in question)
		.F=Form not yet submitted
		0=No
		1=Yes
TOMO_LESION6MONTHREAS_YR0	Reason 6-month FUP imaging was not performed? [taken from _6_MTH_FU_IMAG_NOT_PERF_V2 from the BIRADS 3 Follow-up form located in the Visit 1 folder] ( <u>numeric, code table</u> ).	.N=N/A (6-month FUP imaging was not recommended for the lesion in question, or 6-month FUP imaging was performed)
		.F=Form not yet submitted
		1=Patient refused completion of the follow-up
		2=Patient failed to return for follow-up, reason unknown
		3=Denied by insurance
		4=Patient withdrew consent
		5=Biopsy performed instead – patient or referring physician preferred biopsy instead of follow-up
		6=Biopsy performed instead - radiologist recommended biopsy

		7=Tomo lesion was not seen on MRI, and so was not followed at 6 months 8=Patient deceased
TOMO_LESION6MONTHDATE_YR0_YYYY TOMO_LESION6MONTHDATE_YR0_DAYS	Date of 6-month FUP imaging [taken from _6_MTH_FU_IMAG_DT_V2 from the BIRADS 3 Follow-up form located in the Visit 1 folder] (numeric, date).  <b>NOTE: Per HIPAA standards, for each date, the exact date is not given. Instead, two variables are supplied, one giving the year, and one giving days since the baseline date.</b>	Num  .N=N/A (6-month FUP imaging was not recommended for the lesion in question, or 6-month FUP imaging was not performed) .F=Form not yet submitted
TOMO_LESION6MONTHMODALITY_YR0	Imaging modality used for 6-month FUP imaging [taken from the variables _2D_MAMMO_V2, TOMO_V2, ULTRA_V2, MRI_V2, OTH_IMAG_MODL_V2 from the BIRADS 3 Follow-up form located in the Visit 1 folder] (numeric, code table).	.N=N/A (6-month FUP imaging was not recommended for the lesion in question, or 6-month FUP imaging was not performed) .F=Form not yet submitted 1=2D mammography 2=Tomosynthesis 3=Ultrasound 4=MRI 5=2D mammography and Tomosynthesis 6=2D mammography, Tomosynthesis, and Ultrasound 7=Tomosynthesis and Ultrasound 8=2D mammography and Ultrasound 9=Ultrasound and MRI
TOMO_LESION6MONTHOUTCOME_YR0	BIRADS recommendation based on 6-month FUP imaging for the lesion that was followed [taken from OUTCOME_V2 from the BIRADS 3 Follow-up form located in the Visit 1 folder] (numeric, code table).	.N=N/A (6-month FUP imaging was not recommended for the lesion in question, or 6-month FUP imaging was not performed) .F=Form not yet submitted 1=1:Negative 2=2:Benign 3=3:Probably Benign 4=4:Suspicious Abnormality

TOMO_LESION6MONTHBIOPSY_YR0	If BIRADS 4 or 5, or if biopsy was done instead, what type of biopsy was recommended/done? [taken from BIRADS_4_5_V2 and _6_MTH_FU_BX_V2 from the BIRADS 3 Follow-up form located in the Visit 1 folder] (numeric, code table).	.N=N/A (6-month FUP imaging was not recommended for the lesion in question, or 6-month FUP imaging was not performed, or new BIRADS was 1-3)
		.F=Form not yet submitted
		1=Needle biopsy (FNAB or core needle biopsy)
		2=Surgical biopsy
Year 0 Tomo Core needle biopsy variables [20 variables]		
TOMO_CORE_YR0	Was a core needle biopsy performed? [taken from WAS_BIOP_SURG_PERF from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).	.N=N/A (Core biopsy was not recommended for the lesion in question)
		.F=Form not yet submitted
		0=No
		1=Yes
TOMO_COREREAS_YR0	Reason core needle biopsy was not performed? [taken from REAS_CORE_NDL_BX_NOT_DONE from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b>NOTE: This element is only populated if TOMO_CORE_YR0=0:No.</b>	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was performed)
		.F=Form not yet submitted
		1=Surgical biopsy was performed instead of core needle biopsy
		2=Patient refusal
		3=Patient did not return
		4=Medical contraindications
		5=Changed by radiologist to BIRADS 3
		6=Lesion resolved/benign
TOMO_COREDATE_YR0_YYYY TOMO_COREDATE_YR0_DAYS	Date of core needle biopsy [taken from SURG_DT from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, date).  <b>NOTE: Per HIPAA standards, for each date, the exact date is not given. Instead, two variables are supplied, one giving the year, and one giving days since the baseline date.</b>	Num
		.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed) .F=Form not yet submitted

TOMO_CORETYPE_YR0	Type of needle biopsy [taken from TP_PROC from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed) .F=Form not yet submitted 1=Core needle biopsy 2=Vacuum-assisted biopsy 3=Aspiration – fluid discarded
TOMO_COREGUIDE_YR0	Method of image guidance [taken from IMAG_GUIDE_METHOD from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed) .F=Form not yet submitted 1=Ultrasound 2=Stereotactic prone 3=Stereotactic upright 4=Mammographic 5=MRI 6=No image guidance 98=Unknown 99=Other
TOMO_COREPATH_YR0	Pathology/Cytology results [taken from PATH_CYT_RESULTS from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b><i>NOTE: For case 248152, the T0-1 lesion noted for type of needle biopsy on the Needle Biopsy Pathology form that an aspiration was done and the fluid discarded. Per the study investigator, this is a benign finding. For this instance, TOMO_COREPATH_YR0=1 and TOMO_COREPATH_BENIGN_YR0=23.</i></b>	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed) .F=Form not yet submitted 1=Benign 2=Benign with atypia or high-risk lesion 3=Malignant
TOMO_COREPATH_BENIGN_YR0	If benign, pathology/cytology entity from the most significant lesion [taken from PATH_BENIGN from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b><i>NOTE: This element is only populated if TOMO_COREPATH_YR0 in(1,2); otherwise, it is set to .N.</i></b>	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not benign) .F=Form not yet submitted 1=Fibroadenoma 2=Fibrosis 3=Fibrodenomatoid

		4=Usual ductal hyperplasia 5=Duct ectasia 6=Sclerosing adenosis 7=Fibrocystic changes 8=Apocrine metaplasia 9=Fat necrosis 10=Papilloma without atypia 11=Abscess 12=Lymph node 13=PASH 14=Tubular adenoma 15=Complex sclerosing lesion/radial scar 16=Atypical ductal hyperplasia 17= Atypical lobular hyperplasia 18=Classic LCIS 19=Atypical papilloma 20=Columnar alteration with atypia 21=Columnar cell changes 22=Flat epithelial atypia (FEA) 23=Aspiration – fluid discarded 99=Other
TOMO_COREPATH_BENIGN_OTH_YR0	<p>If benign, pathology/cytology entity from the most significant lesion, other specify [taken from PATH_BENIGN from the Needle Biopsy Pathology form located in the Visit 1 folder] (<u>character</u>).</p> <p><b>NOTE: This element is only populated if TOMO_COREPATH_BENIGN_YR0=99; otherwise, it is set to .N.</b></p>	Char (\$400.)  .N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not benign) .F=Form not yet submitted
TOMO_COREPATH_MALIG_YR0	<p>If malignant, pathology/cytology entity from the most significant lesion [taken from PATH_MALIGNANT from the Needle Biopsy Pathology form located in the Visit 1 folder] (<u>numeric, code table</u>).</p> <p><b>NOTE: This element is only populated if TOMO_COREPATH_YR0=3; otherwise, it is set to .N.</b></p>	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not malignant) .F=Form not yet submitted 1=Invasive (infiltrating) ductal carcinoma 2=Invasive lobular carcinoma

		3=Invasive with mixed ductal/lobular features 4=DCIS
TOMO_COREPATH_GRADE_YR0	Grade of cancer [taken from GRADE from the Needle Biopsy Pathology form located in the Visit 1 folder] ( <u>numeric, code table</u> ).  <b>NOTE: This element is only populated if TOMO_COREPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b>	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not malignant) .F=Form not yet submitted 1=Low (Grade I) 2=Intermediate (Grade II) 3=High (Grade III) 99=Grade cannot be assessed/not reported
TOMO_COREPATH_DCPATTERN_YR0	Ductal carcinoma pattern [taken from PATTERN_DCIS from the Needle Biopsy Pathology form located in the Visit 1 folder] ( <u>numeric, code table</u> ).  <b>NOTE: This element is only populated if TOMO_COREPATH_MALIG_YR0=4:DCIS; otherwise, it is set to .N.</b>	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not DCIS) .F=Form not yet submitted 1=Cribform 2=Comedo 3=Mixed 4=NOS 5=Solid and cribriform with comedonecrosis 6=Solid 99=Unknown
TOMO_COREPATH_INVASPATTERN_YR0	Invasive pattern [taken from PATTERN from the Needle Biopsy Pathology form located in the Visit 1 folder] ( <u>numeric, code table</u> ).  <b>NOTE: This element is only populated if TOMO_COREPATH_MALIG_YR0 in(1,2,3), i.e. invasive; otherwise, it is set to .N.</b>	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not invasive) .F=Form not yet submitted .M=Missing 1=Tubular 2=Colloid/mucinous 3=Medullary 4=Micropapillary 5=NOS 6=Unknown



TOMO_COREPATH_DIFF_YR0	<p>Differentiation [taken from DIFFNTION from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).</p> <p><b>NOTE: This element is only populated if TOMO_COREPATH_MALIG_YR0 in(1,2,3), i.e. invasive; otherwise, it is set to .N.</b></p>	<p>.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not invasive)</p> <p>.F=Form not yet submitted</p> <p>1=Well differentiated</p> <p>2=Moderately differentiated</p> <p>3=Poorly differentiated</p>
TOMO_COREPATH_VASCULAR_YR0	<p>Was vascular or lymphovascular or angiolymphatic invasion present? [taken from VASC_LYMPH_INV_CNCR from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).</p> <p><b>NOTE: This element is only populated if TOMO_COREPATH_MALIG_YR0 in(1,2,3), i.e. invasive; otherwise, it is set to .N.</b></p>	<p>.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not invasive)</p> <p>.F=Form not yet submitted</p> <p>0=No</p> <p>1=Yes</p>
TOMO_COREPATH_ER_YR0	<p>ER status [taken from ADDTL_TST_ER from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).</p> <p><b>NOTE: This element is only populated if TOMO_COREPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b></p>	<p>.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not malignant)</p> <p>.F=Form not yet submitted</p> <p>1=Positive</p> <p>2=Negative</p> <p>3=Weak</p> <p>4=Not performed</p>
TOMO_COREPATH_PR_YR0	<p>PR status [taken from ADDTL_TST_PR from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).</p> <p><b>NOTE: This element is only populated if TOMO_COREPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b></p>	<p>.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not malignant)</p> <p>.F=Form not yet submitted</p> <p>1=Positive</p> <p>2=Negative</p> <p>3=Weak</p> <p>4=Not performed</p>

TOMO_COREPATH_HER2_YR0	HER2 status [taken from ADDTL_TST_HER2 from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b>NOTE: This element is only populated if TOMO_COREPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b>	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not malignant) .F=Form not yet submitted 1=Positive 2=Negative 3=Weak 4=Not performed
TOMO_COREPATH_KI67_YR0	Ki67 status [taken from ADDTL_TST_KI67 from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b>NOTE: This element is only populated if TOMO_COREPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b>	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not malignant) .F=Form not yet submitted 1=Positive 2=Negative 3=Weak 4=Not performed
TOMO_COREPATH_SURG_YR0	Was a surgical biopsy recommended? [taken from SURG_BX_REC from the Needle Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed) .F=Form not yet submitted 0=No 1=Yes
Year 0 Tomo Surgical biopsy variables [28 variables]		
TOMO_SURG_YR0	Was a surgical biopsy performed? [taken from WAS_BIOP_SURG_PERF from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).	.N=N/A (Surgical biopsy was not recommended for the lesion in question) .F=Form not yet submitted 0=No 1=Yes

TOMO_SURGREAS_YR0	<p>Reason surgical biopsy was not performed? [taken from REAS_BIOP_SURG_NOT_DONE from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).</p> <p><b>NOTE: This element is only populated if TOMO_SURG_YR0=0:No.</b></p>	<p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was performed)</p> <p>.F=Form not yet submitted</p> <p>1=Medical contraindications</p> <p>2=Patient refusal</p> <p>3=Core needle biopsy performed instead</p> <p>4=Patient and surgical oncologist decision not to excise</p> <p>5=Patient did not return</p>
TOMO_SURGREAS6MO_YR0	<p>If a surgical biopsy was not performed, was 6-month FUP recommended? [taken from _6_MTH_FU_PERF_YN from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).</p> <p><b>NOTE: This element is only populated if TOMO_SURG_YR0=0:No.</b></p>	<p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was performed)</p> <p>.F=Form not yet submitted</p> <p>0=No</p> <p>1=Yes</p>
TOMO_SURGDATE_YR0_YYYY TOMO_SURGDATE_YR0_DAYS	<p>Date of surgical biopsy [taken from SURG_DT from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, date).</p> <p><b>NOTE: Per HIPAA standards, for each date, the exact date is not given. Instead, two variables are supplied, one giving the year, and one giving days since the baseline date.</b></p>	<p>Num</p> <p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed)</p> <p>.F=Form not yet submitted</p>
TOMO_SURGTYPE_YR0	<p>Type of surgical procedure [taken from TP_PROC_SURG_BX from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).</p>	<p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed)</p> <p>.F=Form not yet submitted</p> <p>1=Excisional biopsy for diagnosis</p> <p>2=Excision of high-risk lesion on needle biopsy</p> <p>3=Lumpectomy for cancer</p> <p>4=Mastectomy</p>

TOMO_SURGLOCALIZE_YR0	Was localization performed prior to surgery [taken from LOCAL_PRIOR_SURG from the Surgical Biopsy Pathology form located in the Visit 1 folder] ( <u>numeric, code table</u> ).	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed) .F=Form not yet submitted 0=No 1=Yes
TOMO_SURGLOCALIZETYPE_YR0	Type of localization [taken from LOCAL_TP from the Surgical Biopsy Pathology form located in the Visit 1 folder] ( <u>numeric, code table</u> ).  <b><i>NOTE: This variable is only populated if TOMO_SURGLOCALIZE_YR0=1:Yes; otherwise, it is set to .N.</i></b>	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or localization was not performed) .F=Form not yet submitted 1=Ultrasound 2=Mammographic grid 3=Stereotactic 4=MRI 5=No image guidance 98=Unknown 99=Other
TOMO_SURGPATH_YR0	Pathology results [taken from PATH_CYT_RESULTS from the Surgical Biopsy Pathology form located in the Visit 1 folder] ( <u>numeric, code table</u> ).	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed) .F=Form not yet submitted 1=Benign 2=Benign with atypia or high-risk lesion 3=Malignant
TOMO_SURGPATH_BENIGN_YR0	If benign, pathological entity from the most significant lesion [taken from PATH_BENIGN from the Surgical Biopsy Pathology form located in the Visit 1 folder] ( <u>numeric, code table</u> ).  <b><i>NOTE: This element is only populated if TOMO_SURGPATH_YR0 in(1,2); otherwise, it is set to .N.</i></b>	.N=N/A (Core biopsy was not recommended for the lesion in question, or core biopsy was not performed, or pathology was not benign) .F=Form not yet submitted 1=Fibroadenoma 2=Fibrosis 3=Fibrodenomatoid 4=Usual ductal hyperplasia 5=Duct ectasia 6=Sclerosing adenosis 7=Fibrocystic changes

		8=Apocrine metaplasia 9=Fat necrosis 10=Papilloma without atypia 11=Abscess 12=Lymph node 13=PASH 14=Tubular adenoma 15=Complex sclerosing lesion/radial scar 16=Atypical ductal hyperplasia 17= Atypical lobular hyperplasia 18=Classic LCIS 19=Atypical papilloma 20=Columnar alteration with atypia 21=Columnar cell changes 22=Flat epithelial atypia (FEA) 99=Other
TOMO_SURGPATH_BENIGN_OTH_YR0	<p>If benign, pathological entity from the most significant lesion, other specify [taken from PATH_BENIGN from the Surgical Biopsy Pathology form located in the Visit 1 folder] (<u>character</u>).</p> <p><b><i>NOTE: This element is only populated if TOMO_SURGPATH_BENIGN_YR0=99; otherwise, it is set to .N.</i></b></p>	Char (\$400.)  .N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not benign) .F=Form not yet submitted
TOMO_SURGPATH_MALIG_YR0	<p>If malignant, pathological entity from the most significant lesion [taken from PATH_MALIGNANT from the Surgical Biopsy Pathology form located in the Visit 1 folder] (<u>numeric, code table</u>).</p> <p><b><i>NOTE: This element is only populated if TOMO_SURGPATH_YR0=3; otherwise, it is set to .N.</i></b></p>	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant) .F=Form not yet submitted 1=Invasive (infiltrating) ductal carcinoma 2=Invasive lobular carcinoma 3=Invasive with mixed ductal/lobular features 4=DCIS

TOMO_SURGPATH_DIAM_YR0	<p>If malignant, largest diameter of the carcinoma (cm) [taken from DIAM_MALIGNANT from the Surgical Biopsy Pathology form located in the Visit 1 folder] (<u>numeric</u>).</p> <p><b>NOTE: This element is only populated if TOMO_SURGPATH_YR0=3; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b></p>	<p>Num</p> <p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant)</p> <p>.F=Form not yet submitted</p> <p>.M=Missing</p>
TOMO_SURGPATH_GRADE_YR0	<p>Grade of cancer [taken from GRADE from the Surgical Biopsy Pathology form located in the Visit 1 folder] (<u>numeric, code table</u>).</p> <p><b>NOTE: This element is only populated if TOMO_SURGPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b></p>	<p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant)</p> <p>.F=Form not yet submitted</p> <p>1=Low (Grade I)</p> <p>2=Intermediate (Grade II)</p> <p>3=High (Grade III)</p> <p>99=Grade cannot be assessed/not reported</p>
TOMO_SURGPATH_DCPATTERN_YR0	<p>Ductal carcinoma pattern [taken from PATTERN_DCIS from the Surgical Biopsy Pathology form located in the Visit 1 folder] (<u>numeric, code table</u>).</p> <p><b>NOTE: This element is only populated if TOMO_SURGPATH_MALIG_YR0=4:DCIS; otherwise, it is set to .N.</b></p>	<p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not DCIS)</p> <p>.F=Form not yet submitted</p> <p>1=Cribform</p> <p>2=Comedo</p> <p>3=Mixed</p> <p>4=NOS</p> <p>5=Solid and cribriform with comedonecrosis</p> <p>6=Solid</p> <p>99=Unknown</p>
TOMO_SURGPATH_INVASPATTERN_YR0	<p>Invasive pattern [taken from PATTERN from the Surgical Biopsy Pathology form located in the Visit 1 folder] (<u>numeric, code table</u>).</p> <p><b>NOTE: This element is only populated if TOMO_SURGPATH_MALIG_YR0 in(1,2,3), i.e. invasive; otherwise, it is set to .N.</b></p>	<p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not invasive)</p> <p>.F=Form not yet submitted</p> <p>.M=Missing</p> <p>1=Tubular</p> <p>2=Colloid/mucinous</p>

		3=Medullary
		4=Micropapillary
		5=NOS
		6=Unknown
TOMO_SURGPATH_DIFF_YR0	Differentiation [taken from DIFFNTION from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b>NOTE: This element is only populated if TOMO_SURGPATH_MALIG_YR0 in(1,2,3), i.e. invasive; otherwise, it is set to .N.</b>	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not invasive) .F=Form not yet submitted .M=Missing 1=Well differentiated 2=Moderately differentiated 3=Poorly differentiated
TOMO_SURGPATH_VASCULAR_YR0	Was vascular or lymphovascular or angiolymphatic invasion present? [taken from VASC_LYMPH_INV_CNCR from the Surgical Pathology form located in the Visit 1 folder] (numeric, code table).  <b>NOTE: This element is only populated if TOMO_SURGPATH_MALIG_YR0 in(1,2,3), i.e. invasive; otherwise, it is set to .N.</b>	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not invasive) .F=Form not yet submitted .M=Missing 0=No 1=Yes
TOMO_SURGPATH_ER_YR0	ER status [taken from ADDTL_TST_ER from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b>NOTE: This element is only populated if TOMO_SURGPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b>	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant) .F=Form not yet submitted .M=Missing 1=Positive 2=Negative 3=Weak 4=Not performed
TOMO_SURGPATH_PR_YR0	PR status [taken from ADDTL_TST_PR from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b>NOTE: This element is only populated if TOMO_SURGPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b>	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant) .F=Form not yet submitted .M=Missing

		1=Positive
		2=Negative
		3=Weak
		4=Not performed
TOMO_SURGPATH_HER2_YR0	HER2 status [taken from ADDTL_TST_HER2 from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b>NOTE: This element is only populated if TOMO_SURGPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b>	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant) .F=Form not yet submitted .M=Missing 1=Positive 2=Negative 3=Weak 4=Not performed
TOMO_SURGPATH_KI67_YR0	Ki67 status [taken from ADDTL_TST_KI67 from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b>NOTE: This element is only populated if TOMO_SURGPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b>	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant) .F=Form not yet submitted .M=Missing 1=Positive 2=Negative 3=Weak 4=Not performed
TOMO_SURGPATH_CHEMO_YR0	Did the patient have neoadjuvant chemotherapy prior to surgery? [taken from PT_NEOADJ_CHEMO from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b>NOTE: This element is only populated if TOMO_SURGPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b>	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant) .F=Form not yet submitted 0=No 1=Yes
TOMO_SURGPATH_LYMPHBIOP_YR0	Did the patient have a preoperative axillary lymph node biopsy? [taken from PT_PREOP_BX from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).  <b>NOTE: This element is only populated if TOMO_SURGPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b>	.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant) .F=Form not yet submitted 0=No 1=Yes



TOMO_SURGPATH_LYMPHINVOL_YR0	<p>Was there histological evidence of lymph node involvement? [taken from HIST_LYMPH_NODE from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).</p> <p><b>NOTE: This element is only populated if TOMO_SURGPATH_LYMPHBIOP_YR0=1:Yes; otherwise, it is set to .N.</b></p>	<p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant, or preoperative axillary lymph node biopsy was not performed)</p> <p>.F=Form not yet submitted</p> <p>0=No</p> <p>1=Yes</p>
TOMO_SURGPATH_SENTINEL_YR0	<p>Was a sentinel node biopsy performed at the time of surgery? [taken from SENT_BX_SURG_YN from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).</p> <p><b>NOTE: This element is only populated if TOMO_SURGPATH_YR0=3:Malignant; otherwise, it is set to .N. However, it is completed for both DCIS and invasive cancers.</b></p>	<p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant)</p> <p>.F=Form not yet submitted</p> <p>0=No</p> <p>1=Yes</p>
TOMO_SURGPATH_DISS_YR0	<p>Was axillary dissection performed at the time of surgery? [taken from AXILL_DISS_SURG_YN from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).</p> <p><b>NOTE: This element is only populated if TOMO_SURGPATH_SENTINEL_YR0=1:Yes; otherwise, it is set to .N.</b></p>	<p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant, or sentinel node biopsy was not performed)</p> <p>.F=Form not yet submitted</p> <p>0=No</p> <p>1=Yes</p>
TOMO_SURGPATH_EXTRACAP_YR0	<p>Was there evidence of extracapsular nodal extension? [taken from EXTR_CAPS_NODES from the Surgical Biopsy Pathology form located in the Visit 1 folder] (numeric, code table).</p> <p><b>NOTE: This element is only populated if TOMO_SURGPATH_SENTINEL_YR0=1:Yes; otherwise, it is set to .N.</b></p>	<p>.N=N/A (Surgical biopsy was not recommended for the lesion in question, or surgical biopsy was not performed, or pathology was not malignant, or sentinel node biopsy was not performed)</p> <p>.F=Form not yet submitted</p> <p>0=No</p> <p>1=Yes</p> <p>99=Unknown</p>

Year 0 Tomo Final lesion outcome variables [2 variables]		
TOMO_LESIONOUTCOME_YR0	Final lesion outcome/resolution [taken from above derived variables] ( <u>character</u> ).	Char (\$400.)  .M=Data element missing  .F=Lesion outstanding/ unresolved
TOMO_LESIONOUTCOMEDetail_YR0	Final lesion outcome/resolution – with detailed pathology for benign lesions and invasive lesions [taken from above derived variables] ( <u>character</u> ).	Char (\$400.)  .M=Data element missing  .F=Lesion outstanding/ unresolved