

SUPPLEMENTAL DATA FILE 2.

FINAL SET OF CONSENSUS DATA ELEMENTS WITH VALUE DOMAIN TYPES AND SPECIFIC VALUES

	Core Data Element	Data Value Domain Type	Data Value Domain Specifics
Patient Identifier	No critical core elements but need a way to trace back		
	Should be able to identify duplicates by comparing data of birth, date of diagnosis, other variables		
Contact Information	No critical core elements		
Consent	No critical core elements but consent form should be broadly framed and a notification mechanism is needed in the event that consent is withdrawn		
Demographics			
	Year of Birth	(numeric)	(4-digit year) yyyy
	Date of Death	(numeric)	(2-digit month; 2-digit day; 4-digit year) mm/dd/yyyy
	Gender	(drop down list)	(Male; Female; Male-to-Female Transsexual; Female-to-Male Transsexual; Unreported or Unknown)
	Cause of Death (choose all that apply)	(drop down list)	(Due to or Related to Cancer; Due to or Related to Cancer Treatment; Neither Due to Nor Related to Either Cancer or Cancer Treatment; Unknown) [See Supplemental Data File 3a for Definitions]
	Ethnicity: Hispanic or Latino or Spanish Origin	(drop down list)	(Yes; No; Unreported or Unknown) [See Supplemental Data File 3a for Definitions]

	Race (choose all that apply)	(drop down list)	(American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; White; Unreported or Unknown) [See Supplemental Data File 3a for Definitions]
Medical History			
	Prior Malignancy 1 (not associated with the current cancer)	(drop down list)	Based on high level ICD-O-3 Topographical Codes. [See Supplemental Data File 3b]
	Date of Diagnosis of Prior Malignancy 1	(numeric)	(2-digit month; 4-digit year) mm/yyyy
	Prior Malignancy 2 (not associated with the current cancer)	(drop down list)	Based on high level ICD-O-3 Topographical Codes. [See Supplemental Data File 3b]
	Date of Diagnosis of Prior Malignancy 2	(numeric)	(2-digit month; 4-digit year) mm/yyyy
	Prior Malignancy 3 (not associated with the current cancer)	(drop down list)	Based on high level ICD-O-3 Topographical Codes. [See Supplemental Data File 3b]
	Date of Diagnosis of Prior Malignancy 3	(numeric)	(2-digit month; 4-digit year) mm/yyyy
Family History	No critical core data elements		
Risk Factors	No critical core data elements		
Physical Exam at First Diagnosis of Cancer of Interest			

	Height Units	(drop down list)	(Inches; Centimeters)
	Height	(numeric)	(nn for inches; nnn for centimeters)
	Weight Units	(drop down list)	(pounds; kgs)
	Weight	(numeric)	(nnn)
	Performance Status	(drop down list)	[See Supplemental Data File 3c]
	Date of Evaluation	(numeric)	(2-digit month; 4-digit year) mm/yyyy
Chemistry Lab Values	No critical core data elements* *NOTE: This is true for most solid tumors. For some other cancers (e.g., lymphoma, multiple myeloma), there may be lab chemistry values that are important prognostic factors (e.g., LDH, creatinine, albumin)		
First Diagnosis of Cancer of Interest			
	Date of Definitive Diagnosis	(numeric)	(2-digit month; 4-digit year) mm/yyyy
	Cancer Site/Topography	(drop down list)	Based on high level ICD-O-3 topographical codes. [See Supplemental Data File 3b]
	Histology/Morphology	(drop down list)	Based on high level ICD-O-3 morphological codes. [See Supplemental Data File 3b]

	Basis of Diagnosis	(drop down list)	(Death Certificate; Clinical; Imaging Modalities; Specific Tumor Markers; Cytology; Histology (metastasis); Histology (primary); Other; Unknown)
	Sample Type	(drop down list)	(Tissue Biopsy; Tissue Scrapings; Plasma; CSF; Pleural Fluid; Urine; Sputum; Pericardial Fluid; Ascitic Fluid; Bone Marrow; Other; None; Unknown)
	Site of Resection/Biopsy/Sample	(drop down list)	Based on high level ICD-O-3 topographical codes. [See Supplemental Data File 3b]
	Grade	(drop down list)	Based on College of American Pathologists' Cancer Protocol Templates [See Supplemental Data File 3d]
	Sites of Metastases (choose all that apply)	(drop down list)	Based on high level ICD-O-3 topographical codes. [See Supplemental Data File 3b]
	Staging System	(alphanumeric)	VARCHAR(20)* *VARCHAR refers to a Variable Character Field that can hold letters and numbers. The number in parentheses indicates the maximum number of characters that can be entered.
	Version or Edition of the Staging System	(alphanumeric)	VARCHAR(10)
	Specific Stage	(alphanumeric)	VARCHAR(10)

	Presence/Absence of Cancer-Specific Prognostic or Predictive Biomarkers	(drop down list of biomarkers for each appropriate cancer with single alpha entry for each)	(<u>P</u> resent; <u>A</u> bsent; <u>E</u> quivocal; <u>U</u> nknown) [See Supplemental Data File 3e for specific biomarkers]
	Biomarker Quantification	(alphanumeric)	VARCHAR(20)
	Was Additional Molecular Diagnostic Testing Performed?	(drop down list)	(Yes; No; Unknown)
	If Yes, What Tests? (choose all that apply)	(drop down list)	(Whole Exome Sequencing; Whole Genome Sequencing; RNA Sequencing; SNP Arrays; Expression Arrays; Targeted Sequencing; Other)
	Laboratory Name, City, & State	(alphanumeric)	VARCHAR(100)
Treatment Episode	The six data elements below comprise the Treatment Episode module. Patients often undergo several rounds of treatment and it is critical that data from each treatment episode can be entered without overwriting data from prior treatment episodes. Thus, multiple Treatment Episode modules should be available for data entry.		
	Treatment Modality	(drop down list)	(Surgery; Radiation Therapy; Hormonal Therapy; Chemotherapy; Immunotherapy; Targeted Drug Therapy; Drug Therapy Not Otherwise Specified; Photodynamic Therapy; Bone Marrow/Stem Cell Transplantation; Other; Unknown)
	Systemic Therapy Agent Name (generic)	(alphanumeric)	VARCHAR(20)
	Treatment Intent	(drop down list)	(Neoadjuvant; Curative; Adjuvant; Control/Palliative; Other; Unknown)

	Beginning Date of Treatment	(numeric)	(2-digit month; 2-digit day; 4-digit year) mm/dd/yyyy
	Ending Date of Treatment (except for surgery)	(numeric)	(2-digit month; 2-digit day; 4-digit year) mm/dd/yyyy
	Reason for Ending Treatment	(drop down list)	(Toxicity; Cost; Disease Progression; End of Planned Therapy; No Noticeable Improvement; Cytogenetic Resistance; Comorbidity; Patient Choice; Death; Lost to Follow-Up; Other; Unknown)
Interim Outcomes	The nine data elements below comprise the Interim Outcomes module. Patients often undergo several rounds of treatment and it is critical that outcomes data from each treatment episode can be entered without overwriting outcomes data from prior treatment episodes. Thus, multiple Interim Outcomes modules should be available for data entry.		
	Date of Assessment	(numeric)	(2-digit month; 2-digit day; 4-digit year) mm/dd/yyyy
	Disease Response or Status	(drop down list)	[See Supplemental Data File 3f for full list of response criteria and response options]
	Method of Determination (choose all that apply)	(drop down list)	(Diagnostic Imaging; Laboratory Testing; Diagnostic Scoping; Clinical Impression; Other; Unknown)
	Summary Stage	(drop down list)	(Localized; Regional; Metastatic; Unknown) [See Supplemental Data File 3a for Definitions]
	Sites of Progression/Recurrence (choose all that apply)	(drop down list)	Based on high level ICD-O-3 topographical codes. [See Supplemental Data File 3b]

	Vital Status	(drop down list)	(Alive; Dead; Lost to Follow-Up; Unknown)
	Weight Units	(drop down list)	(Pounds; Kgs)
	Weight	(numeric)	(nnn)
	Performance Status	(drop down list)	[See Supplemental Data File 3c]