ASCENT Common Data Elements (CDEs) – Adult Patient

Part A: REQUIRED Participant Demographics – <u>required</u> reporting in all ASCENT protocols for prospectively collected data on study participants	
*Required data capture from survey / interview with the patient when these variables are planned to be collected via primary data collection. *ASCENT recognizes that for specific scientific questions more detailed race and/or ethnicity categorization will be critical, and we encourage investigators to use detailed categorization when relevant to their study question.*	
A1a. Who is completing this questionnaire (on behalf of the patient)?	(1) Self (patient) → A2 (2) Caregiver → A1b (3) Health Care Provider (4) Clinical research coordinator (997) Other (specify): _____
A1b. Caregiver relationship to the patient	(1) Child (2) Friend (3) Parent (4) Grandchild (5) Grandparent (6) Life Partner (7) Neighbor (8) Sibling (9) Son/daughter-in-law (10) Spouse (11) Other relative (12) Other non-relative (997) Other: _____ (998) Prefer not to answer
A2. Age	_____ (years)
A3. Sex at Birth	(1) Male

	(2) Female (999) unknown
A4. Ethnicity	(1) Hispanic or Latino (2) Not Hispanic or Latino (998) Prefer not to answer (999) Unknown
A5. Race	(1) American Indian or Alaska Native (2) Asian (3) Black or African American (4) Native Hawaiian or Other Pacific Islander (5) White (6) More than one race (997) Other race: _____ (998) Prefer not to answer (999) Unknown
A6. Marital Status (check one)	(1) Married (2) Living as married or living with a romantic partner (3) Married or partnered, but not living together (4) Divorced (5) Single, never been married-not living with romantic partner (6) Separated (7) Widowed (998) Prefer not to answer (999) Unknown
A7. Patient Insurance Status	(1) Insurance through a current or former employer or union (of yours or another family member's). This would include COBRA coverage.

	(2) Insurance purchased directly from an insurance company (by you or another family member). This would include coverage purchased through an exchange or marketplace (3) Original Medicare (4) Medicare Fee for Service (5) Medicaid, Medical Assistance (MA), the Children's Health Insurance Program (CHIP), or any kind of state or government-sponsored assistance plan based on income or a disability. (6) TRICARE or other military health care, including VA health care. (7) Indian Health Service (8) Any other type of health insurance coverage or health coverage plan (9) Uninsured (998) Prefer not to answer (999) Unknown
A8. Patient Education	(1) No formal schooling (2) Primary/Grade/Elementary School (grades 1st through 5th) (3) Middle School/Lower Secondary Education (grades 6th through 8th) (4) Secondary/High School/Upper Secondary Education (grades 9th through 12th) *without a High School diploma* (5) General Educational Diploma (GED) (6) Secondary/High School/Upper Secondary Education (grades 9th through 12th) *with a High School diploma* (7) Occupational/Technical/Vocational Programs/Short Cycle Tertiary Education (8) Associate's Degree (approximately 2 years)

	(9) College/University/Bachelor's Degree/Equivalent Tertiary Education (approximately 3-5 years) (10) Graduate/Post-graduate/Professional Degree (JD, PhD, MD, EdD, Eng, Master's Degree, etc.) (999) Unknown
A9. Residence area type	(1) A big city (population >= 250,000) including suburbs/outskirts (2) A small town/ small city (population 500-10,000) (3) Rural area (population =< 500) (999) Unknown
A10. Household's financial situation. **Without giving exact dollars, how would you describe your household's financial situation right now? Would you say:**	(1) After paying the bills, you still have enough money for special things that you want. (2) You have enough money to pay the bills, but little spare money to buy extra or special things. (3) You have money to pay the bills, but only because you have cut back on things. (4) You are having difficulty paying the bills, no matter what you do. (998) Prefer not to answer (999) Unknown
A11. Would you say your health in general is excellent, very good, good, fair, or poor?	(1) Excellent (2) Very good (3) Good (4) Fair (5) Poor (998) Prefer not to answer (999) Unknown
Part B: Diagnoses (Dx) – RECOMMENDED for all ASCENT protocols with patient participants	
Recommended data capture from diagnosis lists or text in health and medical records, or ICD diagnosis codes from administrative data	

B1. Complex chronic condition (check all that apply)	(1) Cancer → B2a (2) Cardiovascular → B2b (3) Pulmonary → B2c (4) Gastrointestinal → B2d (5) Renal → B2e (6) Neurological → B2f (7) Infectious → B2g (8) Multi-system → B2h
B2a. Has cancer metastasized?	(0) Metastatic → B2a.2 (1) Non-metastatic → B2a.2 (999) Unknown
B2a.2. Primary Cancer site	(1) Head and neck (2) Thyroid (3) Brain (4) Lung (non-small cell) (5) Lung (small cell) (6) Pancreas (7) Other upper GI (liver, gastric, esophageal, carcinoid, etc.) (8) Breast (9) Colon, rectal, anal (10) Prostate (11) Ovarian /peritoneal (12) Uterine, cervical, vaginal (13) Renal (14) Bladder (including urethral) (15) Melanoma (16) Lymphoma

	(17) Leukemia (including MDS) (18) multiple myeloma (including amyloidosis) (997) Other: _____
B2b. Cardiovascular (CV)	(1) Coronary artery disease (including myocardial infarction) (2) Heart failure (3) Restrictive heart disease (4) Valvular heart disease (5) Peripheral vascular disease (997) Other cardiovascular: _____
B2c. Pulmonary	(1) COPD (including emphysema and chronic bronchitis) (2) Pulmonary fibrosis, ILD, and other restrictive lung disease (3) Bronchiectasis (4) Pulmonary hypertension (5) Cystic fibrosis (997) Other pulmonary: _____
B2d. Gastrointestinal (GI)	(1) Severe bleed (2) Cirrhosis (non-viral) (3) Ischemic colitis including bowel perforation (997) Other GI: _____
B2e. Renal	(1) End-stage renal disease (2) Acute kidney injury (997) Other renal: _____
B2f. Neurological	(1) Stroke – ischemic / embolic (2) Stroke - hemorrhagic (3) Amyotrophic lateral sclerosis (ALS) (4) Traumatic brain injury (TBI)

	(5) Hemi- or para-plegia (6) Alzheimer's disease and related dementias (7) Multiple sclerosis (8) Severe debility (9) Parkinson's (997) Other neurological: _____
B2g. Infectious	(1) Viral hepatitis /cirrhosis (2) HIV / AIDS (3) Pneumonia (4) Osteomyelitis (5) Bacterial endocarditis (997) Other infectious: _____
B2h. Multi-Systemic	(1) Connective Tissue Disease (2) Ulcer Disease (3) Diabetes (uncomplicated) (4) Diabetes (with end organ damage) (5) Multiple contributing conditions (997) Other multi-systemic: _____
Part C: Use of Palliative and/or Hospice Services – RECOMMENDED for all ASCENT protocols with patient participants	
Recommended data capture from health and medical records, or from billing codes specific to Hospice; data capture may also be from survey / interview	
C1a. Enrolled in Hospice? *(collect at each data collection time point)*	(0) No → C2a (1) Yes (999) Unknown → C2a
C1b. If yes, to C1a, where is patient receiving hospice care?	(0) Inpatient → Part D (2) Home → Part D (3) Skilled Nursing Facility/Rehab → Part D (997) Other (specify): _____ → Part D

	(999) Unknown → Part D
C2a. Receiving Palliative Care? (defined as currently under the care of an inpatient or home palliative care service or seen in an outpatient palliative care clinic within the past 3 months; collect at each data collection time point)	(0) No → Part D (1) Yes (999) Unknown
C2b. If yes, to C2a, where is patient receiving palliative care?	(0) Inpatient (1) Outpatient (2) Home (3) Skilled Nursing Facility/Rehab Facility (997) Other (specify): _____ (999) Unknown
Part D: Information at Time of Death - RECOMMENDED for all ASCENT protocols with patient participants	
Recommended data capture from death records, health and medical records; data capture may also be from survey / interviews	
D1. Did the patient die?	(0) No → end Part D (1) Yes (998) Prefer not to answer → end Part D (999) Unknown → end Part D
D2. Source of death information	(1) Family (2) Non-Family legally authorized representative (LAR) (3) Physician report (4) Health record (5) Social Security Death Index (SSDI) (6) National Death Index (NDI) (7) Obituary (8) Internet (997) Other source _____

D3. Location of death	(1) Inpatient acute care facility: general floor (2) Inpatient acute care facility: ICU (3) Inpatient acute care facility: palliative care unit (4) Home (5) Long-term care facility (7) Inpatient hospice (8) Assisted living facility (997) Other (specify): _____ (999) Unknown
D4. Enrolled in Hospice at time of death?	(0) No (1) Yes → end Part D (999) Unknown
D5. Enrolled in palliative care at time of death? (defined as currently under the care of an inpatient or home palliative care service or seen in an outpatient palliative care clinic within the past 3 months)	(0) No (1) Yes (999) Unknown

A full list of Common Data Elements recommended by the National Institutes of Health can be found here: https://cde.nlm.nih.gov/home.