

NIH Resources

The NHLBI encourages researchers to use these NIH developed materials for NHLBI-sponsored research, when appropriate. Utilization of these resources will enable greater consistency for NHLBI-sponsored research studies. Some of these tools are free of charge.

- National Institutes of Health (NIH) Toolbox
- Adult Sickle Cell Quality of Life Measurement Information System (ASCQ-Me)
- Patient-Reported Outcomes Measurement Information System (PROMIS)
- PhenX Toolkit (consensus measures for Phenotypes and eXposures)

Suicidal Ideation

Investigators should review the FDA's "[Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials](#)" for the most up-to-date information about suicidal ideation and behavior. One scale that FDA suggests is the Columbia Suicide Severity Rating Scale (C-SSRS) (available at [Columbia Suicide Severity Rating Scale Website](#)).

Note: Forms with one or more elements that are of a particular classification are listed will be listed more than once in a domain/subdomain.

Domain;Sub-domain	Recommendations
Participant Characteristics; Demographics:	Core: Demographics Supplemental: Demographics
Participant Characteristics; General Health History:	Core: Baseline Abnormal Hematopoiesis, Behavioral History Short Form, Medical History Core, Surgical History, Transfusion History Supplemental: Baseline Abnormal Hematopoiesis, Behavioral History, Behavioral History Short Form, Hospitalization Form, Medical History Supplemental Elements, Sleep Assessment (Pediatric Form), Surgical History, Transfusion History
Participant History and Family History; Social History	Core: Social Status Supplemental: Education School Questionnaire, Social Determinants Screen, Social Status, Adverse Childhood Experiences (ACEs) Screen 1-17 years, ACEs Screen 18+ years
Disease and Treatment Related Events; Anemia:	Core: Acute Anemia, Chronic Anemia Supplemental: Acute Anemia, Chronic Anemia
Disease and Treatment Related Events; Asthma:	Supplemental-Highly Recommended: Asthma Outcomes Instrument Recommendations Supplemental: Asthma Outcomes, Asthma Outcomes Instrument Recommendations, Over-Read Spirometry Report Form

Domain;Sub-domain	Recommendations
Disease and Treatment Related Events; Fertility and Bone	Core: Endocrine, Infertility and Bone Health Supplemental: Endocrine, Infertility and Bone Health
Disease and Treatment Related Events; Lung:	Core: 6 Minute Walk Test, Lung Disease Assessments Guidelines, Pulmonary Function Test Supplemental – Highly Recommended: Lung Disease Assessments Supplemental: Lung Disease Assessments Guidelines, PROMIS Dyspnea Functional Limitations, PROMIS Dyspnea Severity, Pulmonary Hypertension Exploratory: Lung Disease Assessments
Disease and Treatment Related Events; Other:	Supplemental: Leg Ulcer, Retinopathy and Avascular Necrosis, Chronic Malnutrition, Guidelines Malnutrition Identification
Disease and Treatment Related Events; Pain:	Core: Acute Chest Syndrome, Sickle Cell Related Acute Painful Episodes Supplemental: Acute Chest Syndrome, Sickle Cell Related Acute Painful Episodes
Disease and Treatment Related Events; Priapism:	Core: Priapism Core Supplemental: Priapism Impact Profile (PIP), PIP – modified version for minors, Priapism Questionnaire
Disease and Treatment Related Events; Renal:	Core: Renal Function Assessments Supplemental: Renal Function Assessments Exploratory: Renal Function Assessments
Disease and Treatment Related Events; Spleen:	Core: Acute Spleen, Chronic Spleen Supplemental: Acute Spleen, Chronic Spleen, Spleen Assessment, Spleen Assessment from the pediatric hydroxyurea phase III clinical trial (BABY HUG)
Assessments and Examinations; Imaging Diagnostics:	Core: Cardiac Magnetic Resonance Imaging (MRI), Echocardiogram, Silent Cerebral Infarct Supplemental: Cardiac MRI, Echocardiogram, Silent Cerebral Infarct, Functional MRI, Brain MRI, Magnetic Resonance Angiography, Vessel Imaging Transcranial Doppler (TCD) Exploratory: Cardiac MRI, Echocardiogram
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers:	Core: Genetic Diagnostic Testing, Hemoglobin Variant Analysis, Laboratory Tests Supplemental: Genetic Diagnostic Testing, Hemoglobin Variant Analysis, Immune Function Form, Laboratory Assessments- Genetics/Assays, Laboratory Tests

Domain;Sub-domain	Recommendations			
Assessments and Examinations; Non-Imaging Diagnostics:	Supplemental: Electrocardiogram			
Assessments and Examinations; Physical Examinations:	Supplemental: Physical Exam, NIH Stroke Scale			
Assessments and Examinations; Vital Signs and Blood Gases:	Core: Vital Signs and Blood Gases Supplemental: Vital Signs and Blood Gases			
Treatment/Intervention Data; Drugs:	Core: Prior and Concomitant Medications Supplemental: Asthma Medication, Asthma Medications List, PROMIS Medical Adherence Scale, Prior and Concomitant Medications			
Treatment/Intervention Data; Therapies:	Core: Drug Product, Hematopoietic Cellular Transplant Infusion, Genetics and Assays Summary of Recommendations Supplemental: Adhesion and Viscosity, Apheresis, Conditioning Regimen, Genetics and Assays Summary of Recommendations Exploratory: Adhesion Molecules Assay, Genetics and Assays Summary of Recommendations			
Treatment/Intervention Data; Adverse Events/Toxicities:	Core: Cytopenia, Genotoxicity, Infection Form, Infusional Toxicity, Iron overload Supplemental: Adverse Events, Cellular Therapy Essential Data Follow-Up Form, Cytopenia, Genotoxicity, Iron overload, New Malignancy, Serious Adverse Events, Toxicity Form			
Outcomes and End Points: Patient Reported Outcomes	Pain Intensity	Adults, children 8 years old and above	Numeric Rating Scale (NRS)	Core
	Pain Intensity	Adults, 8 years old and above	Visual Analog Scale (VAS)	Supplemental
	Pain Impact/ Interference	Adults	ASCQ-Me Pain Impact	Core
	Painful Crises	Adults, specific to SCD	ASCQ-Me Pain Episodes	Core
	Pain Impact/ Interference	Children ages 5–18 years, specific to SCD.	PedsQL Pain Impact_SCD module (children)	Core
	Pain: Mixed	Children ages 5–18 years, specific to SCD	PedsQL Pain and Hurt, SCD modules	Core

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	Pain Impact/ Interference	Children and Adults, not SCD specific	PROMIS Pain Interference; Adult and Pediatric modules	Core
	Emotional Impact of SCD	Adults, specific to SCD	ASCQ-Me Emotional Impact	Supplemental, Highly Recommended
	Emotional Impact of SCD	Children, specific to SCD	PedsQL, SCD Module Emotions	Supplemental, Highly Recommended
	Emotional Impact of SCD	Children, specific to SCD	PedsQL, SCD Module Worrying	Supplemental
	Negative Affect: Mixed	Children	PROMIS Pediatric Physical Stress Experience	Supplemental, Highly Recommended
	Low Mood	Children and Adults, not SCD specific	PROMIS Emotional Distress: Depression (Pediatric and Adult)	Supplemental, Highly Recommended
	Anxiety	Children and Adults, not SCD specific	PROMIS Emotional Distress: Anxiety (Pediatric and Adult)	Supplemental, Highly Recommended
	Caregiver Burden	Adults, not SCD specific	Caregiver Burden Scale	Supplemental
	Fatigue	Children and Adults, not SCD specific	PROMIS Fatigue/Pediatric Fatigue	Core
	Fatigue	Children with SCD	PedsQL Multidimensional Fatigue Scale	Core
	Sleep Disturbance	Children and adults, not SCD specific	PROMIS Sleep Disturbance	Supplemental, Highly Recommended
	Sleep Disturbance	Adults	Pittsburgh Sleep Quality Index (PSQI)	Supplemental
	Sleep Disturbance	Adults with SCD	ASCQ-Me Sleep Impact	Supplemental, Highly Recommended
	Daytime Sleepiness	Adults, newer scale for children	Epworth Sleepiness Scale (and Epworth CHAD)	Supplemental

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	General Function	Adults	Canadian Occupational Performance Measure (COPM)	Supplemental
	Social Function	Adults with SCD	ASCQ-Me Social Functioning Impact	Supplemental
	Physical Function	Adults with SCD	ASCQ-Me Stiffness Impact	Supplemental, Highly Recommended
	Physical Function	Adults	PROMIS - Physical Function - 12a	Supplemental
	Physical Function	Children with SCD	Other PROMIS Physical Function measures, such as PROMIS Upper Extremity and Mobility, available for Pediatrics but not validated for Adults	Supplemental
	Global Health/Quality of Life	Adults	PROMIS 10 Global Health	Core
	Global Health/Quality of Life	Children	PROMIS 7+2 Global Health	Core
	Global Cognition	0-3.5 years	Bayley-III	Supplemental
	Global Cognition	2.5-7 & 7/12	Wechsler Preschool and Primary Scale of Intelligence WPPSI-IV (+consider WPPSI Cancellation)	Supplemental
	Global Cognition	6-16 & 11/12	Wechsler Intelligence Scale for Children (5th Ed) WISC-V	Supplemental
	Global Cognition	Adults	Wechsler Adult Intelligence Scale WAIS-III	Supplemental
Global Cognition	3-6, 1-17, and 18+ Depending on Battery	NIH Toolbox	Supplemental, Highly Recommended	

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Domain;Sub-domain	Recommendations			
	Executive Functioning (and Attention)	Versions for 3-7, 8-11, and 12+	NIH Toolbox: Flanker Inhibitory Control and Attention Test	Supplemental, Highly Recommended
	Executive Function	Versions for 3-7, 8-11, and 12+	NIH Toolbox: Dimensional Change Card Sort Test	Supplemental, Highly Recommended
	Executive Function	9 and up	Trail Making Test, parts A and B	Supplemental
	Executive Function	8-89 years	Delis-Kaplan Executive Function System D-KEFS	Supplemental
	Executive Function	6 years, 5 months to 89	Wisconsin Card Sort Test	Supplemental
	Processing Speed	Age 7+	NIH Toolbox: Pattern Comparison Processing Speed Test	Supplemental, Highly Recommended
	Processing Speed	Adults	Processing Speed Index (of WAIS-III)	Supplemental
	Working Memory	7+	NIH Toolbox: List Sorting Working Memory Test	Supplemental, Highly Recommended
	Pain Mechanism	Adult	Quantitative Sensory Testing	Exploratory
	Sleep Impact/Sleep Disturbance	Adult	Polysomnography	Exploratory
	Life Satisfaction	Pediatric	PROMIS Pediatric Item Bank Life Satisfaction (Short Form 4a)	Exploratory
	Stigma	Adult	Measure of Sickle Cell Stigma	Exploratory
	Coping Skills / Pain Coping	Adult	Coping Strategies Questionnaire – Revised for SCD	Exploratory
	Outcomes and End Points; Mortality and Survival	Core: Death Report Supplemental: Death Report		