



**NIH Resources**

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

- National Institutes of Health (NIH) Toolbox
- Quality of Life in Neurological Disorders (Neuro-QOL)
- Patient-Reported Outcomes Measurement Information System (PROMIS)

**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](#)).

Disease and Subdomains	Recommendations and List of Forms
<b>Spinal Muscular Atrophy (SMA)</b>	<b>Core CDEs:</b> See Start-Up Resource Listing document <a href="#">SMA Start-Up Resource Listing</a>
<b>Participant / Subject Characteristics; Demographics</b>	<b>Core:</b> Demographics <b>Supplemental:</b> None
<b>Participant / Subject Characteristics; Social Status</b>	<b>Core:</b> Social Status <b>Supplemental:</b> None
<b>Participant / Subject History and Family History; General Health History</b>	<b>Core:</b> Family History; Medical History; Prenatal and Perinatal History; Surgical and Hospitalization History <b>Supplemental:</b> None
<b>Disease / Injury Related Events; History of Disease / Injury Event</b>	<b>Core:</b> None <b>Supplemental:</b> Medical History of SMA; Motor Milestones and Current Level of Function
<b>Assessments and Examinations; Physical / Neurological Examination</b>	<b>Core:</b> None <b>Supplemental:</b> Physical Examination; Polysomnography
<b>Assessments and Examinations; Vital Signs and Other Body Measures</b>	<b>Core:</b> None <b>Supplemental:</b> Vital Signs



Disease and Subdomains	Recommendations and List of Forms
<b>Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers</b>	<p><b>Core:</b> None</p> <p><b>Supplemental:</b> Biomarkers and Sample Data Guidelines; Biospecimen Collection Guidelines for Use; Fat Aspirate Tissue Specimens; Gene Table and Guidelines for Use; Laboratory Tests and Tracking; Laboratory Tests Recommendations Table and Guidelines for Use; Muscle Biopsy and Autopsy Tissue; Mutation Analysis; Nerve Biopsy; NINDS Repository Spinal Muscular Atrophy Data Elements; Skin Biopsies for Qualification of Intraepidermal Nerve Fibers</p>
<b>Assessments and Examinations; Imaging Diagnostics</b>	<p><b>Core:</b> None</p> <p><b>Supplemental:</b> Brain Magnetic Resonance Imaging (MRI); Cardiac Magnetic Resonance Imaging (MRI); Diffusion Tensor Imaging (DTI); Dual-Energy X-Ray Absorptiometry (DEXA); Magnetic Resonance Imaging (MRI); Magnetic Resonance Spectroscopy (MRS)</p>
<b>Assessments and Examinations; Non-Imaging Diagnostics</b>	<p><b>Core:</b> None</p> <p><b>Supplemental:</b> Echocardiogram; Electrocardiogram (ECG); Electrophysiology; Holter Examination</p>
<b>Treatment/Intervention Data; Devices</b>	<p><b>Core:</b> None</p> <p><b>Supplemental:</b> External Devices</p>
<b>Treatment/Intervention Data; Therapies</b>	<p><b>Core:</b> None</p> <p><b>Supplemental:</b> Gastrointestinal Therapies; Respiratory Interventions</p>
<b>Outcomes and Endpoints; Summary of All Outcome Recommendations</b>	<p><b>Core:</b> None</p> <p><b>Supplemental:</b> SMA Clinical Outcomes Recommendations by Domain and Classification</p>
<b>Outcomes and Endpoints; Emotional and Cognitive Status</b>	<p><b>Core:</b> None</p> <p><b>Supplemental:</b> Cognitive Guidelines for Use</p>
<b>Outcomes and Endpoints/End Points</b>	<p><b>Core:</b> None</p> <p><b>Supplemental:</b> Death Report</p>
<b>Outcomes and Endpoints; Functional Status</b>	<p><b>Core:</b> None</p> <p><b>Supplemental:</b> 10 Meter Timed Walk; 6 Minute Walk Test; Grip Strength; North Star Ambulatory Assessment (NSAA); Pinch Strength; Purdue Pegboard; Timed Up and Go (TUG)</p>



Disease and Subdomains	Recommendations and List of Forms
<b>Outcomes and Endpoints; Muscle Strength Testing</b>	<b>Core:</b> None <b>Supplemental:</b> Manual Muscle Testing-Using the Medical Research Council Muscle Grading Scale; Maximum Voluntary Isometric Contraction Scale (MVIC)
<b>Outcomes and Endpoints; Pulmonary Function Testing/Respiratory Status</b>	<b>Core:</b> None <b>Supplemental:</b> Measures of Gas Exchange; Pulmonary Assessment Master Outline and Guidelines for Use; Pulmonary Function Testing
<b>Outcomes and Endpoints; Pediatric</b>	<b>Core:</b> None <b>Supplemental:</b> Pediatric Cognitive Instrument Recommendations by Domains and Classification; Pediatric Cognitive Instrument Table; SMA Pediatric Clinical Outcomes Recommendations by Domain and Classification
<b>Outcomes and Endpoints; Quality of Life</b>	<b>Core:</b> None <b>Supplemental:</b> Canadian Occupational Performance Measure (COPM); Nine Hole Peg Test; Pediatric Quality of Life Inventory (PEDSQL); Short Form 36-Item Health Survey (SF-36)