



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](#)).

Domain; Sub-Domain	Recommendations
Friedreich’s Ataxia	<p>These instruments and elements are recommended for use in all FA studies:</p> <p>Core instruments: Friedreich Ataxia Rating Scale (FARS), International Cooperative Ataxia Rating Scale (ICARS), Scale for the Assessment and Rating of Ataxia (SARA), Low Contrast Letter Acuity, Timed 25-Foot Walk, 9-Hole Pegboard</p> <p>Core elements: Friedreich's Ataxia Start-Up Resource Listing</p> <p>Exploratory: None</p>
Participant Characteristics; Demographics	<p>Core: Demographicsⁱ, General Coreⁱⁱ</p> <p>Supplemental: Demographics, General Core</p> <p>Exploratory: Demographics, General Core</p>
Participant Characteristics; Social Status	<p>Core: Social Statusⁱⁱⁱ</p> <p>Supplemental: Social Status</p> <p>Exploratory: Social Status</p>
Participant History and Family History; General Health History	<p>Core: Behavioral History^{iv}, History Data Source Reliability^v, Medical History^{vi}</p> <p>Supplemental: Behavioral History, Family History, History Data Source Reliability, Medical History, Pediatric Developmental History^{vii}, Pregnancy History, Prenatal and Perinatal History^{viii}</p> <p>Exploratory: History Data Source Reliability, Pediatric Developmental History, Prenatal and Perinatal History</p>



Domain; Sub-Domain	Recommendations
Disease/Injury Related Events; History of Disease/Injury Event	Core: Medical History of Friedreich's Ataxia ^{ix} Supplemental: Medical History of Friedreich's Ataxia Exploratory: None
Assessments and Examinations; Physical/ Neurological Examination	Core: Physical Examination ^x Supplemental: Physical Examination Exploratory: None
Assessments and Examinations; Vital Signs and Other Body Measures	Core: Vital Signs ^{xi} Supplemental: Vital Signs Exploratory: None
Assessments and Examinations; Laboratory Tests and Biospecimens/ Biomarkers	Core: Laboratory Tests ^{xii} Supplemental: Laboratory Tests Exploratory: None Guideline Documents: Plasma Collection Guidelines, Urine Collection Guidelines
Assessments and Examinations; Imaging Diagnostics	Core: Cardiac and Magnetic Resonance Imaging ^{xiii} Supplemental: Cardiac and Magnetic Resonance Imaging Exploratory: None
Assessments and Examinations; Non-Imaging Diagnostics	Core: Echocardiogram, Electrocardiogram, Holter Exam Supplemental: None Exploratory: None
Treatment/Intervention Data; Drugs	Core: Prior and Concomitant Medications ^{xiv} Supplemental: Prior and Concomitant Medications Exploratory: None
Outcomes and Endpoints; Summary of All Outcome Recommendations	Core: None Supplemental: None Exploratory: None Recommendations: FA CDE Instrument Recommendations by Outcome Domain and Classification



Domain; Sub-Domain	Recommendations
Outcomes and Endpoints; Activities of Daily Living / Performance	<p>Core: Activities of Daily Living and Gait^{xv}</p> <p>Supplemental: Activities of Daily Living and Gait, PaTaKa Speech Test, PROMIS, NIH Toolbox</p> <p>Exploratory: Acoustic Analysis of Speech, Barthel Index, Functional Independence Measure, Jebsen-Taylor Hand Functioning Test, Stride Analysis and Gait Variability</p>
Outcomes and Endpoints; Ataxia and Performance Measures	<p>Core: Friedreich's Ataxia Rating Scale (FARS), International Cooperative Rating Scale (ICARS), Nine Hole Peg Test, Scale for the Assessment and Rating of Ataxia (SARA), Sloan Low Contrast Letter Acuity, Timed 25-Foot Walk (T25FW)</p> <p>Supplemental: Assessment of Intelligibility of Dysarthric Speech (AIDS), Boston Diagnostic Aphasia Exam (BDAE-III), Friedreich's Ataxia Impact Scale (FAIS), Modified Fatigue Impact Scale (MFIS), Tardieu Scale</p> <p>Exploratory: Bladder Control Scale (BLCS), Bowel Control Scale (BWCS), Delis Kaplan Executive Function System (DKEFS), Impact of Visual Impairment Scale (IVIS), MOS Pain Effects Scale (PES), Phonemic Verbal Fluency (PVF)</p>
Outcomes and Endpoints; Quality of life	<p>Core: None</p> <p>Supplemental: Pediatric Quality of Life Inventory (PEDIQL), 36-Item Short Form Health Survey (SF-36), Short Form Health Survey 10 for Children (SF-10), Quality of Life in Neurological Disorders (Neuro-QOL)</p> <p>Exploratory: None</p>
Outcomes and Endpoints; Clinical Event End Points	<p>Core: Cardiac End Points</p> <p>Supplemental: None</p> <p>Exploratory: None</p>

ⁱ CRF has Core, Supplemental, and Exploratory elements
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