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).

<table>
<thead>
<tr>
<th>Domain; Sub-Domain</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Friedreich’s Ataxia</td>
<td>These instruments and elements are recommended for use in all FA studies:</td>
</tr>
<tr>
<td></td>
<td><strong>Core instruments:</strong></td>
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<tr>
<td></td>
<td>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</td>
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<tr>
<td></td>
<td><strong>Core elements:</strong> Friedreich’s Ataxia Start-Up Resource Listing</td>
</tr>
<tr>
<td></td>
<td><strong>Exploratory:</strong> None</td>
</tr>
<tr>
<td>Participant Characteristics;</td>
<td><strong>Core:</strong> Demographics, General Core</td>
</tr>
<tr>
<td>Demographics</td>
<td><strong>Supplemental:</strong> Demographics, General Core</td>
</tr>
<tr>
<td>Participant Characteristics;</td>
<td><strong>Exploratory:</strong> Demographics, General Core</td>
</tr>
<tr>
<td>Social Status</td>
<td></td>
</tr>
<tr>
<td>Participant History and Family</td>
<td><strong>Core:</strong> Behavioral History, History Data Source Reliability, Medical History</td>
</tr>
<tr>
<td>History; General Health History</td>
<td><strong>Supplemental:</strong> Behavioral History, Family History, History Data Source Reliability, Medical History, Pediatric Developmental History, Pregnancy History, Prenatal and Perinatal History</td>
</tr>
<tr>
<td></td>
<td><strong>Exploratory:</strong> History Data Source Reliability, Pediatric Developmental History, Prenatal and Perinatal History</td>
</tr>
</tbody>
</table>
## Friedreich’s Ataxia (FA) CDE Highlight Summary

<table>
<thead>
<tr>
<th>Domain; Sub-Domain</th>
<th>Recommendations</th>
</tr>
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</table>
| **Disease/Injury Related Events; History of Disease/Injury Event**                 | **Core:** Medical History of Friedreich’s Ataxia<sup>ix</sup>  
**Supplemental:** Medical History of Friedreich’s Ataxia  
**Exploratory:** None                                                       |
| **Assessments and Examinations; Physical/Neurological Examination**                | **Core:** Physical Examination<sup>x</sup>  
**Supplemental:** Physical Examination  
**Exploratory:** None                                                        |
| **Assessments and Examinations; Vital Signs and Other Body Measures**             | **Core:** Vital Signs<sup>xi</sup>  
**Supplemental:** Vital Signs  
**Exploratory:** None                                                          |
| **Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers**   | **Core:** Laboratory Tests<sup>xii</sup>  
**Supplemental:** Laboratory Tests  
**Exploratory:** None  
**Guideline Documents:** Plasma Collection Guidelines, Urine Collection Guidelines |
| **Assessments and Examinations; Imaging Diagnostics**                             | **Core:** Cardiac and Magnetic Resonance Imaging<sup>xiii</sup>  
**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<sup>xiv</sup>  
**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 |
<table>
<thead>
<tr>
<th>Domain; Sub-Domain</th>
<th>Recommendations</th>
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</table>
| **Outcomes and Endpoints; Activities of Daily Living / Performance** | **Core:** Activities of Daily Living and Gait<sup>xv</sup>  
**Supplemental:** Activities of Daily Living and Gait, PaTaKa Speech Test, PROMIS, NIH Toolbox  
**Exploratory:** Acoustic Analysis of Speech, Barthel Index, Functional Independence Measure, Jebsen-Taylor Hand Functioning Test, Stride Analysis and Gait Variability |
| **Outcomes and Endpoints; Ataxia and Performance Measures** | **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)  
**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  
**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) |
| **Outcomes and Endpoints; Quality of life** | **Core:** None  
**Supplemental:** Pediatric Quality of Life Inventory (PEDSQL), 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)  
**Exploratory:** None |
| **Outcomes and Endpoints; Clinical Event End Points** | **Core:** Cardiac End Points  
**Supplemental:** None  
**Exploratory:** None |

<sup>1</sup> CRF has Core, Supplemental, and Exploratory elements  
<sup>2</sup> CRF has Core, Supplemental, and Exploratory elements  
<sup>3</sup> CRF has Core, Supplemental, and Exploratory elements  
<sup>4</sup> CRF has Core and Supplemental elements  
<sup>5</sup> CRF has Core, Supplemental, and Exploratory elements  
<sup>6</sup> CRF has Core and Supplemental elements  
<sup>7</sup> CRF has Core, Supplemental, and Exploratory elements  
<sup>8</sup> CRF has Supplemental and Exploratory elements  
<sup>9</sup> CRF has Supplemental and Exploratory elements  
<sup>10</sup> CRF has Core and Supplemental elements  
<sup>11</sup> CRF has Core and Supplemental elements  
<sup>12</sup> CRF has Core and Supplemental elements  
<sup>13</sup> CRF has Core and Supplemental elements  
<sup>14</sup> CRF has Core and Supplemental elements  
<sup>15</sup> CRF has Core and Supplemental elements