

Start-up Resource – NINDS Friedreich's Ataxia CDE Recommendations

The National Institute of Neurological Disorders and Stroke (NINDS) and other Federal agencies and international organizations have the common mission of developing data standards for clinical research. Through the efforts of subject-specific working groups, topic-driven data elements have been created. The first set of Common Data Elements (CDEs) for Friedreich's Ataxia was developed in 2011. The Core data elements to be used by an investigator when beginning a research study in this disease/disorder are listed in this resource document. All other recommendations are listed on the website and should be considered based on study type.

Each CDE or instrument could be classified according to the definitions below:

General Core: A data element that is required for all NINDS funded studies.

Disease Core: A data element that collects essential information applicable to any disease-specific study, including all therapeutic areas. The NINDS and its appointed working groups assign the disease "Core" classification based on the current clinical research best practices. In each case, the disease Core CDEs are a small subset of the available CDEs, where it is anticipated that investigators will need to collect the disease Core CDEs on any type of study. These are required for all disease-specific studies.

Disease Supplemental - Highly Recommended: A data element which is essential based on certain conditions or study types in clinical research studies. In most cases, these have been used and validated in the disease area. These data elements are strongly recommended for the specified disease condition, study type or design.

Disease Supplemental: A data element which is commonly collected in clinical research studies. Use depends upon the study design, protocol or type of research involved. These are recommended, but not required, for studies.

Disease Exploratory: A data element that requires further validation, but may fill current gaps in the CDEs and/or substitute for an existing CDE once validation is complete. Such data elements show great promise, but require further validation before they are ready for prime-time use in clinical research studies. They are reasonable to use with the understanding that it has limited validation in the target group.



Summary of Core Recommendations: Friedreich's Ataxia CDEs

<p>National Institute of Health (NIH) Resources: <i>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.</i></p>	<ul style="list-style-type: none"> • NIH Toolbox <ul style="list-style-type: none"> • Quality of Life in Neurological Disorders (Neuro-QOL) • Patient-Reported Outcomes Measurement Information System (PROMIS)
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Core CDEs for all NINDS Studies¹:

CDE Domain	CDE Name	CDE ID	Classification	Study Type
Demographics	Birth date	C00007	CORE	All studies
Demographics	Ethnicity USA category	C00020	CORE	All studies
Demographics	Race USA category	C00030	CORE	All studies
Demographics	Gender Type	C00035	CORE	All studies
General Health History	Medical history condition text	C00322	CORE	All studies
General Health History	Medical history condition SNOMED CT code	C00313	CORE	All studies

Core CDEs for FA Studies:

Domain; Sub-Domain	Data Element	CDE ID
Disease/Injury Related Events; History of Disease/Injury Event	Ambulation affected by disease indicator	C10524
Disease/Injury Related Events; History of Disease/Injury Event	Clinical event or milestone achieved age value	C12658
Disease/Injury Related Events; History of Disease/Injury Event	Clinical trial previous participation indicator	C18253
Disease/Injury Related Events; History of Disease/Injury Event	Diagnosis initial age value	C10501

¹ Note: Education year count C00015 is no longer a general Core CDE

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Domain; Sub-Domain	Data Element	CDE ID
Disease/Injury Related Events; History of Disease/Injury Event	Friedrich's ataxia length of GAA repeat allele 1 measurement	C10512
Disease/Injury Related Events; History of Disease/Injury Event	Friedrich's ataxia length of GAA repeat allele 2 measurement	C10513
Disease/Injury Related Events; History of Disease/Injury Event	Genetic diagnosis confirmation type	C10507
Disease/Injury Related Events; History of Disease/Injury Event	Genetic diagnosis established indicator	C10506
Disease/Injury Related Events; History of Disease/Injury Event	Genetic diagnosis point mutation result	C10514
Assessments and Examinations; Physical/Neurological Examination	Hand preference type	C00023
Assessments and Examinations; Physical/Neurological Examination	Heart rate	C01521
Assessments and Examinations; Physical/Neurological Examination	Lab specimen collection date and time	C01701
Assessments and Examinations; Physical/Neurological Examination	Lab test abnormality significance type	C01707
Assessments and Examinations; Physical/Neurological Examination	Lab test name	C01705
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Lab test other text	C18731
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Lab test result status	C01709

Summary of Core Recommendations: Friedreich's Ataxia CDEs

Domain; Sub-Domain	Data Element	CDE ID
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Lab test result unit of measure	C01711
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Lab test result value	C01706
Participant/Subject History and Family History; General Health History	Medical history for body system indicator	C00321
Participant/Subject History and Family History; General Health History	Medical history taken date and time	C00314
Treatment/Intervention Data; Drugs	Medication prior or concomitant end date and time	C02008
Treatment/Intervention Data; Drugs	Medication prior or concomitant name	C02014
Treatment/Intervention Data; Drugs	Medication prior or concomitant ongoing indicator	C02003
Treatment/Intervention Data; Drugs	Medication prior or concomitant start date and time	C02016
Disease/Injury Related Events; History of Disease/Injury Event	Scoliosis diagnosis indicator	C10515
Disease/Injury Related Events; History of Disease/Injury Event	Symptom first experienced text	C10502
Disease/Injury Related Events; History of Disease/Injury Event	Symptom onset age value	C10500
Assessments and Examinations; Vital Signs and Other Body Measures	Vital signs date and time	C01519

Summary of Core Recommendations: Friedreich's Ataxia CDEs

Domain; Sub-Domain	Data Element	CDE ID
Outcomes and Endpoints; Activities of Daily Living/Performance	Walking ability status	C10698

Supplemental-Highly Recommended CDEs for FA Studies:

Domain; Sub-Domain	Data Element	CDE ID
Outcomes and Endpoints; Activities of Daily Living/Performance	Bladder control status	C10700
Assessments and Examinations; Vital Signs and Other Body Measures	Blood pressure diastolic measurement	C01507
Assessments and Examinations; Vital Signs and Other Body Measures	Blood pressure systolic measurement	C01565
Outcomes and End Points; Activities of Daily Living/Performance	Cutting food or use of items functioning level status	C10694
Outcomes and End Points; Activities of Daily Living/Performance	Dressing level status	C10695
General Health History; Participant/Subject History and Family History	Drug or substance current illicit use indicator	C00713
Outcomes and End Points; Activities of Daily Living and Gait	Fall rate	C10697
Outcomes and End Points; Activities of Daily Living and Gait	Genetic diagnosis established by lab name	C10509
Disease/Injury Related Events; History of Disease/Injury Event	Genetic diagnosis established date and time	C10508
Disease/Injury Related Events; History of Disease/Injury Event	Genetic diagnosis established in city name	C10510

Summary of Core Recommendations: Friedreich's Ataxia CDEs

Domain; Sub-Domain	Data Element	CDE ID
Disease/Injury Related Events; History of Disease/Injury Event	Genetic diagnosis established in country name	C10511
Disease/Injury Related Events; History of Disease/Injury Event	Height measurement	C01522
Assessments and Examinations; Vital Signs and Other Body Measures	Height unit of measure	C01582
Disease/Injury Related Events; History of Disease/Injury Event	Neuromuscular scoliosis surgery treat indicator	C06452
Outcomes and End Points; Activities of Daily Living/Performance	Personal hygiene level status	C10696
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Pregnancy test date and time	C01702
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Pregnancy test not applicable reason	C01714
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Pregnancy test performed indicator	C10896
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Pregnancy test qualitative result value	C01710
Assessments and Examinations; Vital Signs and Other Body Measures	Respiratory rate	C01535
Outcomes and End Points; Activities of Daily Living/Performance	Sitting ability status	C10699
Disease/Injury Related Events; History of Disease/Injury Event	Speech level status	C10522

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Domain; Sub-Domain	Data Element	CDE ID
Outcomes and End Points; Activities of Daily Living/Performance	Surgery lifetime total count	C10692
Outcomes and End Points; Activities of Daily Living/Performance	Swallowing level status	C10693
Assessments and Examinations; Vital Signs and Other Body Measures	Temperature measurement	C01539
Assessments and Examinations; Vital Signs and Other Body Measures	Temperature unit of measure	C01580
Participant/Subject History and Family History; General Health History	Tobacco current use indicator	C00710
Assessments and Examinations; Vital Signs and Other Body Measures	Weight measurement	C01541
Assessments and Examinations; Vital Signs and Other Body Measures	Weight unit of measure	C01581

General Core for all Studies:

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](#)).

Core Instruments for Friedreich's Ataxia Studies:

1. [Friedreich's Ataxia Rating Scale \(FARS\)](#)
2. [International Cooperative Ataxia Rating Scale \(ICARS\)](#)
3. [Scale for the Assessment and Rating of Ataxia \(SARA\)](#)
4. [Low Contrast Letter Acuity](#)
5. [Timed 25-Foot Walk](#)
6. [9-Hole Pegboard](#)



Summary of Core Recommendations: Friedreich's Ataxia CDEs

For the complete list of NINDS CDE recommendations for FA, please see the [NINDS CDE website](#).