

Common Data Elements

The National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), has developed Friedrich's Ataxia (FA) Common Data Elements (CDEs) for use in clinical research. The NINDS recently assembled an external working group of experts, the FA CDE Working Group, to develop "Version 1.0" of the Friedrich's Ataxia CDEs and they are now ready for use in Friedrich's Ataxia clinical research community.

[Friedreich's Ataxia CDE Standards Version 1.0](#)

The [NINDS CDE Web site](#) fully describes the NINDS CDE Project and its goals. In summary, the CDE Project aims to develop content standards, both generic and disease-specific, that enable clinical investigators to systematically collect, analyze, and share data across the research community. The NINDS first convened the Friedrich's Ataxia CDE Working Group in June 2010. Over a one-year period the Friedrich's Ataxia CDE Working Group identified and defined a catalog of CDEs investigators can choose from when assembling their clinical study materials. The Friedrich's Ataxia CDE Working Group has not attempted to define the complete universe of variables a clinical study will collect; rather, their goal has been to isolate elements that will be useful across multiple FA clinical studies.

To develop the Friedrich's Ataxia (FA) CDEs, the [FA CDE Working Group](#) divided into subgroups to focus on identifying and defining data elements in the domains of:

- Ataxia and Performance Measures
- Biomarkers
- Cardiac and Clinical Outcomes
- Demographics, Medical History/ Prior Health Status, Laboratory Tests/ Vital Signs

Scientific Reference

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[Common data elements for clinical research in Friedrich's ataxia](#)

Lynch DR, Pandolfo M, Schulz JB, Perlman S, Delatycki MB, Payne RM, Shaddy R, Fischbeck KH, Farmer J, Kantor P, Raman SV, Hunegs L, Odenkirchen J, Miller K, Kaufmann P

FARA encourages all investigators doing clinical research studies in FA to consult these guidelines. The FA CDEs include case report form (CRF) modules, standardized data element definitions, and instructions intended to expedite the development of data collection tools. There is also significant gain from the ability to share and compare data across studies – these common data elements are a platform ensuring uniformity in data collection across multiple distinct studies so that later comparative analyses may be performed.