NINDS Common Data Elements (CDE) Survey

General information

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Background

The NINDS Common Data Elements (CDE) Project was launched in 2005 with the primary goal to develop data standards for clinical research involving neurological disorders so that data are captured consistently across different studies. In addition to one set of general CDEs that are applicable to all neurology studies, 18 disease-specific sets of CDEs have been developed through the program. NINDS is interested in getting feedback from the community based on their experience with CDEs so that we can assess how well the current program is meeting the needs of clinical researchers.

Why you should participate

The information we collect from this survey will help give NINDS a clearer picture of the research community's perspectives on the current NINDS CDEs. This survey will help define future strategies related to the development and maintenance of NINDS CDEs, and identify opportunities to enhance the project's impact on clinical research for neurological disorders. Participation in this survey is voluntary and should only take 10 minutes to complete.

* 1. What neurological disease or condition best describes the primary focus of your clinical research?

* 2. Have you used any NINDS CDEs or served on any committees related to the development of NINDS CDEs?

- ◯ I have used NINDS CDEs and was involved in NINDS CDE development
- ◯ I have used NINDS CDEs
- ◯ I served on an NINDS CDE development working group
- ◯ I have no experience with NINDS CDEs

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Participants with NINDS CDE experience & development

* 3. Below is a list of NINDS CDEs that are currently available to the research community. Please indicate which set(s) are relevant to your area(s) of research, and which set(s) you have used. You do not need to make a selection for those that are not relevant to your research area.

	relevant, but have not used	relevant and have used
General	○	○
Amyotrophic Lateral Sclerosis	○	○
Epilepsy	○	○
Friedreich's Ataxia	○	○
Headache	○	○
Huntington's Disease	○	○
Mitochondrial Disease	○	○
Multiple Sclerosis	○	○
Neuromuscular Diseases	○	○
Congenital Muscular Dystrophy	○	○
Myasthenia Gravis	○	○
Spinal Muscular Atrophhy	○	○
Parkinson's Disease	○	○
Spinal Cord Injury	○	○
Stroke	○	○
Traumatic Brain Injury	○	○

* 4. What was your role in the research study or studies that used CDEs? Check all that apply.

- [ ] Trial PI
- [ ] Site PI
- [ ] Co-investigator
- [ ] Colleague/Collaborator
- [ ] Project Coordinator
- [ ] Data management role
- [ ] Other (please specify)

* 5. What type of clinical study did you use NINDS CDEs with?

- [ ] Observational / cohort study (including epidemiology, genetics, biomarkers, etc)
- [ ] Human subjects basic research study (e.g. small hypothesis-generating studies not classified as clinical trials)
- [ ] Exploratory clinical trials (including Phase I/II trials, or other early stage clinical trial)
- [ ] Phase III clinical trial
- [ ] Other (please specify)

* 6. How did you become aware of the NINDS CDEs?

- [ ] Scientific meeting
- [ ] NINDS staff/Program Director
- [ ] NINDS website
- [ ] NLM website
- [ ] NINDS FOA
- [ ] Other (please specify)

7. What were the primary reasons you chose to use CDEs for your study?

* 8. Were there any disadvantages to using the NINDS CDEs?

- ◯ Yes
- ◯ No

If yes, what were they? (e.g. difficulty incorporating necessary forms, lacked important data elements, increased effort to develop databases...)

* 9. One goal of the CDE program is to provide data collection tools to facilitate efficient study start up. Did access to the NINDS CDEs make it easier to set up the data collection processes for your study?

- ◯ Yes
- ◯ No

Please explain whether/how the CDE tools influenced efficiency of study start-up processes:

* 10. How would you rate the overall level of effort/burden associated with using the CDEs in your research study, as compared to your previous experiences with non-CDE studies?

More effort, highly burdensome	More effort, burdensome	More effort but manageable	Similar amount of effort	Less effort
◯	◯	◯	◯	◯

Comments:

* 11. Do you agree that NINDS CDEs are or could be a valuable resource for the neuroscience community?

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
○	○	○	○	○

Comments:

* 12. The process of achieving community consensus on common data elements for a whole field of research is challenging. Keeping in mind the complex nature of such an effort, how efficient do you feel the process was for initial development of the CDEs for your research area?

Very inefficient	Inefficient	Neutral opinion	Efficient	Highly efficient
○	○	○	○	○

Comments:

13. Updating the CDEs is an important process for ensuring the CDEs are optimized and reflect the state of the science. How frequently do you think the NINDS CDEs should be reviewed and what factors should determine when a topic gets updated?

14. Do you have any additional suggestions for ways to improve the CDE development or review process?

15. Broad awareness and buy-in among the research community is key to realizing the long-term benefits of common data elements. Do you believe there is broad awareness of the NINDS CDEs in your research field, and do you believe there is wide buy-in of the concept? Why/why not?

NINDS Common Data Elements (CDE) Survey

Participants with NINDS CDE experience

* 16. Below is a list of NINDS CDEs that are currently available to the research community. Please indicate which set(s) are relevant to your area(s) of research, and which set(s) you have used. You do not need to make a selection for those that are not relevant to your research area.

	relevant, but have not used	relevant and have used
General	○	○
Amyotrophic Lateral Sclerosis	○	○
Epilepsy	○	○
Friedreich's Ataxia	○	○
Headache	○	○
Huntington's Disease	○	○
Mitochondrial Disease	○	○
Multiple Sclerosis	○	○
Neuromuscular Diseases	○	○
Congenital Muscular Dystrophy	○	○
Myasthenia Gravis	○	○
Spinal Muscular Atrophhy	○	○
Parkinson's Disease	○	○
Spinal Cord Injury	○	○
Stroke	○	○
Traumatic Brain Injury	○	○

* 17. What was your role in the research study or studies that used CDEs? Check all that apply.

- [ ] Trial PI
- [ ] Site PI
- [ ] Co-investigator
- [ ] Colleague/Collaborator
- [ ] Project Coordinator
- [ ] Data management role
- [ ] Other (please specify)

* 18. What type of clinical study did you use NINDS CDEs with?

- [ ] Observational / cohort study (including epidemiology, genetics, biomarkers, etc)
- [ ] Human subjects basic research study (e.g. small hypothesis-generating studies not classified as clinical trials)
- [ ] Exploratory clinical trials (including Phase I/II trials, or other early stage clinical trial)
- [ ] Phase III clinical trial
- [ ] Other (please specify)

* 19. How did you become aware of the NINDS CDEs?

- [ ] Scientific meeting
- [ ] NINDS staff/Program Director
- [ ] NINDS website
- [ ] NLM website
- [ ] NINDS FOA
- [ ] Other (please specify)

20. What were the primary reasons you chose to use CDEs for your study?

* 21. Were there any disadvantages to using the NINDS CDEs?

- ◯ Yes
- ◯ No

If yes, what were they? (e.g. difficulty incorporating necessary forms, lacked important data elements, increased effort to develop databases...)

* 22. One goal of the CDE program is to provide data collection tools to facilitate efficient study start up. Did access to the NINDS CDEs make it easier to set up the data collection processes for your study?

- ◯ Yes
- ◯ No

Please explain whether/how the CDE tools influenced efficiency of study start-up processes:

* 23. How would you rate the overall level of effort/burden associated with using the CDEs in your research study, as compared to your previous experiences with non-CDE studies?

More effort, highly burdensome	More effort, burdensome	More effort but manageable	Similar amount of effort	Less effort
◯	◯	◯	◯	◯

Comments:

* 24. Do you agree that NINDS CDEs are or could be a valuable resource for the neuroscience community?

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
○	○	○	○	○

Comments:

NINDS Common Data Elements (CDE) Survey

Participants involved in NINDS CDE development

* 25. The process of achieving community consensus on common data elements for a whole field of research is challenging. Keeping in mind the complex nature of such an effort, how efficient do you feel the process was for initial development of the CDEs for your research area?

Very inefficient	Inefficient	Neutral opinion	Efficient	Highly efficient
○	○	○	○	○

Comments:

26. Updating the CDEs is an important process for ensuring the CDEs are optimized and reflect the state of the science. How frequently do you think the NINDS CDEs should be reviewed and what factors should determine when a topic gets updated?

27. Do you have any additional suggestions for ways to improve the CDE development or review process?

28. Broad awareness and buy-in among the research community is key to realizing the long-term benefits of common data elements. Do you believe there is broad awareness of the NINDS CDEs in your research field, and do you believe there is wide buy-in of the concept? Why/why not?

NINDS Common Data Elements (CDE) Survey

Experience with non-NINDS CDEs

* 29. Have you used any other (non-NINDS) CDEs? Examples include topic-specific CDEs from other NIH Institutes, or data elements that are required for specific research activities (e.g. FDA CDISC). Please mark all that you have used.

- [ ] I have not used other CDEs
- [ ] Asthma CDEs
- [ ] cLBP
- [ ] EDRN
- [ ] eyeGENE
- [ ] GRDR
- [ ] Neuro-QOL
- [ ] NIDA EHR
- [ ] NIH Toolbox
- [ ] PhenX
- [ ] PROMIS
- [ ] CDEs provided by a society or foundation
- [ ] Other (please specify)

* 30. Are you likely to use NINDS CDEs in future studies (if available for the particular topic under study)?

	Yes	No
NINDS-funded studies:	○	○
Non-NINDS funded studies:	○	○

Why or why not?

* 31. In general, do you think CDEs have the potential to (check all that apply):

- [ ] improve data quality
- [ ] enable data sharing
- [ ] facilitate more meta-analyses
- [ ] lead to improved quality or validity in systematic reviews
- [ ] none of the above
- [ ] Other (please specify)

32. Are there any comments or suggestions you would like to provide to help NINDS improve the CDE program's processes, products, or overall impact on the research community?

NINDS Common Data Elements (CDE) Survey

No experience with NINDS CDEs

* 33. What was your reason for not using NINDS CDEs? Check all that apply.

- [ ] not aware of them
- [ ] no disease specific CDEs available for field of study
- [ ] inconvenient
- [ ] did not capture data needed
- [ ] Other (please specify)

* 34. Have you used any other (non-NINDS) CDEs? Examples include topic-specific CDEs from other NIH Institutes, or data elements that are required for specific research activities (e.g. FDA CDISC). Please mark all that you have used.

- [ ] I have not used other CDEs
- [ ] Asthma CDEs
- [ ] cLBP
- [ ] EDRN
- [ ] eyeGENE
- [ ] GRDR
- [ ] Neuro-QOL
- [ ] NIDA EHR
- [ ] NIH Toolbox
- [ ] PhenX
- [ ] PROMIS
- [ ] CDEs provided by a society or foundation
- [ ] Other (please specify)

* 35. Are you likely to use NINDS CDEs in future studies (if available for the particular topic under study)?

	Yes	No
NINDS-funded studies:	○	○
Non-NINDS funded studies:	○	○

Why or why not?

* 36. In general, do you think CDEs have the potential to (check all that apply):

- ☐ improve data quality
- ☐ enable data sharing
- ☐ facilitate more meta-analyses
- ☐ lead to improved quality or validity in systematic reviews
- ☐ none of the above
- ☐ Other (please specify)

37. Are there any comments or suggestions you would like to provide to help NINDS improve the CDE program's processes, products, or overall impact on the research community?