

May 07, 2021

The following comments were submitted via an online submission form in response to the National Institutes of Health Request for Information (RFI): Use of Common Data Elements (CDEs) in NIH-funded research. Our response was developed by the Endocrine Society's Research Affairs Core Committee. We hope that our input will assist NIH in their efforts to advance the use of CDEs in NIH-funded research.

Challenges to adopting CDEs. NIH seeks broad input on barriers to adopting CDEs in the context of both research activities generally and COVID-19 research specifically.

- a. Describe the major barriers you have encountered in using CDEs.
- b. Provide specific examples of challenges you have encountered in identifying and/or using CDEs in your research.
- c. Describe why you have or have not chosen to use CDEs in your research.

One barrier to the widespread utilization of common data elements (CDEs) in research is the lack of sufficient funding for the development of disease-specific CDEs. Where such CDEs exist, our members report that they are enormously valuable in the context of a variety of research projects, and numerous research areas would benefit from the development of dedicated CDEs. However, the development of useful CDEs across research areas is a challenging task that requires broad engagement from research teams and consensus-building. We are not aware of Funding Opportunity Announcements (FOAs) to support the development of CDEs and recommend that the National Library of Medicine (NLM) work with the institutes and centers to support consensus-building efforts to design CDEs that are applicable to specific diseases. To ensure that these CDEs achieve widespread adoption by the research community, NIH guide notices should refer to existing CDEs to encourage their use.

While disease-specific CDEs are warranted, there is also a need for CDEs that are applicable to cross-cutting research topics. In particular, CDEs that relate to social determinants of health (e.g., distance to nearest pharmacy, ability to afford medications) and related parameters (e.g., mental health, quality of life) are applicable to clinical research interests across disciplines. These elements are particularly relevant in the context of the COVID-19 pandemic, which has further exposed and exacerbated longstanding health disparities. We urge NLM to develop CDEs for social determinants of health for COVID-19 research, and work across NIH to ensure that these CDEs are also useful for research exploring health disparities across other research areas.



CDE guidance, tools, infrastructure, and incentives. NIH seeks broad input on what guidance, tools, and incentives would facilitate wider uptake of CDEs.

- d. Suggest specific guidance or information that would enhance your understanding and use of CDEs.
- e. Describe how the [NIH CDE Repository](#) could be enhanced to facilitate discovery and use of relevant CDEs.
- f. Describe resources that would enable use of CDEs, such toolkits for including CDEs in studies or tools that support researchers' mapping existing data to CDEs.
- g. Describe incentives that would encourage and increase use of CDEs.
- h. Provide specific examples of questions you have about how to identify, select, deploy and use CDEs.

To facilitate understanding and use of CDEs, it would be helpful to identify common sets of questions that can inform the development of CDEs across research topics, for example medical history or other instruments that are in widespread use and can be easily surveyed by the institutes and centers. Further, it would be helpful for NIH to identify an office or that is charged with driving the agenda for CDEs or implementing proposals identified in earlier questions. A office that serves as a central point of contact would further facilitate engagement, learning, and adoption of CDEs. We acknowledge NLMs lead role in maintaining and curating the CDE repository and encourage NIH to coordinate efforts across the NIH ICs to promote the use of CDEs among the research communities supported by the different ICs.

To facilitate discovery and use of relevant CDEs, the repository should become a more interactive platform that encourages users to contribute to the resource. Outreach to investigators will continue to be important to ensure that they know of the resource and understand how the CDEs can be used in their research. NLM should survey researchers across the ICs according to the CDEs currently in the repository to gather information on how the CDEs are used and the publications that they contributed to.