Endocrine Society comments in response to NOT-OD-24-063. "Request for Information (RFI): Proposed Use of Common Data Elements (CDEs) for NIH-Funded Clinical Research and Trials."

Introduction

Common Data Elements (CDEs) are standardized questions used to collect information for data analysis and exchange for clinical research and clinical trials to ensure consistent data collection. The National Institutes of Health (NIH) is seeking feedback on CDEs that will shape the minimum core set of CDEs and streamline data collection through their Request for Information (RFI): Proposed Use of Common Data Elements (CDEs) for NIH-Funded Clinical Research and Trials. The following comments were developed by the Endocrine Society's Research Affairs Core Committee and submitted via an online submission form.

Comments submitted electronically via online submission form on April 24, 2024.

1. Recommended CDEs for NIH-funded clinical research/trials, including a set of minimal core CDEs.

Please provide comments on CDEs for clinical and research domains and high-level CDEs for the SDoH domain.

In response to the previous NIH RFI on the Use of Common Data Elements (CDEs) in NIH-funded research, the Endocrine Society recognized the need for CDEs that identify social determinants of health (SDoH). In the current proposal, we welcome the acknowledgement of the importance of SDoH and how they can shape patients' health outcomes. We note that some of the examples of high-level CDEs can potentially intersect with one another and generate confusion. For example, the question that asks about access to household needs such as clothing, housing, and food can intersect with other SDoH such as stress of poverty or an adverse life event and create confusion or redundancy for the patient and patient data. Further refinement of questions regarding topics such diet and accessibility to food sources such as grocery stores, convenience stores, or farmers markets would be beneficial along with the refinement of the question on environmental exposure to specify the type of exposure (noise, toxins, etc.) and the method of exposure (workplace, household, air, self, etc.) To better evaluate the proposed CDEs and ensure meaningful data is collected from patients, it would be helpful for NIH to provide examples of permitted responses for each SDoH element. Providing examples of responses will ensure that researchers are able to effectively use the CDEs as intended and compare results across different studies. Finally, one area of SDoH not listed in the example questions that should be considered for addition is to collect information about access to areas for physical fitness such as community gyms or proximity or access to green spaces, as these can shape a person's level of physical activity and overall physical health.

Please provide suggestions on alternative approaches to determining a set of minimum core CDEs which might be required for all NIH funded or conducted clinical research/trials, as well as whether any categories of importance to research across the NIH that were missed.

We urge NIH to consider an approach that explicitly recognizes women's health, consistent with the recent White House Executive Order. While we appreciate the importance of common core CDEs suitable for all sexes and genders, collecting information on elements specific to women such as parity, lactation, age at puberty, and age at menopause, is important because of their

roles in predicting women's health outcomes as they age. We note Dr. Carolyn Mazure's statement at the recent NIH Advisory Committee on Research on Women's Health as the chair of the White House Women's Health Research Initiative, highlighting the need for CDEs that impact women's health research and the potential power of collecting this information to shape research across federal agencies. We support the call for women's health focused CDEs and appreciate the benefit this would have for endocrine science.

3. NIH policies and governance on CDEs. NIH seeks input on policies and governance that could facilitate and incentivize broader CDE usage in research and in data sharing and management. Please provide your feedback on:

Useful policies and governance regarding CDEs for data sharing and management.

We appreciate the benefit of a centralized NIH-wide CDE repository to select and manage the minimum core CDEs that capture standardized information across all NIH and NIH-funded clinical research/trials. We suggest that for disease-specific CDEs, NIH collaborate with relevant ICs to issue RFIs for disease-specific CDEs under the IC's management. For the diseases that span multiple ICs, relevant ICs should form partnerships to develop and maintain CDEs for those diseases. This approach of creating centrally managed minimum core CDEs followed by disease-specific CDEs will help researchers efficiently discover CDEs specific to their field of research.

While we appreciate that the current RFI is focused on clinical research, we emphasize that the need for CDEs transcends the need for standardization, accessibility, and uniformity in clinical research/trials. CDEs are also important for basic science research. Basic science research would benefit from having CDEs that clearly communicate experimental research assays with sufficient details and protocols. For instance, protocol details such as time of collection of samples should be collected to identify potential alterations in circadian rhythm. Similarly, researchers should have common ways to report materials such as rodent diet for experiments involving nutrition, energy, and metabolism, as diet can have significant effects on experimental outcomes. Collection of assay descriptions and details using common elements and standardized language would also help researchers with data comparisons and address reproducibility issues.