

Office of Rare Diseases Research Global Rare Diseases Patient Registry and Data Repository-GRDR

Common Data Elements

Goal

The Office of Rare Diseases Research (ORDR), within the National Institutes of Health (NIH), has established a committee to develop a set of common data elements (CDEs) for patient data entry to be used in any rare disease registry in conjunction with the Global Rare Diseases Patient Registry and Data Repository-GRDR that is being developed through the ORDR. The goal is to recommend a set of required CDEs that can be used in any rare disease registry. The list of the CDEs is divided into 10 different categories, for example, current contact information, socio-demographic information, diagnosis, and family history.

Purpose

CDEs are necessary to ensure that data are defined in the same way and use the same standards and vocabularies. The use of CDEs facilitates the standardization of data entry, allows sharing and exchange of information across registries and diseases, and facilitates various analyses and studies of specific rare diseases.

These CDEs are not intended to address the needs of a specific rare disease registry. These CDEs are designed to capture the information at a minimum level of detail that is needed for all or most clinical rare diseases. A specific registry could choose to use a more precise level of detailed information for a data element. If that is done, however, it should map to the original CDE. For example, if more detail is desired for “How diagnosis was made,” it can be added to the permissible values but it should map to “How diagnosis was made.”

Future steps will include the development of CDEs for rare disease-specific related organ systems and for data entry/reporting by clinicians, other health care professionals, and researchers. All future recommended CDEs will be established in collaboration with the various NIH Institutes and Centers and other professional patient organizations that have already developed related CDEs or are in the process of developing them.

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Background

In January 2010, a workshop entitled ***Advancing Rare Disease Research: the Intersection of Patient Registries, Biospecimen Repositories, and Clinical Data*** launched the development of an Internet-based federated GRDR to link already existing registries, future registries, and biorepositories.

More information on *Advancing Rare Disease Research: The Intersection of Patient Registries, Biospecimen Repositories, and Clinical Data* is available at: http://rarediseases.info.nih.gov/PATIENT_REGISTRIES_WORKSHOP/