CURE SICKLE CELL.

Overview and Instructions
Cure Sickle Cell Initiative (CureSCi) Common Data Element (CDE) Project
Public Review

The Cure Sickle Cell Initiative (CureSCi) Standard Forms/Common Data Elements (CDEs) Working Groups have released a draft version (Pre-Release of Version 1.0) for public review. The groups are in the process of finalizing these documents and strongly encourage input during this public review period. Information about the CureSCi CDE project can be found at https://curesickle.org/datatools-overview.

Overview: The goals are to support the National Institute of Health (NIH) data-sharing roadmap and address challenges of varied data collection standards and difficulties in comparing between studies. CDEs are recommended by the NIH Strategic Plan for Data Science to improve data quality, facilitate collection of data, data-sharing and comparison and reduce study start-up time and overall study cost.

Classifications: The CDEs are given a classification (*Figure 1*) for their use in clinical research genetic studies in sickle cell disease (SCD).

Disease Core: Data element should be collected in any sickle cell study. It is anticipated that investigators will need to collect the Disease Core CDEs.

Core: Data element that collects essential/required information based on the current clinical research best practices. If these elements are absent/lacking, it may impact the utility of the domain. These have been used previously in SCD studies and are required should the study design involve this domain as an important target outcome. Validated measures were used when available.

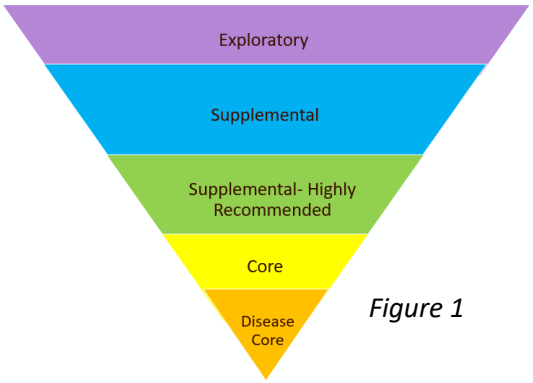

Figure 1

Supplemental-Highly Recommended: Data element that is important for study design or protocol but not required for collection.

Supplemental: Data element which is commonly collected in clinical research studies. Use depends upon the study design, protocol or type of research involved.

Exploratory: Data elements that require further development but address gaps in data reporting and/or could substitute for an existing element after validation. These type of data elements show promise but require validation before they are ready for standard use in clinical research studies.

Instructions: The Public Review Package contains the following documents:

- Overview and Instructions (current document)
- Materials prepared by the working groups, which include:
  - Working Group Summaries
  - Case Report Forms[1]
  - Instrument Recommendations (or hyperlinks to the measures)
- Roster of contributors
- Comments spreadsheet which can be filled out and sent to CureSCinfo@emmes.com

Please send all comments by **January 31, 2021.**

After this comment period, the CureSCi Standard Form/CDE working groups will review and revise the recommendations. Version 1.0 of the CureSCi recommendations will be posted in Spring 2021.

[1] The Case Report Form (CRF) modules are template data collections that include the CDEs identified and defined by the working groups. Each CRF will have corresponding data dictionary to define the CDEs on the form.