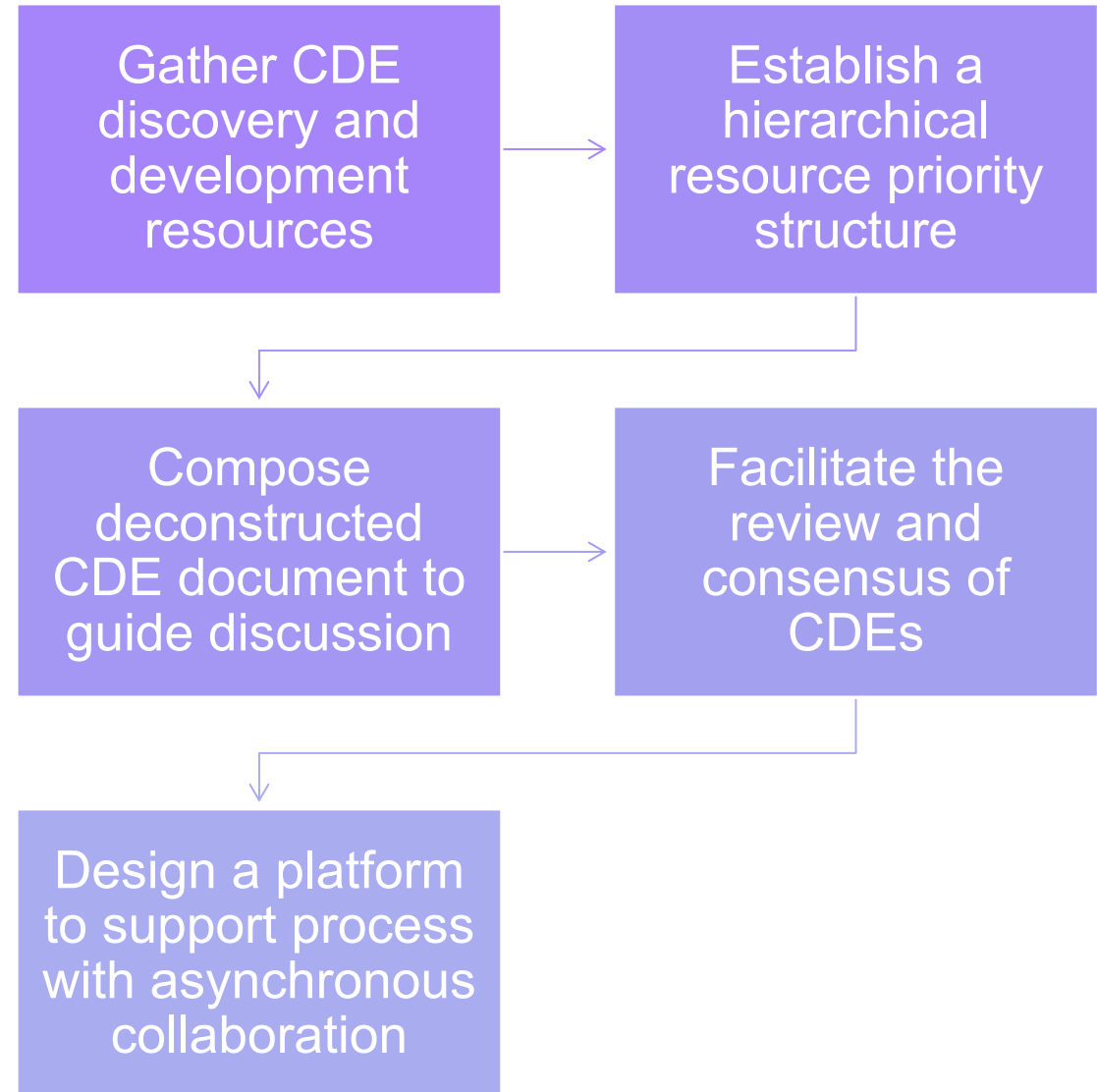


Presentation by Elliot Bearden and Geovani Castro

Project 5: Supporting Collaborative CDE Development

Trans NIH Project 5 Goals



CDE Development Process

- **Step 1:** Establish CDE Labels to Guide Research
- **Step 2:** Define CDE Label Terms
- **Step 3:** Search for Related CDEs and Protocols (In Order of Resource Priority)
- **Step 4:** Formatting, Organization, and Communicative Notetaking (Discussion Template)
- **Step 5:** Review and Revisions

CDE DISCOURSE TOOL: DISCOVERY PROCESS INTRODUCTION AND USER GUIDE

THE PURPOSE OF THIS GUIDE IS TO BOTH INTRODUCE THE CURRENT PROCESS OF CDE (COMMON DATA ELEMENT) CANDIDATE DISCOVERY AND PROVIDE A STEP-BY-STEP GUIDE TO USING THE DISCOURSE TOOL TO SUBMIT AND VOTE ON PROPOSED CDES.

INTRODUCTION

The goal of CDE discovery process is to curate a list of existing resources (and new protocols) to propose to promote the harmonization of HHS data resources; as such, this procedure quite long and requires attention to detail to execute efficiently. In light of this, the Project 5 team has constructed a template to standardize and format results in the [CDE Discussion Document Template](#); this template also includes descriptions for each column and the color legend for sources reported.

STEP 1: ESTABLISH CDE LABELS TO GUIDE RESEARCH

The first step in the procedure for discovering existing CDEs to propose for adoption (or developing concepts for new CDEs) is to understand what non-mandatory subject attributes you would like to capture; fortunately, Project 5 has a preordained list of CDE labels to start with, to ensure that scope is implied prior to conducting cursory research. These labels are released periodically and can be obtained with approval from Denise Warzel or Deborah Duran.

STEP 2: DEFINE CDE LABEL TERMS

Next, it is important to establish clear and concise definitions of the terms constructing each CDE label to ensure you understand what the intended meaning is for each; one of the largest repositories that proves extremely useful for this step is the NCI (National Cancer Institute) Thesaurus website.

STEP 3: SEARCH FOR RELATED CDES AND PROTOCOLS (IN ORDER OF RESOURCE PRIORITY)

After you have defined the CDE labels you can move on to leveraging the resources available to search for exact (or related) CDEs and Protocols. It is important to note that the NIH (National Institute of Health) sub-institutes work to achieve the same central mission by carrying out their own individual objectives. This means that that one institute considers extremely important may be less of a priority to another, which underscores the importance in the diversity of the source of the proposed CDEs and harmonization with widely used data elements.

To that effect, the recognized set of resources used by Project 5 are the following (in order of precedence):

- [RADxUP Data Harmonization Guidance](#)
- [HHS COVID-19 Guidance](#)

CDE Consensus Tool: Prototype Design and Development

- **Goal:** Serve as a solution to the pain points of the cross-IC collaboration process
- **Contribute:** Simple interface to create CDEs
- **Version:** Paging through different versions of CDEs
- **Collaborate:** Facilitate consensus with live voting and feedback threads

Person Focused Set 2 (Marriage and Sex) Tier 2

1.0 2.0 3.0 4.0

Choose File no file selected

Label: Self-Identified Gender

CDE Name	CDE Name
Gender Identity	Gender Identity (Transgender/Non-binary Identity)
Specification	Specification
1a. What terms best express how you describe your gender identity? (Check all that apply)	1b. Are any of these a closer description to your gender identity?
<ul style="list-style-type: none">• Man• Woman• Non-binary• Transgender• None of these describe me, and I'd like to consider additional options• Prefer not to answer	<ul style="list-style-type: none">• Trans man/Transgender Man/FTM• Trans woman/Transgender Woman/MTF• Genderqueer• Genderfluid• Gender variant• Questioning or unsure of your gender identity
Collection	Collection
Self-Report	Self-Report
Source	Source
RADx [All of Us Research Program PPI]	RADx [NIH SGMRO]
Definition	Definition
NCIt and CDISC: Gender Identity (Code C158277) – Definition: A person's internally held sense of their gender, which may or may not correspond to the individual's genotypic or phenotypic sex.	NCIt and CDISC: Gender Identity (Code C158277) – Definition: A person's internally held sense of their gender, which may or may not correspond to the individual's genotypic or phenotypic sex.
Vote	Vote
Current vote count is: 1	Current vote count is: 1
<input type="button" value="No"/> <input type="button" value="Yes"/>	<input type="button" value="No"/> <input type="button" value="Yes"/>

CDE Consensus Tool: Product Management

- Goal: Prepare consensus Tool for adoption by creating a model user guide
- Discovery Process Guidance (green)
 - Detail clear and concise directives for CDE discovery
- Consensus Tool User Guide (blue)
 - Guide user signup
 - Introduce the collaboration platform and features

DISCOURSE APPLICATION USER GUIDE (INSTITUTE SUBJECT MATTER EXPERTS AND SPECIALISTS)

THIS SECTION ENUMERATES STEPS FOR IC SUBJECT MATTER EXPERTS AND OTHER SPECIALISTS TO PARTICIPATE IN THE PROPOSAL, REVISION, AND APPROVAL PROCESS THAT WILL BE FACILITATED ON THE CDE CONSENSUS/DISCOURSE TOOL IN THE FUTURE.

INTRODUCTION

The goal for the CDE Consensus/Discourse Tool is to facilitate the review of proposed data elements in a web interface to enable persistent versioning of tier sets and allow asynchronous collaboration and communication to reach consensus for proposals.

STEP 1: CREATE AN ACCOUNT

To start, create an account on the site:

Next, navigate to your email application and click the activation link present in the email you have received from the app.

STEP 2: LOG INTO THE TOOL

Once you have activated your account, log in with the username and password you have set:

(Optional): Navigate to your profile page to fill out details regarding your role, IC, and preferred name:

STEP 3: NAVIGATE TO THE OPEN TIER AND SET THAT YOU ARE REVIEWING

Once you have logged in, you can navigate to the [CDE Set Directory] to view the open sets that are pending, and click on the one you desire to contribute feedback to:

STEP 4: REVIEW THE SET LABELS AND CONTRIBUTE FEEDBACK

Once you have been redirected to the collaboration page, you can scroll to view different versions of the labels in the sets to review; it is here that you can vote on versions that you support, and comment in the field below to provide feedback, suggestions, or support for proposed items:

CDE Consensus Tool: Next Steps

- Software Development

- Complete web app and optimize responsiveness
- Select platform for version control and CI/CD
- Allocate resources for staging environment (QA)
- Deploy web application to production

- Product Management

- Finalize discovery process guide
- Add prototype final version screenshots
- Define change management for documents
- Implement user survey system for platform on launch

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Thank you for
listening!