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Public reporting burden for this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0648). Do not return the completed form to this address.

Pre-test Questions:

- 1. Can you tell us about yourself and your experience with CDEs & the repository?
- 2. Do you use the NIH CDE Repository website regularly? If not, Which *CDE* websites do you use and why?
 - a. How often do you visit these websites?
 - b. What do you like/dislike about these websites?
- 3. How do you usually prepare your clinical research forms?
- 4. Home page Questions
 - a) Having now seen the home page, what is your initial reaction? What is your opinion of the design and content?
 - b) If you visited this page, which link would you start with? Why? What would you expect?
 - c) Without clicking, describe the options you see? What do you think they are for? Any
 - d) Is there anything that stands out? Why do you say this?
 - e) Is there anything you would have expected/wanted/needed to see on this page that is not here?
 - f) Is there anything you like/dislike? Why do you say this?
 - g) Is there anything unclear? Why do you say this?
 - h) Do you think the sample content available is helpful and engaging? Why do you say this?

Task based usability testing

Activity #1, Find CDE and Export

Goal/Output:	Understand findability and learnability				
Inputs:	CDE Name "Race"				
Steps:	1. Go to the NIH CDE R website (Starting Point)				
	2. Click on CDEs link in the header				
	3. Search for "race"				
	4. Click on the 3 rd CDE "Race" with "LOINC" identifier				
	5. Click on "Export" button				
	6. Click on "JSON or XML" (Finish Point)				
Success	Exporting the "Race" CDE as in JSON or XML format				
Criteria:					
Notes:					

Scenario:

You are working on a new research project and you need to collect race data using LOINC codes. Go to the NIH CDE Repository website and export the appropriate "Race" CDE.

- 1. Where would you start to look for this information?
- 2. What keyword are you specifically looking for?
- 3. Upon finding the page, is this what you expected?
- 4. Is this where you expected this information to be?
- 5. What do you think about the page layout? Why do you say that?
- 6. How did you find this task? Was this an easy/difficult task? Why do you say this?
- 7. Can you suggest any improvements?

Activity #2, Find Form and Export

Goal/Output:	Understand findability and learnability			
	 Understand the ability to export forms for different formats 			
Inputs:	Form Name "Demographics"			
Steps:	1. Go to the NIH CDE R website (Starting Point)			
	2. Click on Forms link in the header			
	3. Search for "Demographics"			
	4. From the filters panel, click on "NINDS"			
	5. Select the form			
	6. Click on "Export" button			
	7. Select and click on "FHIR Questionnaire" (Finish Point)			
Success	Exporting the "Demographics" form as FHIR Questionnaire format			
Criteria:				
Notes:				

Scenario:

Your team is working on an existing clinical research project for the National Institute of Neurological Disorders and Stroke (NINDS) that utilizes FHIR standards. You were tasked to find an existing demographics form that has at least 30 questions. **Go to the NIH CDE Repository website and export an appropriate "Demographics" form.**

- 1. Where would you start to look for this information?
- 2. Upon selecting this page, what do you think of the layout and information on the page?
- 3. Is there anything unclear?
- 4. Have a read of the information. Do you think the copy is clear and easy to follow?
- 5. Is there enough information?
- 6. How did you find this task? Was this an easy/difficult task? Why do you say this?
- 7. Can you suggest any improvements?

Activity #3, Find CDE source

Goal/Output:	Understand how the users evaluate the credibility of the CDEs				
Inputs:	CDE "Gender Code"				
Steps:	1. Go to the NIH CDE R website (Starting Point)				
	2. Click on CDEs link in the header				
	3. Search for "Gender Code"				
	4. From the filters panel, click on "Qualified" from the registration				
	status group				
	5. From the filters panel, click on "NCI" from the Classification				
	group				
	6. From the table				
	a. The user can Identify the CDE source; or				
	b. Click on the CDE				
	i. From the General Details, the user can find the				
	CDE source				
Success	Finding and identifying the "caDSR: 2179640 v1" CDE source				
Criteria:	(additional measures of success will be evaluated across all activities,				
	see PowerPoint document for additional measures of success)				
Notes:					

Scenario:

Your team is working on clinical research for the National Cancer Institute (NCI), and you were asked to find a qualified Gender Code Common Data Element (CDE). **Go to the NIH CDE**Repository website, find a qualified Gender Code CDE, and identify the source of the CDE.

- 1. Where would you start to look for this information?
- 2. What keyword are you specifically looking for?
- 3. Is this what you would expect? Why do you say this?
- 4. What do you think of the layout of this page?
- 5. Is this a useful tool? Is this something you are likely to use? Why do you say that?
- 6. Are there any other features would you expect or like to find?
- 7. How did you find this task? Was this an easy/difficult task? Why do you say this?
- 8. Can you suggest any improvements?

Activity #4, Find CDE Linked Forms

Goal/Output:	Understand the use of research tools and scales				
Inputs:	CDE "Feeling down, depressed, or hopeless in last 2 weeks" page				
Steps:	Go to the CDE page (<u>Starting Point</u>)				
	2. Click on CDEs "Linked Forms" button on the page				
Success	Finding and Identifying how many forms are linked to the "Feeling				
Criteria:	down, depressed, or hopeless in last 2 weeks" CDE.				
	Answer: 4 forms				
	(additional measures of success will be evaluated across all activities				
	see Powerpoint document for additional measures of success)				
Notes:					

Scenario:

You are working on clinical research and you want to know if the "Feeling down, depressed, or hopeless in last 2 weeks" CDE is used in other clinical research. How many forms use the "Feeling down, depressed, or hopeless in last 2 weeks" CDE?

- 1. Where would you start to look for this information?
- 2. What keyword are you specifically looking for?
- 3. Is this what you would expect? Why do you say this?
- 4. What do you think of the layout of this page?
- 5. Is this a useful tool? Is this something you are likely to use? Why do you say that?
- 6. Are there any other features would you expect or like to find?
- 7. How did you find this task? Was this an easy/difficult task? Why do you say this?
- 8. Can you suggest any improvements?

Activity #5, Find CDE Used By

Goal/Output:	Better understand the navigation system and findability				
Inputs:	CDE "Person Birth Date" page				
Steps:	1. Go to the CDE page (Starting Point)				
	2. Identify the organization name				
Success	Finding and identifying the organization name for "Person Birth Date"				
Criteria:	CDE.				
	Answer: NINR NCI				
Notes:					

Scenario:

You are examining the "Person Birth Date" common data element. Find the name(s) of the organization(s) that used the CDE.

- 1. Where would you start to look for this information?
- 2. Is there anything unclear or unexpected?
- 3. How did you find this task? Was this an easy/difficult task? Why do you say this?
- **4.** Can you suggest any improvements?

Activity #6, Find "More like this" CDE

Goal/Output:	Understand the navigation system and findability			
Inputs:	CDE "Body Weight" page			
Steps:	1. Go to the CDE page (Starting Point)			
	2. Click on CDEs "More Like This" button on the page			
Success	Finding and identifying how many similar.			
Criteria:	Answer: 10 CDEs			
Notes:				

Scenario:

How many CDEs are similar to the "Body Weight" CDE?

- 1. Where would you start to look for this information? Where would you expect it to be?
- 2. Having found this information, is it what you expected? Why do you say this?
- 3. Is there anything unclear or unexpected?
- 4. How did you find this task? Was this an easy/difficult task? Why do you say this?
- 5. Can you suggest any improvements?

Activity #7, Compare CDE

Goal/Output:	 Understand how the end users interact and pick a specific CDE Understand usage of unique forms 					
Inputs:	No input					
Steps:	 Go to the website home page (Starting Point) Find 2 CDEs through the search page a. Export the results i. Compare the results b. Compare the results on the page Add the CDEs to board a. Export the result i. Compare the results b. Compare the result on the page 					
Success Criteria:	Find the CDEs and compare them					
Notes:						

Scenario:

You are interested in comparing the permissible values of two or more CDEs. **Using the website, compare two or more CDEs' permissible values.**

- 1. Where would you start to look for this information? Where would you expect it to he?
- 2. Having found this information, is it what you expected? Why do you say this?
- 3. Is there anything unclear or unexpected?
- 4. How did you find this task? Was this an easy/difficult task? Why do you say this?
- 5. Can you suggest any improvements?

Post-test Survey

1. System Usability Scale

Thinking about the NIH CDE Repository website, how much do you agree or disagree with each of the following statements:

Questions	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
I think that I would like to use this					
system frequently					
I found the system unnecessarily					
complex.					
I thought the system was easy to use.					
I think that I would need the support of					
a technical person to be able to use this					
system.					
I found the various functions in this					
system were well integrated.					
I thought there was too much					
inconsistency in this system.					
I would imagine that most people would					
learn to use this system very quickly.					
I found the system very cumbersome to					
use.					
I felt very confident using the system.					
I needed to learn a lot of things before I					
could get going with this system.					

Ask if they have any further comments

Tasks
See Worksheet to develop tasks for testing on how to create tasks from the user stories.

Index	Starting point	Instruction to participants	What to observe	Focus on issue
Index	Starting point	Instruction to participants	What to observe	Focus on issue
Т0	Interview	Please share with us what do you do. How much do you already know about NLM CDE Repo?		
T1	Browser starting page	You are working on a new research and you need to find a common data element to measure blood pressure. You have been told to use the CDE Repository to find one. • What can you do on this site?	 Website findability 	
T2	CDE home → Search vs browsing		If browsing or searching is used Prompt participant to browse if needed	2
Т3	CDE results → Narrow down of results	What will you do to narrow down the results?	Filter usability	1
T4	CDE results	Which one will you choose? Why?	What do users think/do when there are many identical or similar elements?	1

Index	Starting point	Instruction to participants	What to observe	Focus on issue
Index	Starting point	Instruction to participants	What to observe	Focus on issue
T5	Single CDE display	What information are displayed for this CDE ?	Tabbed display of a CDE page - visibility	4
Т6	CDE home	What will you do if you want to find how other studies have ask people about blood pressure?	Visibility of the forms search - visual and conceptual	3
Т7	CDE home		Browsing or searching Prompt participant to browse if needed	2
Т8	CDE form search results	Which one of the forms will you choose? Why?	recognization of the source	1
Т9	CDE form	What information are displayed for the form you've chosen?	Tabbed display usability	4