

Complete the following Practice Groups to learn how to use the OC Global Library System. This Practice includes instructions on Global Library Domains, Questions, Discrete Value Groups, and Question Groups.

Other objects that can be created at the study or Glib level are included in the appropriate Modules. DCMs/DCIs are included in the Study Definition Practice and Validation/Derivation Procedures are included in the Procedures Module.

The practices are identified within the presentation and should be performed following the appropriate section. Prior to starting the Practice you should have been assigned an ID. Make sure that the account with which you are working has access to the Glib Domains identified below.

Before beginning the exercises, browse through the Global Library menu items and note that for each Global Library object there are three sets of menus: standard, provisional and query.

- The Standard menu items are used by the Global Librarians to create and activate GLIB objects.
- The Provisional menu items are used to create provisional GLIB objects, which are later activated by the Global Librarians.
- The Query menu items are used solely to view GLIB objects that have already been created.

STUDENT ID =	<input type="text"/>
PRIMARY DOMAIN =	GLIB_<ID>

***\*Substitute your student ID for <ID> wherever it appears in the Practice.***

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**GROUP 1 - VERIFY DOMAIN ASSIGNMENTS**

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Perform the following steps to verify that you have access to the appropriate domains:

1. Navigate to the Define User Domain Searchlist screen.

**Menu Path:** Admin ⇨ Glib Admin ⇨ User Domain

2. Verify that only your domain is listed in the Domain field. Delete any domains that are not identified at the beginning of this practice. Save.
3. Navigate to the Questions module.

**Menu Path:** Glib ⇨ Questions ⇨ Questions

4. Select Special, Define Domain Searchlist.
5. Verify that the same domains appear. Note that users may change their domain Searchlist order from any Global Library screen using this Special Menu.

## GROUP 2 - CREATE DISCRETE VALUE GROUPS

Perform the following steps to create the DVGs that are circled on the Demography CRF, G1, and the Physical Examination/Allergies CRF, G2.

1. Navigate to the Maintain Provisional Discrete Value Groups screen.

**Menu Path:** Glib ⇨ Discrete Value Grps ⇨ Prov Discrete Value Grps

2. Create the DVG for the YES NO responses (*CRF G2*). Save. The screen shot below displays the set-up for this DVG. Use the values identified in the following screen shot to create the DVG. Note that your domain will be different.

The screenshot shows the 'Maintain Provisional Discrete Value Groups' window. The title bar reads 'Maintain Provisional Discrete Value Groups'. The main window title is 'Discrete Value Groups'. The form contains the following fields and values:

- Name: YES NO
- Domain: STUD\_DEF
- Subset Number: 0
- Description: Yes No Responses
- DVG Type: GENERAL
- Thesaurus or Internal or Alpha: INTERNAL
- Status: P
- Subsettable?:
- Expandable?:
- Enter by Seq?:
- Resequence?:
- Upper Case?:
- Max Value Length: 15
- Retirement Reason: (empty)
- Status Comment: (empty)

Below the form is a table titled '<< Discrete Values >>':

Seq #	Value	Long Value	Active?
1	YES	YES	<input checked="" type="checkbox"/>
2	NO	NO	<input checked="" type="checkbox"/>
3	UNKNOWN	UNKNOWN	<input checked="" type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

At the bottom of the window are three buttons: 'Exit', 'Save', and 'Thesaurus'.

Notes:

- For the Thesaurus or Internal or Alpha field, enter INTERNAL if the DVG is assigned to a CHARACTER Question. If the DVG is to be assigned to a Question of Data Type NUMBER or DATE TIME, enter ALPHA. If the DVG is to be used as a Thesaurus DVG pointing to an external list of terms, enter THESAURUS.
- The Subsettable?, Expandable?, and Enter by Sequence? Fields can optionally be checked on or off depending upon the requirements for this DVG. These settings are not applicable to THESAURUS DVGs. Enter by Sequence is not applicable to ALPHA DVGs.
- Make sure that Max Value Length is equal to or greater than the longest acceptable value for the DVG.

3. Create Subset 1 for the DVG YES NO.
  - Select the menu Special → Create DVG Sub
  - Click Yes when prompted to create a subset of the current DVG.
4. Create Subset 2 for the DVG YES NO.
5. Modify Subset 2 so that only the Discrete Values YES and NO will be available during Data Entry. (Check off the Active? flag off for the Discrete Value UNKNOWN).
  - Change the description to something that more accurately describes this subset (e.g. Yes No only). This description is displayed in the Questions, Question Group Questions, and DCM Questions screen to allow the user to assign the desired subset to each question.
6. Create the other DVGs that have been circled on the Demography CRF, G1, and the Physical Examination/Allergies CRF, G2.

Use names for the DVGs that match your company's naming standards or if no standards exist use any reasonable name. Refer to the CRFs to identify the appropriate characteristics for each DVG.

- Make sure that the values are ordered the way they appear on the CRF.
  - Check Enter by Seq? only if you think it would be appropriate for Data Entry Operators to enter the sequence number instead of the actual values.
  - **Create at least one Subset for each DVG. The subset is required because only Subsets can be assigned to Questions.**
  - Check off the Active Flag for the values in subsets that are not required for the specific Question to which it is to be assigned.
7. The DVGs do not need to be activated in order to be assigned to Questions in the Global Library. They will, however, have to be activated by the Global Librarian in the Maintain Questions screen in order to be assigned to Questions at the Study level (DCM Questions) or before the Questions are activated.

**Note:** Upon activation, the system either creates subset 1 for each new DVG or activates the existing Subset 1.

## GROUP 3 - CREATE QUESTIONS

Perform the following steps to create the Questions that are boxed on the Demography CRF, G3, and the Physical Examination/Allergies CRF, G4:

1. Navigate to the Maintain Provisional Questions screen.

**Menu Path:** Glib ⇄ Questions ⇄ Prov Questions

2. Change to Single mode (click on Single). Create the DATE\_BIRTH Question (CRF G3) in your domain. Save.

The screenshot shows the 'Maintain Provisional Questions' window with the following fields and values:

- Question Name: DATE\_BIRTH
- Domain: TEST\_TRAIN2
- Status: A
- Medical Eval Type: DEMOGRAPHY
- Intent: Date of Birth
- Question Type: DATE TIME
- Data Type: DATE
- Date Time Type: DMY
- Date Time Format: DMY
- Length: 8
- Decimal Places:
- SAS Name: DTBRTH
- SAS Label: Date of Birth
- Safety Question?:
- Extract Macro: O\_DATE
- Derived?:
- Question Set Name:
- DVG> Mod?  Name:
- Domain:
- Sub#:
- Alpha DVG> Mod?  Name:
- Domain:
- Sub#:
- Lower Bound:
- Upper Bound:
- Valid. Failure Type: NORMAL
- Upper Case?:
- Sight Verify?:
- Default Prompt: Date of Birth
- Status Comment:
- Retirement Reason:
- Question Categories: DEMOGRAPHY, Demography

Buttons at the bottom: Exit, Save, Multi

3. Create the remaining Questions that are boxed on the Demography CRF, G3, and the Physical Examination/Allergies CRF, G4. Save.

- You can create the questions in single or multi mode (try both to see which works best for you).
- Use appropriate names for the Questions (there are no right answers - name based on Company Standards or your best judgment).
- Note that question names may not begin with numbers or have spaces.
- Assign SAS Names that are 6 characters or fewer. Use company conventions if they exist.

- Assign DVGs or Alpha DVGs where they are needed. To assign a DVG or Alpha DVG to a question, place the cursor in the DVG Name field or Alpha DVG Name field for the appropriate question and do one of the following:
  - Enter the Name directly.
  - Press F9 and select from the LOV (you can now see the DVG subset description)
  - Use the Special, Locate DVG function (this allows you to search the Global Library for all DVGs in accessible domains and assign one to the question).

**Note:** The DVG Modifiable? or Alpha DVG Modifiable? Flag must be checked on to allow the DVG or Alpha DVG to be assigned. After the assignment the Global Librarian can uncheck these fields to prevent the modification of the DVG at the Study Level.

4. The Medical Evaluation Type is automatically assigned as the Question Category. You can assign other categories if desired.
5. Note: Questions do not need to be activated to be added to Question Groups. They will need to be activated before the Question Group is activated and assigned to a DCM.

**GROUP 4 - CREATE QUESTION GROUPS**

Perform the following steps to create the Question Groups that are boxed on the Demography CRF, G5, and the Physical Examination/Allergies CRF, G6.

1. Navigate to the Maintain Provisional Question Groups screen.

**Menu Path:** Glib → Question Groups → Prov Question Groups

2. Create the Question Group DEMOGRAPHICS from the Demography CRF (G5). Enter the following values. Save.

<b>Question Group Name</b>	DEMOGRAPHICS
<b>QG Type</b>	DEMOGRAPHY
<b>Description</b>	General Demographics
<b>Expand?</b>	[Check On]

3. Create the remaining Question Groups that are boxed on the Physical Examination/Allergies CRF, G6, and save.

**Note:** Always make Question Groups Expandable if Questions may need to be added later at the study level.

4. Below are a list of the Question Groups from the attached CRFs that need to be created (Name the Question Groups as appropriate based on your company Standards). Note that Question Groups cannot have spaces in the names.

- VITAL SIGNS
- ALLERGIES
- PHYSICAL EXAM

**GROUP 5 - ASSIGN QUESTIONS TO QUESTION GROUPS**

Perform the following steps to assign Questions to the Question Groups created.

1. Select the DEMOGRAPHICS Question Group in the Maintain Provisional Question Groups screen.
2. Click on the Question Group Questions button.
3. Assign the Questions to the Question Groups as appropriate based on the attached CRFs.
  - **Method 1 - Manually**  
If you know the name of the Question, type it into the Question Name field.
  - **Method 2 - Using the LOV**  
Press F9 to bring up the LOV for Question names and search by the first letter of the Question names.
  - **Method 3 - Copying Questions** (This is the only way to copy multiple questions into a Question Group simultaneously)
    - Select Special > Copy Questions to display the Locate Questions screen.
    - Enter criteria to query, then press F8 to retrieve them.
    - Select the desired Questions by clicking the Sel field and click on OK.