

SOP-10 FITBIR Data Element (DE) Creation & Publication

The FITBIR Data Dictionary incorporates and extends the Common Data Element (CDE) definitions developed by the NINDS (National Institute of Neurological Disorders and Stroke) CDE Workgroup. The Data Dictionary also allows investigators to define the data they submit as well as provide alternate terms (aliasing) and translation rules for the same element.

Occasionally, research data may not align perfectly to the Common Data Elements. In this case, researchers may extend the Data Dictionary and create unique data elements (DE).

A data element is a logical unit of data, pertaining to information of one kind. A data element has a name, precise definition, and clear enumerated values (codes) if applicable. A data element is not necessarily the smallest unit of data; it can be a unique combination of one or more smaller units. A data element occupies the space provided by field(s) on a paper/electronic case report form (CRF) or field(s) in a database record.

Prerequisites:

1. Valid FITBIR account with Data Dictionary privilege
2. FITBIR Data Dictionary has been searched and **NO** CDE or DE describes/matches the desired data element

Procedure:

This procedure provides process steps for creating a data element request initiation, authorization, and validation. The entire procedure typically requires 1-3 business days (assuming Prerequisites are already met)

Data Element Request Initiation

1. Point your browser to the FITBIR website at <http://fitbir.nih.gov>.
2. Click the LOG INTO FITBIR tab.
3. There are two ways to find the Data Dictionary Tool:
 - a) Through Workspace -> Data Dictionary Tool

-OR-

 - b) Through the Data Dictionary tab in the top blue navigation
4. Launch Data Dictionary Tool
5. Click Create Data Element
6. Step 1. Edit Details: Fill in all required fields marked with an asterisk *

Note: For additional information about category groups and classification, redirect to <https://fitbir.nih.gov/jsp/define/dataElements.jsp> OR <http://www.commondataelements.ninds.nih.gov/#page=Default>

7. Click Continue when complete.
8. Step 2. Define the Data: Fill in all required fields with an asterisk *
9. Click Continue when complete
10. Step 3. Associate Keywords:
Note: There are no required fields; however, it is beneficial to associate keywords with a data element.
11. Click Save & Finish when complete.
12. A confirmation message will appear alerting you that the data element is in a draft state.

Data Element Publication Request Initiation

1. When ready to request publication, open the Data Dictionary tool.
2. Select the Search Data Elements option from the left hand menu.
3. Search for the desired data element and click on it once found.
4. Under Publication State, click the Request Publication link. The status is now changed to Awaiting Publication.
5. A message will appear under the Publication State heading along with the option to Cancel Publication.

Data Element Request Review and Authorization

1. FITBIR Staff review the information provided in the data element publication request.
2. FITBIR Staff verify that the data element does not already exist in FITBIR as a CDE or as another data element.
3. FITBIR Staff reviews the information and authorizes or denies the publication request.
4. The FITBIR Admin sends you an automated email message notifying you of the decision.

Data Element Publication Validation

1. Watch your email inbox for a message from FITBIR-help@nih.gov with subject "Request to publish data element has been approved/denied by an admin."
2. If the data element is approved for publication, the next time you log into FITBIR, it should be available for use in Form Structures.