**FITBIR Study Closeout Report**

**Study Name:**

**Study ID:**

**Principal Investigator:**

**Date:**

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# Purpose

The purpose of this report is to provide the results and FITBIR recommendations based on the following tasks performed for quality check:

1. **Demographic Information for GUIDs**
   1. Identify GUIDs that are present in other form structures, but are not present in the base file for comparison (the FITBIR Demographics form is usually used as the base file).
2. **Duplicate Entries within the Form Structure**
   1. Identify GUIDs that have the exact data submitted populated at least twice in the form structure.
3. **Partial Data Submitted within a Form Structure**
   1. Identify GUIDs that do not have data submitted to Data Elements that have been populated at least once.
4. **Scoring Validation for Form Structures**
   1. Scoring algorithms have been created for a subset of standard form structures in FITBIR based on the clinical assessment scoring guidelines.
   2. Identify GUIDs that have a difference in scoring as determined by the clinical assessment scoring guidelines.
5. **Check if GUID and Subject IDs are one-to-one**
   1. Check if each GUID is associated with one or more Subject IDs.
   2. Check if each Subject ID is associated with one of more GUIDs.

For questions about the report or results, please reach out to the study assigned FITBIR Point of Contact or FITBIR Operations ([fitbirops@mail.nih.gov](mailto:fitbirops@mail.nih.gov)).

# Closeout Analysis Folder Contents

Analysis files have been provided to you and will assist in making any necessary changes. Please look at the folder contents diagram below and read the file descriptions:

**Closeout\_Analysis**

***StudyID\_[StudyID]\_Closeout\_Analysis\_Summary\_Table.xlsx***

*Highlighting Key:*

* Empty Data Elements (*hidden*)
* Partial Data
* Duplicate Data
* GUID multiple Subject IDs
* Subject ID multiple GUIDs
* Extra-validation Error
* Sheet1 – *Summary Table*
  + Summary table of the closeout analysis.
* Sheet2 – *GUID-Subject ID Master List*
  + Master List of all GUIDs with data
* Sheet3 – *GUID multiple Subject IDs*
  + GUIDs with multiple Subject IDs across forms
* Sheet4 – *Subject ID multiple GUIDs*
  + Subject IDs with multiple GUIDs across forms

***FITBIR Study Closeout Report\_[PI name].docx***

**[StudyID]\_output\_excel\_files**

***StudyID\_[StudyID]\_[Form Structure]\_results.xlsx***

* Sheet1 – *All Submitted Data*
  + - All data submitted against this form (unflattened format).
      * Closeout findings highlighted (see highlighting key)
* Sheet2 – *Validation Report*
  + - resultDetails output from validation tool (ERRORS + WARNINGS)
      * \*Row/Column index reflects location in “*All Submitted Data*” tab
* Sheet3 – *Empty Data Elements*
  + - A list of data elements that have no subject data.
* Sheet4 – *DEs With Partial Data*
  + - For each DE that has partial data, the GUIDs with missing data are listed.
* Sheet5 – *Duplicated Data*
  + - Duplicate records are displayed.
* Sheet6 – *GUID Counts in this Form*
  + - The number of records per GUID in the form.
* Sheet7 – *[BaseFile] not in [Form Structure]*
  + - GUIDs in BaseFile but not in this Form Structure
* Sheet8 – *[Form Structure] not in [BaseFile]*
  + - GUIDs in this Form Structure but not in BaseFile
* Sheet9 – *GUIDs\_Mult\_SubjIDs*
  + - A list of GUIDs with multiple Subject IDs in this Form Structure
* Sheet10 – *SubjIDs\_Mult\_GUIDS*
  + - A list of Subject IDs with multiple GUIDs in this Form Structure

# Closeout Analysis Summary Table:

This summary table provides an overview of the quality check results.

# Closeout Analysis Details

Please provide your team’s response in **red** under each FITBIR comment or recommendation below.

## Demographic Information for GUIDs:

We have identified GUIDs that are present in the following forms, but not in the *DemogrFITBIR* form:

**FITBIR Recommendations:**

* Please review *Sheet7 – [BaseFile] not in [Form Structure]* and *Sheet8 – [Form Structure] not in [BaseFile]* of ***StudyID\_[StudyID]\_[Form Structure]\_results.xlsx***
* Please confirm if the list of GUIDs indicated above are to be included in the Demographics Form Structure. If not, please provide documentation reflecting explanation for the missing GUIDS.

## Duplicate Entries within the Form Structure:

The following form structures currently have duplicate entries:

**FITBIR Recommendations**

* Please review *Sheet 5 – Duplicated Data* of ***StudyID\_[StudyID]\_[Form Structure]\_results.xlsx*** and confirm the duplicate entries.
* To remove duplicate entries in FITBIR, please request the datasets to be archived prior to resubmission.

## Partial Data Submitted within a Form Structure:

Partial data have been submitted against all form structures.

**FITBIR Recommendations:**

* Please review *Sheet 4 – DEs with Partial Data* of ***StudyID\_[StudyID]\_[Form Structure]\_results.xlsx.***
* If there are data for the GUIDs, please provide the values. If there are no values for the GUIDs, please provide explanation for missing data for documentation

## Scoring Validation for Form Structures:

Validation errors were found in the following form structures:

**FITBIR Recommendations:**

* Please review *Sheet 2 – Validation Report* of ***StudyID\_[StudyID]\_[Form Structure]\_results.xlsx.***

## Check if GUID and Subject IDs are one-to-one

There is not a one-to-one correspondence between GUID and Subject ID in the following form structures:

**FITBIR Recommendations:**

* Please review *Sheet9 – GUIDs\_Mult\_SubjIDs* and *Sheet10 – SubjIDs\_Mult\_GUIDs* of ***StudyID\_[StudyID]\_[Form Structure]\_results.xlsx*** and provide a response to this discrepancy.
* You can also look at *Sheet2 – GUID multiple Subject IDs* and *Sheet3 – Subject ID multiple GUIDs* of ***StudyID\_[StudyID]\_Closeout\_Analysis\_Summary\_Table.xlsx*** for comparisons across all forms.