NDA Office Hours

QA Errors

March 2023





Who should be resubmitting data?

NDA expects you to resubmit data if your NDA Collection received a "QA Results" email from the NDA Help Desk.

IMPORTANT NOTICE: NIMH Data Archive (NDA) has identified one or more data quality issues in your data submission(s) from the 01/15/2023 submission cycle in NDA Collection C4218.

Your task is to correct the identified QA errors and resubmit your corrected data before you submit any new data.

IMPORTANT: Do not submit any new data in your QA resubmissions. New data should never be submitted until all known QA Errors have been resolved.

How to Resolve QA Errors:

- 1. Save your QA Results Report as a .csv file using the Viewing your QA Report instructions.
- 2. Review the QA errors found in your data submission(s) outlined in your QA Results Report.
 - If needed, <u>download previous submissions</u> to help you identify and resolve your errors. Your submission download will include a text file, QA_info.txt, outlining the QA errors in the submission.
- 3. Correct all QA errors in your data locally using the NDA suggested resolution for each error.
- 4. Resubmit your corrected data using our How to Provide Corrected Files guide.

Need Assistance?

<u>Register</u> for one or more NDA QA Office Hours to answer your questions about resolving each error and how to successfully resubmit your corrected data. If you have any questions you'd like answered during the session, please email them to the NDA Help Desk in advance.

Review our QA Resubmission FAQ if you can't make Office Hours or want more information!

Please reply to this email if you have any additional questions.

Regards, NIMH Data Archive Staff NDAHelp@mail.nih.gov

How to Read the QA Report

Open the QA results Report link in Step 1.

IMPORTANT NOTICE: NIMH Data Archive (NDA) has identified one or more data quality issues in your data submission(s) from the 01/15/2023 submission cycle in NDA Collection C4218.

Your task is to correct the identified QA errors and resubmit your corrected data before you submit any new data.

IMPORTANT: Do not submit any new data in your QA resubmissions. New data should never be submitted until all known QA Errors have been resolved.

How to Resolve QA Errors:

- 1. Save your QA Results Report as a csv file using the Viewing your QA Report instructions.
- 2. Review the QA errors found in your data submission(s) outlined in your QA Results Report.
 - If needed, <u>download previous submissions</u> to help you identify and resolve your errors. Your submission download will include a text file, QA_info.txt, outlining the QA errors in the submission.
- 3. Correct all QA errors in your data locally using the NDA suggested resolution for each error.
- 4. Resubmit your corrected data using our How to Provide Corrected Files guide.

Need Assistance?

Register for one or more NDA QA Office Hours to answer your questions about resolving each error and how to successfully resubmit your corrected data. If you have any questions you'd like answered during the session, please email them to the NDA Help Desk in advance.

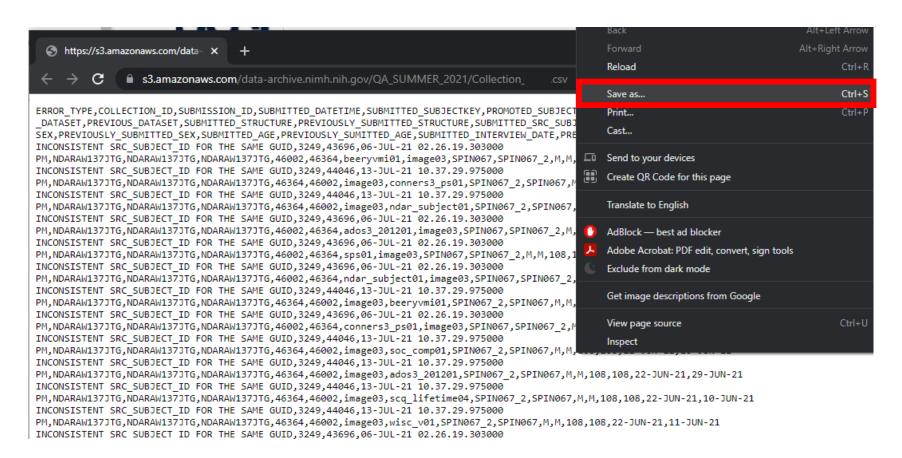
Review our QA Resubmission FAQ if you can't make Office Hours or want more information!

Please reply to this email if you have any additional questions.

Regards,
NIMH Data Archive Staff
NDAHelp@mail.nih.gov

How to Read the QA Report

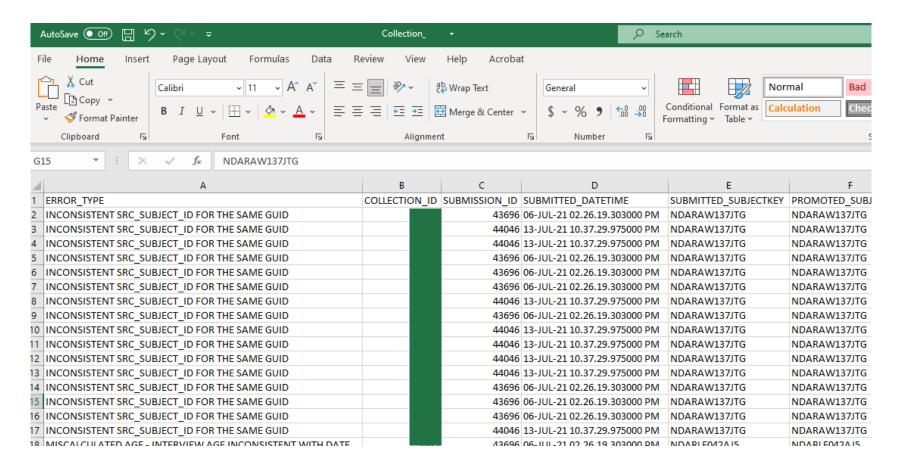
2. Right-click on the page and save the file as a .csv





How to Read the QA Report

Open the .csv file to view the errors





Use the How to Provide Corrected Files instruction guide linked in the QA Results email.

Your task is to correct the identified QA errors and resubmit your corrected data before you submit any new data.

IMPORTANT: Do not submit any new data in your QA resubmissions. New data should never be submitted until all known QA Errors have been resolved.

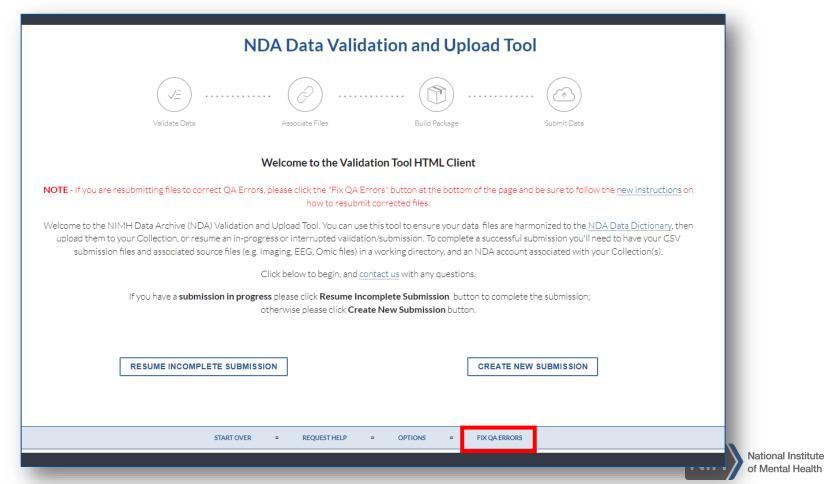
How to Resolve QA Errors:

- 1. Save your QA Results Report as a .csv file using the Viewing your QA Report instructions.
- Review the QA errors found in your data submission(s) outlined in your QA Results Report.
 - a. If needed, <u>download previous submissions</u> to help you identify and resolve your errors. Your submission download will include a text file, QA info.txt, outlining the QA errors in the submission.
- 3. Correct all QA errors in your data locally using the NDA suggested resolution for each error.
- 4. Resubmit your corrected data using our How to Provide Corrected Files guide.

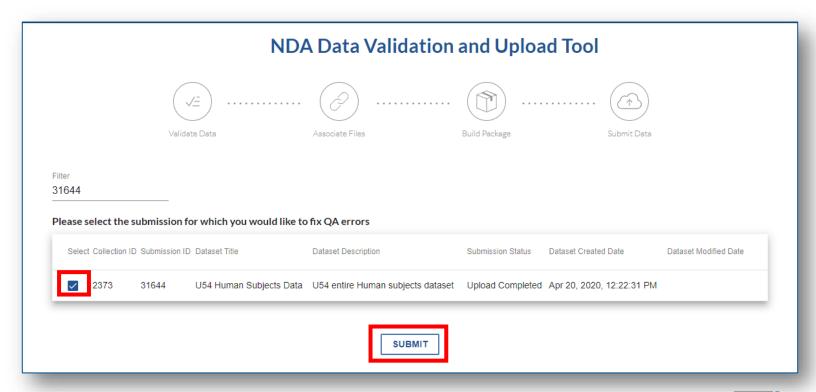
Need Assistance?



1. Launch the Validation and Upload Tool, then click "Fix QA Errors" in the right of the bottom banner

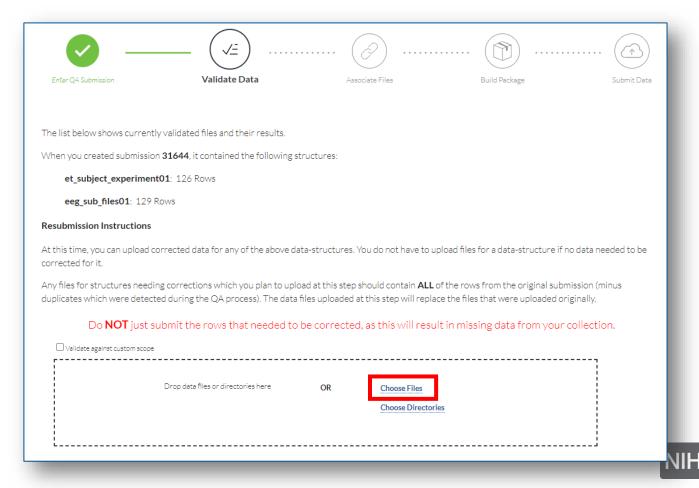


- 2. Select the submission in which you have corrected data and click "Submit"
 - Note that you can only resubmit for one submission at a time





3. Select "Choose Files" and choose your corrected data file(s), or you can drag and drop your files.



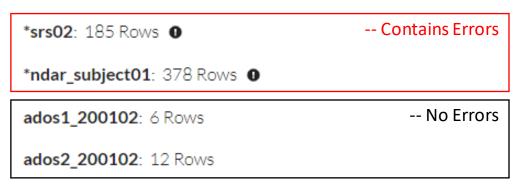
National Institute

Only resubmit data for data structures that contain errors.

Indicates data structure contains error

The list below shows currently validated files and their results.

When you created submission **35592**, it contained the following structures:



Only resubmit the srs02 and ndar_subject01 structure.



The same # of rows from the original submission must be uploaded in your resubmission.

When you created submission 35592, it contained the following structures:



Resubmission Instructions

At this time, you can upload corrected data for any of the above data-structures. You do not have to upload files for a data-structure if no data needed to be corrected for it.

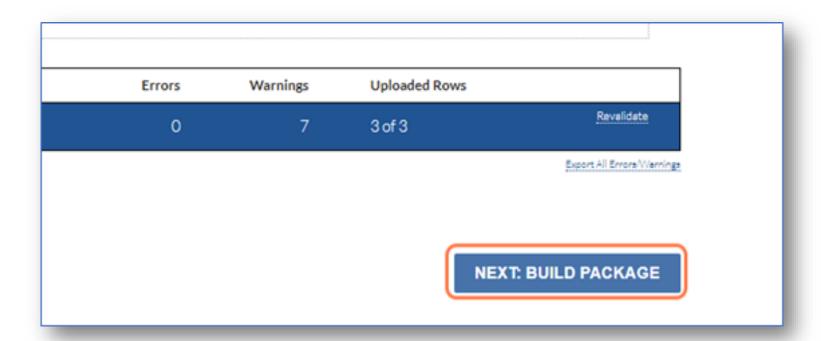
Any files for structures needing corrections which you plan to upload at this step should contain **ALL** of the rows from the original submission (minus duplicates which were detected during the QA process). The data files uploaded at this step will replace the files that were uploaded originally.

Do NOT just submit the rows that needed to be corrected, as this will result in missing data from your collection.



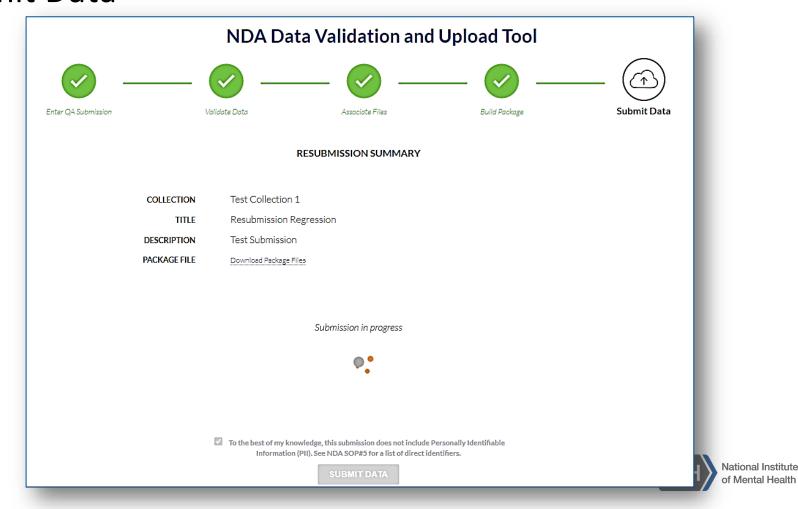
Export All Errors/Warnings

4. Once your files have validated with no errors, click "Next: Build Package"





5. Verify that your listed information is correct & click "Submit Data"



DUPLICATE RECORDS WITHIN A SUBMISSION

Error Description

Indicates identical data has been submitted for a subject within a data structure.

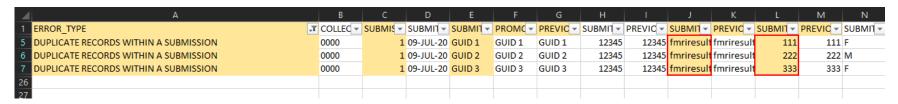
Suggested Action

- 1. Identify the duplicate subject using the SUBMITTED_SRC_SUB JECT_ID value (column L)
- 2. Remove the duplicate record from the data structure
- 3. Resubmit your data

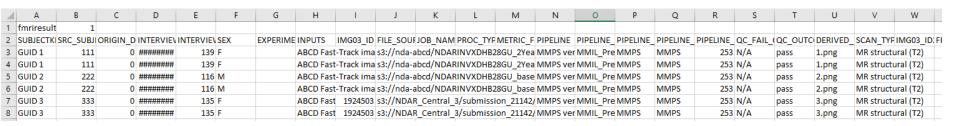


DUPLICATE RECORDS WITHIN A SUBMISSION

Error Report



Submission Template with Error



Corrected Submission Template

4	Δ	В	С	D	F	F	G	н	1	J	K		М	N	0	р	0	R	S	Т	U	V	W	X	γ	7
1 f	mriresult	1					_		•	_	.,	_													•	_
			ORIGIN D	INTERVIEV	INTERVIEV	SEX	EXPERIME	INPUTS	IMG03 ID	FILE SOUR	JOB NAM	PROC TYP	METRIC F	PIPELINE	PIPELINE	PIPELINE	PIPELINE	PIPELINE	QC FAIL	QC OUTO	DERIVED	SCAN TY	IMG03 ID	FILE_SOUF	SESSION I	IMAGE HI
	GUID 1	111		***********	139							RINVXDHB2					MMPS	253		pass		MR struct				gradient ur
4 6	GUID 2	222	0	***********	116	M		ABCD Fast	-Track ima	s3://nda-a	bcd/NDA	RINVXDHB2	8GU_base	MMPS ver	MMIL_Pre	MMPS	MMPS	253	N/A	pass	2.png	MR struct	ural (T2)		ABCD-MPI	gradient ur
5 6	GUID 3	333	0	########	135	F		ABCD Fast	1924503	s3://NDAF	Central_	3/submissi	on_21142/	MMPS ver	MMIL_Pre	MMPS	MMPS	253	N/A	pass	3.png	MR struct	ural (T2)		ABCD-MPI	gradient ur
6																										
7																										
8																										



MISCALCULATED AGE - INTERVIEW AGE INCONSISTENT WITH DATE

Error Description

Indicates different interview ages (in months) are listed for a subject for the same interview_date element

- Interview_age = the age at which the interview was done
- Age must be consistent across all data structures.

Suggested Action

- Review the ages (in months) recorded for the subjects across the data structures noted on the error report.
- 2. Ensure that the correct age is recorded.
- Age in months should be determined using the following rule:
 - If <=15 days into the next month, round the age down in months.
 - If >15 days into the next month, round the age up to the next month.
- Once records have been corrected, resubmit the data.



MISCALCULATED AGE - INTERVIEW AGE INCONSISTENT WITH DATE

Error Report

A	В	С	D	E						K	L	М	N	0	P	Q	R		
1 ERROR_TYPE	, ▼ COLLEC ▼	SUBMIS -	SUBMIT▼	SUBMIT	▼ PROMC ▼	PREVIC	▼ SUBMIT ▼	PREVIC 🕶	SUBMI1 ▼	PREVIC -	SUBMI1 ▼	PREVIC ▼	SUBMI1 ▼	PREVIC *	SUBMI1 ▼	PREVIC ▼	SUBMITTED_I 🔻	PREVIOUSLY_5	NITTED_IN
8 MISCALCULATED AGE - INTERVIEW AGE INCONSISTENT WITH DAT	E 0000	1	1 09-JUL-20	GUID 1	GUID 1	GUID 1	12345	12345	fmriresult	t ndar_subj	111	111	F	F	139	130	1/14/2019	1/14/2019)
9 MISCALCULATED AGE - INTERVIEW AGE INCONSISTENT WITH DAT	E 0000	1	L 09-JUL-20	GUID 2	GUID 2	GUID 2	12345	12345	fmriresult	t ndar_subj	222	222	M	M	116	130	2/13/2017	2/13/2017	7
10 MISCALCULATED AGE - INTERVIEW AGE INCONSISTENT WITH DAT	E 0000	1	L 09-JUL-20	GUID 3	GUID 3	GUID 3	12345	12345	fmriresult	t ndar_subj	333	333	F	F	135	130	1/10/2019	1/10/2019)
26																			
27																			

Submission Template with Error

A	Α	В	С	D	E	F	G	Н	1	J	K	L	М	N	0
1	fmriresult	1													
2	SUBJECTKI	SRC_SUBJ	ORIGIN_D	INTERVIEW_DATE	INTERVIEW_AGE	SEX	EXPERIME	INPUTS	IMG03_ID	FILE_SOU	JOB_NAM	PROC_TYP	METRIC_F	PIPELINE	PIPELINE_
3	GUID 1	111	0	1/14/2019	139	F		ABCD Fast	-Track ima	s3://nda-a	abcd/NDAI	RINVXDHB	28GU_2Yea	MMPS ver	MMIL_Pre
4	GUID 2	222	0	2/13/2017	116	М		ABCD Fast	-Track ima	s3://nda-a	abcd/NDAI	RINVXDHB	28GU_base	MMPS ver	MMIL_Pre
5	GUID 3	333	0	1/10/2019	135	F		ABCD Fast	1924503	s3://NDAI	R_Central_	3/submiss	ion_21142	MMPS ver	MMIL_Pre
6															
7															
8															

Corrected Submission Template

	Α	В	C	D	E	F	G	Н	1	J	K	L	M	N	0
1	fmriresult	1													
2	SUBJECTKI	SRC_SUBJ	ORIGIN_D	INTERVIEW_DATE	INTERVIEW_AGE	SEX	EXPERIME	INPUTS	IMG03_ID	FILE_SOUR	JOB_NAM	PROC_TYF	METRIC_F	PIPELINE	PIPELINE_
3	GUID 1	111	0	1/14/2019	130	F		ABCD Fast	t-Track ima	s3://nda-a	abcd/NDAF	RINVXDHB	28GU_2Yea	MMPS ver	MMIL_Pre
4	GUID 2	222	0	2/13/2017	130	М		ABCD Fast	t-Track ima	s3://nda-a	abcd/NDAF	RINVXDHB	28GU_base	MMPS ver	MMIL_Pre
5	GUID 3	333	0	1/10/2019	130	F		ABCD Fast	1924503	s3://NDAF	R_Central_	3/submiss	ion_21142,	MMPS ver	MMIL_Pre
6															
7															
8															

MISCALCULATED AGE - INTERVIEW DATE INCONSISTENT WITH AGE

Error Description

Indicates different interview dates are listed for a subject for the same interview_age element

- Interview_age = the age at which the interview was done
- Age must be consistent across all data structures.

Suggested Action

- 1. Review interview_date recorded for the subjects across the data structures
- 2. Ensure that the correct date is recorded.
- 3. Age in months should be determined using the following rule:
 - If <=15 days into the next month, round the age down in months.
 - If >15 days into the next month, round the age up to the next month.
- 4. Resubmit the data



MISCALCULATED AGE - INTERVIEW DATE INCONSISTENT WITH AGE

Error Report

4	A	В	С	D	E		G	Н		J	K	L	M	N	0	P	Q	R	S	
	ERROR_TYPE	▼ COLLEC ▼	SUBMIS ▼	SUBMIT▼	SUBMI1 -	PROMC -	PREVIC -	SUBMI1 ▼	PREVIC ▼	SUBMI1 ▼	PREVIC -	SUBMI1 ▼	PREVIC -	SUBMIT▼	PREVIC ▼	SUBMIT▼	PREVIC ▼	SUBMITTED_I	PREVIOUSLY_	NITTED_INT
11	MISCALCULATED AGE - INTERVIEW DATE INCONSISTENT WITH AGE	0000	1	09-JUL-20	GUID 1	GUID 1	GUID 1	12345	12345	fmriresul	t ndar_subj	111	111	F	F	139	139	1/14/2019	11/14/2009	
12	MISCALCULATED AGE - INTERVIEW DATE INCONSISTENT WITH AGE	0000	1	09-JUL-20	GUID 2	GUID 2	GUID 2	12345	12345	fmriresul	t ndar_subj	222	222	M	M	116	116	2/13/2017	12/13/2007	
	MISCALCULATED AGE - INTERVIEW DATE INCONSISTENT WITH AGE	0000	1	09-JUL-20	GUID 3	GUID 3	GUID 3	12345	12345	fmriresul	t ndar_subj	333	333	F	F	135	135	1/10/2019	10/10/2009	
26																				
27																				

Submission Template with QA Error

4	Α	В	С	D	Е	F	G	Н	1	J	K	L	M	N	0
1	fmriresult	1													
2	SUBJECTKI	SRC_SUBJ	ORIGIN_D	INTERVIEW_DATE	INTERVIEV	SEX	EXPERIME	INPUTS	IMG03_ID	FILE_SOUR	JOB_NAM	PROC_TYP	METRIC_F	PIPELINE	PIPELINE_
3	GUID 1	111	0	1/14/2019	139	F		ABCD Fast	-Track ima	s3://nda-a	bcd/NDAF	RINVXDHB	28GU_2Yea	MMPS ve	r MMIL_Pre
4	GUID 2	222	0	2/13/2017	116	M									MMIL_Pre
5	GUID 3	333	0	1/10/2019	135	F		ABCD Fast	1924503	s3://NDAF	R_Central_	3/submiss	ion_21142,	MMPS ve	r MMIL_Pre
6															
7															
8															

Corrected Submission Template

4	А	В	С	D	Е	F	G	Н	1	J	K	L	М	N	0
1	fmriresult	1													
2	SUBJECTKI	SRC_SUBJ	ORIGIN_D	INTERVIEW_DATE	INTERVIEV	SEX	EXPERIME	INPUTS	IMG03_ID	FILE_SOUF	JOB_NAM	PROC_TYP	METRIC_F	PIPELINE	PIPELINE_
3	GUID 1	111	0	11/14/2009	139	F		ABCD Fast	-Track ima	s3://nda-a	bcd/NDAF	RINVXDHB	28GU_2Yea	MMPS ver	MMIL_Pre
4	GUID 2	222	0	12/13/2007	116	M		ABCD Fast	-Track ima	s3://nda-a	bcd/NDAF	RINVXDHB	28GU_base	MMPS ver	MMIL_Pre
5	GUID 3	333	0	10/10/2009	135	F		ABCD Fast	1924503	s3://NDAF	R_Central_	3/submiss	ion_21142,	MMPS ver	MMIL_Pre
6															
7															
8														Nationa	I I I'l I .

INCONSISTENT SRC_SUBJECT_ID FOR THE SAME GUID

Error Description

Indicates a given GUID is associated with multiple src_subject_ids (the subject ID how it's defined in the lab)

- A single participant should only have 1 src_subject_id and 1 GUID mapped to their data.
- SUBMITTED_SUBJECTKEY = GUID
- SRC_SUBJECT_ID = locally used ID

Suggested Action

- Review the source documents for the subject's correct src_subject_id (locally used ID).
- 2. Correct data locally and resubmit.
- Document this change
 & upload it to the
 Supporting
 Documentation



INCONSISTENT SRC_SUBJECT_ID FOR THE SAME GUID

Error Report

A	В	С	D	E		G	Н	ı		K	L	М	N	0	P	Q	R	S	
1 ERROR_TYPE	, ▼ COLLEC ▼	SUBMIS ▼	SUBMI1 ▼	SUBMIT	▼ PROMC ▼	PREVIC -	SUBMI1 ▼	PREVIC ▼	SUBMI1 ▼	PREVIC -	SUBMI1 ▼	PREVIC 🕶	SUBMI1 ▼	PREVIC *	SUBMI1 ▼	PREVIC ▼	SUBMITTED_[🔻	PREVIOUSLY_	NITTED_IN
17 INCONSISTENT SRC_SUBJECT_ID FOR THE SAME GUID	0000	1	09-JUL-20	GUID 1	GUID 1	GUID 1	12345	12345	fmriresul	t fmriresult	222	111	F	F	139	139	1/14/2019	1/14/2019	
18 INCONSISTENT SRC_SUBJECT_ID FOR THE SAME GUID	0000	1	09-JUL-20	GUID 2	GUID 2	GUID 2	12345	12345	fmriresul	t fmriresult	333	222	M	M	116	116	2/13/2017	2/13/2017	
19 INCONSISTENT SRC_SUBJECT_ID FOR THE SAME GUID	0000	1	09-JUL-20	GUID 3	GUID 3	GUID 3	12345	12345	fmriresul	t fmriresult	333	333	F	F	135	135	1/10/2019	1/10/2019	
26																			
27																			

Submission Template with QA Error

\square	Α	В	С	D	E	F	G	Н	1	J	K	L	M	N	0
1	fmriresult	1													
2	SUBJECTK	SRC_SUBJ	ORIGIN_D	INTERVIEV	INTERVIEV	SEX	EXPERIME	INPUTS	IMG03_ID	FILE_SOUR	JOB_NAM	PROC_TYP	METRIC_F	PIPELINE	PIPELINE_
3	GUID 1	222	0	########	139	F		ABCD Fast	-Track ima	s3://nda-a	bcd/NDAF	RINVXDHB	28GU_2Yea	MMPS ver	MMIL_Pre
4	GUID 2	333	0	########	116	M		ABCD Fast	-Track ima	s3://nda-a	bcd/NDAF	RINVXDHB	28GU_base	MMPS ver	MMIL_Pre
5	GUID 3	333	0	########	135	F		ABCD Fast	1924503	s3://NDAF	R_Central_	3/submiss	ion_21142/	MMPS ver	MMIL_Pre
6															
7															

Corrected Submission Template

A	Α	В	С	D	Е	F	G	Н	1	J	K	L	М	N	0
1	fmriresult	1													
2	SUBJECTK	SRC_SUBJ	ORIGIN_D	INTERVIEV	INTERVIEV	SEX	EXPERIME	INPUTS	IMG03_ID	FILE_SOUR	JOB_NAM	PROC_TYP	METRIC_F	PIPELINE	PIPELINE_
3	GUID 1	111	0	#########	139	F		ABCD Fast	-Track ima	s3://nda-a	abcd/NDAF	RINVXDHB	28GU_2Yea	MMPS ver	MMIL_Pre
4	GUID 2	222	0	#######################################	116	M		ABCD Fast	-Track ima	s3://nda-a	abcd/NDAF	RINVXDHB	28GU_base	MMPS ver	MMIL_Pre
5	GUID 3	333	0	#########	135	F		ABCD Fast	1924503	s3://NDAF	R_Central_	3/submiss	ion_21142/	MMPS ver	MMIL_Pre
6															
7															



INCONSISTENT GUID FOR SAME SRC_SUBJECT_ID

Error Description

Indicates that a src_subject_id (the subject ID how it's defined in the lab) is assigned to multiple GUIDs in a data structure

- A single participant should only have 1 src_subject_id and 1 GUID mapped to their data.
- SUBMITTED_SUBJECTKEY = GUID
- SRC_SUBJECT_ID = locally used ID

Suggested Action

Review the source documents for the subject's correct GUID.

- If necessary, use the GUID Tool to validate the GUID.
- Correct data locally and resubmit.



INCONSISTENT GUID FOR SAME SRC_SUBJECT_ID

Error Report

		А		В	С	D E	F (K		M	N	0		Q	R		
1	ERROR_TYPE			▼ COLLECT	▼ SUBMIS ▼ SU	BMIT V SUBMIT	▼ PROMC ▼ PREV	IC ▼ SUBMIT	PREVIC -	SUBMI1 ▼ F	PREVIC -	SUBMI1 ▼ PR	EVIC 🔻 S	SUBMIT - F	PREVIO V	SUBMIT -	PREVIC -	SUBMITTED_[-	PREVIOUS	TATED IN.
14	INCONSISTENT GUID	FOR SAME SRC_SU	JBJECT_ID	0000	1 09-	JUL-20 GUID 1	GUID 2 GUID	1 1234	5 1234	5 fmriresult r	ndar_subj	111	111 F	F F	-	139	139	1/14/2019	1/14	/2019
15	INCONSISTENT GUID	FOR SAME SRC_SU	JBJECT_ID	0000	1 09-	JUL-20 GUID 2	GUID 3 GUID	2 1234	5 1234	5 fmriresult r	ndar_subj	222	222 N	M	VI	116	116	2/13/2017	2/13	/2017
16	INCONSISTENT GUID	FOR SAME SRC_SU	JBJECT_ID	0000	1 09-	JUL-20 GUID 3	GUID 1 GUID	3 1234	5 1234	5 fmriresult r	ndar_subj	333	333 F	F F	-	135	135	1/10/2019	1/10	/2019
26																				
27																				
					Subr	nissi	on Ter	npla	te v	with	QA	A Err	ors	5						
4	A	В	С	D	E	F	G		H	1		J		K	L	-	М		N	0
1	fmriresult	1																		
2	CLIDIFCTV	CDC CLIDII	ODICINI D	NITEDVIEV	INITEDIALE	CEV	EVDEDI	ME INIDI	ITC	INACOS	ID EI	LE COLL	IOD	NIABA	DDO	TVE	METRI	C E DIDE	TIME	DIDELINIE

1	fmriresult	1													
2	SUBJECTK	SRC_SUBJI	ORIGIN_D	INTERVIEV	INTERVIEV	SEX	EXPERIME	INPUTS	IMG03_ID	FILE_SOUF	JOB_NAM	PROC_TYP	METRIC_F	PIPELINE	PIPELINE
3	GUID 2	111	0	########	139	F		ABCD Fast	-Track ima	s3://nda-a	bcd/NDAR	RINVXDHB2	28GU_2Yea	MMPS ver	MMIL_Pre
4	GUID 3	222	0	########	116	M		ABCD Fast	-Track ima	s3://nda-a	abcd/NDAR	RINVXDHB2	28GU_base	MMPS ver	MMIL_Pre
5	GUID 1	333	0	########	135	F		ABCD Fast	1924503	s3://NDAF	R_Central_	3/submissi	on_21142/	MMPS ver	MMIL_Pre
6															

Corrected Submission Template

\square	Α	В	С	D	Е	F	G	Н	1	J	K	L	M	N	0
1	fmriresult	1													
2	SUBJECTKI	SRC_SUBJI	ORIGIN_D	INTERVIEV	INTERVIEV	SEX	EXPERIME	INPUTS	IMG03_ID	FILE_SOUR	JOB_NAM	PROC_TYP	METRIC_F	PIPELINE	PIPELINE_
3	GUID 1	111	0	#######################################	139	F		ABCD Fast	-Track ima	s3://nda-a	bcd/NDAF	RINVXDHB	28GU_2Yea	MMPS ver	MMIL_Pre
4	GUID 2	222	0	#######################################	116	M		ABCD Fast	-Track ima	s3://nda-a	bcd/NDAF	RINVXDHB	28GU_base	MMPS ver	MMIL_Pre
5	GUID 3	333	0	#########	135	F		ABCD Fast	1924503	s3://NDAF	R_Central_	3/submiss	ion_21142/	MMPS ver	MMIL_Pre
6															
7															
8															



MISSING SUBJECTS FOR DATA STRUCTURE PROVIDED

Error Description

Indicates there are fewer subjects submitted than in previous submissions

Note: Neurosignaling and omics subject data are excluded from this report as those data are only expected to be submitted once.

Suggested Action

NDA expects clinical data to be submitted cumulatively.

- Review the submission to confirm all subjects collected so far were included in your cumulative submission.
- 2. Resubmit your data.



MISSING SUBJECTS FOR DATA STRUCTURE PROVIDED

Error Report

A	В	С	D	Е	F	G	Н	- 1	J	K	L	М	N	0
1 ERROR_TYPE	, ▼ COLLEC ▼	SUBMIS ▼	SUBMIT ▼	SUBMI1 ▼	PROMC ▼	PREVIC ▼	SUBMIT▼	PREVIC ▼	SUBMI1 ▼	PREVIC ▼	SUBMI1 ▼	PREVIC -	SUBMIT▼	PREVIC ▼
2 MISSING SUBJECTS FOR DATA STRUCTURE PROVIDED	0000	1	9-Jul-20			GUID 1		11111		ndar_sub	ject01	111		F
3 MISSING SUBJECTS FOR DATA STRUCTURE PROVIDED	0000	1	9-Jul-20			GUID 2		11111		ndar_subj	ject01	222		M
4 MISSING SUBJECTS FOR DATA STRUCTURE PROVIDED	0000	1	9-Jul-20			GUID 3		11111		ndar_sub	ject01	333		F
26														
27														



MISSING DATA STRUCTURE

Error Description

Indicates a data structure you submitted cannot be found in later submissions.

 The data structure's shortname in question is provided in the report

Suggested Action

NDA expects clinical data to be submitted cumulatively.

- 1. Confirm all cumulative data were submitted.
- Upload missing structures or confirm with NDA to resolve.



INCONSISTENT SEX PROVIDED

Error Description

A discrepancy with the sex at birth value across data structures

 Male (M) in one data structure, but Female (F) in another

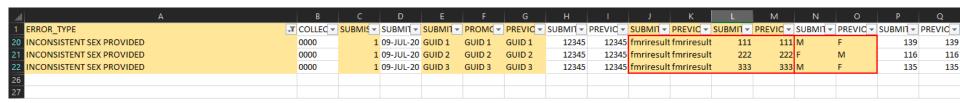
Suggested Action

- Review the source documents for the correct sex.
- Record the appropriate code (Male (M), Female (F), Other (O), Not Reported (NR)) on all subject records locally and resubmit.
- If the change in sex is a valid change:
 - document this change
 - upload to the Supporting Documentation

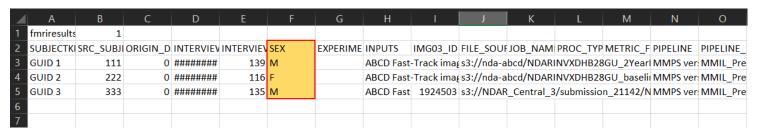


INCONSISTENT SEX PROVIDED

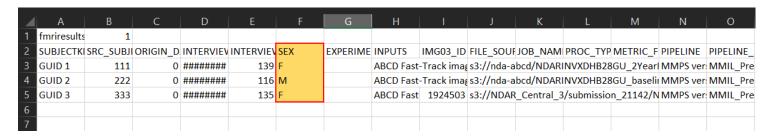
Error Report



Submission Template with QA Errors



Corrected Submission Template





SEX VALUE THRESHOLD WARNING

Error Description

The percentage of the Other (O) and/or Not Reported (NR) values for the data element 'sex' exceeds acceptable thresholds

- The acceptable threshold for Other (O) is 25%
- The acceptable threshold for Not Reported (NR) is 50%.

Suggested Action

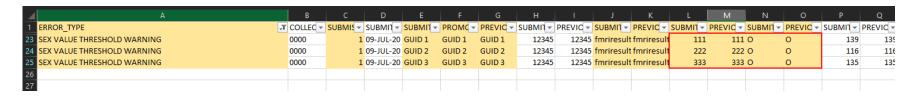
- Review the data to confirm that the values reported in the sex element are accurate.
- Update the data accordingly.

*When this warning occurs, the submission can continue without further action.



SEX VALUE THRESHOLD WARNING

Error Report





Let's start the Q&A!





More Questions?

If you have further questions, please email the NDA Help Desk at NDAHelp@mail.nih.gov.

To request a copy of the presentation, please contact the NDA Help Desk.

Thank you for joining!

