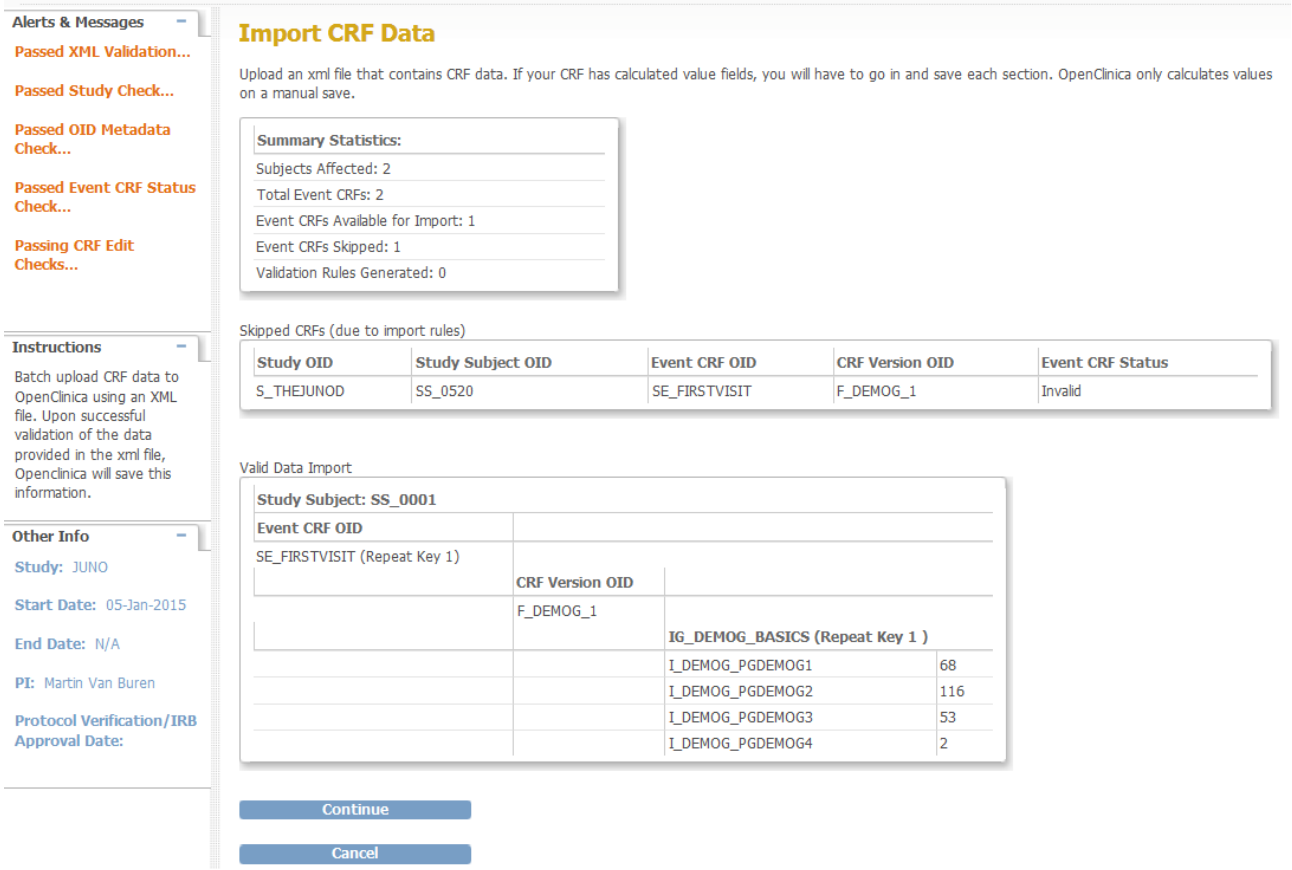
2.5.5 Validate and Check the Data Import File

When you import a data file, OpenClinica validates the file format and performs validity checking for the data, then displays any error messages in the Alerts and Messages sidebar panel. Correct any errors in the file and import it again.

OpenClinica also displays Summary Statistics of imported and skipped records and displays detailed information about the import. Details on the validation and rules applied during import are listed below the screen shot.



Validation that OpenClinica Performs on the Data Import File

- XML is well-formed against the ODM.
- The Study OID in the import file matches the current Study in the OpenClinica session you are performing the import from.
- Study Subject OIDs exist for the current Study.
- Study Event Definition OIDs exist for the current Study.
- OIDs for the CRF versions exist for the Study Event Definition OID.
- Study Subject OIDs are scheduled for the Study Events.
- Data values for the Items comply with the metadata. For example, if the metadata for an Item calls for a value of 1 or 2, the data value for that Item in your import file must be 1 or 2.
- Data values are in the correct format. For example, when an integer is required, a decimal value generates an error.

Edit Checks that OpenClinica Performs on the Data Import File

If your study is configured to flag errors in Edit Checks, OpenClinica checks the following:

- The status of the CRF (prior to import) is not "double data entry started" or "data entry complete."
- Data is in the correct format. For example, a date that is not in the required YYYY-MM-DD format generates an error.
- Data values are within limits specified for CRF Items. For example, when the CRF accepts 90 to 110 degrees for temperature, a value of 200 is not accepted.
- Data values match acceptable criteria for CRF Items. For example, if a Yes answer is required for an Item and the value in the import file for that Item is No, a discrepancy note is required.
- Required fields are not empty.

Approved for publication by Paul Bowen. Signed on 2025-02-10 1:46PM

Not valid unless obtained from the OpenClinica document management system on the day of use.