Validation Plan (v1)

The process of uploading adverse events to EudraCT will involve the use of three programs originally written by AH:

1. EUTCT\_formats\_V22.sas – Changes text SOC to number.
2. XML\_Input\_Checker\_V1.0.SAS– Checks that the data is in the correct form.
3. XML\_Creator\_V1.0.SAS – Changes SAS code to XML to upload to EudraCT.

Therefore there are three steps to the validation process:

1. Check that the input checker works for all possible violations.
2. Check that the XML file uploads correctly for:
3. Correct data.
4. Correct data with no AEs, as some trials may not collect them.
5. SAEs with unique SOCs (this check will be performed for the formats program).
6. A large SAE and AE dataset.
7. Write a work instruction of the exact process for future users.

**Plan**

The validation will be conducted as follows:

1. Correct dummy data will be generated using two reporting groups and the full process checked to ensure it works in the correct case.
2. The dummy data will be modified in turn to violate each of the eight conditions.
3. Various versions of the dummy data will be uploaded to EudraCT and manually compared with the original data.
4. A work instruction will be created to explain the process.

The full validation process will be documented in:

[P:\CTRU\Stats\Programming\SAS\Eudract\Validation](../Validation)

With the formats program documented here:

P:\CTRU\Stats\Programming\SAS\Eudract\EudraCT\_Upload\_V1.0\EudraCT\_FormatsValidation\V22