4.5.1.1 Header Table Format

The header table includes the following information:

- Dataset name
- Dataset description
- Study name
- Protocol ID the study protocol ID
- Date the date the data set was created
- Subjects the number of subject records in the dataset
- Study Event Definitions the number of study event definitions included in the dataset
- For each of the included study event definitions, the name of the event defintion plus an identifier which is used to reference the event definition in the data table

For each of the included case report forms (CRFs), the name of the CRF plus an identifier which is used to reference the CRF in the data table

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