

## Standardized Reporting using ADaM (STREAM model)

ADaM was implemented in Ferring in 2008 and over the years the model has become more mature and stable. The datasets used for reporting in Ferring are of basically 3 different types: Subject level (ADSL), occurrence data structure (e.g. ADAE) and base data structure (e.g. ADLB). This means that these 3 data structures are same across domains but with different content which is perfectly suited for standardization of output.

Previously in Ferring the reporting was performed based on definitions in the SAP and Tables, Listings and Figures (TLF) shells and specifications. Standard programs were developed and customized for each type of output. Any changes to the TLFs required an update of the SAP, TLF shells and specification as well as the program. This was inefficient and caused problems with consistency.

By designing ADaM datasets to include all the metadata used in production of TLFs 2-3 standard macros can be built to produce 90% of the summary tables for a clinical trial or integrated summary. The figure below show how the ADaM dataset is linked to the report and the next figure show how generic this is. The third figure show how the information in the SAP is linked to ADaM and the report.

**Figure 1: Tables**

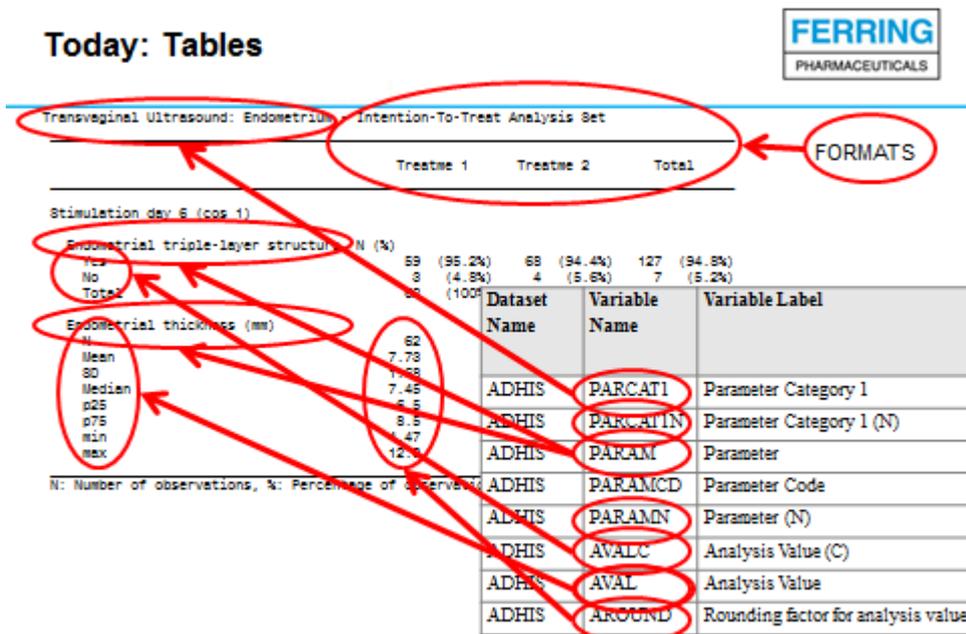


Figure 2: Generic Tables

Today: Generic Tables

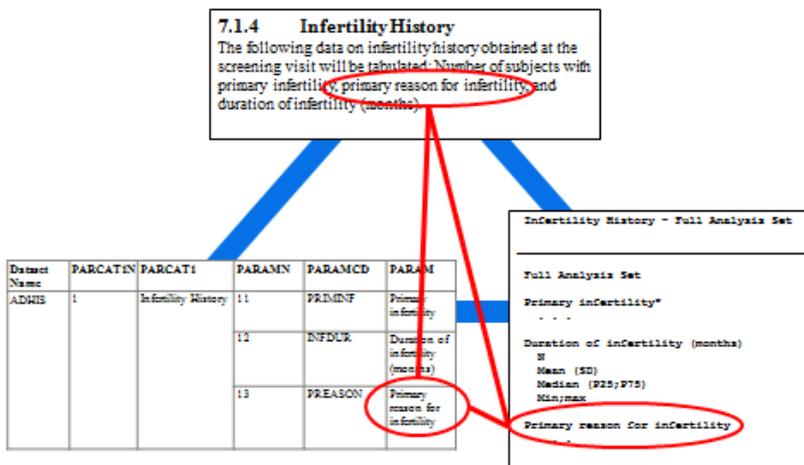


```

<PARCAT1 by PARCAT1N> - <ANALYSIS SET FORMAT>
-----
                <ACTARM 1>      <ACTARM 2>      Total
-----
<GROUP by GROUPN (e.g. AVISIT by AVISITN)>
<PARAM by PARAMN>
If PARAM is categorical then present as
<PARAM>, n (%)
<AVIALD by AVIAL>
Total                xxx ( xx%)      xxx (100%)      xxx ( xx%)
                    xxx (100%)      xxx (100%)      xxx (100%)
If PARAM is continuous then present as
<PARAM>
n                    xxx                xxx                xxx
Mean (SD)            xxx.x (xx.x)      xxx.x (xx.x)      xxx.x (xx.x)
Median              xxx.x                xxx.x                xxx.x
IQ-range            xxx; xxx          xxx; xxx          xxx; xxx
Range              xxx; xxx          xxx; xxx          xxx; xxx
-----
n: Number of observations
%: Percentage of observations
FE99049/ART/000004/DCIMMYYY-XXX/PROGRAM.E.SAS
  
```

Figure 3: Consistency through ADaM Specs

Today: Consistency through ADaM Specs



In the STREAM model all information needed for reporting is put in to the ADaM dataset and therefore a change in the TLF will only need a change in ADaM to be automatically rolled out across all TLFs. The method requires that the statistician writing the SAP has a good understanding of ADaM and STREAM and that the programmer strictly follows the STREAM model when designing the ADaMs and uses standard macros for reporting.

By implementing the STREAM model and putting more efforts in to designing ADaM programmers will ensure consistency, reduce the need for table shells and specifications as well as shortening the time for programming and validation.