General Output Tips and Considerations

A PHUSE White Paper led by Karin LaPann of Takeda Inc.

Abstract

This white paper written by the PHUSE Standard Analyses and Displays White Papers project team is intended as a useful guide on important elements to consider when creating tabular displays. It offers vocabulary on parts of a paper and handy tips in tip boxes. The audience is for Pharmaceutical companies that may not have general guidance in place. General principles are provided with as much flexibility as possible for actual use by members of pharmaceutical companies, CROs or other service providers as they create deliverables for regulatory agencies.

Scope: general elements for Tables and Listings for clinical study reports (CSRs) and other similar regulatory reports.

Intended audience: Members of Pharmaceutical companies engaged in the production, planning or programming table outputs.

Types of Tables discussed:

Category- Items are listed in the stub, with columns showing attributes of the item

- Comparison- Attributes are listed in the stub with subsequent columns showing values for different items
- Analysis- A table containing data and the results of statistical analysis of data, or summary statistics.

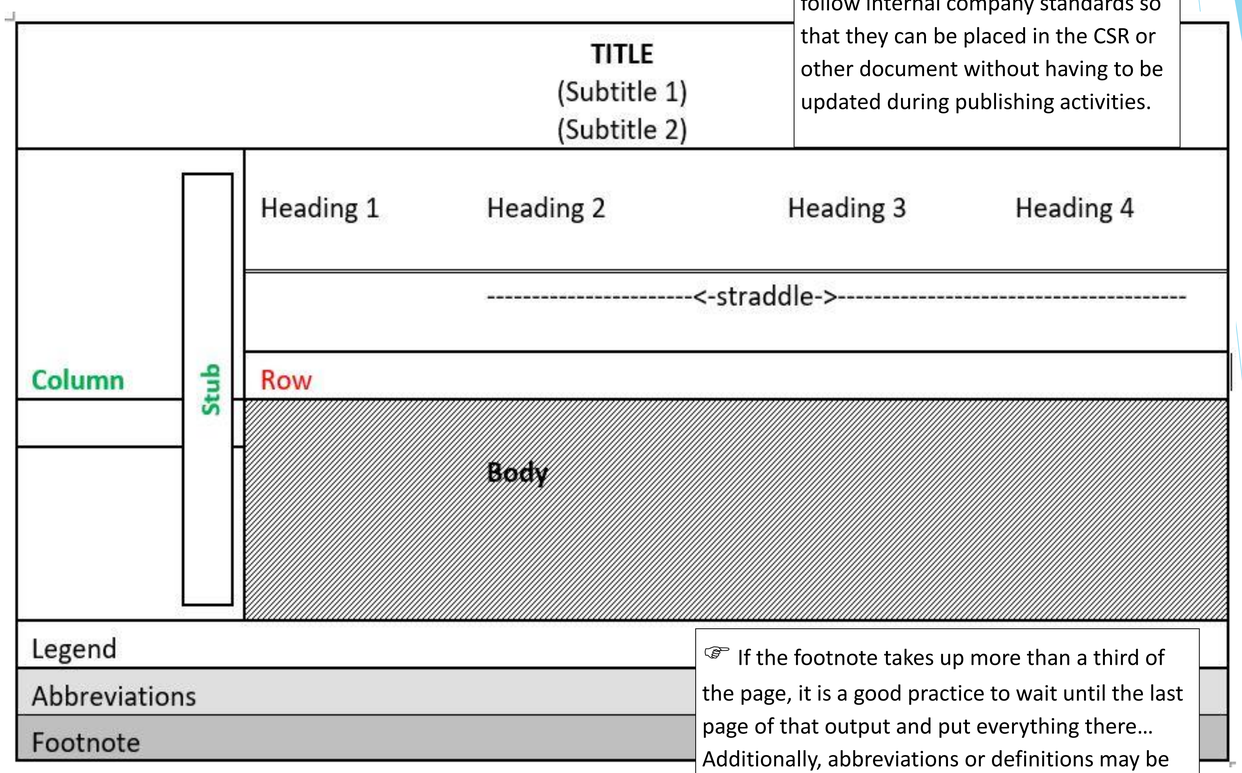
Definitions for content

- Demographics and baseline characteristics - These may be study population dispositions such as age, weight, gender, laboratory measures, disease state, concomitant medications, treatment compliance, discontinuations.
- Safety - Study results for treatment emergent adverse events, serious adverse events, deaths, overdose, particular safety values for particular body systems such as vital signs, EKGs
- Efficacy - Analyses of endpoint results, changes from baseline, per visit and per patient changes, drug dosage and responses, pharmacokinetic/pharmacodynamic analyses, etc.
- Tabulation - Complete listing of collected data by subject or another identifier.

Parts of a Table

Below is a depiction of table parts. This graphic allows for a detailed conversation of contents for each part of the table.

☞ Tip boxes in the paper provide additional information to the reader. You will see examples throughout this poster.



☞ At the minimum, titles should follow internal company standards so that they can be placed in the CSR or other document without having to be updated during publishing activities.

☞ If the footnote takes up more than a third of the page, it is a good practice to wait until the last page of that output and put everything there… Additionally, abbreviations or definitions may be added to each page, but footnotes left to the end.

- **Legend, Abbreviations and Footnotes:** To the casual reader, these three items are considered one item. In actuality they are three concepts shown at the bottom of a table.
- The first element is a legend item, which is a group sentences that applies to the overall table.
- The abbreviations may come first or second to define acronyms or terms that might need explanation.
- The third item is the footnote.
- The order of these elements is flexible and is based on your company's process or preference.

☞ A good rule to follow is that tabular material must stand alone, therefore all symbols and abbreviations used should be defined at first use.

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You might ask after reviewing the graphic above, what is a stub?

Here is an example

Example of a Stub	
Overall	
Any Major Deviation	xx (xx.x%)
<Deviation #1>	xx (xx.x%)
<Deviation #2>	xx (xx.x%)