Tables, figures, and listings shells template

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This document is a template for tables, figures and shells. It contains the backbone structures and instructions to fill out the sections. Instructions are in italic blue and hidden when document is printed out. Remove this front page before finalizing the document.

Company logo

Tables, figures, and listings shells

|  |  |
| --- | --- |
| **Protocol title:** |  |
| **Protocol number:** |  |
| **TFLs Version (date):** |  |
| **Sponsor:** | Company name  Address |
| **Investigational therapy:** |  |
| **Development phase:** |  |
| **EudraCT number:** |  |
| **IND number:** |  |

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Signature page

Instructions: Update signature page as relevant.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author** | | | | |
|  |  |  |  |  |
| **Name, Degree(s)**  **Title** |  | **Date** |  | **Signature** |
| **Reviewer** | | | | |
|  |  |  |  |  |
| **Name, Degree(s)**  **Title** |  | **Date** |  | **Signature** |
| **Approver** | | | | |
|  |  |  |  |  |
| **Name, Degree(s)**  **Title** |  | **Date** |  | **Signature** |

Tables, figures, and listings shells amendment history

Instructions: Complete the tables, figures, and listings shells amendment history as relevant.

Document history

|  |  |
| --- | --- |
| **Protocol version** | **Date** |
| Amendment N | DD-Mmm-YYYY |
| Amendment N-1 | DD-Mmm-YYYY |
| … | DD-Mmm-YYYY |
| Amendment 1 | DD-Mmm-YYYY |
| Original | DD-Mmm-YYYY |

Amendment N (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the tables, figures, and listings shells

Amendment N-1 (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the tables, figures, and listings shells

Amendment 1 (DD-Mmm-YYYY)

Amendment rationale

Changes to the previous version of the tables, figures, and listings shells

Table of contents

[Signature page 3](#_Toc124423307)

[Tables, figures, and listings shells amendment history 4](#_Toc124423308)

[Document history 4](#_Toc124423309)

[Amendment N (DD-Mmm-YYYY) 4](#_Toc124423310)

[Amendment N-1 (DD-Mmm-YYYY) 4](#_Toc124423311)

[Amendment 1 (DD-Mmm-YYYY) 4](#_Toc124423312)

[List of abbreviations 6](#_Toc124423313)

[1. Introduction 7](#_Toc124423314)

[2. Programming considerations 8](#_Toc124423315)

[2.1. General considerations 8](#_Toc124423316)

[2.2. Tables, figures, and listings format 8](#_Toc124423317)

[2.2.1. General 8](#_Toc124423318)

[2.2.2. Document header 8](#_Toc124423319)

[2.2.3. Output title 8](#_Toc124423320)

[2.2.4. Column header 8](#_Toc124423321)

[2.2.5. Body of the output 9](#_Toc124423322)

[2.2.5.1. Table convention 9](#_Toc124423323)

[2.2.5.2. Figure convention 9](#_Toc124423324)

[2.2.5.3. Listing convention 9](#_Toc124423325)

[2.2.5.4. Footnotes 10](#_Toc124423326)

[2.2.5.5. Document footer 10](#_Toc124423327)

[3. Index of tables 11](#_Toc124423328)

[3.1. Out-text tables 11](#_Toc124423329)

[3.2. In-text tables 11](#_Toc124423330)

[4. Index of figures 12](#_Toc124423331)

[4.1. Out-text figures 12](#_Toc124423332)

[4.2. In-text figures 12](#_Toc124423333)

[5. Index of listings 13](#_Toc124423334)

[5.1. Out-text listings 13](#_Toc124423335)

[5.2. In-text listings 13](#_Toc124423336)

[6. Out-text tables, figures, and listings shells 14](#_Toc124423337)

[6.1. Out-text tables shells 14](#_Toc124423338)

[6.2. Out-text figures shells 14](#_Toc124423339)

[6.3. Out-text listings shells 14](#_Toc124423340)

[7. In-text tables, figures, and listings shells 15](#_Toc124423341)

[7.1. In-text tables shells 15](#_Toc124423342)

[7.2. In-text figures shells 15](#_Toc124423343)

[7.3. In-text listings shells 15](#_Toc124423344)

[8. Appendices 16](#_Toc124423345)

List of abbreviations

Instructions: Provide list of all abbreviations used in the document. Abbreviations and acronyms are defined where first used in the document.

| **Acronym** | **Definition** |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |

# Introduction

Instructions: Complete information with regards to protocol number and version.

This document provides information relative to the production of tables, figures, and listings (TFLs) for the clinical study protocol <Protocol number and version>. It covers information related to the production of TFLs for the clinical study report (CSR) and any potential interim analyses. This document gives information on:

* Programming considerations for out-text and in-text TFLs, see Section 2.
* Index of tables, figures, and listings, see Section 3 to Section 5.
* Shells for out-text outputs, see Section 6.
* Shells for in-text outputs, see Section 7.

# Programming considerations

Instructions: This section covers information related to programming considerations to produce TLFs (out- and in-text).

## General considerations

Instructions: General text not to be modified

* One program can create several outputs, or a unique program will be created by output.
* One output file can contain several outputs, or each output can be printed in a separate file.
* Output file will be delivered in Open XML format and in portable document format (pdf). Outputs can additionally be delivered on alternative media (e.g., webpages).

## Tables, figures, and listings format

### General

Instructions: General text not to be modified, except information related to the margin’s size, the font (in-text only) and font size.

* All out-text outputs (i.e. to be integrated into the appendices of the CSR) will be produced at least in landscape format on A4 paper size, <xx> cm margin on all 4 sides, with Courier New font, size <xx> pt.
* All in-text outputs (i.e. to be integrated within the main body of the CSR) will be produced at least in portrait format on A4 paper size, <xx> cm margin on all 4 sides, with <xx> font, size <xx> pt.
* Only unicode characters can be used in the TFLs.
* Mixed case is to be used for the document header, title elements, column headers, as appropriate.

### Document header

Instructions: General text not to be modified, except information related to the protocol number and the analysis name.

All out-text outputs should have the following document header. For the page numbering, n corresponds to the actual page number and N corresponds to the total number of pages of the output.

|  |  |
| --- | --- |
| <Protocol number> | Company name |
| <Analysis name> | Page n of N |

As in-text outputs are to be integrated into the body of the CSR, no document header will be created.

### Output title

Instructions: General text not to be modified.

For out-text outputs, the title will be composed of the following elements:

* Element 1: A designation (Table, Figure or Listing).
* Element 2: A numbering composed by the concatenation of numbers collapsed with “.”. Numbering should be compliant with the recommendation of the latest version ICH E3. Number should be unique to the combination of the designation, the description and analysis set.
* Element 3: A description of the output. The description should be short and self-explanatory.
* Element 4: An analysis set specified in between brackets.
* Element 5 (optional): A subgroup specification.

Elements 1-4 will be concatenated with a single space collapsing, centered with output starting on the first row of each page of the output. It will be followed by one (1) blank line. If a subgroup is to be specified, it will be output left aligned just after the blank line. A solid line spanning the margin will mark the end of the output title.

The title of in-text outputs will be composed with the same elements and format the title of the out-text outputs, except for element 2 that will be required to be constructed based on field and sequence elements.

### Column header

Instructions: General text not to be modified.

Column headers are displayed below the solid line marking the end of the output title.

Unless otherwise specified, the variables column will be on the left, followed by the groups to be displayed and a total column (if required). The order of the treatment in the tables or listings will be first the placebo or the control group, then the experimental groups followed by the total column, as applicable.

Size of the population will be presented for each group in the column header (or row header, as appropriate) as “(N = xx)” where xx is the size of the population.

For numeric variables, the unit is to be specified in between brackets in column (or row heading, as appropriate).

### Body of the output

#### Table convention

Instructions: General text not to be modified.

For categorical variables, unless otherwise specified, the following conventions are to be applied:

* Frequency and percentage of non-missing and missing values is to be reported out the size of the analysis set within the reported group.
* For the non-missing values:
  + All levels will be presented in the table.
  + Frequency and percentage will be provided, with percentage computed out of the number of non-missing values within the reported group.
* Percentage will be reported to one decimal place, in between parenthesis and without % sign.
* Reporting for levels in which frequency is null will be “-”.

For continuous variables other than time-to-event, unless otherwise specified, the following conventions are to be applied:

* Every effort should be done to report the summary statistics in the following order:
  + The number of non-missing values.
  + The mean with the standard deviation in between parenthesis.
  + The median with in between parenthesis the 1st and 3rd quartiles concatenated with a semicolon.
  + The minimum and the maximum concatenated with a semicolon.
* The mean, median, 1st and 3rd quartile are to be reported to one decimal place more than the one used for the collection of the continuous variable. The standard deviation is to be reported to two decimal places more than the one used for the collection of the continuous variable. The minimum and maximum are to be reported with the same decimal place than the one used for the collection of the continuous variable.

P-values are to be reported rounded to 3 decimal places, except if:

* smaller than 0.001 where it will be presented as “< 0.001”.
* larger than 0.999 where it will be presented as “> 0.999”.

#### Figure convention

Instructions: General text not to be modified.

Legend will be used on all figures with more than 1 variable, group or item displayed.

#### Listing convention

Instructions: General text not to be modified.

* Unless otherwise specified, listings will be sorted per treatment group (placebo or the control group first, then the experimental groups, as applicable), subject number, and datetime.
* When applicable, dates and times are to be expressed according to ISO 8601 standard.
* Missing data a represented on listings using an hyphen “-”.

#### Footnotes

Instructions: General text not to be modified, except information related to the program path, the data source, the run datetime, the database extraction datetime, and the database cutoff date. In case of multiple data sources, those have to be concatenated with “, ”. Datetimes are to be expressed according to ISO 8601 standard.

* A solid line spanning the margin will mark the end of the body of the output.
* The footnotes should start immediately after a single-line spacing after the solid line spanning and should be left justified.
* Acronyms will be provided first, sorted in alphanumeric order, separated with a semicolon.
* Informational footnotes, if any, should be provided on a new line after the acronyms.
* Reference footnotes, if any, should be provided on a new line after the informational footnotes.
* Every effort should be done to limit the full footnote’s size to 6 lines.

#### Document footer

Instructions: General text not to be modified.

All out-text outputs should have the following document footer repeated on each page.

|  |  |  |
| --- | --- | --- |
| Program path:<Program path> |  | Data source:<Data source> |
| Run datetime:<[YYYY]-[MM]-[DD]T[hh]:[mm]:[ss]> | Database extraction date: <[YYYY]-[MM]-[DD] T[hh]:[mm]:[ss]> | Database cutoff date:<[YYYY]-[MM]-[DD] T[hh]:[mm]:[ss]> |

As in-text outputs are to be integrated into the body of the CSR, no document footer is to be created.

# Index of tables

## Out-text tables

Instructions: The table below provides the template for the index for out-text tables to be produced. The index is to be completed in accordance with the latest version of ICH E3. Add rows as necessary. In case a section number is provided but not a table numbering, then the description corresponds to the section name associated to the section number. If both the section number and the table numbering are provided, then the description corresponds to the description of the output. An analysis set is to be completed only when a table numbering is non-missing. When table numbering is non missing, table numbering, description and analysis set should be aligned with elements 2-4 from Section 2.2.3. Section number and table numbering should start with 14.

|  |  |  |  |
| --- | --- | --- | --- |
| **Section number** | **Table numbering** | **Description** | **Analysis set** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## In-text tables

Instructions: The completion of the index of in-text tables follows similar rules than the completion of the index of out-text tables, see Section 3.1.

# Index of figures

## Out-text figures

Instructions: The completion of the index of out-text figures follows similar rules than the completion of the index of out-text tables, see Section 3.1.

## In-text figures

Instructions: The completion of the index of in-text figures follows similar rules than the completion of the index of out-text tables, see Section 3.1.

# Index of listings

## Out-text listings

Instructions: The completion of the index of out-text listings follows similar rules than the completion of the index of out-text tables, see Section 3.1. Please note that section number and listing numbering should start with 16.

## In-text listings

Instructions: The completion of the index of in-text listings follows similar rules than the completion of the index of out-text tables, see Section 3.1.

# Out-text tables, figures, and listings shells

Instructions: Provide shells for the out-text tables, figures, and listings.

## Out-text tables shells

## Out-text figures shells

## Out-text listings shells

# In-text tables, figures, and listings shells

Instructions: Provide shells for the in-text tables, figures, and listings.

## In-text tables shells

## In-text figures shells

## In-text listings shells

# Appendices

Instructions: Add appendices as relevant.