Clinical Evaluation Plan (CEP) Template

https://clinicalstudytemplates.com/

Template Use

This Clinical Evaluation Plan (CEP) Template is specifically designed, and intended for straightforward transfer of information to the associated Clinical Evaluation Report (CER) Template.

Although each clinical evaluation is unique in its design, the sections of this CEP Template include all the fundamental components of an EU MDR 2017/745-compliant CEP. Moreover, the structure and sections as well as their order and content follow the MEDDEV 2.7/1 Rev. 4 guidelines and Medical Device Coordination Group (MDCG) 2020-6 recommendations conforming to the expectations by the Notified Body (NB). This enables content of the finalized CEP to be directly copied into the equivalent sections of the associated CER Template, with only minor modifications to the tense as instructed throughout.

- For more information on the EU MDR 2017/745, visit https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
- For more information on MDCG guidelines, visit https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
- For more information on MEDDEV 2.7/1 Rev. 4 guidelines, visit https://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/en/renditions/native

Note that, although the EU MDR 2017/745 became effective on May 2017, the transition period for the remediation of MDD-compliant clinical evaluations to MDR-compliant clinical evaluations has been extended to December 2027 for Class III and Class IIb devices, and to December 2028 for Class IIa and Class I devices.

The integration of automated formatting features through the customized Styles gallery, and the exceptional ease of using this CEP Template allow experienced authors to save valuable time by eliminating labor-intensive generation of standard

verbiage and repetitive formatting, and offer novice writers clear guidance to create MDR-compliant, high-quality documents that ensure consistency across other CEPs.

Taking into account the various types of clinical devices with different classifications, and Intended Purpose-associated statements, such as Intended Use, Indications for Use, Contraindications, Target Patient Population, Users, Warnings, Cautions, Warnings, Claims, and Clinical Benefits, CEP authors should work with their device development team members (i.e., Research and Development, Regulatory Affairs, Clinical Affairs, Medical Affairs, Manufacturing, Post-Market Surveillance, Post-Market Clinical Follow-up, etc.) to ensure that the document's content and data are presented in a clear and concise manner, which may require this template to be modified accordingly, so that it is in line with the device's unique aspects and specific characteristics.

Text Color-coded Instructions

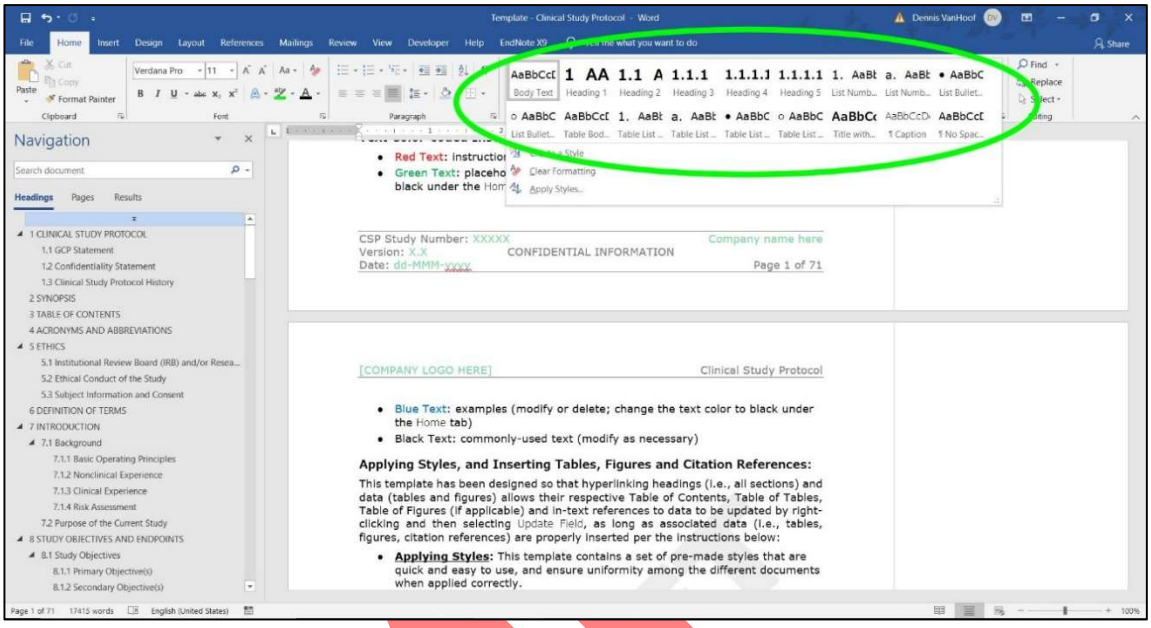
- Red Text: instructions (delete)
- Green Text: placeholder (replace, modify or delete; select and convert the text color to black by changing the Font Color under the Home tab)
- Blue Text: examples (modify or delete; select and convert the text color to black by changing the Font Color under the Home tab)
- Black Text: commonly-used text (modify as necessary)

Applying Styles, and Inserting Tables, Figures and Citation References

Visit https://clinicalstudytemplates.com/tutorials/ for short videos that explain how to use the automated features of this template.

This template has been designed so that hyperlinking the headings of sections and other data (e.g., tables and figures) allows their respective Table of Contents (TOC), Table of Tables, Table of Figures (if applicable) and in-text references to data to be updated by right-clicking on the TOC, and then selecting Update Field, as long as associated data (e.g., tables, figures, citation references) are properly inserted per the instructions outlined below.

- **Applying Styles:** This template contains a set of 18 pre-made styles (see the available styles of the Styles gallery displayed in the green oval below) that are quick and easy to use, and ensure uniformity among the different documents when applied correctly.



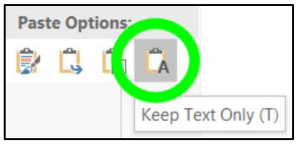
When using these styles, complete and consistent formatting is applied to the selected text with a single click. If certain words in the text need to be italicized, bolded, underlined, etc., then apply manual changes to the font only *after* the style has been applied. For the rest, follow the instructions below, and refrain from manually changing the text as much as possible.

- For general text, apply the Body Text style
- For headings of sections, apply the appropriate Heading styles (there are 5 pre-made levels)
- For numbered lists in the body text, apply the List Numbered Level styles (there is a first and second-level style available)
- For bulleted lists in the body text, apply the List Bullets Level styles (there is a first and second-level style available)
- For captions of tables and figures, the Caption style should be applied automatically when tagging tables and figures with clickable captions as described below
- For general text in tables, apply the Table Body Content style
- For numbered lists in tables, apply the Table List Numbered Level styles (there is a first and second-level style available)
- For bulleted lists in tables, apply the Table List Bullets Level styles (there is a first and second-level style available)

  - There are 2 additional pre-made styles (Title without Heading and No Spacing) that can be used and modified, as necessary

- **Numbered Sections:** Headings define the start of a new section (e.g., Introduction, Study Objectives, Investigational Plan, etc.). When changing, modifying or adding a heading, make sure to tag it with the appropriate Heading style under the Home tab, so that MS Word recognizes the heading and its (sub)level as such.
  To then insert a clickable link to a section (i.e., a cross reference) somewhere else in the text, place the cursor where the clickable link needs to be inserted, go to the References Tab, select Cross-reference, look under Reference type for the heading, and then insert the cross reference by choosing Heading number under the Insert reference to drop-down menu.
- **Sections without Numbers:** For subheadings that do not require a designated section number, and that should remain absent from the Table of Contents, use the Title Without Heading style.
- **Tables, Figures and other data:** To insert a table or figure that can be reached via a clickable link somewhere else in the text, first select the newly-inserted table or figure, then go to the Reference Tab, select Insert Caption; next choose the appropriate Label from the drop-down menu (i.e., Table or Figure), and click on the Numbering button to check the box for Include chapter number, if preferred. After clicking OK, a sequential number is automatically generated and assigned to the table/figure. Note that table captions appear *above* the table, and figure captions appear *below* the figure. Next, expand the caption with a descriptive text as necessary.
  To then reference this table or figure somewhere else in the text with a clickable link, place the cursor where the clickable link needs to be inserted, go to the Reference Tab, select Cross-reference, and look under Reference type for the referable table/figure. Note that it is best to choose Only label and number under the Insert reference to drop-down menu.
- **Citation References:** To insert a new citation reference (i.e., a reference to journal article, book, report, poster, website, etc.), first go to the Reference Tab and select Insert Citation. Then select Add new source, choose the appropriate Type of source, and fill out the required information. The reference should appear in Section 11 after updating that field.
  To then insert a citation somewhere in the text to reference in the reference list, place the cursor where the citation needs to be inserted, go to the Reference Tab and select Insert Citation, and then choose the appropriate reference from the presented list.
  To reference this reference list somewhere else in the text with a clickable link, place the cursor where the clickable link needs to be inserted, go to the Reference Tab, select Cross-reference, and look under Reference type for section 11, and then insert the cross reference by choosing Heading number under the Insert reference to drop-down menu.

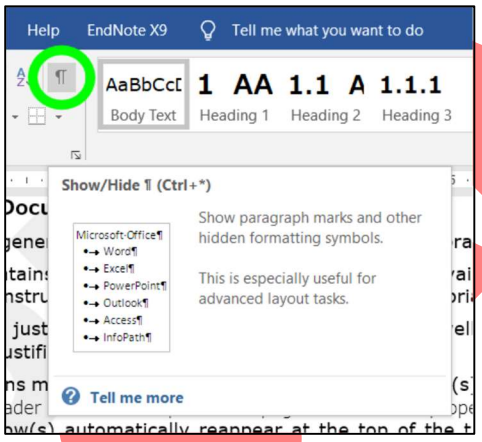
- **References to Externally-linked Files:** When Appendix documents and other files (e.g., Excel sheets or PDF files) need to be referenced in the text, clickable hyperlinks can be created in the final (approved) version of the CEP, by selecting the clickable text, then right-clicking on the selection and choosing Link to hyperlink the referenced file. To be able to easily recognize these as clickable links, the font color of the clickable text can be underlined and changed to a distinguishable blue.
- **Copying text from other documents:** When copying text from other documents, it is strongly advised to paste the text in this template without the source formatting, so that conflicting styles are not carried over. To do so, select and copy the source text, then right-click in this template where the source text needs to be pasted via Paste Options > Keep Text Only (T):



And then apply the desired style from the Styles gallery.

General Good Document Creation Practices

Below are some general guidelines for good document creation practices. Visualizing the paragraph formatting can be extremely helpful to display any hidden formatting and for cleaning up the document:



This template contains the most frequently used styles that are available in the Styles gallery (see the instructions above for how to apply these appropriately).

Body text can be justified, but numbered and bulleted lists as well as text in tables is generally not justified.

When a table spans multiple pages, select the descriptive top row(s) of the table, and use Repeat as header row at the top of each page under Table properties to have the descriptive top row(s) automatically reappear at the top of the table parts across multiple pages.

To start a new page, use the Page Break (short-cut key: Ctrl+Enter) to mark the end of the current page (instead of hitting the Enter key until the end of the page is reached). Note that Section Breaks should be avoided as much as possible, as they serve a different purpose (e.g., to change the page orientation from Portrait to Landscape), which is generally not needed; even if tables are large), or to change the headers/footers for a particular set of pages.

When aligning text vertically, use the appropriate Tab Stop Positions (instead of hitting the space bar or Tab keys many times).

To prevent a paragraph from being separated from a following paragraph (e.g., the text preceding a bullet list), select the paragraph, and check the Keep with next property under Home > Paragraph > Line and Page Breaks.

Per the University of Oxford Style Guide, there is *no* space between a number and percent, degree, or mathematical characters, like +, -, ±, >, <, ≥, ≤, ×, = (e.g., ≤5%, -4°C, and 5×3=15; be sure to use the actual degree character instead of a superscripted "o"). On the other hand, there *is* a space between a number and unit (e.g., 25 mL, 65 kg, 15 minutes); to prevent the number and unit being separated over 2 lines when at the end of the line, use the "non-breaking space" with Ctrl+Shift+Space (the same can be applied to prevent a hyphen or minus-sign getting separated from the number).

Per international standards, it is advised to use a 2-number day (dd), 3-letter capitalized month (MMM), and 4-number year (yyyy) dating format (separated by hyphens) as exemplified: August 9th, 2021 would be written as 09-AUG-2021.

Final Notes

- Delete these instructions prior to finalizing the document
- Remove the "DRAFT" watermark prior to finalizing the document via Design > Watermark > Remove Watermark
- Update the TOC last, so that the correct page numbers are displayed, by right-clicking on the TOC, and then selecting Update Field

– This line and everything above should be deleted prior to finalizing document. –

TITLE PAGE

Clinical Evaluation Plan

for

Device Name(s)

Version X.X

dd-MMM-yyyy

Company name

Address

City, State and Zip Code

Country

Confidentiality Statement

This document is confidential. It contains proprietary information of company name. Any viewing or disclosure of such information that is not authorized in writing by company name is strictly prohibited. Such information may be used solely for the purpose of reviewing the Clinical Evaluation Plan (CEP).

Clinical Evaluation Plan History

Version	Date	Description
1.0	dd-MMM-yyyy	Initial Clinical Evaluation Plan (CEP).

Add a new row for each new version, and briefly summarize (e.g., as bullet points) the edits in the Description.

SIGNATURE PAGE

Clinical Evaluation Plan Number: XXXXX

Version: X.X

First and surname
Head of Medical Affairs
Company name
Phone: +1 (XXX) XXX-XXXX
E-Mail: XXXXX@XXXX.com

Signature | Date (dd-MMM-yyyy)

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Signature | Date (dd-MMM-yyyy)

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Signature | Date (dd-MMM-yyyy)

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E-Mail: XXXXX@XXXX.com

Signature | Date (dd-MMM-yyyy)

First and surname
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Company name
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E-Mail: XXXXX@XXXX.com

Signature | Date (dd-MMM-yyyy)

First and surname
Any other department representative as needed
Company name
Phone: +1 (XXX) XXX-XXXX
E-Mail: XXXXX@XXXX.com

Signature | Date (dd-MMM-yyyy)

Update the TOC below at the very last, and *after* the instructions pages at the beginning of this Template as well as this sentence have been deleted, to ensure that correct titles of the headings and page numbers are reflected; to update, right-click anywhere on the Table of Contents below, and then select Update Field > Update Entire Table.

1 TABLE OF CONTENTS

TABLE OF TABLES

TABLE OF FIGURES

2 ACRONYMS AND ABBREVIATIONS

Below are commonly-used acronyms and abbreviations. Carefully check for usage in this document and add/delete rows as necessary. Keep in alphabetical order.

Note that abbreviated terms should be spelled out and the abbreviation indicated in parentheses at first appearance in the text.

AE	Adverse Event
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
CAPA	Corrective and Preventive Action
CDP	Clinical Development Plan
CEP	Clinical Evaluation Plan
CER	Clinical Evaluation Report
DAEN	Database of Adverse Event Notifications
ER	Essential Requirement
EU	European Union
FDA	Food and Drug Administration
GMDNS	Global Medical Device Nomenclature System
GSPR	General Safety and Performance Requirement
IFU	Instructions for Use
IMDRF	International Medical Device Regulators Forum
MAUDE	Manufacturer and User Facility Device Experience
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive
MDR	Medical Device Regulation
MHRA	Medicines and Healthcare Products Regulatory Agency
PICO	Patient characteristics, type of Intervention, Comparator group(s)/Control(s), and Outcome(s)/endpoint(s)
PMC	PubMed Central
PMCF	Post-market Clinical Follow-up
PMS	Post-market Surveillance
PSUR	Periodic Safety Update Report
R&D	Research and Development

RCT	Randomized Controlled Trial
SOTA	State-of-the-Art
TGA	Therapeutic Goods Administration
TPLC	Total Product Life Cycle
UDI-DI	Unique Device Identification-Device Identifier
US	United States
WET	Well-Established Technology

3 EXECUTIVE SUMMARY

3.1 Background

Provide the device name and model, and its device classification with a reference to the European Union (EU) Medical Device Regulation (MDR) 2017/745, Annex VIII.

If applicable, indicate since when the device was cleared for use in the United States (US) through the Food and Drug Administration (FDA) 510(k) pathway, and provide the certificate number.

If applicable, indicate since when the device was first CE-marked under the Medical Device Directive (MDD) 93/42/EEC on Medical Devices, and provide the certificate number.

If applicable, indicate since when the device was first CE-marked under the EU MDR 2017/745, and provide the certificate number.

3.2 Purpose

The purpose of this Clinical Evaluation Plan (CEP) is to define the scope, and to document the approach for the clinical evaluation of the device name to assess conformity to the European Union (EU) Medical Device Regulation (MDR) 2017/745. The clinical evaluation is intended to assess the performance and safety as well as the acceptability of the benefit/risk ratio of the subject device by identifying, appraising, and analyzing pertinent clinical and non-clinical data to determine whether the device under evaluation is in compliance with the General Safety and Performance Requirements (GSPRs) detailed in the EU MDR 2017/745 Annex I. Non-clinical tests held by the manufacturer and post-market clinical experience data from regions in which the subject device is already available will also be included in the evaluation.

The CEP is the document that provides the framework for the process of the clinical evaluation to be conducted for the generation of a Clinical Evaluation Report (CER). The CEP specifies the intended purpose of the subject device, identifies the GSPRs that require support from clinical data, and outlines how the clinical evaluation will be conducted. The documented information includes device specifications, safety and performance claims, and other aspects necessary to compile the CER.

The subsequent CER is an output of the clinical evaluation process to document the collection, appraisal, and analysis of the available clinical data relevant to the subject device, and to determine whether there is sufficient clinical evidence on the safety and performance in accordance with the intended purpose of the device. In addition, the CER documents the benefit-risk profile, including side effects in the intended target patient populations, and medical indications, if applicable, by assessing the clinical benefits against the potential hazards and patient harms, as informed by the risk management and Post-market Surveillance (PMS) documentation. The report

also evaluates the acceptability of the benefit-risk profile based on the current knowledge/state-of-the-art (SOTA) in the concerned medical field.

3.3 Scope

The scope of this CEP is limited to the planning and documentation of the conformity assessment of the EU MDR 2017/745 requirements for only the subject device.

3.4 Strategy

This CEP summarizes the systematic and planned process for collecting, analyzing, and reporting clinical data to demonstrate the safety and performance of the subject device, in accordance with EU MDR 2017/745 Article 61 and Part A of Annex XIV, following the guidelines outlined in MEDDEV 2.7/1 Rev. 4, Medical Device Coordination Group (MDCG) 2020-6, and International Medical Device Regulators Forum (IMDRF) MDCE WG/N56: 2019.

The clinical evaluation follows the strategy outlined in the Clinical Development Plan (CDP; see Section 4)