Clinical Study Protocol (CSP) Template

https://clinicalstudytemplates.com/

Template Use

This Clinical Study Protocol (CSP) Template is specifically designed to be used in conjunction with the Clinical Study Protocol Synopsis (CSPS) Template, and intended for straightforward transfer of information to the associated Clinical Study Report (CSR) Template.

Although each clinical study is unique in its design, the sections of this CSP Template include all the fundamental components of a study design, per the International Council for Harmonisation (ICH) guidelines. Moreover, the structure and sections as well as their order and content follow the ICH E3 guidelines for CSRs, conforming to the and Food and Drug Administration (FDA) requirements for proper study conduct. This enables content of the finalized CSP to be directly copied into the equivalent sections of the associated CSR Template, with only minor modifications to the tense as instructed throughout.

- For more information on ICH guidelines for CSPs, visit https://ichgcp.net/6-clinical-trial-protocol-and-protocol-amendments
- For more information on ICH guidelines for CSRs, visit https://www.ich.org/page/efficacy-guidelines
- For more information on FDA guidelines for CSRs, visit https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e3-structure-and-content-clinical-study-reports

Note that, if conducting a study with healthy volunteers, these may be referred to as "subjects" instead of "patients," except when referring to subjects that may become patients due to adverse events (AEs).

The integration of automated formatting features through the customized Styles gallery, and the exceptional ease of using this CSP 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 clinical-grade, high-quality documents that ensure consistency across other CSPs.

Taking into account the various types of clinical studies with differing designs, objectives, and endpoints, CSP authors should work with their study development team members to ensure that the design 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 product's unique aspects and specific characteristics.

Text Color-coded Instructions

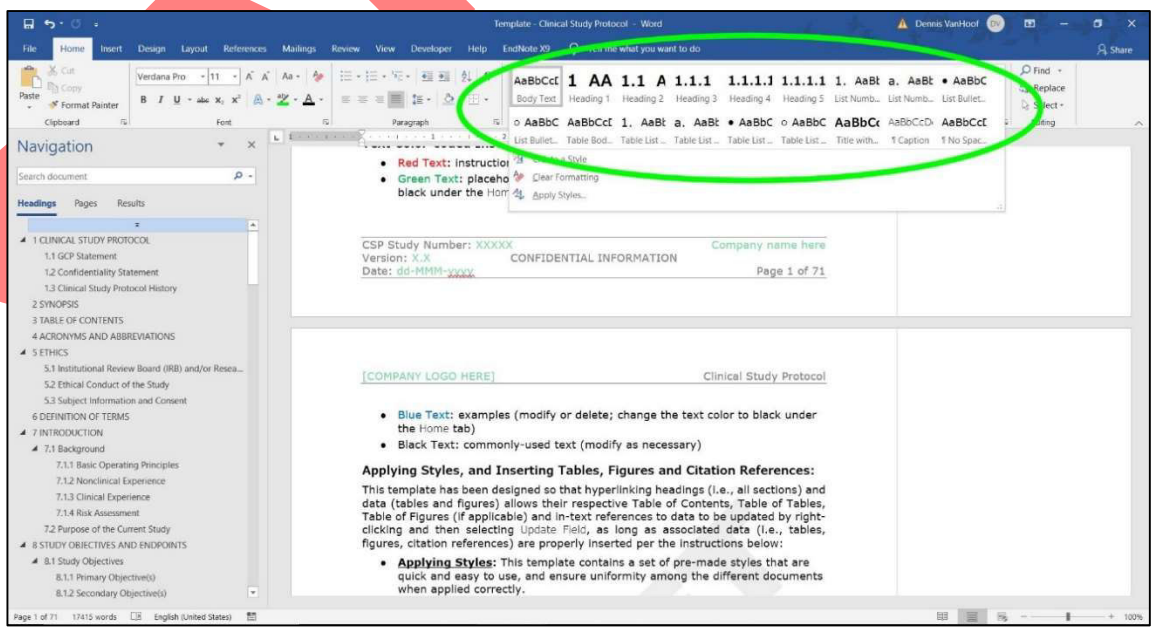
- Red Text: instructions (delete)
- Green Text: placeholder (replace, modify or delete; select and convert the text color to black by changing the Font Color under the Home tab)
- Blue Text: examples (modify or delete; select and convert the text color to black by changing the Font Color under the Home 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)
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- 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
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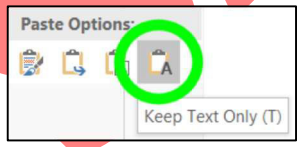
- There are 2 additional pre-made styles (Title without Heading and No Spacing) that can be used and modified, as necessary

- **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.

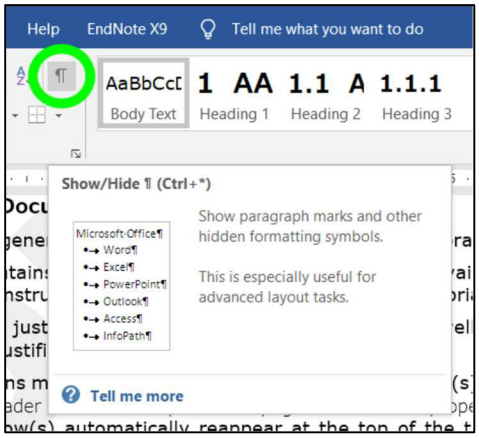
- **Citation References:** To insert a new citation reference (i.e., a reference to journal article, book, report, poster, website, etc.), first go to the Reference Tab and select Insert Citation. Then select Add new source, choose the appropriate Type of source, and fill out the required information. 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 CSP, 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. –

This is the "Title Page", which should contain the following information, and may span multiple pages.

1 CLINICAL STUDY PROTOCOL

Title	Study Title
Study product(s)	Enter the name of the test drug/investigational/study product; list all, if more than one will be used. • Study product 1 • Study product 2
Indication studied	State for which indication/disease the study will be conducted
Study design	If not apparent from the title, provide a brief (one to two sentences) description giving design (parallel, cross-over, blinding, randomized) comparison (placebo, active, dose/response), duration, dose, and patient population. Delete this row if not necessary.
Sponsor	Company name Address City, state and ZIP-code Country Phone number +XX XXX-XXX-XXXX
Study identification number	Most companies assign an internal study code or number to each study. This is optional; remove this row if not used. XXXXX
NCT number	Clinical studies should be submitted to clinicaltrials.gov. Including the assigned number here is optional; remove this row if not applicable (N/A). NCTXXXXXXXX
Development phase of the study	Phase 0, I, II, III, or IV.
Anticipated study duration	Anticipated duration of the study from the first patient enrolled, to the last study procedure completed by the last patient.
Principal Investigator or	Enter the name and affiliation of principal or coordinating investigator(s) (address and other contact information is optional) or the Sponsor's responsible medical officer.

Sponsor's responsible Medical Officer	Name Institute Address E-mail address Phone number +XX XXX-XXX-XXXX
Sponsor signatory	Enter the name and contact information of the company/sponsor person who is responsible for the study execution. This is usually the person to be contacted for questions that arise prior to or during study execution. If not included here, the contact information should be in the letter of application. Name and surname Address City, state and ZIP-code Country E-mail address Phone number +XX XXX-XXX-XXXX
Date:	dd-MMM-yyyy
Version number:	X.X

1.1 GCP Statement

The study is to be performed in full compliance with this Clinical Study Protocol (CSP), Good Clinical Practices (GCP), and applicable regulatory requirements. All required study documentation will be archived as required by regulatory authorities.

1.2 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 or performing this study.

1.3 Clinical Study Protocol History

Version	Date	Description
1.0	dd-MMM-yyyy	Initial Protocol.

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

2 SYNOPSIS

The Clinical Study Protocol Synopsis (CSPS) should be a separate document that has been reviewed and approved, prior to generating this CSP. The CSPS should contain all critical information and details to be able to generate this CSP. Copy the CSPS and paste it below. Apply the "Table Body" style if formatting is lost, and cross reference any sections of the CSP that are referred to in the CSPS (e.g., a complete list of the inclusion/exclusion criteria).

Below is a list of the frequently used sections and their order.

- Study title
- Protocol study number
- Patient population
- Medical term of the disease/disorder
- Study products
- Study purpose
- Study objectives
- Study endpoints
- Study design
- Screening and safety assessments
- Main inclusion criteria (see section 9.3.1 for a complete list)
- Exclusion criteria (see section 9.3.2 for a complete list)
- Sample size
- Study duration
- Duration of follow-up
- Study assessment summary
- Unique aspects of this study

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.

3 TABLE OF CONTENTS

Clinical Study Report (CSR) Template

https://clinicalstudytemplates.com/

Template scope and purpose

This Clinical Study Report (CSR) Template is specifically designed to be used in conjunction with the Clinical Study Protocol (CSP) Template.

The structure and sections as well as their order and content follow the International Council for Harmonisation (ICH) E3 guidelines for CSRs, as recommended by the Food and Drug Administration (FDA). As such, this CSR Template is the foundation for an "integrated" full report of any study with a therapeutic, prophylactic, or diagnostic agent (i.e., drug or treatment) conducted in patients or healthy volunteers.

Note that, if conducting a study with healthy volunteers, these may be referred to as "subjects" instead of "patients", except where subjects have become patients due to adverse events (AEs).

Per the ICH guidelines, the clinical and statistical description, presentation, and analyses are to be integrated into a single report (i.e., the CSR), incorporating tables and figures into the main text of the CSR or at the end of the text, with appendices containing such information as the CSP, sample case report forms (CRFs), investigator-related information, information related to the test drugs/investigational products (also referred to as study products), including active control/comparators, technical statistical documentation, related publications, patient data listings, and technical statistical details, such as derivations, computations, analyses, and computer output. Note that the CSR of a study should *not* be created by simply joining a separate clinical and statistical report. Although this CSR Template is mainly developed for the most common efficacy and safety clinical studies (also referred to as clinical trials), the basic principles and structure can be applied to other kinds of studies, such as clinical pharmacology studies (e.g., pharmacokinetic [PK] or biomarker of exposure [BOE] studies). Depending on the nature and importance of such studies, a less detailed report might be acceptable.

- For more information on ICH guidelines for CSRs, visit https://www.ich.org/page/efficacy-guidelines

- For more information on FDA guidelines for CSRs, visit https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e3-structure-and-content-clinical-study-reports

Template use

The integration of automated formatting features through the customized Styles gallery, and the exceptional ease of using this CSR 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 (including explanations and example text) to create clinical-grade, high-quality documents that ensure consistency across CSRs.

Taking into account the various types of clinical studies with differing designs, objectives, and endpoints, CSR authors should work with their clinical study team members to ensure data is presented in a clear and concise manner, which may require this template to be modified, so that it is in line with the product's unique aspects and specific characteristics.

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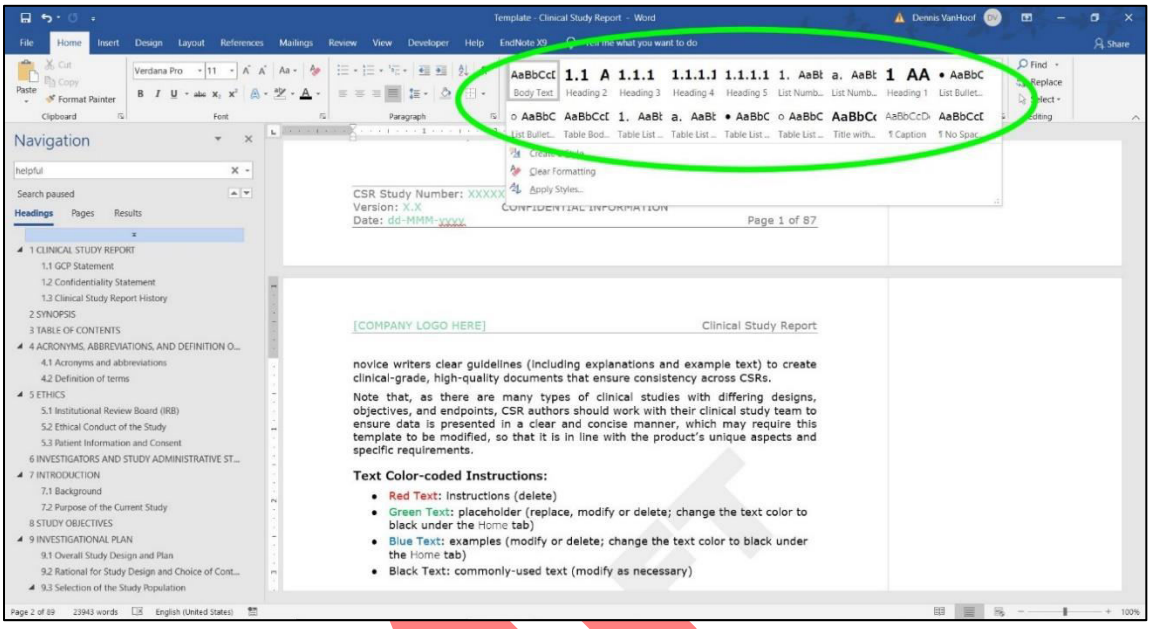

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- **Sections without Numbers:** For subheadings that do not require a designated section number, and that should remain absent from the Table of Contents, use the Title Without Heading style.
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- **Citation 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 15 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 15, 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 CSR, 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.
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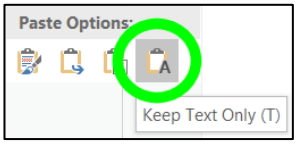

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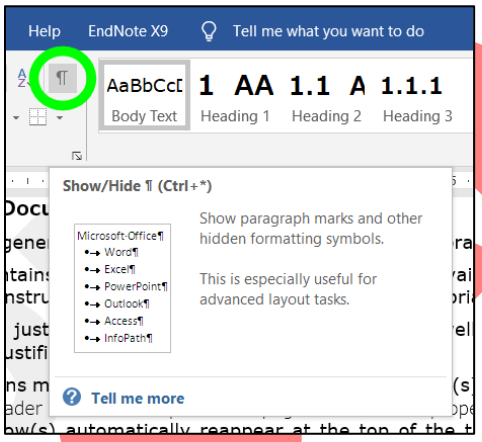

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Per international standards, it is advised to use a 2-number day (dd), 3-letter capitalized month (MMM), and 4-number year (yyyy) dating format (separated by hyphens) as exemplified: August 9th, 2021 would be written as 09-AUG-2021.

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. –

This is the "Title Page", which should contain the following information, and may span multiple pages. Copy the information from the CSP, and convert to past tense where necessary; note that the study start, end, and (if applicable) early termination dates are absent from the CSP, and only confirmed after completion of the study.

1 CLINICAL STUDY REPORT

Title	Study Title
Study product(s)	Enter the name of the test drug/investigational/study product; list all, if more than one was used. • Study product 1 • Study product 2
Indication studied	State for which indication/disease the study was conducted
Study design	If not apparent from the title, provide a brief (one to two sentences) description giving design (parallel, cross-over, blinding, randomized) comparison (placebo, active, dose/response), duration, dose, and patient population. Delete this row if not necessary.
Sponsor	Company name Address City, state and ZIP-code Country Phone number +XX XXX-XXX-XXXX
Study identification number	Most companies assign an internal study code or number to each study. This is optional; remove this row if not used. XXXXX
NCT number	Clinical studies should be submitted to clinicaltrials.gov. Including the assigned number here is optional; remove this row if not applicable (N/A). NCTXXXXXXXX
Development phase of the study	Phase 0, I, II, III, or IV.
Study initiation date	First patient enrolled, or any other verifiable definition. dd-MMM-yyyy
Date of early study termination	Remove this row if N/A. dd-MMM-yyyy

Study completion date	Last patient completed. dd-MMM-yyyy
Principal Investigator or **Sponsor's responsible Medical Officer**	Enter the name and affiliation of principal or coordinating investigator(s) (address and other contact information is optional) or the Sponsor's responsible medical officer. Name Institute Address E-mail address Phone number +XX XXX-XXX-XXXX
Sponsor signatory	Enter the name and contact information of the company/sponsor person who is responsible for the study report. This is usually the person to be contacted for questions that arise during review of the CSR. If not included here, the contact information should be in the letter of application. Name and surname Address City, state and ZIP-code Country E-mail address Phone number +XX XXX-XXX-XXXX
Date:	dd-MMM-yyyy
Version number:	X.X

1.1 GCP Statement

All clinical studies involving human participants should follow Good Clinical Practices (GCP).

This study was performed in full compliance with the Clinical Study Protocol (CSP), Good Clinical Practices (GCP), and applicable regulatory requirements. All required study documentation was archived as required by regulatory authorities.

1.2 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 or performing this study.

1.3 Clinical Study Report History

Version	Date	Description
1.0	dd-MMM-yyyy	Initial Report.

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

2 SYNOPSIS

The majority of information (except Summary and Conclusions, Study Outcome and Conclusions) can be copied from the Clinical Study Protocol (CSP) (converted to past tense) to complete the table below.

The Summary and Conclusions, and its subsections can be copied from the respective sections of the completed CSR.

Per ICH guidelines, a brief synopsis (usually limited to no more than 3 pages) that summarizes the study should be provided. The synopsis should include numerical data to illustrate results (not just text or *p*-values).

<table>
<tr><td>Name of Sponsor/Company:
Company name</td><td>Individual study table referring to part of the Dossier:
Enter here</td><td rowspan="3">(For national authority use only)</td></tr>
<tr><td>Name of finished product:
Copy from the CSP.</td><td>Volume:
Enter here</td></tr>
<tr><td>Name of active ingredient:
Enter here</td><td>Page:
Enter here</td></tr>
<tr><td colspan="3">Title of study:
Copy from the CSP.</td></tr>
<tr><td colspan="3">Investigators:
Enter here</td></tr>
<tr><td colspan="3">Study center(s):
Enter here</td></tr>
<tr><td colspan="3">Publication(s) (reference):
Publications that are based on the data of this study.
Enter here</td></tr>
<tr><td rowspan="2">Studied period:
Enter days/weeks/ months/years here</td><td colspan="2">Date of first enrollment:
dd-MMM-yyyy</td></tr>
<tr><td colspan="2">Date of last completed study procedure (i.e., end of study visit):
dd-MMM-yyyy</td></tr>
<tr><td>Objectives</td><td colspan="2">Primary objective(s):
Copy from the CSP; convert to past tense.</td></tr>
</table>

	Secondary objective(s): Copy from the CSP; convert to past tense.
Methodology: Summarize how patients were randomized to study groups/cohorts, the type(s) and order of study products that were administered to each of the cohorts, and how data were collected and analyzed.	
Number of patients planned: Copy from the CSP; convert to past tense.	
Number of patients analyzed: Enter here	
Diagnosis and main criteria for inclusion: Copy from the CSP; convert to past tense.	
Test product(s), batch/lot numbers, dose/amount/volume/concentration(s), mode(s) of administration: Copy from the CSP; convert to past tense.	
Duration of treatment: This is usually interpreted as the treatment period of a single patient from first to last product administration, and the post-monitoring period after the last treatment. Copy from the CSP; convert to past tense.	
Reference therapy, batch/lot numbers, dose/amount/volume/concentration(s), mode(s) of administration: Copy from the CSP; convert to past tense.	
Criteria for evaluation	**Efficacy:** Enter here
	Safety: Enter here
Statistical methods: Copy from the CSP or the Statistical Analysis Plan (SAP); convert to past tense.	
Summary & Conclusions: Enter here **Efficacy results (excluding safety):** Enter clinical endpoint results here **Safety results:** Enter here	

Conclusions:
Enter here

Date of report (date report issued):
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.

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