

Clinical Study Report

Write the ICH E3 clinical study report synopsis of a phase 1, 2 or 3 trial, with the disposition reconciled, the primary endpoint and its confidence interval calculated and the safety reporting checked.

WRITES

5.3.5.1

2.7 input

PRODUCT TYPE

Small molecule and
biologics

**GUIDANCE IT
FOLLOWS**

ICH E3 Structure
and Content of
Clinical Study
Reports (and
Questions &
Answers R1); ICH
E6(R3) GCP; ICH E9
and E9(R1)
estimands; 21 CFR
312.33, 314.50(d)
(5); EU CTR
536/2014 Article 37
(summary of
results); FDA
Guidance on
Submission of
Abbreviated
Reports and
Synopses (1999)

TIME TO LEARN

About 20 minutes
with the example

Open the tool at <https://app.cmcfy.com/app/clinical-study-report.html>. This guide is also online at <https://cmcfy.com/guides/clinical-study-report.html>

1. What this module does

You give the study, the primary endpoint with its alpha and p-value, the disposition and efficacy results by arm, the important deviations, the adverse events by arm, the number of narratives and the status of each E3 section.

The tool checks randomised = completed + discontinued in each arm, calculates the difference from control with a 95% confidence interval, compares the conclusion with the alpha, checks there is a

narrative for each death, serious adverse event and discontinuation for an adverse event, and tracks the E3 sections.

What you get

- A Word or PDF file: clinical study report synopsis (Module 5.3.5.1).

2. Before you start

Have these ready. You can still start with the example data and replace it piece by piece.

- Disposition and primary endpoint results by arm.
- Adverse event summary by arm.
- The statistical analysis plan (alpha, multiplicity).

Your data stays on your computer. The bar under the title counts every network request the page makes; it stays at 0 because your data never leaves your computer. [Download offline](#) [copy](#) saves a single file that opens from your own computer with all network access blocked, for air-gapped PCs.

3. Step by step with the example

Open the tool at app.cmcfy.com/app/clinical-study-report.html. The example is loaded when the page opens, so every panel already has realistic data. Follow the steps to see how it works, then replace the example with your own data.

1

Describe the study

Give the study number, phase, title, primary endpoint, alpha, p-value and the conclusion.

CMCfy

Clinical Study Report

ProjectsAll modulesTrainingSecurity

Runs entirely on this deviceTraining guide

PROJECTS

Keep this work in a project, with version history and your company logo on every report.

Choose projects folderKeep in this browser

Network requests since load: 0

Counted live by your browser. Your data never leaves this device.

Works offline

Everything the tool needs is inside this page.

Locked offline copy

Save a single file that opens from your own computer with all network access blocked.

5.3.5.12.7 input

Save projectOpen projectStart blankLoad example

Write the clinical study report of a phase 1, 2 or 3 trial to ICH E3. The tool checks the disposition adds up in each arm, calculates the primary endpoint and its 95% confidence interval, compares the conclusion with the pre-specified alpha, and checks deaths and serious adverse events have narratives, deviations are reported and each E3 section is ready.

Guidance: ICH E3 Structure and Content of Clinical Study Reports (and Questions & Answers R1); ICH E6(R3) GCP; ICH E9 and E9(R1) estimands; 21 CFR 312.33, 314.50(d)(5); EU CTR 536/2014 Article 37 (summary of results); FDA Guidance on Submission of Abbreviated Reports and Synopses (1999)

1 - STUDY

Investigational product

CMX-205 capsules

Study number

CMX-205-201

Phase

Phase 2

Title

A randomised, double-blind, placebo-controlled, 12-week st

Sponsor

CMX Therapeutics Inc.

First subject in to last subject out

2027-09-06 to 2028-04-21

Conducted in compliance with GCP, with IRB/IEC approval and

RESULT

Primary endpoint met · CMX-205 100 mg 46.7 points vs placebo

180 randomised, 19 discontinued (11%); 11 events needing a narrative, 11 written; 9 of 10 E3 sections complete.

RANDOMISED180

P-VALUE0.0004

NARRATIVES11/11

E3 SECTIONS9/10

DISPOSITION AND PRIMARY ENDPOINT

2 Enter disposition, efficacy and safety

One row per arm. Name the control arm "Placebo", "Control" or the comparator so the tool compares against it.

3 Read the result

The headline gives the outcome: "Primary endpoint met · CMX-205 100 mg 46.7 points vs placebo".

DISPOSITION AND PRIMARY ENDPOINT				
ARM	RANDOMISED	COMPLETED	DISCONTINUED	RESPONDERS
CMX-205 100 mg	60	55	5	34 (56.7%)
CMX-205 25 mg	60	54	6	21 (35.0%)
Placebo	60	52	8	6 (10.0%)

Disposition and the primary endpoint.

4 Resolve alerts and download

A disposition that does not add up, a "met" conclusion with p above alpha and a missing GCP statement are critical. Missing narratives and E3 sections are flagged. Then preview and download.

One row per arm, numbers of subjects.

Preview and review before download

Close

Review

Checked on this device: gaps in the data, gaps in the report against ICH and regional expectations, and differences from the protocol.

2 recommended

DATA AND INPUTS (2)

Some important deviations were not excluded from the per-protocol set.

State how each category of deviation was handled in the analysis sets.

recommended · Deviations · ICH E3 10.2, 11.1 Ignore

Section 16 (appendices (protocol, sample CRF, randomisation, audit certificates, statistical methods)): in progress.

Complete it before the report is signed.

recommended · ICH E3 · ICH E3 16 Ignore

Compare with the protocol

Load or paste the approved protocol. Every requirement and acceptance criterion in it is looked for in the report.

Paste the protocol text here, or load the file.

Load protocol file Compare

5.3.5.1 Clinical study report synopsis

CMX-205 capsules · CMX-205-201 · Phase 2

Study	CMX-205-201
Title	A randomised, double-blind, placebo-controlled, 12-week study of CMX-205 in adults with moderate to severe plaque psoriasis
Sponsor	CMX Therapeutics Inc.
Phase	2
Study period	2027-09-06 to 2028-04-21
Investigational product	CMX-205 capsules
Primary endpoint	Proportion of subjects achieving PASI 75 at week 12

Ethics

The study was conducted in accordance with ICH E6(R3) Good Clinical Practice and the Declaration of Helsinki. The protocol was approved by the institutional review boards and independent ethics committees, and each subject gave written informed consent.

Subject disposition

Arm	Randomised	Completed	Discontinued
CMX-205 100 mg	60	55	5
CMX-205 25 mg	60	54	6
Placebo	60	52	8

Reasons for discontinuation: Adverse event 7, withdrawal by subject 6, lost to follow-up 4, lack of efficacy 2.

Important protocol deviations

Category	Subjects	Excluded from per-protocol set
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Download Word (.docx)

Download PDF

4. Field reference

Every input in the tool, panel by panel. Tables accept rows pasted straight from Excel, comma-separated text, or a loaded file; check the columns after loading a file. Fields marked “when it applies” appear only for the choices that need them.

1 · Study

FIELD	WHAT TO ENTER
Investigational product	Type it in.
Study number	Type it in.
Phase	Choose one: Phase 1; Phase 2; Phase 3.
Title	Type it in.

FIELD	WHAT TO ENTER
Sponsor	Type it in.
First subject in to last subject out	Type it in.
Conducted in compliance with GCP, with IRB/IEC approval and informed consent	Tick the box if it applies.
Primary endpoint	Type it in.
Primary endpoint type	Choose one: Responder (yes/no); Mean change from baseline.
Two-sided alpha	Type a number.
p-value of the primary analysis	Type a number.
Conclusion on the primary endpoint	Choose one: Met; Not met; Descriptive only (no hypothesis test).

2 · Disposition and efficacy

One row per arm. For a responder endpoint give the number of responders; for a mean change give the mean and SD.

FIELD	WHAT TO ENTER
Arms	Put the control arm last, or name it Placebo or Control. A table. Columns: Arm Randomised Completed Discontinued Responders (n) Mean change SD. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Reasons for discontinuation	Type it in.
Important protocol deviations	A table. Columns: Category Subjects Excluded from per-protocol set (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Safety

One row per arm, numbers of subjects.

FIELD	WHAT TO ENTER
Adverse events	A table. Columns: Arm Any TEAE Serious AE Deaths Discontinued for AE. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Patient narratives written (number)	Type a number.
Most common adverse events	Type it in.

4 · ICH E3 sections

FIELD	WHAT TO ENTER
Section status	A table. Columns: Section Status. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

5. Checks and alerts

Calculations and pass/fail outcomes always come from fixed rules, never from AI. The tool checks:

- Disposition in every arm.
- Primary result, confidence interval and conclusion.
- Narratives, deviations and E3 sections.

How to resolve alerts

- **Critical** alerts block the download and must be fixed in the data. A failing result can instead be linked to an investigation: type the investigation reference and outcome and press [Record](#).
- **Major** alerts block the download until you fix them or type a justification and press [Accept justification](#).
- **Minor** alerts do not block anything. They are listed in the documents so the reviewer sees them.
- Some alerts have an [Apply fix](#) button that makes the change for you. [Reopen](#) undoes a justification.

Narratives

This module writes: Synopsis conclusions. Each narrative is written by fixed rules from your data. You can edit it in the box. **Rewrite with AI** (where your plan includes AI) rewrites it in regulatory style; every number in the text is checked against your data, and a number that does not match is flagged under the box and blocks the download until you correct it. **Reset to rule-based text** brings back the original.

6. Preview, gap review and download

1. Press **Preview** next to a section, or **Preview and download all**. The document opens in a preview window, exactly as the Word file will read.
2. The left side lists the review, run on your device: **gaps in the data** (missing values, open alerts), **gaps in the report** (missing content the guidance expects, placeholders such as [site] or TBD left in the text) and, if you load the approved protocol under **Compare with the protocol**, **differences from the protocol** (requirements, criteria, batches or time points it plans that the report does not show).
3. Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
4. Optional **AI review**: a second read for contradictions, claims without data and vague wording. The report text is sent to Claude only when you press it, and only where your plan includes AI. Check every AI finding; AI can be wrong.
5. Press **Download Word (.docx)** or **Download PDF**. With several documents open, **All as Word (.zip)** and **All as PDF (.zip)** download the set. The download buttons stay disabled while a blocking alert is open; the preview still works.

Documents this module produces

SECTION	DOCUMENT
5.3.5.1	Clinical study report synopsis

Use **Save project** to keep your work as a file on your computer, and **Open project** to continue later. **Start blank** clears every field; **Load example** brings the example back. Nothing is stored on CMCfy servers.

7. US and EU submissions

ICH E3 applies in the US and the EU. The EU also needs a lay summary and a results summary in CTIS (Regulation (EU) 536/2014).

8. Working with other modules

- Plan the trial in the Clinical Trial Protocol; the CSR goes in Module 5 of the NDA & BLA Submission.

9. Common pitfalls

- Claiming a met endpoint on a p-value above alpha.
- Fewer narratives than serious adverse events.

10. Practice exercises

Each exercise starts from the example (press [Load example](#) to reset). We run these on every update of this guide, so the result you see should match.

1. Check the conclusion

Change the p-value to 0.08.

EXPECTED RESULT

The headline shows a critical issue: the conclusion says met but p is not below alpha.

Guide updated 28 October 2026 for the current version of the tool. CMCfy drafts are for review by a qualified person before use in a submission.