

Clinical Trial Protocol

Write a phase 1, 2 or 3 protocol synopsis to ICH M11, with the elements expected for the phase checked and the sample size recalculated from your assumptions.

WRITES

Protocol

5.3.x

PRODUCT TYPE

Small molecule and
biologics

GUIDANCE IT FOLLOWS

ICH M11 Clinical
electronic
Structured
Harmonised
Protocol (CeSHarP);
ICH E6(R3) GCP
(principles, Annex 1
and Annex 2,
2026); ICH E8(R1);
ICH E9 and E9(R1)
estimands; ICH E10
(choice of control);
21 CFR 312.23(a)(6);
FDA Phase 1 IND
guidance (1995);
FDA Estimating the
Maximum Safe
Starting Dose
(2005); EMA
Guideline on first-
in-human clinical
trials (2017); SPIRIT
2013

TIME TO LEARN

About 20 minutes
with the example

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

1. What this module does

You give the phase, title, population and design, the objectives with their endpoints, the primary estimand, the design elements and the sample size assumptions.

For phase 1 the tool checks the starting dose against the MRSD, sentinel dosing and the dose-limiting toxicity definition. For phases 2 and 3 it checks the estimand, randomisation, blinding, control and multiplicity. It recalculates the sample size for two proportions or two means, with the allocation ratio and dropout.

What you get

- A Word or PDF file: protocol synopsis (ICH M11 section 1).

2. Before you start

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

- Objectives and endpoints.
- The primary estimand.
- The sample size assumptions (rates or difference and SD, alpha, power, dropout).

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-trial-protocol.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 trial

Choose the phase and give the protocol number, title, population and design.

CMCfy Clinical Trial Protocol Projects All modules Training Security Runs entirely on this device Training guide

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

Protocol 5.3.x Save project Open project Start blank Load example

Write a phase 1, 2 or 3 clinical trial protocol synopsis to ICH M11. The tool checks the elements expected for the phase (starting dose, sentinel dosing, DLT definition and stopping rules for phase 1; estimand, randomisation, blinding, control and multiplicity for phases 2 and 3), recalculates the sample size from your assumptions and checks every objective has an endpoint.

Guidance: ICH M11 Clinical electronic Structured Harmonised Protocol (CeSHaP); ICH E6(R3) GCP (principles, Annex 1 and Annex 2, 2026); ICH E8(R1); ICH E9 and E9(R1) estimands; ICH E10 (choice of control); 21 CFR 312.23(a)(6); FDA Phase 1 IND guidance (1995); FDA Estimating the Maximum Safe Starting Dose (2005); EMA Guideline on first-in-human clinical trials (2017); SPIRIT 2013

1 - TRIAL

Investigational product

CMX-205 capsules

Protocol number

CMX-205-301

Phase

Phase 3

Title

A randomised, double-blind, placebo-controlled, 16-week pt

Population

Adults 18-75 years with plaque psoriasis for at least 6 month

RESULT

Phase 3 protocol complete · 43 subjects needed, 450 planned

5 objectives (2 primary); double-blind, placebo control.

PHASE	OBJECTIVES	NEEDED
3	5	43
PLANNED	450	

OBJECTIVES AND ENDPOINTS

2 Enter objectives and design elements

One row per objective with its endpoint. For phase 1, give the starting dose, MRSD and DLT definition.

3 Read the result

The headline gives the outcome: "Phase 3 protocol complete · 43 subjects needed, 450 planned".

OBJECTIVES AND ENDPOINTS

TYPE	OBJECTIVE	ENDPOINT
primary	Show that CMX-205 is superior to placebo in clearing psoriasis	PASI 75 response at week 16
primary	Show that CMX-205 is superior to placebo on the physician global assessment	sIGA 0/1 at week 16
key secondary	Compare complete clearance	PASI 100 at week 16
secondary	Assess maintenance of response	PASI 75 at week 52 in week-16 responders
safety	Assess safety and tolerability	TEAEs; laboratory values; vital signs

Objectives and endpoints.

4 Resolve alerts and download

No primary objective, a non-randomised phase 3, a starting dose above the MRSD and no DLT definition are critical. A missing estimand, multiplicity strategy or schedule of activities, and a sample size below the calculation, are flagged. Then preview and download.

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.

1 recommended

REPORT CONTENT (1)

Repeated word: "Protocol Protocol".

Correct the typing error.

recommended **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

AI review against guidance

AI reads the report, the protocol and the data against the ICH, FDA or EMA requirements for these sections, and lists gaps with the guideline it applies, protocol and data mismatches, and how to fix them. You see exactly what is sent before anything leaves this device. Results and pass/fail are not changed.

Run AI review

Protocol Protocol synopsis (ICH M11 section 1)

CMX-205 capsules · CMX-205-301 · Phase 3

Protocol	CMX-205-301
Title	A randomised, double-blind, placebo-controlled, 16-week phase 3 study of CMX-205 in adults with moderate to severe plaque psoriasis, with a 36-week extension
Phase	3
Investigational product	CMX-205 capsules
Population	Adults 18–75 years with plaque psoriasis for at least 6 months, PASI ≥ 12, sIGA ≥ 3 and BSA ≥ 10%, candidates for systemic therapy
Planned sample size	450
Blinding	Double-blind
Control	Placebo

Objectives and endpoints

Type	Objective	Endpoint
Primary	Show that CMX-205 is superior to placebo in clearing psoriasis	PASI 75 response at week 16
Primary	Show that CMX-205 is superior to placebo on the physician global assessment	sIGA 0/1 at week 16
Key secondary	Compare complete clearance	PASI 100 at week 16
Secondary	Assess maintenance of response	PASI 75 at week 52 in week-16 responders
Safety	Assess safety and tolerability	TEAEs; laboratory values; vital signs

Rationale and design

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 · Trial

FIELD	WHAT TO ENTER
Investigational product	Type it in.
Protocol number	Type it in.
Phase	Choose one: Phase 1; Phase 2; Phase 3.
Title	Type it in.
Population	Type it in.
Design	Type or paste text.

2 · Objectives and endpoints

One row per objective. Type: primary, key secondary, secondary, exploratory or safety.

FIELD	WHAT TO ENTER
Objectives	Type is primary, key secondary, secondary, exploratory or safety. A table. Columns: Type Objective Endpoint. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Primary estimand (ICH E9(R1): population, variable, intercurrent events and strategy, summary measure)	Type or paste text.

3 · Design elements

FIELD	WHAT TO ENTER
Randomised when it applies	Tick the box if it applies.

FIELD	WHAT TO ENTER
Blinding	Choose one: Double-blind; Single-blind; Open label.
Control	Choose one: Placebo; Active comparator; Dose comparison; None.
Multiplicity control for more than one primary or key secondary endpoint when it applies	Type it in.
Independent data monitoring committee	Tick the box if it applies.
Schedule of activities included	Tick the box if it applies.
Starting dose (mg) when it applies	Type a number.
MRSD from the NOAEL (mg) when it applies	Type a number.
Sentinel dosing when it applies	Tick the box if it applies.
Dose-limiting toxicity definition and stopping rules when it applies	Type it in.

4 · Sample size

FIELD	WHAT TO ENTER
Primary endpoint type	Choose one: Two proportions; Two means; No formal calculation (phase 1 or pilot).
Response, test arm (%) when it applies	Type a number.
Response, control arm (%) when it applies	Type a number.
Difference to detect when it applies	Type a number.

FIELD	WHAT TO ENTER
Standard deviation when it applies	Type a number.
Two-sided alpha when it applies	Type a number.
Power (%) when it applies	Type a number.
Allocation ratio (test : control) when it applies	Type a number.
Expected dropout (%) when it applies	Type a number.
Planned total sample size	Type a number.

5. Checks and alerts

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

- Every objective has an endpoint.
- Phase-specific design elements.
- Sample size from the assumptions.

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 rationale and design. 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
Protocol	Protocol synopsis (ICH M11)

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 M11, E6(R3) and E9(R1) apply in the US and the EU; first-in-human checks follow FDA (2005) and the EMA FIH guideline (2017).

8. Working with other modules

- The protocol is part of the IND Application; report the trial in the Clinical Study Report. CMC study protocols are in the Protocol Builder.

9. Common pitfalls

- Two primary endpoints and no multiplicity strategy.
- A sample size that leaves out the dropout.

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. Plan a smaller trial

Change the planned total sample size from 450 to 40.

EXPECTED RESULT

The headline shows the sample size is below what the assumptions need.

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.