

IND Application

Assemble a complete initial IND under 21 CFR 312.23, with each item tracked to its eCTD location, the clinical hold risks checked and the earliest start date set.

WRITES

IND 1571

IND (a)(3)

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

21 CFR 312.20–312.23, 312.40–312.42, 312.53; FDA Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies (1995); FDA Investigator's Brochure and IND content guidance; FDA Estimating the Maximum Safe Starting Dose (2005); ICH M3(R2); FDA Providing Regulatory Submissions in Electronic Format (eCTD); 21 CFR 25.31(e)

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You give the sponsor, drug, indication and IND type, the first trial with its dosing duration and doses, the safety safeguards and the status of each IND item.

The tool lists the items 21 CFR 312.23 requires (an Investigator's Brochure is not needed for a sponsor-investigator IND), flags the clinical hold risks FDA reviews (toxicology shorter than the dosing, a starting dose above the MRSD, no stopping rules) and writes the cover letter, introductory statement and general investigational plan.

What you get

- Two Word or PDF files: cover letter with introductory statement and general investigational plan; IND content checklist with the Form FDA 1571 commitments.

2. Before you start

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

- The pre-IND meeting minutes.
- The first protocol, its dosing duration and doses.
- The MRSD from the Nonclinical Overview.

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/ind-application.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 sponsor and product

Choose commercial or research IND and give the indication, review division and planned submission date.

CMCfy IND Application 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.

IND 1571 IND (a) (3) Save project Open project Start blank Load example

Assemble a complete initial IND under 21 CFR 312.23: Form FDA 1571 and the forms that go with it, the introductory statement and general investigational plan, the Investigator's Brochure, the protocol, CMC, pharmacology and toxicology and previous human experience. The tool shows what is ready, checks the clinical hold risks FDA looks at in the 30-day review, and gives the earliest date the trial can start.

Guidance: 21 CFR 312.20–312.23, 312.40–312.42, 312.53; FDA Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies (1995); FDA Investigator's Brochure and IND content guidance; FDA Estimating the Maximum Safe Starting Dose (2005); ICH M3(R2); FDA Providing Regulatory Submissions in Electronic Format (eCTD); 21 CFR 25.31(e)

1 · SPONSOR AND PRODUCT

Drug

CMX-205 capsules, 25 mg and 100 mg

Sponsor

CMX Therapeutics Inc., Ralt

IND type

Commercial (eCTD requi

Indication

Moderate to severe plaque psoriasis

FDA review division

Division of Dermatology and

RESULT

11 of 14 IND parts ready · 3 still open

Commercial IND in eCTD; first in human. Planned submission 2026-12-01; FDA has 30 days to review before the trial may start.

READY	OPEN	EARLIEST START
11/14	3	2026-12-31
START / MRSD		
10 / 58 mg		

IND CONTENT (21 CFR 312.23)

2 Describe the first trial

Give the longest dosing, the longest toxicology study, the starting dose, MRSD and highest dose, and tick the safeguards.

3 Read the result

The headline gives the readiness: "11 of 14 IND parts ready · 3 still open".

IND CONTENT (21 CFR 312.23)			
ITEM	REGULATION	STATUS	DOCUMENT
Form FDA 1571	21 CFR 312.23(a)(1)	complete	m1/us/1571.pdf
Cover letter	FDA IND application guidance	complete	m1/us/cover.pdf
Table of contents	21 CFR 312.23(a)(2)	complete	eCTD backbone
Introductory statement and general investigational plan	21 CFR 312.23(a)(3)	complete	m1/us/introductory-statement.pdf
Investigator's Brochure	21 CFR 312.23(a)(5)	In progress	m1/us/ib v0.9
Clinical protocol	21 CFR 312.23(a)(6)	complete	m5 CMX-205-101 v1.0
Chemistry, manufacturing and controls	21 CFR 312.23(a)(7)	complete	m3 (IND & IMPD Quality)
Pharmacology and toxicology	21 CFR 312.23(a)(8)	complete	m2.4 and m4 (Nonclinical Overview)
Previous human experience	21 CFR 312.23(a)(9)	complete	m1/us/introductory-statement.pdf
Additional information (drug dependence, radioactive drugs, paediatric studies)	21 CFR 312.23(a)(10)	complete	m1/us/additional-information.pdf
Form FDA 1572 (each investigator)	21 CFR 312.53(c)	In progress	m1/us/1572 (2 of 3 sites)
Form FDA 3674 (ClinicalTrials.gov certification)	42 U.S.C. 282(j)(5)(B)	complete	m1/us/3674.pdf
Environmental assessment or claim of categorical exclusion	21 CFR 25.31(e)	complete	m1/us/categorical-exclusion.pdf
Letters of authorisation for referenced DMFs or INDs	21 CFR 312.23(b)	Not started	m1/us/loa

IND content under 21 CFR 312.23.

4

Resolve alerts and download

Toxicology shorter than the dosing, a starting dose above the MRSD, no stopping rules and a missing required item are critical. Then preview and download.

psoriasis.

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.

3 to fix

DATA AND INPUTS (3)

Investigator's Brochure: in progress.
Complete it before submission.
major · Content · 21 CFR 312.23(a)(5) Ignore

Form FDA 1572 (each investigator): in progress.
Complete it before submission.
major · Content · 21 CFR 312.53(c) Ignore

Letters of authorisation for referenced DMFs or INDs: not started.
Complete it before submission.
major · Content · 21 CFR 312.32(b) 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.

IND (a)(3) Cover letter, introductory statement and general investigational plan

CMX-205 capsules, 25 mg and 100 mg · CMX-205-101: randomised, double-blind, placebo-controlled single and multiple ascending dose study in healthy adults

Cover letter

Division of Dermatology and Dentistry (CDER) Center for Drug Evaluation and Research, Food and Drug Administration

Re: Initial Investigational New Drug Application (Serial No. 0000), CMX-205 capsules, 25 mg and 100 mg

CMX Therapeutics Inc., Raleigh NC submits this initial IND for CMX-205 capsules, 25 mg and 100 mg for moderate to severe plaque psoriasis. The application contains Form FDA 1571, the introductory statement and general investigational plan, the Investigator's Brochure, protocol CMX-205-101, chemistry, manufacturing and controls information, pharmacology and toxicology information and previous human experience, with letters of authorisation for the referenced master files. It is provided in eCTD format.

The trial will not start before 2026-12-31, 30 days after FDA receives the application, unless FDA notifies us earlier that it may proceed.

Introductory statement

CMX Therapeutics Inc., Raleigh NC submits this initial Investigational New Drug Application for CMX-205 capsules, 25 mg and 100 mg for the treatment of moderate to severe plaque psoriasis.

CMX-205 is an oral, selective TYK2 inhibitor. In a mouse imiquimod model it reduced ear thickness and IL-23/IL-17 pathway gene expression in a dose-dependent manner. Selectivity for TYK2 over JAK1-3 is more than 1 000-fold in cellular assays, which is expected to avoid the laboratory changes seen with JAK inhibitors.

Previous human experience: none. CMX-205 has not been given to humans and is not marketed in any country.

The first protocol is CMX-205-101: randomised, double-blind, placebo-controlled single and multiple ascending dose study in healthy adults. The longest planned dosing is 2 weeks, supported by GLP repeat-dose toxicity studies of 4 weeks in a rodent and a non-rodent species. The starting dose of 10 mg is below the maximum recommended starting dose of 58 mg derived from the NOAEL, and doses will be escalated to at most 400 mg under the stopping rules and

Fix or justify the 3 blocking alerts before downloading. Or choose "Download anyway".

Download anyway 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 · Sponsor and product

FIELD	WHAT TO ENTER
Drug	Type it in.
Sponsor	Type it in.
IND type	Choose one: Commercial (eCTD required); Research (sponsor-investigator).
Indication	Type it in.
FDA review division	Type it in.
Pre-IND meeting held (date and key agreements)	Type it in.

FIELD	WHAT TO ENTER
DMFs or other INDs referenced	Tick the box if it applies.
Planned submission date	Type it in.

2 · Clinical plan and safety

FIELD	WHAT TO ENTER
First trial	Choose one: Phase 1 (first in human); Phase 1 (not first in human); Phase 2; Phase 3.
First protocol	Type it in.
Longest planned dosing in the trial (weeks)	Type a number.
Longest GLP repeat-dose toxicity study, rodent and non-rodent (weeks)	Type a number.
Starting dose (mg)	Type a number.
Maximum recommended starting dose from the NOAEL (mg)	Type a number.
Highest planned dose (mg)	Type a number.
Sentinel dosing and staggered cohorts	Tick the box if it applies.
Stopping rules and dose escalation criteria in the protocol	Tick the box if it applies.
General investigational plan for the coming year	Type or paste text.
Rationale for the drug and the research	Type or paste text.
Previous human experience	Type it in.

3 · IND content

Status: complete, in progress, not started or not applicable. Add the document or the module where it sits.

FIELD	WHAT TO ENTER
Items	<p>Write the status as complete, in progress, not started or not applicable. A table. Columns: Item Status Document or location.</p> <p>Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).</p>

5. Checks and alerts

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

- Every 21 CFR 312.23 item and the forms that go with it.
- Toxicology duration, starting dose and first-in-human safeguards.
- Earliest start 30 days after receipt.

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: Introductory statement; General investigational plan. 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.

- 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).
- Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
- 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.
- 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
IND (a)(3)	Cover letter, introductory statement and investigational plan
IND 1571	IND content checklist

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

US only: FDA IND under 21 CFR Part 312. For an EU clinical trial application use the IMPD in IND & IMPD Quality.

8. Working with other modules

- Write the CMC part in IND & IMPD Quality and the pharmacology and toxicology part in Nonclinical Overview & Summaries.

9. Common pitfalls

- A 4-week toxicology package for a 12-week trial.
- Marking the IB not applicable for a commercial IND.

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 longer trial**

Change the longest planned dosing from 2 to 12 weeks.

EXPECTED RESULT

The headline shows a clinical hold risk: toxicology is shorter than the dosing.

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.