

# Submission Builder

How regulatory  
work *flows*

## THE ONE THING STANDING BETWEEN YOU AND FASTER DRUG APPROVALS ISN'T WHAT YOU THINK.

It's not regulatory complexity or FDA requirements (well, not just that). **It's the workflow.** When data and requirements change, maintaining accuracy, alignment, and defensibility becomes a bottleneck. Submission Builder is the only regulatory AI platform designed to reduce that friction across complex dossiers, enabling teams to move faster with confidence.

## ONE POWERFUL PLATFORM FROM PRECLINICAL TO APPROVAL

You've got the **expertise** to transform therapeutic outcomes. Now you have the platform to match. Upload your source files, customize your templates, and collaborate live with your team. Generate high-quality first drafts in minutes, not months, and watch as formatting, citations, and compliance checks become effortless while you build a compelling case for approval.

## BUILT FOR THE REALITIES OF REGULATORY WORK

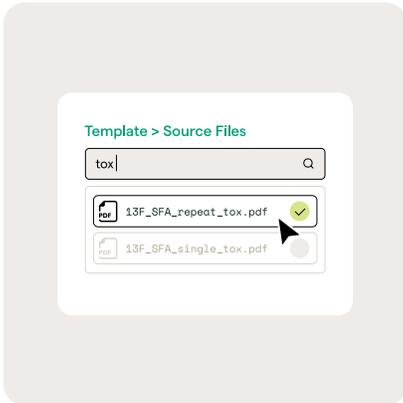
With two-click source tracing, real-time version control, and documents completed up to **70% faster**, Submission Builder helps teams maintain clarity and defensibility as submissions evolve—turning the workflow from a bottleneck into a strength.

GO FROM

1  
month

TO

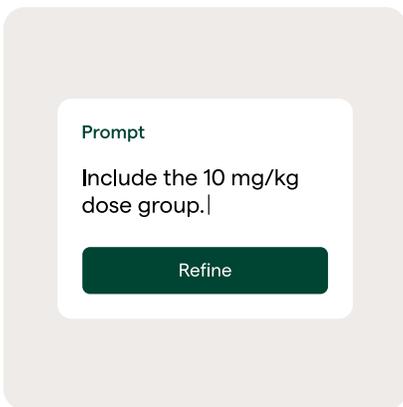
1  
hour  
for first draft



01

## Upload & draft

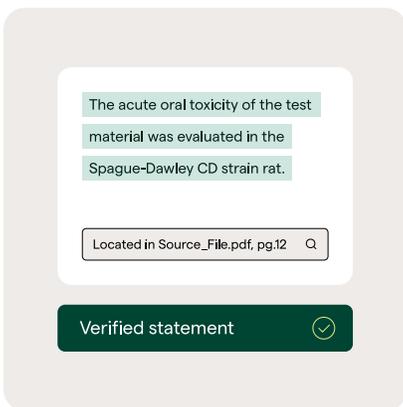
Import your source files and customize your templates for a first draft in 43 minutes. (We timed it.)



02

## Refine & review

You direct the AI like a conductor guides an orchestra, while your team collaborates in real time—AI review included.



## Verify & publish

Stay agile when requirements shift. Trace any claim back to source data in two clicks and export submission-ready docs.

Think at full speed. Work at full strength.