weave

WEAVE.BIO

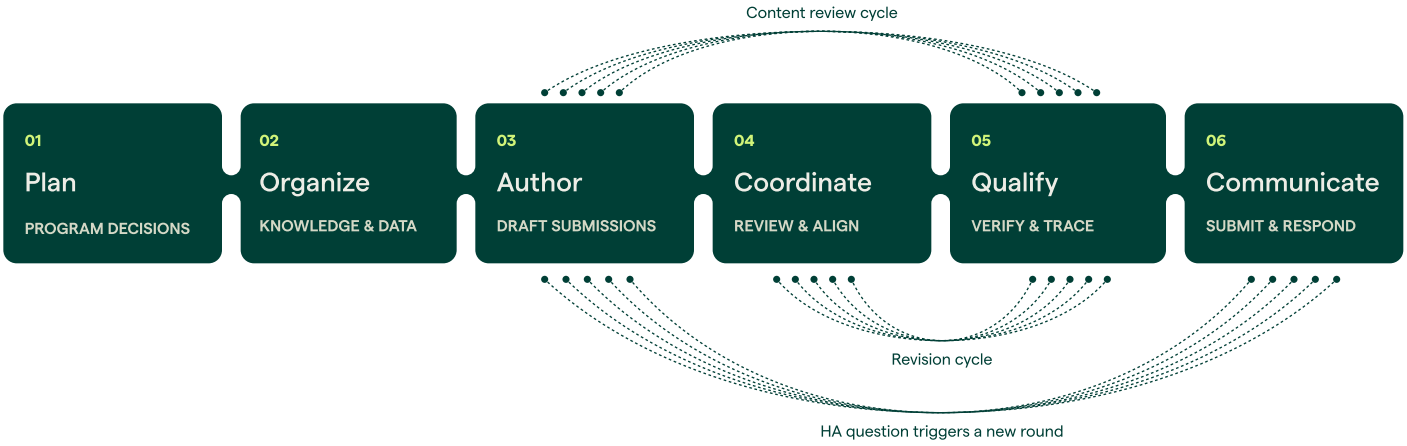
How regulatory work *flows*

An AI-native platform built for regulatory teams — from first program planning through every health authority interaction.

TRUSTED BY BIOTECHS, TOP 20 PHARMA, AND CROS

6	97%	60%	5 min
SUCCESSFUL FDA SUBMISSIONS	FASTER FIRST DRAFTS	FASTER NDA TIMELINE	HAQ TO RTQ

DELIVERING SPEED + RIGOR ACROSS SIX CORE WORKFLOWS



01 PLAN

Smarter program decisions

Coming soon: AI-guided program planning support

Management of program metadata, gap analysis (e.g. what data do we have or need to acquire), and predictive planning based on prior HAQs.

02 ORGANIZE

Centralized, searchable knowledge

Knowledge and metadata centralization and curation

AI Data Room auto-classifies, summarizes, and extracts data from source files. Deep search by keyword or description — synced with Veeva.

03 AUTHOR

High-quality drafts in a fraction of the time

Templated content creation and effortless iteration

Auto-draft and AI-refine documents for US and global submissions, including all eCTD modules (1-5) and CTAs. Customizable templates, dynamic variables, and one-click export to Word or Veeva.

04 COORDINATE

Align teams and CROs without bottlenecks

Collaborative review across teams and orgs

Live co-authoring, in-platform commenting, AutoReview, and redline suggesting mode — with controlled roles and configurable dossier visibility.

05 QUALIFY

Every claim traced, every dataset verified

Comprehensive data provenance and history

Sentence-level source tracing, automated data verification, and full version history with restore — so you can submit with complete confidence.

06 COMMUNICATE

Faster, more complete HA responses

Share content with any global health authority

HAQ Manager auto-extracts and routes HA questions, surfaces relevant source files, and publishes eCTD-structured PDFs for any global health authority.

One platform, *every stage of development.*

PRE-IND | BRIEFING BOOKS | IND / CTA | PROTOCOLS | IB | CSR | NDA / BLA / MAA | HA Q&A

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