AI by the Numbers: Quantified Impact on Regulatory Workflows in Clinical Development

Daniel Pointing – Associate Director, Business Development

weave

About Weave

Diverse Customers

- Top 20 Pharma
- Mid-size therapeutics
- Small + startup biotechs
- Global CROs
- CDMOs

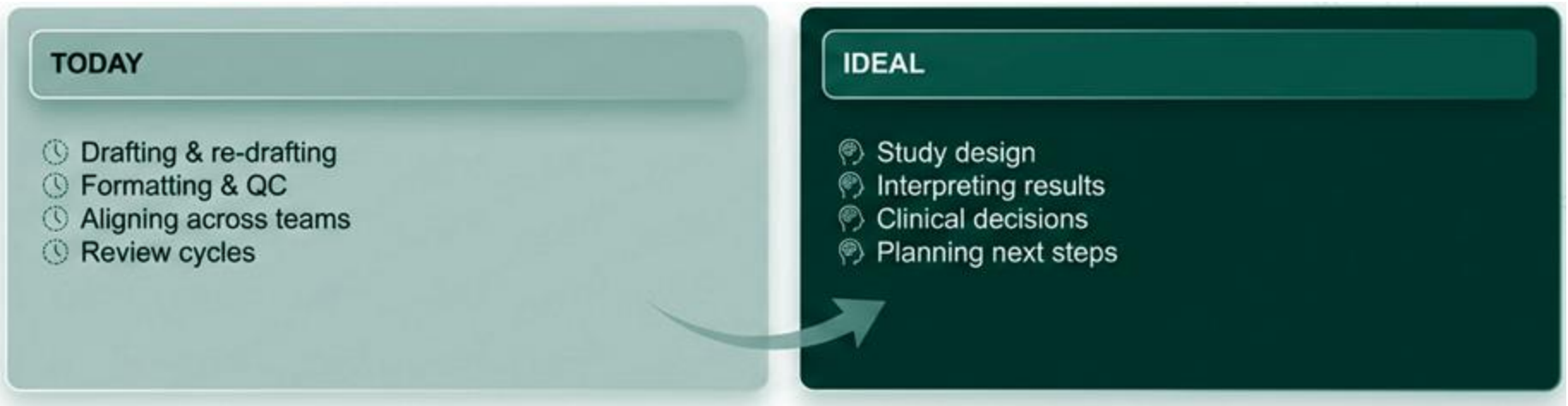
$36 Million Raised

- USVP
- Innovation Endeavors
- Magnetic Ventures
- Character
- TMV

Our perspective

1. Document workflows sit on the critical path
2. Much of the work is still manual
3. This creates delays and variability

Timeline allocation today vs ideal

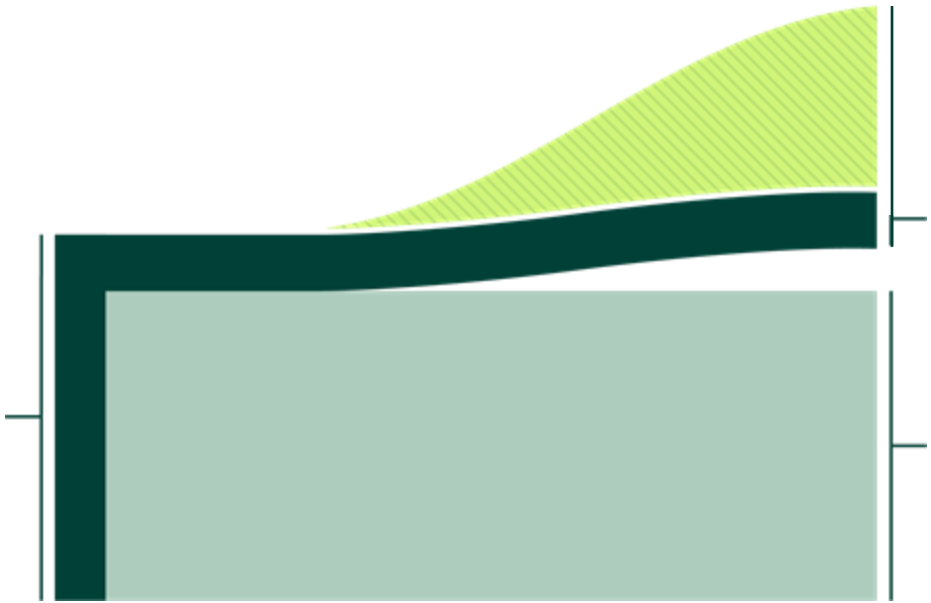


Shifting effort, not replacing expertise

Where AI actually helps (and where it doesn't)

Without AI

Humans do everything



With AI Support

Humans focus on what matters most

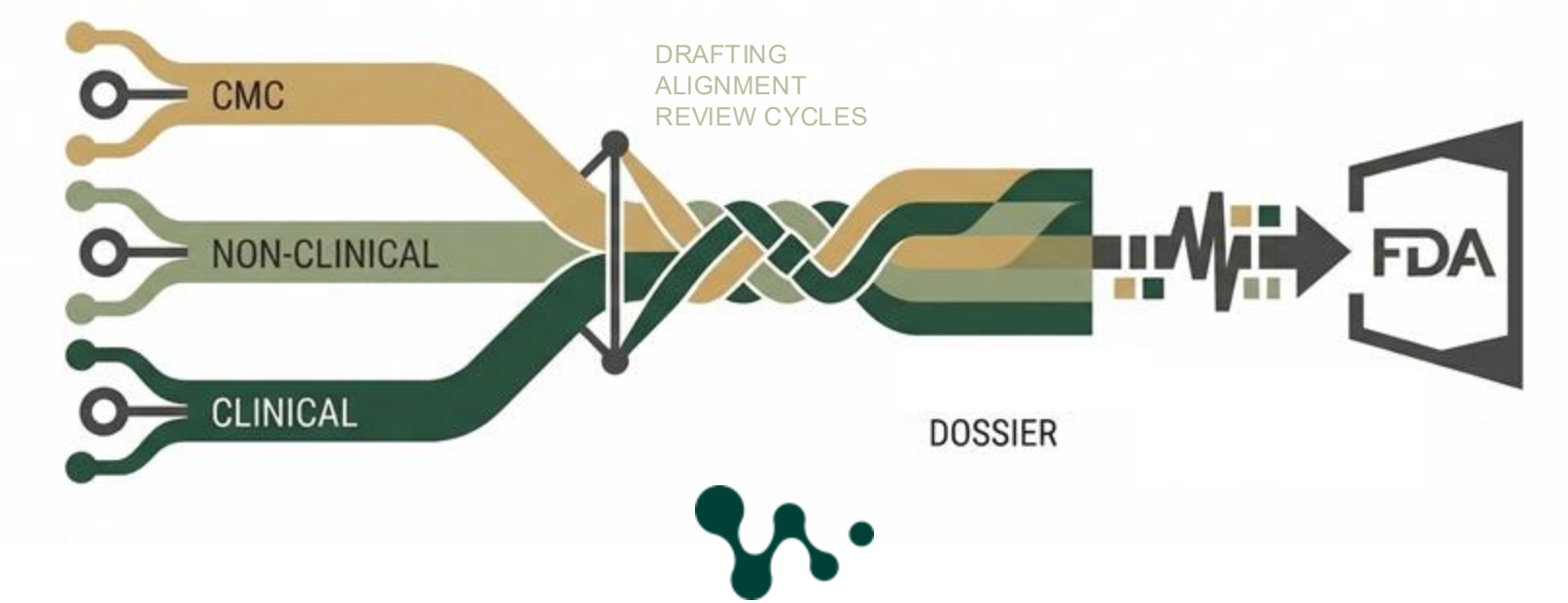
Experiment, interpret, strategize, narrate, plan, decide...and more

AI handles structured work

Structure information, draft first-pass content, support QC and consistency, track changes

Where this work shows up

These workflows are still largely manual—and remain on the critical path



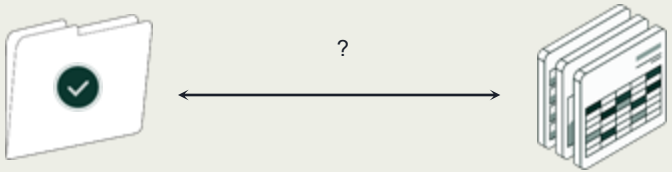
What changed

WEAVE + TAKEDA

Drafting time

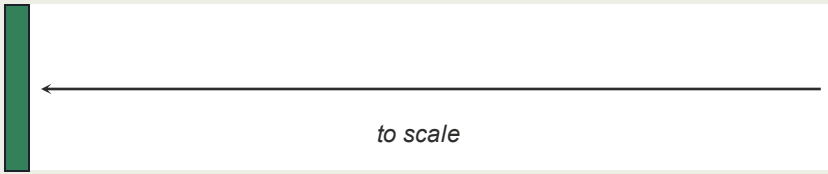
MANUAL ⟶ WEAVE

- 2 historical INDs
- 100 first draft study summaries
- Pharmacology, PK, toxicology



TIME

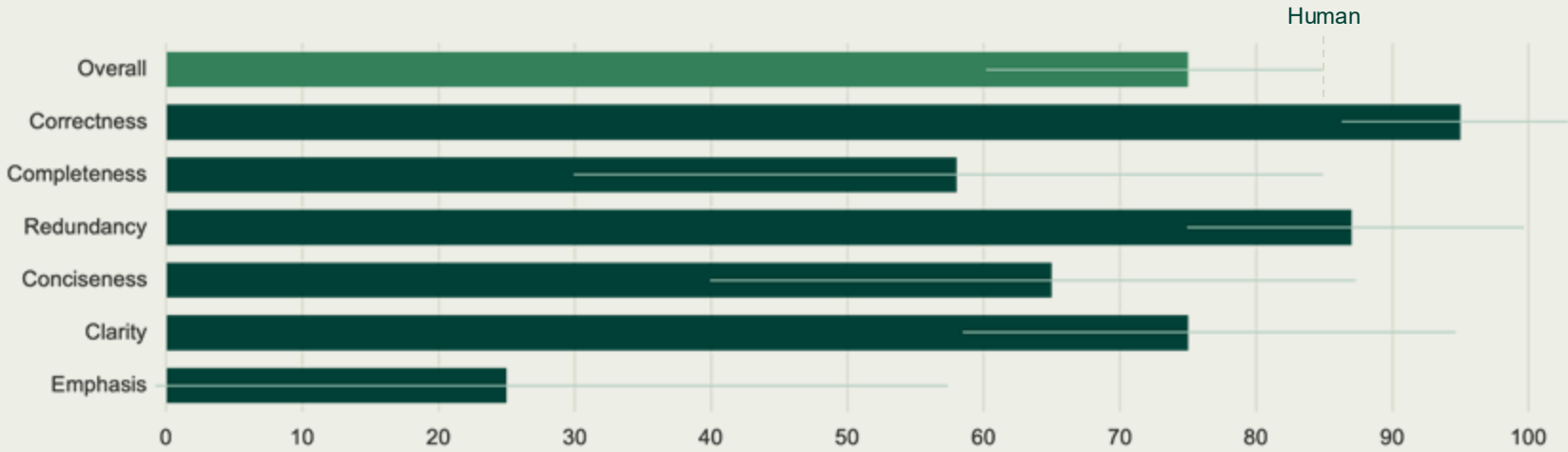
100 hours (Manual)
⟶ **3 HOURS** (Weave, 97% faster)



WEAVE + TAKEDA

Quality & consistency

QUALITY

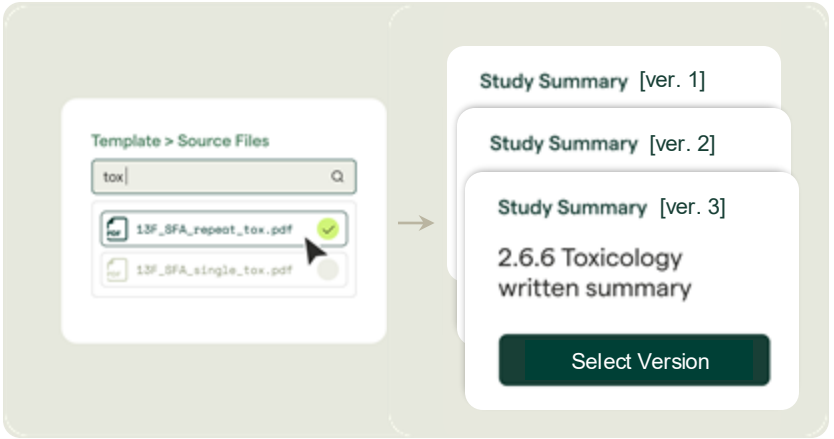


Review cycles

Fewer iteration loops, faster alignment across teams
Reduced iteration cycles (e.g., 5–7 → 2–3)

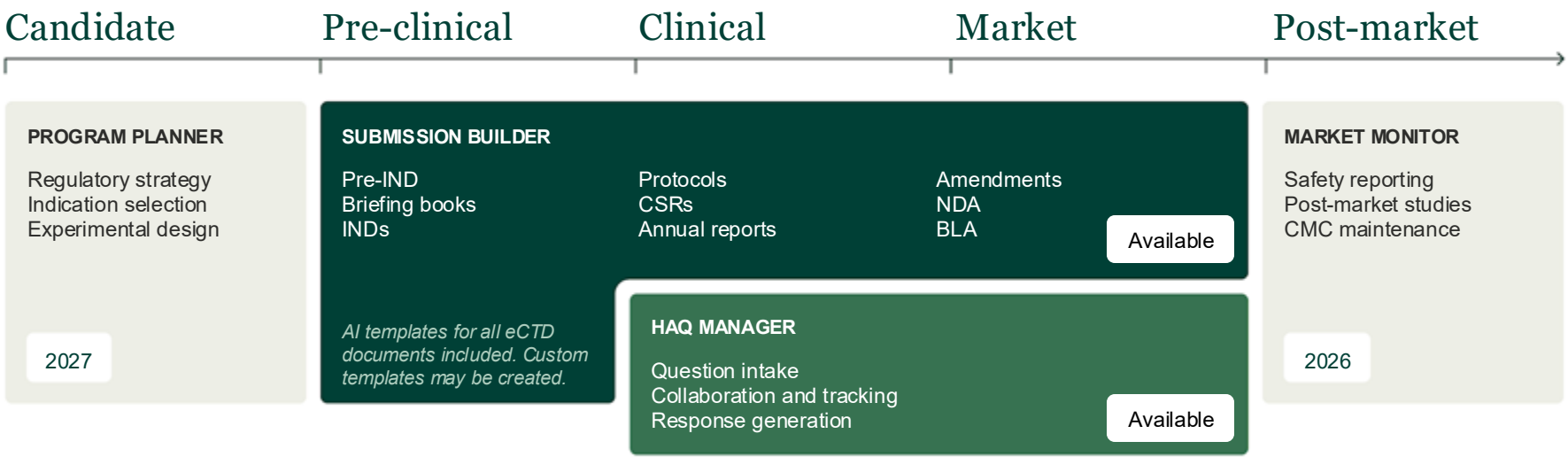
QC/REVIEW EVERY DRAFT

A NARRATIVE FOR EVERY OUTCOME



WRITE TO THINK

Lifecycle from beginning to end



Hands-on time savings **50%**

IND prep acceleration **66%**

NDA (2.3) timeline acceleration **60%**

Real-world impact

Faster timelines with consistent quality

Contract to draft IND

2 weeks

Submission-ready IND

50 days

“I’ve been able to put my time towards other things that are essential to our success.”

- Nathan McMahon, PhD, Director of Clinical Operations

Reports to draft IND **<1 day**

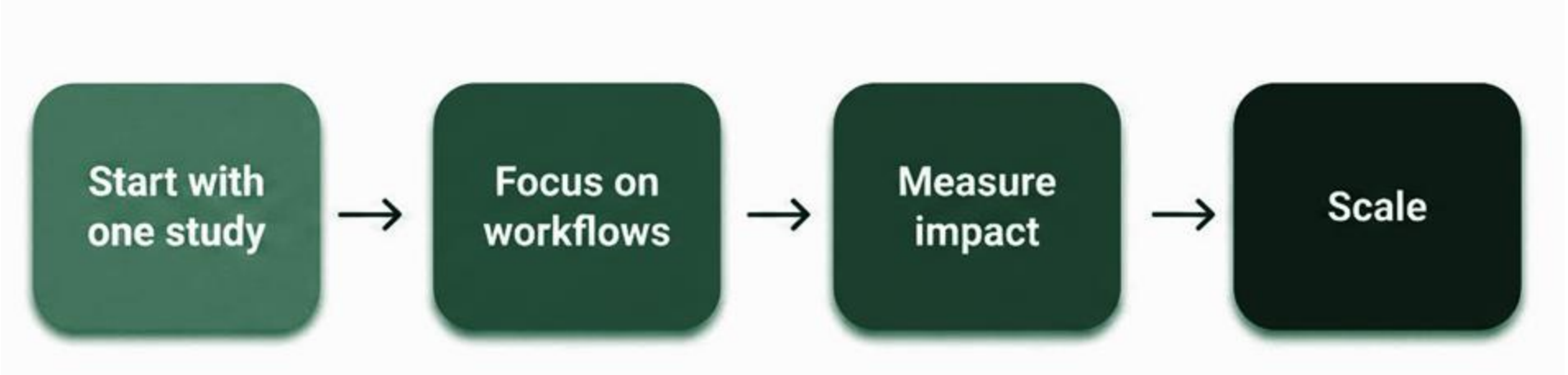
Users **20**

enveda®

“It was done at record speed.”

- Niranjan Rao, PhD, FCP, Chief Development Officer

A how-to guide



Start small, measure impact, then expand

Thank you.

Visit us @ booth #13

Please reach out with questions or comments:

daniel@weave.bio

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