



Faster Access to Medicines

From Pilot to Production: A Pfizer and Vivpro AI Case Study on Scaling AI-Enabled Document Generation Across R&D

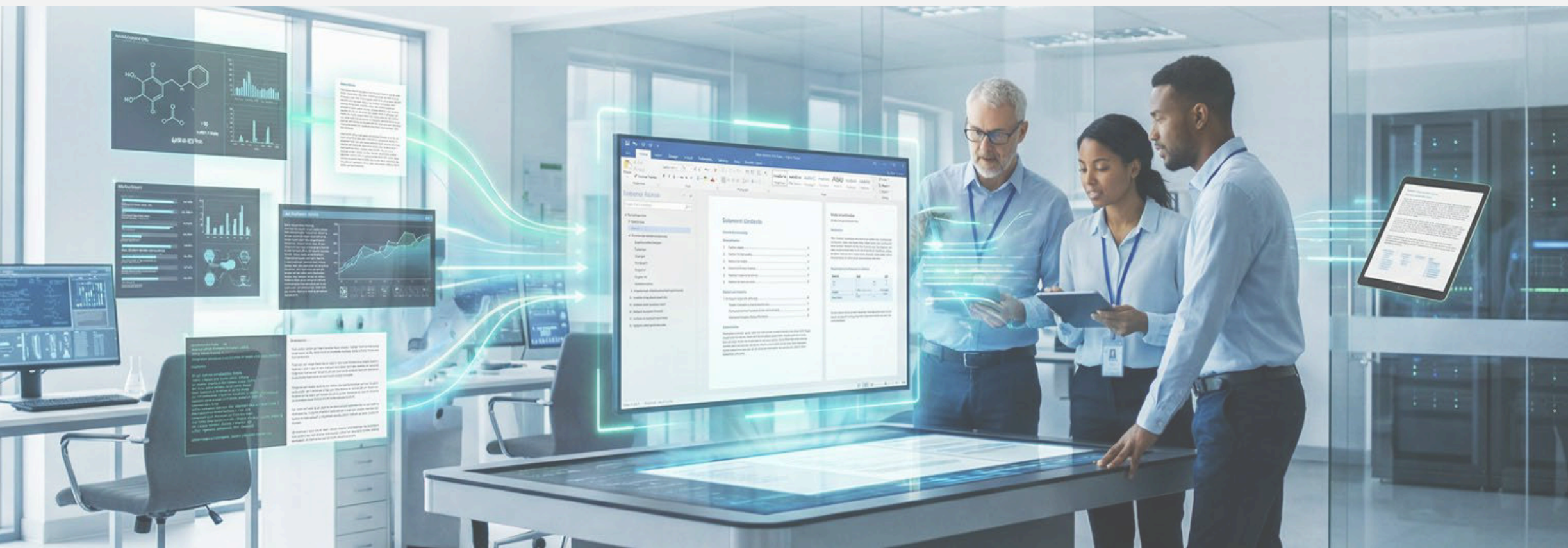
regain



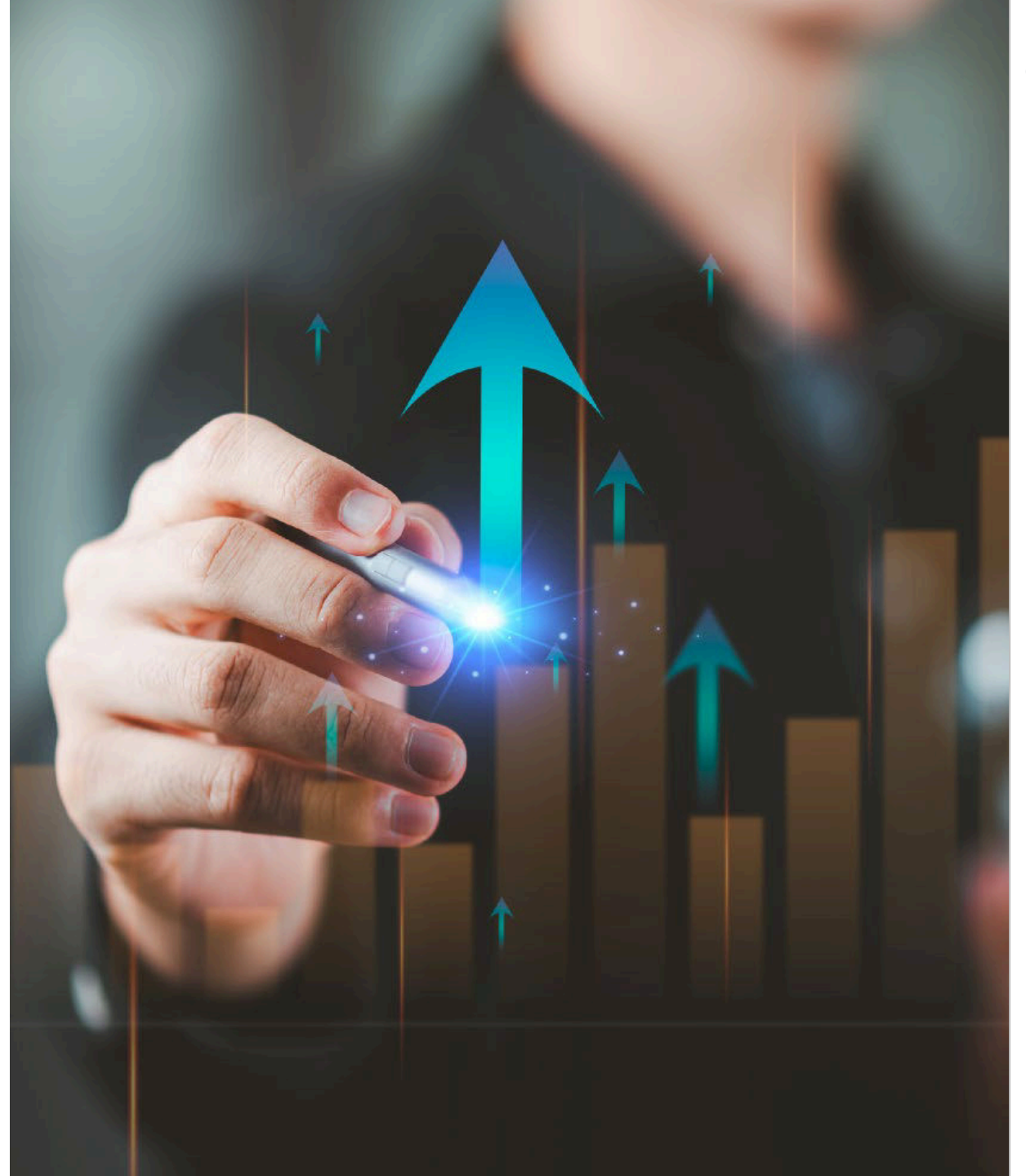
Imagine this, a bold vision...

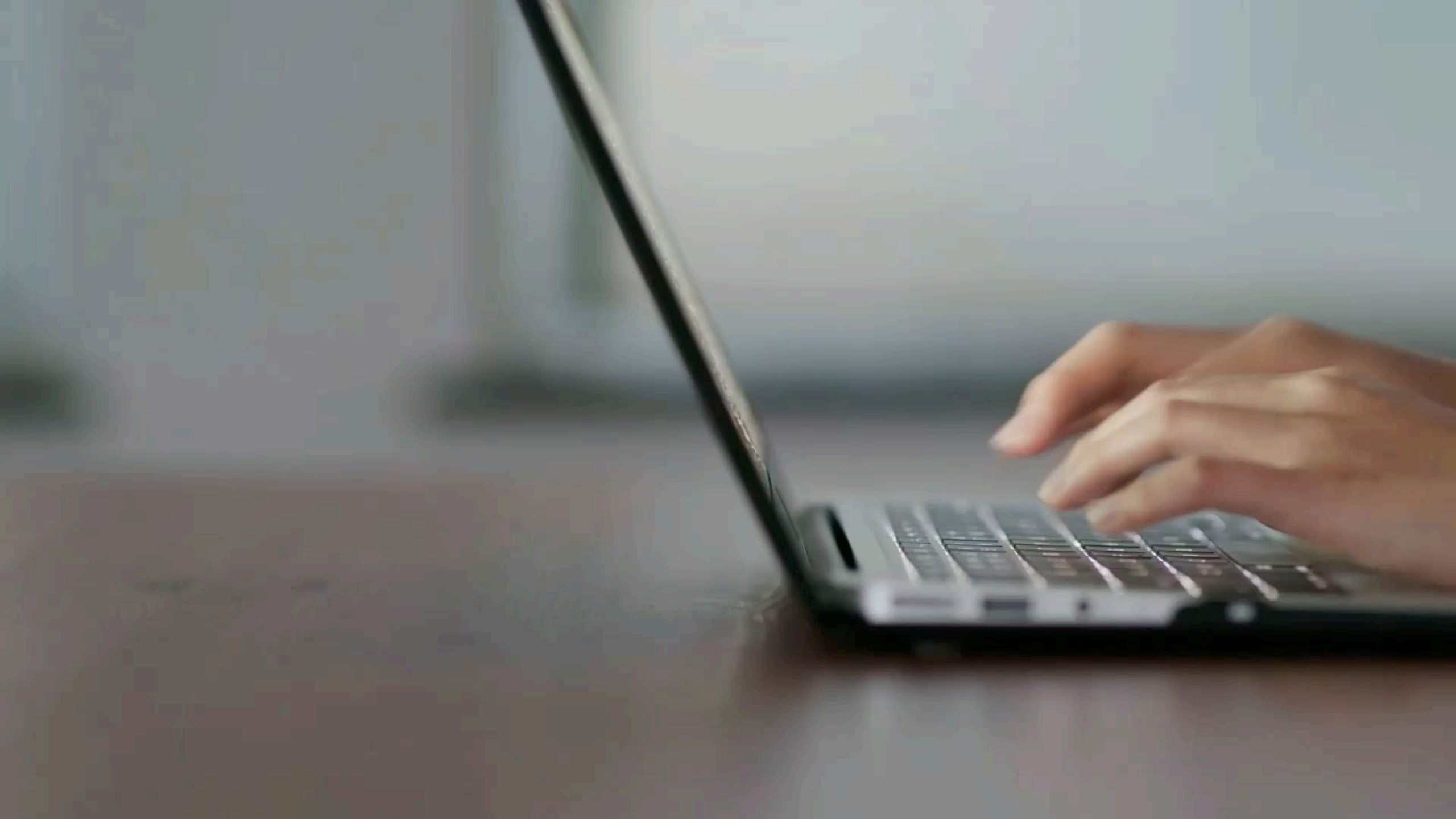
Automate all R&D document authoring with one single platform

Clinical Study Reports | Plain language summaries | Protocols |
CTD Summaries (M2) | PADER/PABRER | ICD | SAP | Manuscript | SRD



Welcome to REGAIN
where the only limit
is creativity !





Guest Speaker



Helen Kotze
Director of Medical Writing, TA Lead
Pfizer

Helen Kotze is Director of Medical Writing and therapeutic area lead for inflammation and immunology. Since joining Pfizer in 2020, she has provided medical writing leadership across the development portfolio. Helen plays a key role in evaluating and adopting AI assisted authoring and automation technologies, with a focus on change management, and capability building that enable responsible, scalable use of AI in regulated R&D environments.



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Helen Kotze

Director of I&I Medical Writing Team, Pfizer

This case study reflects Pfizer's experience and is intended to share high-level patterns rather than prescriptive guidance.



25 March 2026

**The opinions expressed are my own and
not that of Pfizer Inc**



The Journey from Pilot to Production



R&D DocGen: ambitious goal to automate & transform the way content is generated across R&D

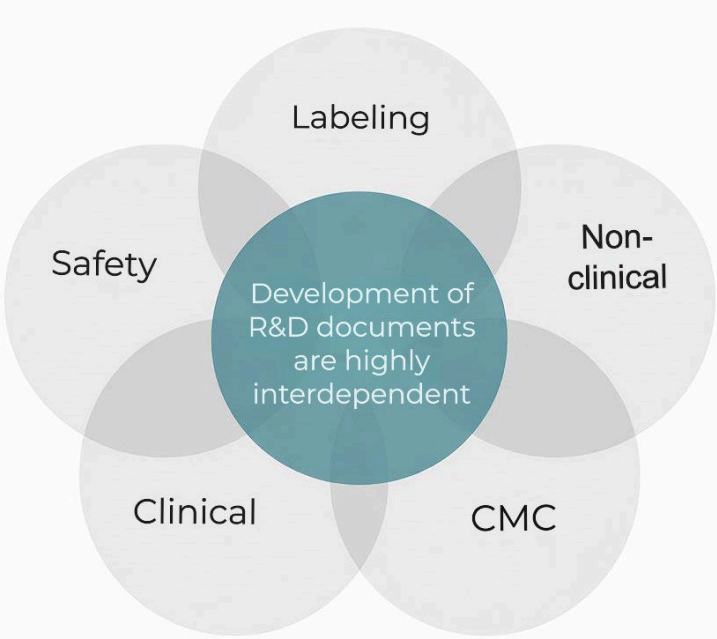
Problem: R&D authoring

- Major manual undertaking: 1000s of reports, 1000s of FTE hours
- Rate limiting step: Document completion often on critical path of trials

Solution

Transform Content Generation powered by GenAI to:

- Accelerate critical path cycle times
- Increase efficiencies
- Improve quality
- Enabling simplification & standardization of outputs

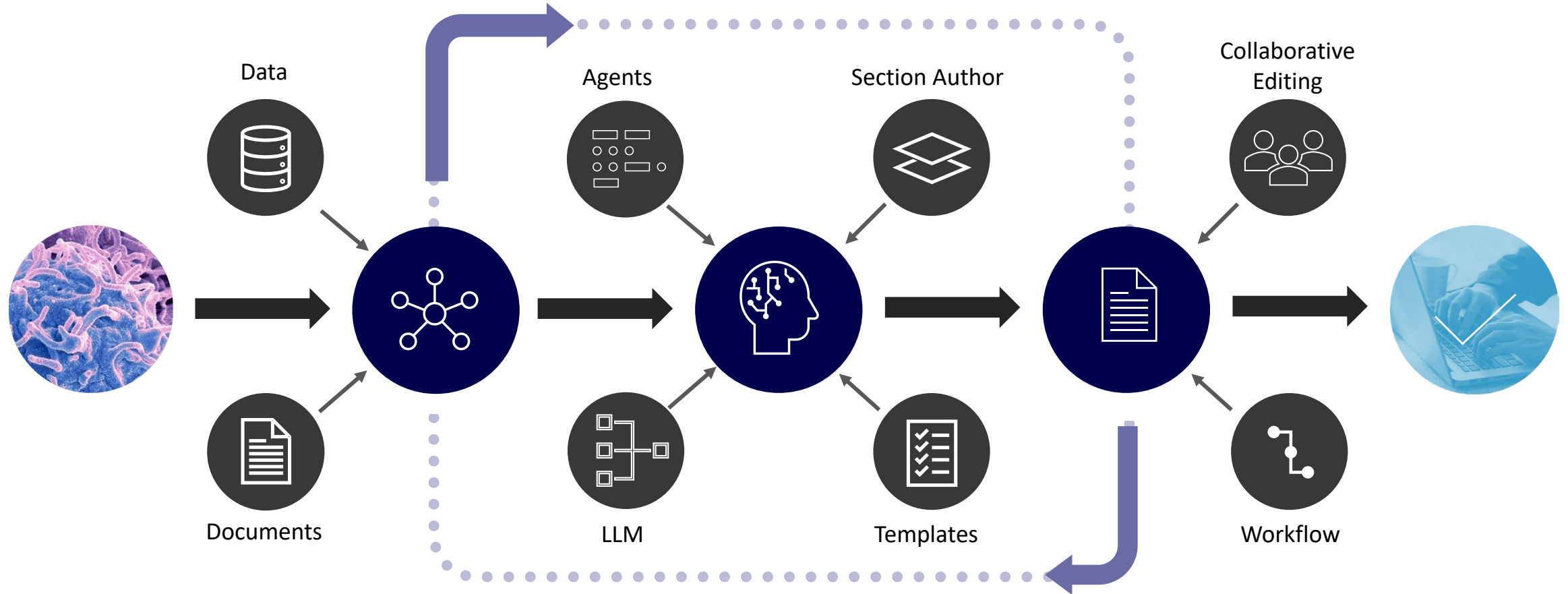


Radical focus and scaling needed to yield transformative impact

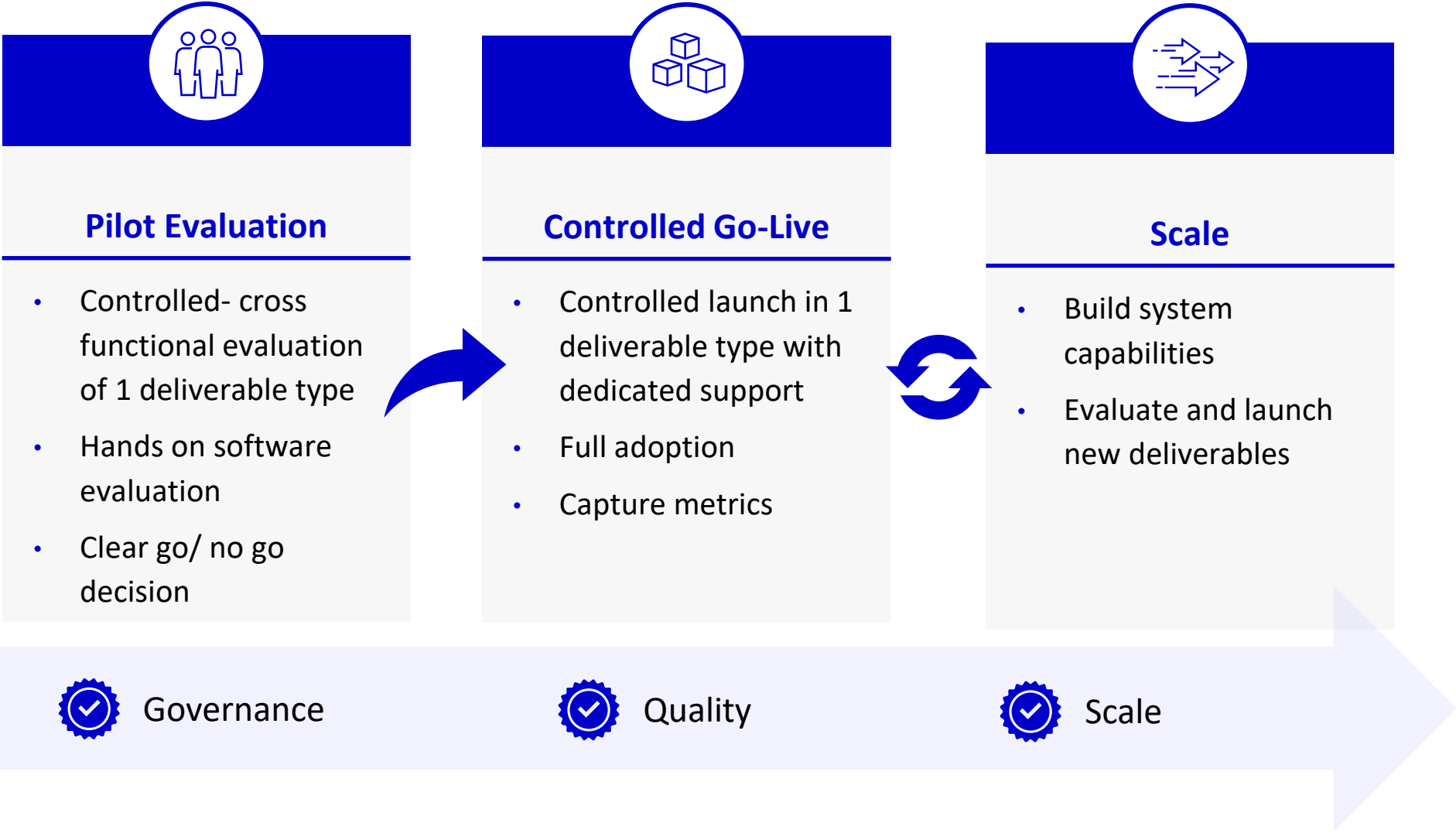
R&D Document Scaling by Design: The Vision



Amplify
Human Potential



From Pilot to Sustainable Production



Transferable Patterns: From Pilot to Sustainable Production

What Worked

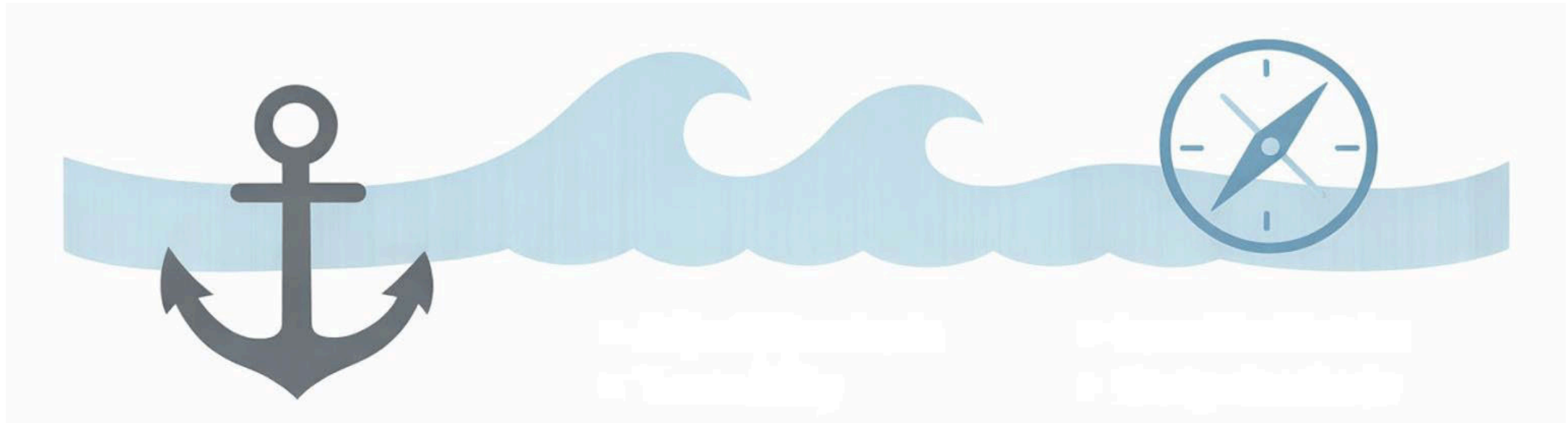
Invest earlier in shared understanding, not just enablement.

What Became Clear

The north star articulated the destination clearly; the path required staged capability build-up.

What We'd Do Differently

Invest earlier in AI fluency across all teams.



DocGen Change Management: Enabled Adoption at Scale

Change Management Accelerators

Communication & Engagement

Engage teams with clear and consistent communications – highlighting the business value and inspiring teams to engage with the platform

Training & Enablement

Empower teams to confidently integrate AI as their way of working

Process Simplification

Simplify document workflows to reduce complexity and boost AI efficiency

Dedicated Guidance

Build confidence through a strong Change Champion network, hands-on sessions and hypercare support

Measure Adoption & Sustainability

DocGen Adoption
(# of new users)



Platform Usage
(# of document drafts generated)



Value Realization
(time / cost savings)



Sustainability
(user satisfaction)



Unlocking new ways of working where people and AI collaborate to create smarter, faster, and higher-quality outcomes

Thank you



25 March 2026

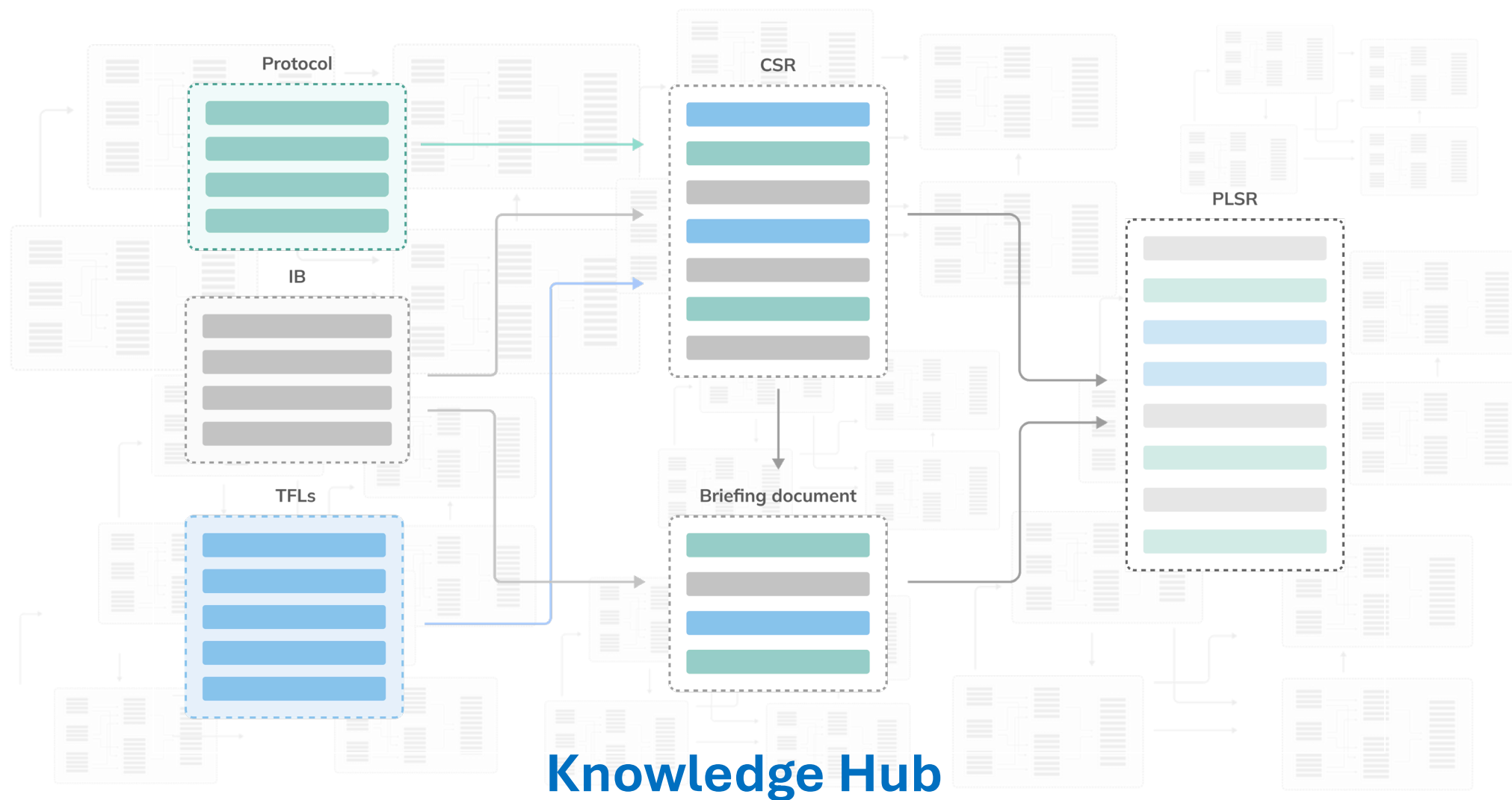
What is REGAIN?

Structured Content Supercharged by GenAI





Structured Content Supercharged by GenAI



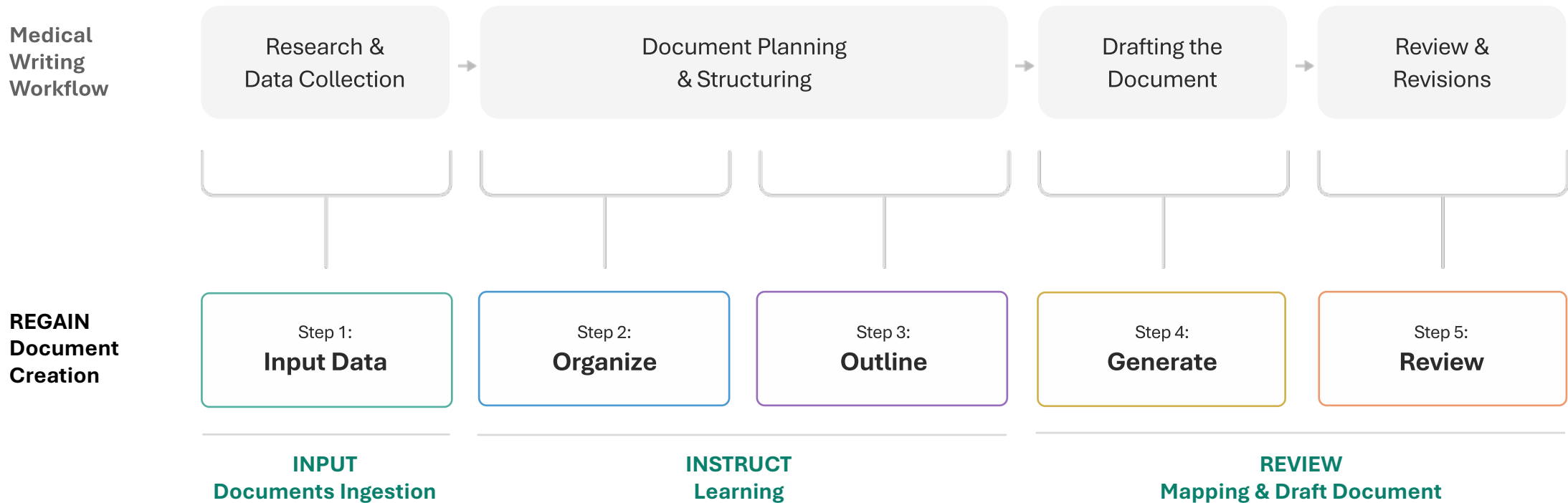
How does REGAIN work?





REGAIN is an AI agent

that aligns with a typical medical writing workflow





REGAIN is agnostic to document type

✓ **Config-over-Code**

Faster onboarding for new use cases, lower total cost of ownership.

✓ **Universal Ingestion Pipeline**

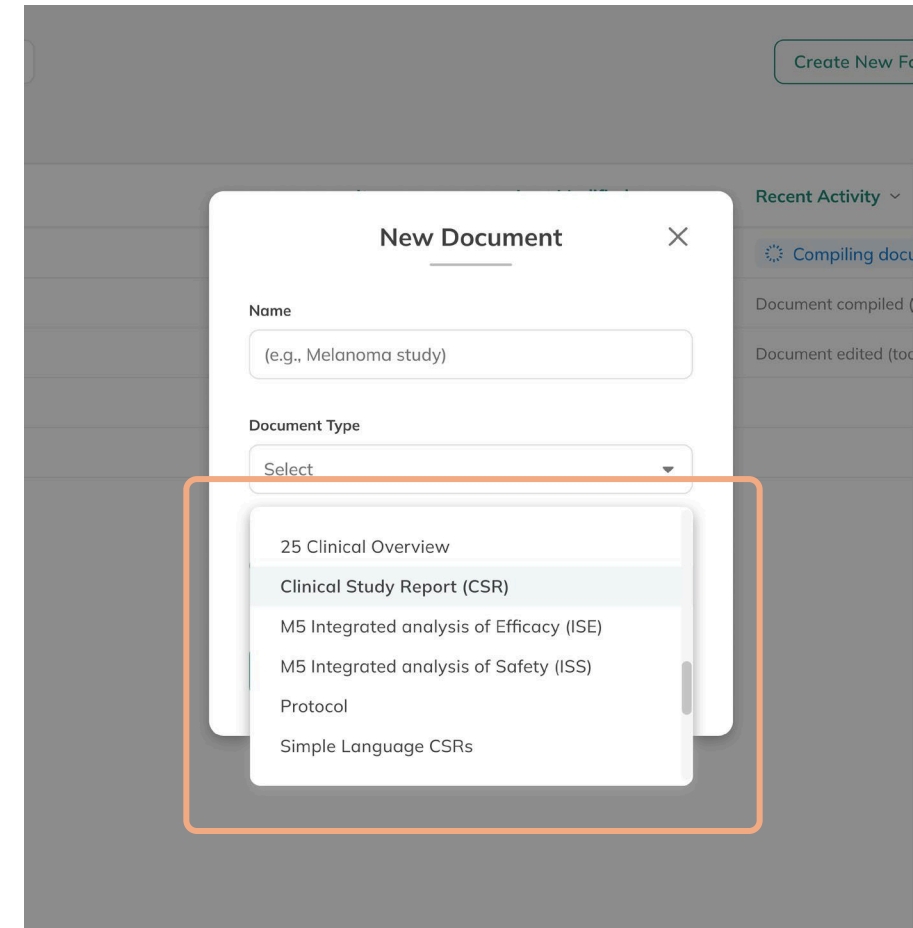
Accepts Word, PDF, plain-text, spreadsheets, emails, or XML. The system normalizes everything into a unified knowledge index as long structure is learned.

✓ **Schema-Free Knowledge Graph**

Metadata is attached dynamically rather than forcing a rigid template up front.

✓ **Prompt-Driven Section Builder**

The same prompt logic works regardless of the final output.



REGAIN Features that truly save time

Content Strategy Builder

- Structure and plan content for faster creation and decision-making
- Reduce rework with clear, reusable frameworks

Adaptive Template Builder

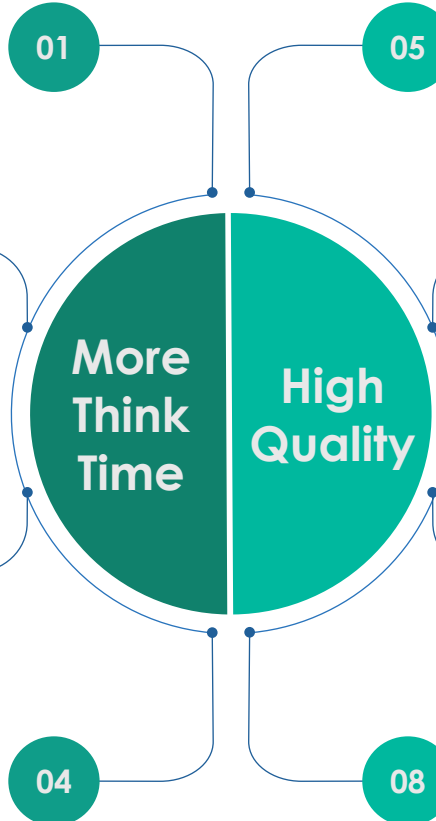
- Auto-adjust templates to fit different studies
- Eliminate manual creation and setup time

Lock sections; Avoid rework

- Track progress clearly with real-time status visibility
- Prevent conflicts with controlled editing and version locks

Collaboration Without Bottlenecks

- Enable teams to work together in one shared environment
- Cut delays by reducing back-and-forth communication



QC Checks: The Verify button

- In app reference to verify content against source
- Catch errors early before they scale

Regenerate & Refresh with Confidence

- Identify and update stale content quickly
- Maintain accuracy with minimal manual effort

Prompt Library for Reliable Outputs

- Use proven prompts to ensure consistent results
- Save time while improving content quality

Custom Templates for Controlled Quality

- Standardize outputs with tailored templates
- Balance flexibility with consistency across content

Overall Impact

Faster Time to Delivery

Consistent and High Quality Output

Increased Team Productivity

Better Compliance and Visibility



Value

Why REGAIN?



Intelligent Assistant

- Expert guidance at every step
- Access to a rich, evolving knowledge base
- **End to end traceability (Built in QC)**
- Self service platform



Continuous Learning

- Expands with every use case
- Built-in domain awareness
- Learns and improves with user input
- Controlled Privileged & Confidential learning



Scalable & Dynamic

- Grows effortlessly with your data
- Modular for any use case
- Adapts seamlessly to client needs
- Repeatable across multiple domains



Efficient by Design

- Drastically reduces time to first draft
- Full end-to-end automation
- Built with User experience in mind
- User is always in control (Hero in the loop)

Integration of External Knowledge in REGAIN





Protocol writing Reimagined in the age of AI

Imagine you are creating a new protocol, what REGAIN could suggest content based on external sources to increase probability of technical and regulatory success (PTRS).

The screenshot shows the REGAIN web application interface for protocol writing. The top navigation bar includes the REGAIN logo, a breadcrumb trail for 'melanoma study', and a progress indicator with steps: 1. Upload, 2. Organize, 3. Outline, 4. Connect (active), 5. Review, and 6. Output. A status bar indicates 'All changes saved' and an 'Exit' button. The main content area is titled 'Connect' and includes a sub-instruction: '(Attach your input files to each section and customize output with AI prompt or custom text.)'. A 'Next: Review' button is visible in the top right of the main area.

The main content is organized into sections:

- Protocol**
 - 4. STUDY DESIGN**
 - 4.1. Overall Design (Complete)
 - 4.2. Scientific Rationale for Study Design (Complete)
 - 4.3. Justification for Dose (Complete)
 - 4.4. End of Study Definition (Complete)
 - 5. STUDY POPULATION**
 - 5.1. Inclusion Criteria** (Auto-detected)
 - 5.2. Exclusion Criteria (Auto-detected)
 - 5.3. Lifestyle Considerations (Auto-detected)
 - 5.3.1. Contraception (Auto-detected)
 - 5.4. Screen Failures (Auto-detected)
 - 6. STUDY INTERVENTION(S) AND CONCOMITANT THER...**
 - 6.1. Study Intervention(s) Administered (Auto-detected)
 - 6.1.1. Administration (Auto-detected)

The right-hand panel is titled '5.1. Inclusion Criteria' and contains:

- Input(s):** A toggle switch is turned on. Two files are listed: 'Protocol_1' and 'Protocol_1.1', each with a close button (x). An 'Add / Edit Input(s)' button is present.
- Text Generation:** A toggle switch is turned on. Two options are available: 'AI-generated' (selected) and 'Custom text'. An 'Edit Prompt' button is next to the 'AI-generated' option.
- A call-to-action button: 'Need help with trial design criteria?' with an 'Ask RIA' button.
- Bottom buttons: 'Mark as Draft' and 'Complete'.

Thank you



Panel Discussion



Helen Kotze
Director of Medical Writing, TA Lead
Pfizer



Joga Gobburu
President
Vivpro





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regain

Trusted to build RIA & REGAIN

Our deep commitment to customer delight and industry excellence led to the invitation to create REGAIN.



Trusted by 40+ leading organizations



60% more think time unlocked for users



Powering 50% of the Top 30 Pharma leaders

Results. Reputation. Relationships.

