

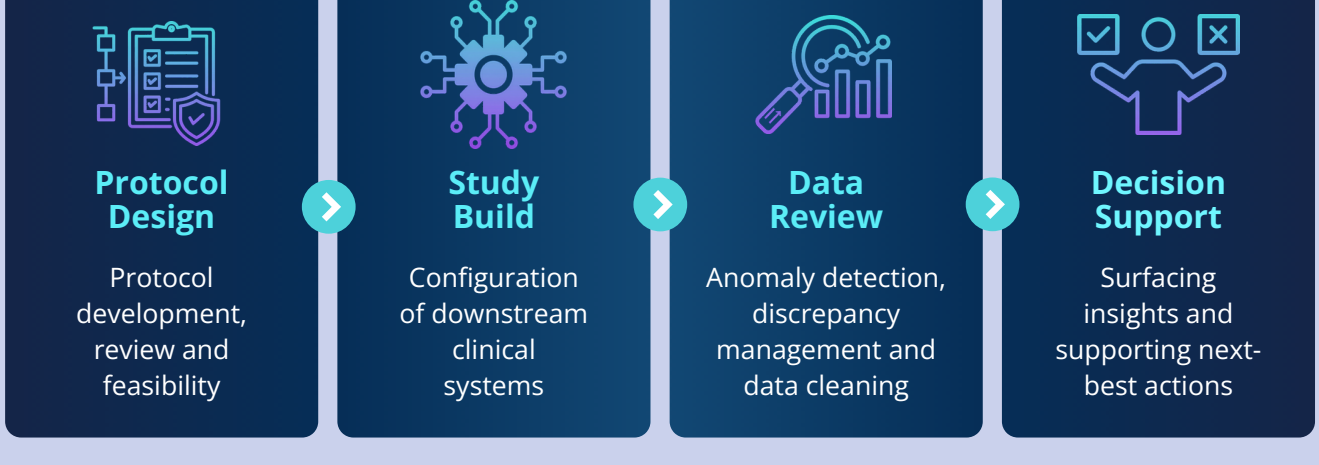
REDUCE LIVE STUDY RISK WITH AI IN ECLINICAL WORKFLOWS

From Focused Use Cases to Scalable, Governed Workflows



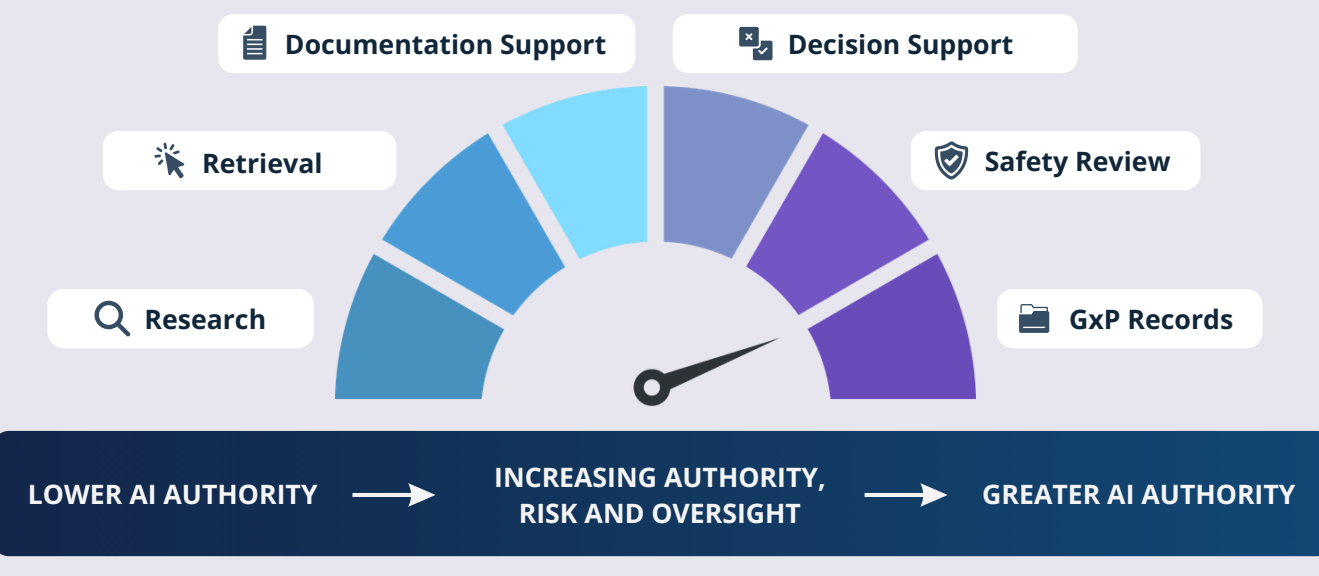
1 Where AI Can Add Value

AI can support multiple points in the clinical trial workflow, from protocol development and study build to anomaly detection, data review and decision support.



2 Where AI Risk Changes

AI that primarily surfaces information has a different risk profile from AI that begins to influence decisions, suppress or change information, or affect a GxP record.



Does the AI influence a regulated decision, process or record?

3 What Needs to Be Validated?

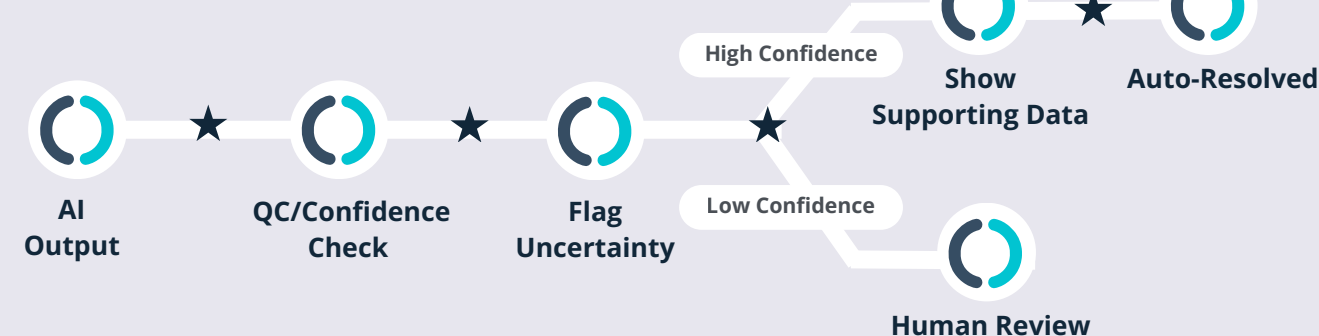
Model performance is only one part of validation. Clinical teams also need to evaluate the system around the AI and how people interact with its outputs.



Is human review meaningful? Measures such as reviewer time can help identify potential rubber-stamping.

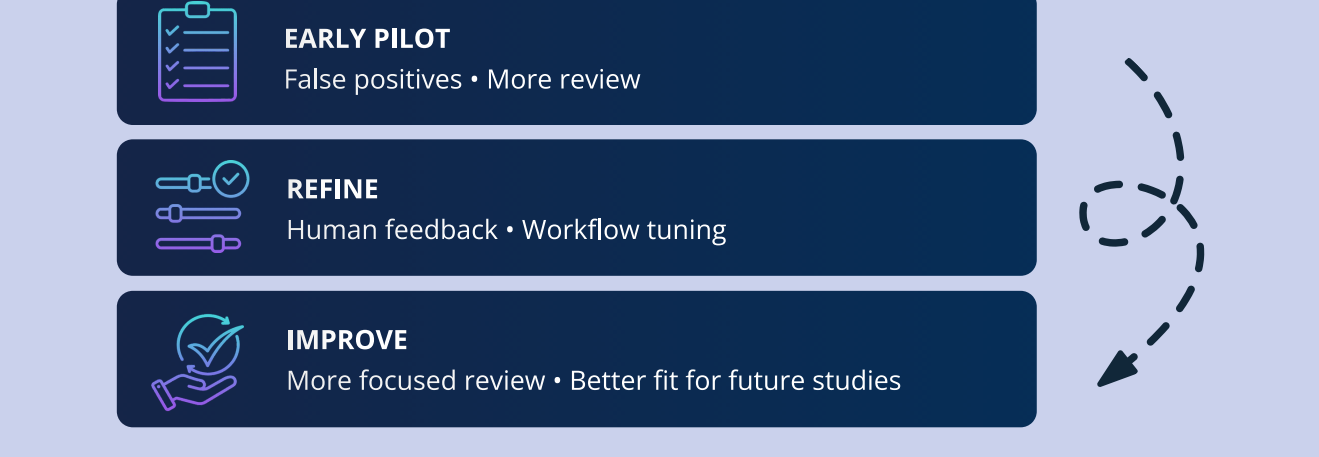
4 Make Human Oversight Work

Human review should focus on outputs where uncertainty or risk is highest, instead of requiring the same level of review for every AI-generated result.



5 Expect a Learning Curve

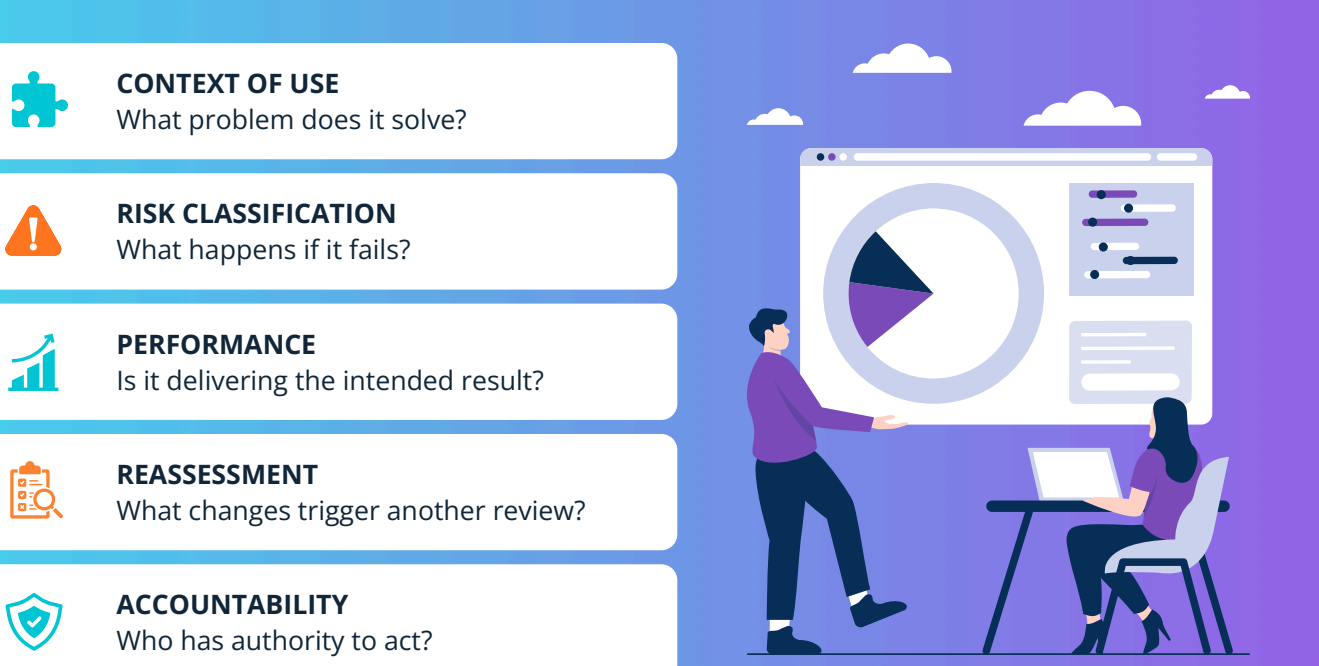
Early AI pilots may increase workload before they reduce it. False positives and additional review can reveal where models, workflows and implementation plans need refinement.



Choose pilot studies and teams that can accommodate early learning.

6 Build Governance for Scale

Before expanding an AI workflow, define its context of use, risk classification, performance measures, reassessment triggers and accountable owner.



WHO HAS THE STOP SWITCH?
A named owner should have access to quality data and the authority to modify, pause or stop the AI-enabled workflow if performance changes.

7 From Pilot to Scale



AI should scale when it demonstrates value within a controlled, fit-for-purpose workflow.