

The AI-Augmented CRO

Leveraging Closed-Loop Systems for Sponsor Oversight

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The Paradigm Shift



Traditional Model

- ✓ **Reactive remediation:** Fixing issues after they occur
- ✓ Manual oversight relying on brute force
- ✓ Siloed data leading to delayed insights
- ✓ Static risk thresholds



AI-Driven Model

- ✓ **Proactive prevention:** Predicting risks before escalation
- ✓ Automated, real-time analytics
- ✓ Integrated data ecosystem
- ✓ Dynamic, continuous risk scoring

Defining Agentic AI



Perception

Designed to perceive the clinical environment and process complex, unstructured information from disparate sources.



Autonomy

Goal-oriented software that makes decisions and takes specific actions without constant human intervention.



Action

Acts as a "digital workforce" available 24/7 to execute tasks, vastly increasing operational capacity.

Closed-Loop Security



The "Walled Garden" Concept: AI models must be fully embedded within the clinical



Data Sovereignty: Proprietary data never leaves the secure infrastructure to public LLMs



Continuous Feedback: Actions taken by AI are fed back into the system to improve future accuracy



Compliance: Ensures strict adherence to GDPR, HIPAA, and sponsor confidentiality

Proactive Risk Forecasting



AI continuously analyzes data points to forecast potential risks, enabling preventive action that drives risk scores down significantly faster than traditional oversight.

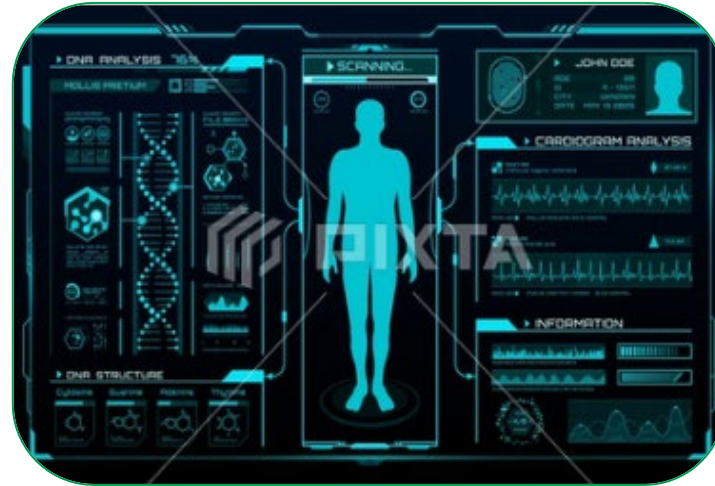
Operational Acceleration

Orchestration



Intelligent agents coordinate complex tasks across role-based workflows without fragmentation

Recruitment



NLP sifts through EHRs to pinpoint patients 30% faster than traditional screening

Data Quality



Automated anomaly detection across genomic and EDC data sources ensures uniformity

The Vendor Landscape

Organizations face a cluttered marketplace with no central database for verification

The stakes are high: Sponsors place ultimate responsibility for vendor oversight on the CRO



Risk: Uploading confidential material to unvetted AI tools can lead to immediate breaches



Build your insights catalog

Find clinical trial data insights others can't!
Your private AI agent, Sidekick, will help you discover actionable insights.



Chat with Sidekick

Chat with Sidekick

Strategic Vendor Engagement



Initiate Dialogue Early: AI technology expectations must be a primary topic during initial vendor selection, not an afterthought



Define Expectations in RFI: Clearly describe requirements for system capabilities and third-party integrations in the Request for Proposal



Contractual Clarity: Mandate specific text regarding system capabilities, security protocols, and liability in the final contract

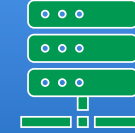
Qualification & Risk Assessment



Assess Capability

Vendor capabilities vary considerably. Deeply assess their level of knowledge and the maturity of their AI models.

Do not rely on marketing claims alone.



"Fit for Use" Data

Ensure data used for training and tuning is relevant, reliable, and traceable. Validate the privacy infrastructure to prevent confidentiality breaches.

Integration & Compliance



Interoperability

AI platforms must standardize data formats to ensure seamless flow with existing CDMS and CTMS systems.



Transparency

Sponsors must be informed of AI-driven results on an ongoing basis to enable timely corrective action.



Mitigation

If a vendor cannot guarantee data integrity, implement heavy mitigations or choose not to use them.

The Hybrid Future: Human-in-the-Loop



Robust Governance

The level of credibility assessment must match the AI model risk. We must actively manage bias, data privacy, and model drift.

Augmented, Not Replaced

Even with autonomous agents, a human expert remains ultimately responsible for the outcome, especially in high-risk clinical situations.

The Astronaut Metaphor

Selecting an AI vendor is like hiring a specialized astronaut.

- ✓ Rigorously vet their training data
- ✓ Verify their life-support (security) is compliant
- ✓ Ensure seamless communication

**You are Mission Control.
You validate every move.**



Q&A

Thank you!

Contact SDC



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