

Ethical AI Adoption

Best Practices and Lessons Learned

Jason Driesbaugh

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What is Ethical AI?

- Ethical AI is the design, development, and deployment of artificial intelligence systems that align with human values, fairness, transparency, and societal well-being. Ethical AI addresses concerns such as algorithmic bias, privacy protection, accountability for AI's decisions, and the potential negative impacts of AI on employment. **The goal is to ensure AI systems are fair, explainable, respect human rights, and are developed responsibly with consideration for their broader consequences.**
 - The Stanford Institute for Human-Centered AI (HAI)

Best Practices

- Focus on the problem.
- Data access, interoperability, and connectivity.
- Clean data leads to a higher likelihood of success and return on investment.
- Human in the lead.
- Continuous tracking and oversight.
- Exhaust all means of automation first.



Data Ingestion

- Aggregate and harmonize data across all sources.
 - EDC data in automatic, 15-minute incremental delivery.
 - 3rd party data ingestion validates structure and harmonizes all sources.
- Automatic change detection and updated listings.
- Clean patient tracker, refreshed hourly.
- Auto checks and query automation.



Auto Check Queries

Results from a top 10 biopharma

Up to 50%

Query
Automation



500,000+
auto-queries

Executed at scale
without manual
intervention.

32%

Faster Query
Replies



5.5 vs. 8.0 days
($p < 0.0001$)

Sites respond 2+ days
faster to auto-check
queries.

40%

Faster Query
Closure



11.0 vs. 18.7 days
($p < 0.0001$)

Auto-check queries cut
site turnaround time by
more than one week.

14.8%

More Effective
Queries



47% vs. 40%
led to data changes
($p < 0.0001$)

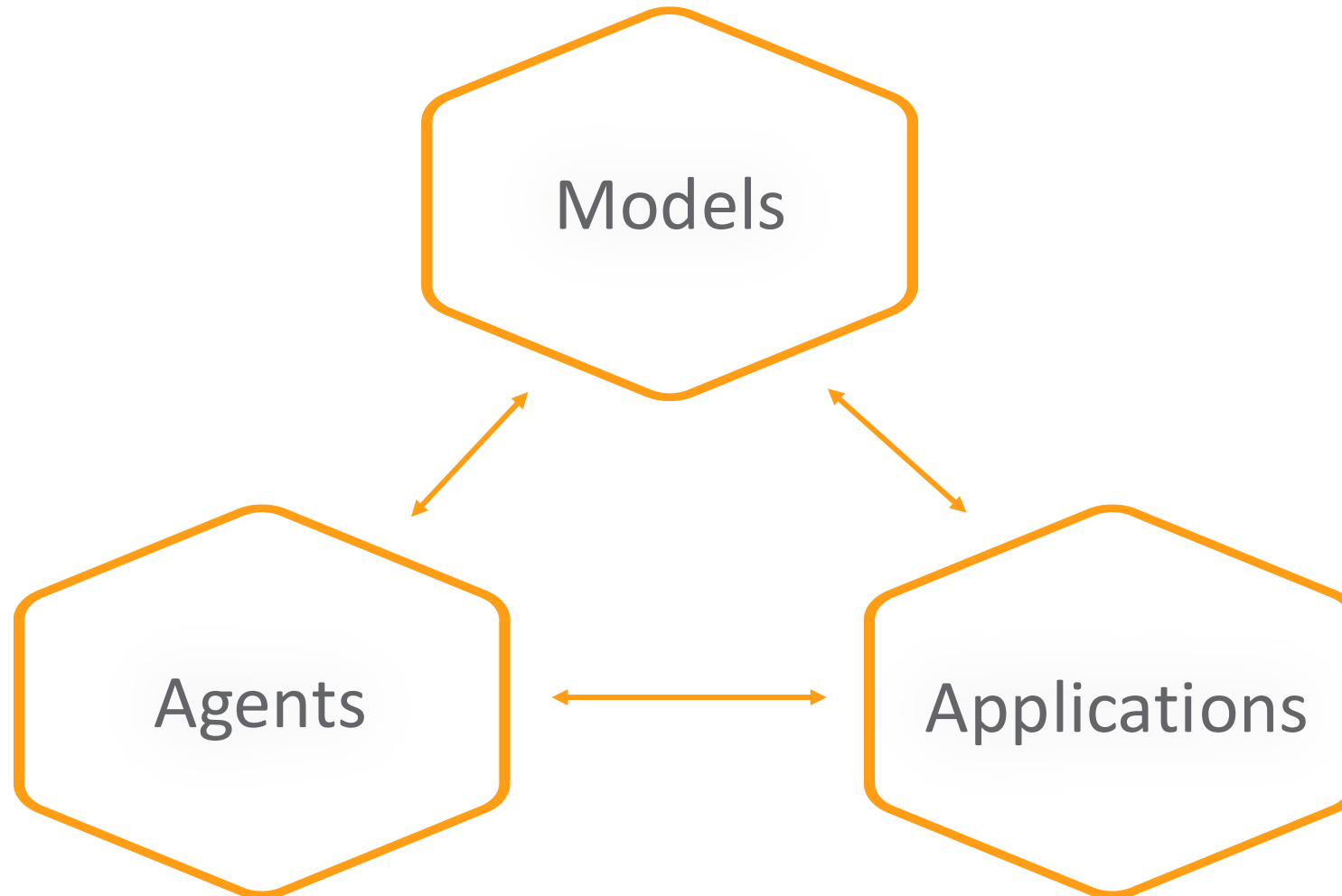
Auto checks targeted data
anomalies with greater
precision.

Protocol Deviations (PDs)

- Manual or automatic PDs created by rule in EDC.
- DQS can have manually created PDs and can also use auto check functionality to automatically create PDs.
- All flow to CTMS - review, workflows, and approvals (AND click to send to Quality to review and create a CAPA as applicable).
- Nearly 3000 protocol deviations automated in the first year since release.



MAAP Architecture



Study Build QC Agent

- Study Grade Report in EDC.
- QC Agent processes report using the Casebook Design Export (CDE).
 - The agent is broken into three actions where each action processes a different set of checks.
 - Each action is given a subset of the CDE that has the data for the specific check.
 - LLM uses check definitions in the instructions to return results.
 - Agent combines results of the three into a single file and attaches it to the study grade record.
- Why?
 - To help augment our Study Grade checks which are meant to improve the site user experience and validations.
 - Delivered in a checklist format allowing the user to leverage it as a document for sign-off.
 - Some checks are non-deterministic and couldn't be accomplished outside of a LLM, such as language, grammar, and tone.
- High Impact, Low Cost.
 - Catch issues up front, improving user experience and fewer post go-live changes.
 - Low token usage per request.



Veeva Study Builder Agent

Human-led agentic framework from study protocol to study build

Compliance by Design

- Humans lead and approve
- Configuration by deterministic APIs
- Audit-ready

Standards First

- USDM conformant
- Reuses validated EDC form and DQS listing libraries

Faster Builds

- Quickly configure studies using agentic workflow
- Agents draft EDC schedules, eCRFs, edit checks, and test data

Early Collaboration

- Aligns cross-functional teams sooner
- Reduces downstream misalignment
- Produces more complete requirements



Vault AI for Clinical Data

Features In Progress



QuickStart AI Listings

Ready-to-use, AI-generated listings for most requested use cases

Immediate value with minimal setup



26R3



Local Lab Agent

Automate data extraction and loading from Lab Reference Range source

Reduce site data entry with quality



26R3



Listing Agent

Augment programming generation and reporting from natural language in DQS

Reduce clinical programming effort



27R1



Test Data Agent

Automate test data generation to test collection instruments through statistical programming

Working toward automated testing



27R1



Takeaways

- Focus on the problem.
 - Start with the process first.
 - Exhaust all automation opportunities through process and capabilities before applying AI.
- “The type of AI or company won’t matter, like the type of web browser being used doesn’t matter. It’ll be the operational model that provides the biggest opportunity for differentiating and gaining efficiencies.” Bernhard Glombitza, PhD, Bayer at DPHARM 2026





Questions