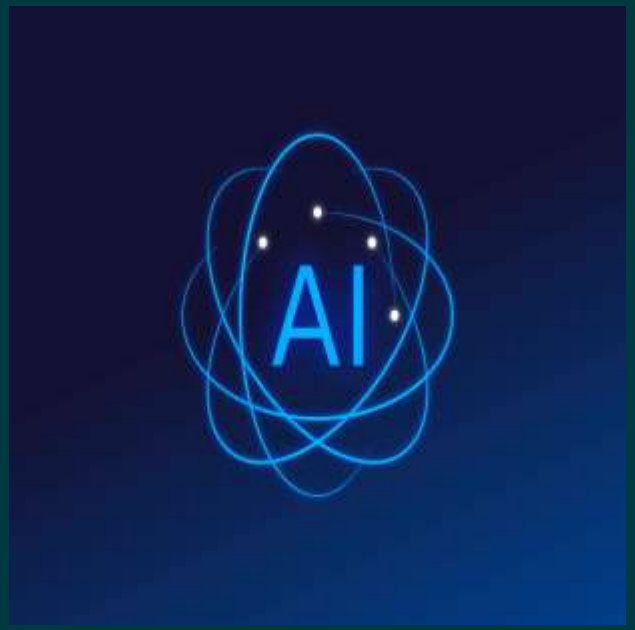
EVOLUTION: HOW AI IS SHAPING DRUG DEVELOPMENT

WELCOME

Hello, I’m Debiprasad (Debi) Roy

- VP, Head of Digital Strategy, Analytics, and Programming
- 25+ years of experience in Pharma and Biotech
- Passionate about digital transformation and innovation in R&D

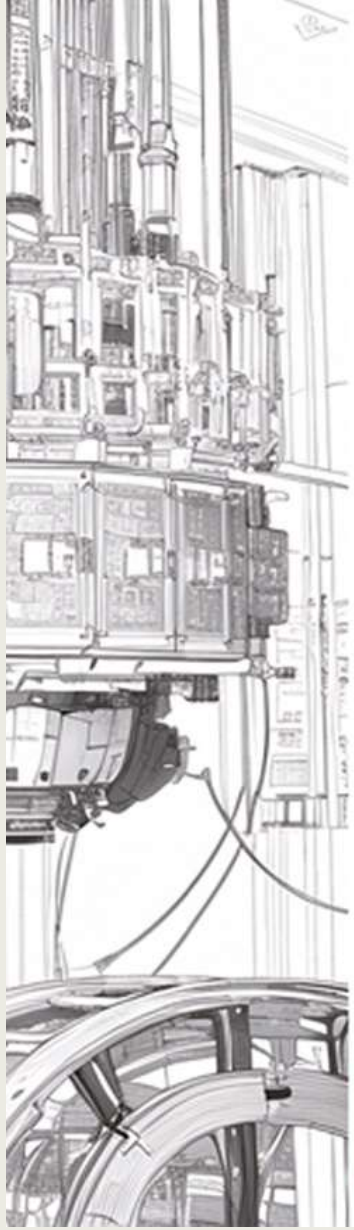


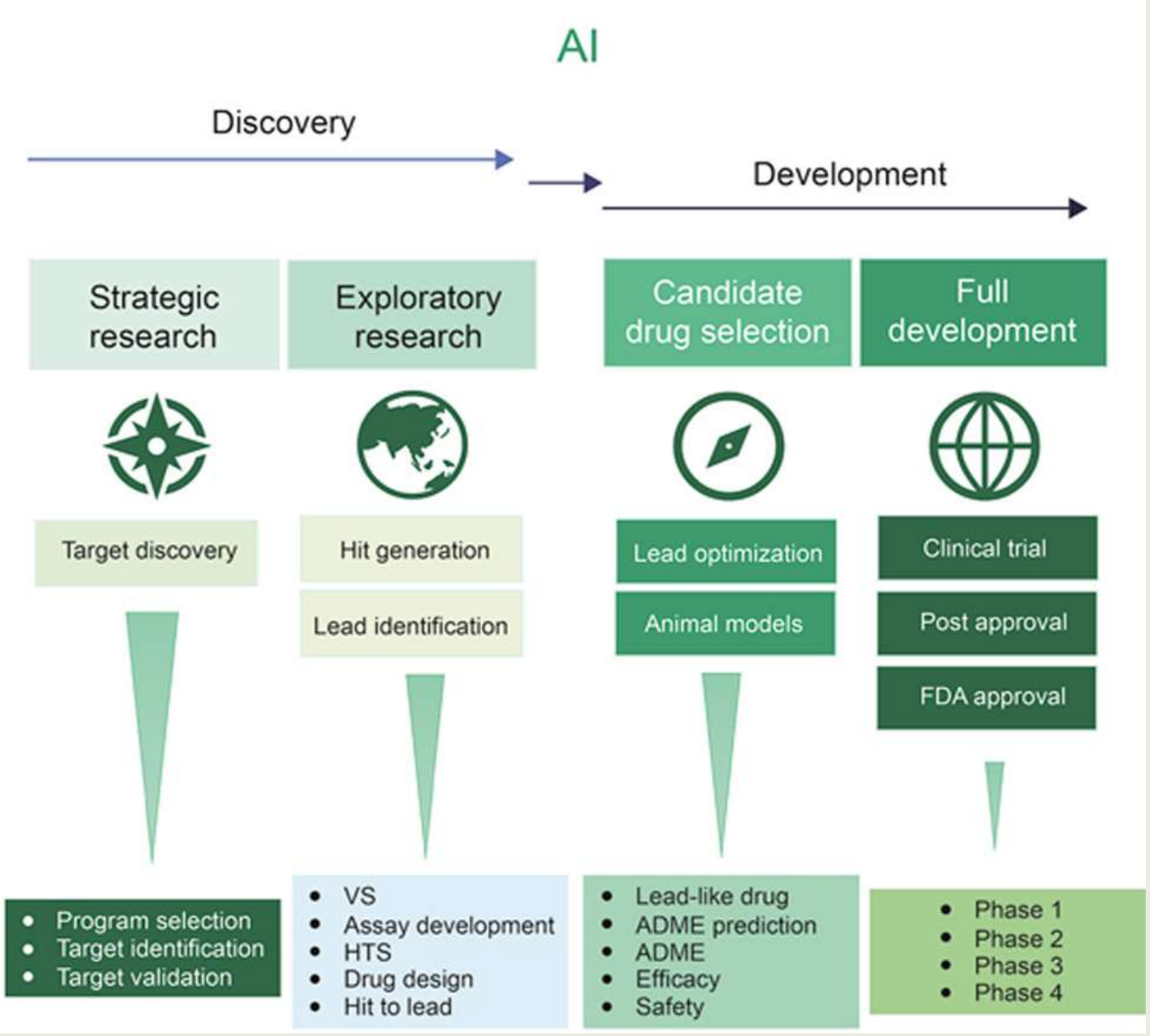
PharmaSUG SDE
APRIL 11, 2026

"*AI is the automation of automation, where software writes software*."

Jensen Huang (CEO of NVIDIA)

COMPREHENDING MARKET TRENDS





AI in Clinical Development – Unlocking peak operational performance

Value Drivers from AI and AI effects

Cost Efficiency | Improved Speed | Increased Possibility of Success

Protocol co-developer
25% faster protocol approval
30-50% *fewer amendments*

"One click" real-world evidence and historical trial summaries
Protocol synopsis drafting
Automated protocol quality control

Randomized control trial optimizer
10-20% Cost Efficiency
5-10% Trial Acceleration

- Subpopulation and inclusion/exclusion recommendations
- Endpoint recommendations

Study start-up engine
10-20% faster enrollment
30% *faster activation*

AI-based site selection
Feasibility copilot
Informed consent form auto-generator
Site initiation visit material localization

Trial performance copilot
20% cost *efficiency*
10-20% faster enrollment

Study team companion (alerts, conversational AI, O&A)
Predictive trial trajectory with explanatory drivers

Site management copilot
50% *fewer deviations*
20% higher principal investigator satisfaction

Site next-best-action engine-personalized principal investigator engagement
Next-generation risk-based site monitoring

Data from McKinsey & Company

AI in Clinical Development – Unlocking peak operational performance

Value Drivers from AI and AI effects

Cost Efficiency | Improved Speed | Increased Possibility of Success

Smart data management
30% cost *efficiency*
70%+ *fewer manual queries*

One-click database creator case report from auto-generator (based on digital protocol)
Single source of truth for all patient data
AI-based smart data cleaning and query engine

Biostats builder
30-50% *cost efficiency*

Standard statistical analysis (e.g, efficacy, safety, chemistry, manufacturing, controls, population pharmacokinetics)
Auto-database build /quality control

Regulatory intelligence engine
30% *faster responses*
50% *fewer regulatory affairs (RA) follow-ups*

RA360 informed by RA responses, advisory committee insight
Intelligent health assessment questionnaire response
Competitive label monitoring

Major submission content writer
40% faster
2x fewer quality control issues
50% *cost efficiency*

Clinical study report auto-drafting
Routine tables, listings, and figures generation
Auto quality control
Safety and Health Economics and Outcomes Research insights driven by a real-world evidence engine

Post-market regulatory /pharmacovigilance
30%+ *cost efficiency*

Annual report auto-drafting
Routine adverse-event report auto-drafting
Label drafting/translations
Signal management
AI-powered signal detection and assessment

Data from McKinsey & Company

THREE HIGH INTEREST USE CASES

Digitalization of Protocol to downstream artifacts

AI-assisted digitalization of protocol content into a USDM model - searchable, comparable, reusable - with explainable links back to source text.

Faster study starts; less rework, more reuse.

Consistent semantics across sponsors and therapeutic areas.

Audit-ready provenance for governance and reviews.

Digital Protocol can be used to build CRFs, EDC, Edit Checks, Data Management Plan, and SDTM.

30-40% reduction in database, edit check, and SDTM builds.

Edit Check Automation

An LLM-powered application that converts logical check descriptions into code.

Consistent, reviewable code for Edit checks with explainable links back to source specification.

Faster study build and lower QC overhead with traceable changes and versioned outputs.

~30% reduction in development and test step creation time.

High quality and consistent checks.

Easily scales across multiple studies.

AI-Assisted Regulatory document generation

AI-assisted CSR, IB, DSUR, and Patient Safety Narrative generator. Automate the compilation of various documents and their lineage management.

CSR drafts aligned to sponsor templates with per-section citations for traceability.

Reusable template library; quick onboarding for new document types.

Faster first drafts; Up to 40% reduction in time with greater consistency across medical writers.

Audit-friendly outputs with explicit sources. Document lineage knowledge graph.

WHERE DO WE GO FROM HERE?

Vital Strategies for AI Deployment and Adoption

Adapt & Innovate

Align Workflow Designs& Data Management;

Encourage Collaboration;

Evolve Change Management;

Drive Leadership & Vision

Invest in Tech Infrastructure

High Performance Computing;

Secure Cloud storage;

Implement Advanced Data Analytics, AI/ML Tools;

Scalable, Secure & Integrated Architecture

Encourage Teamwork & Collaboration

Bring together experts from AI Tech, Data Engineers, Data Science, Biology, Clinical SMEs & Business Operations;

Hire right Expertise & Experience;

Develop Communities of Practice

Ensure Regulatory Compliance

Incorporate Regulatory Expertise;

Consult FDA, EMEA & GDPR Guidelines;

Set Strong Enterprise Governance Framework & Policies

Establish a Solid Data Foundation

Ensure Data Quality;

Data Integration & Standardization;

Incorporate Common Ontology;

Continuous Model & Operational Monitoring;

"*The true power of AI lies not in replacing humans, but in working alongside us to achieve what neither can do alone*."

Sebastian Thrun (AI pioneer)

CEO of Kitty Hawk, Founder of Waymo, Google X

THANK YOU