AI: Rewriting the Clinical Development Handbook

The life-sciences industry is at a critical and unprecedented inflection point in terms of AI. Since the start of the global pandemic the use of AI by biopharma has gone from tactical to transformational. Traditionally employed during the research phase of R&D to identify drug candidates, synthesize proteins, etc., AI was exploited — in the best way possible — by the development side of R&D in 2020. World population and global health are now benefiting from life-saving COVID-19 vaccines that are stemming the tide of the pandemic.

Think of that as chapter one in the new AI clinical development handbook. AI is now entrenched in drug development, and that is as it should be. Look no further than the visionary use of a state-of-the-art machine learning tool in last year's Phase III COVID-19 vaccine trial to see the rationale for this seismic shift in the life sciences. AI empowered biopharma to analyze data, find signals in a 46,000-person study, and ensure that the data was available less than one day after primary efficacy case counts were met. This was a stark and compelling contrast to a process that typically takes one month. There is no going back.

A Turning Point

Toss the old clinical development handbook out the window. In the space of a few short months everything changed. We witnessed a historical milestone — AI disrupting and reimagining the drug development paradigm. What was done with AI for the Pfizer COVID-19 vaccine trial can and will be democratized across all therapeutic areas and all clinical development segments via ClinTech, the exciting new category of purpose-built, AI-based clinical insights and automation platforms. This intelligent infrastructure realizes sustainable transformation for drug development to achieve scale, acceleration, and repeatability across therapeutic areas. AI used to touch only a few points during the drug development process, but now a future exists in

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which it is integrated and woven throughout the continuum. Little will be left untouched or un-enhanced by the power of AI. Though the "D" may still be positioned behind the "R" in the phrase "R&D," it has finally caught up. The result: delivering safe and effective drugs to patients faster than ever before.

AI-Infused Clinical Development

Decentralized clinical trials are the setting in which the ClinTech story is unfolding, and AI is writing the narrative. AI was the enabler of decentralized clinical trials during the pandemic, and the prevalence of decentralized trials will only accelerate. That doesn't mean that legacy trials are a thing of the past — yet — and AI enhances those as well. From start to finish, today there is no aspect of drug development that remains on the outside looking in at the power of artificial intelligence. Highlights include:

Patient Identification & Recruitment: AI-enabled personal health information (PHI) scrubbers make the structured data from re-al-world evidence datasets that are traditionally used for identifying patients more effective.

Data Collection: AI-powered sensors, wearables, and smartphone apps enable 24/7 collection and reporting of trial data.

Operations Insights: AI-infused, persona-based dashboards with virtual assistants for querying trial data automate oversight and collaboration between clinops, study and site leads, CRA managers, data managers, c-level executives, and other stakeholders to avoid milestone delays.

Clinical Insights: AI aggregates patient safety and subject-level data from sources as diverse as EDC, eCOA, ePro, IxRS, labs, etc. into a unified study data model that meets SDTM standards.

Risk Based Monitoring (RBM): By leveraging machine learning, RBM leaves behind the traditional approach of monitoring clinical trials that required frequent site visits and 100% SDV (Source Data Verification), instead promoting a centralized approach to data collection and monitoring.

Safety Monitoring: Advanced, cloud-based active safety AI analytics engines that leverage real-world surveillance and real-time data identify potential adverse events and safety issues, improving patient safety and overall study quality and operational efficiencies.

AI Breaking Boundaries

AI was instrumental in enabling the acceleration of massive Phase 3 COVID-19 vaccine trials. That promise and opportunity can now be extended to other therapeutic categories and research efforts to make that process more mainstream and align patients living with a spectrum of diseases with qualified therapies more quickly. AI makes it possible to leapfrog directly to real-world Phase III engagement for promising drugs. Potential adverse events and safety issues can be identified through active safety AI analytics engines that leverage real-world surveillance and real-time data. Pfizer set the bar in this regard by processing over 100 million data points per day for their trial

and leveraging AI to isolate .2% of the most relevant safety and efficacy data.

No One Left Behind

Electronic clinical (e-clinical) development courtesy of AI benefits all stakeholders in the drug development process:

Patients: Decentralized clinical trials make it easier for patients to participate, removing previous constraints and enabling broader en-gagement - a critical benefit based on research indicating that only 52% of clinical research sites reach enrollment targets.

Patients can also access promising new therapies faster than ever before if drug candidates are made available to qualified patients through restricted use Phase III trial access.

Physicians: Historically, a very concentrated group of physicians run most clinical trials. Using AI to cast a wider net to identify potential study sites and participating clinicians has the added benefit of also attracting more robust patient participation. Phase III clinical trials also empower physicians, including specialists, to prescribe promising drug candidates in a real-world setting.
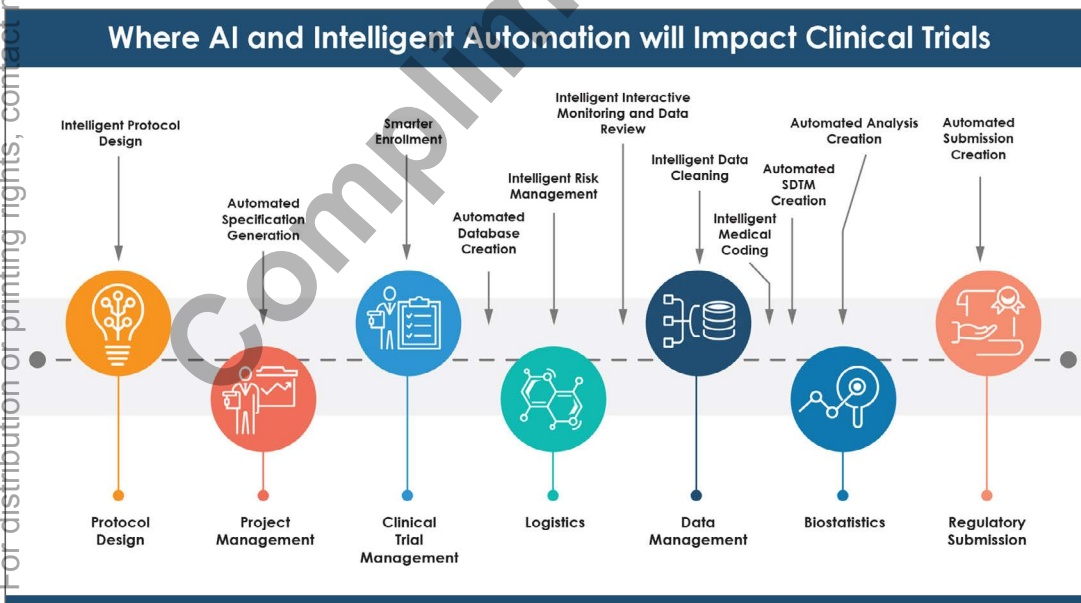
Regulators: Deep learning AI systems streamline study data and can facilitate FDA submission as quickly as three days post-database lock.

Manufacturers: AI helps biopharma manufacturers forecast demand accurately and optimize just-in-time (JIT) inventory systems that align component orders with production schedules, increasing efficiency and decreasing waste.
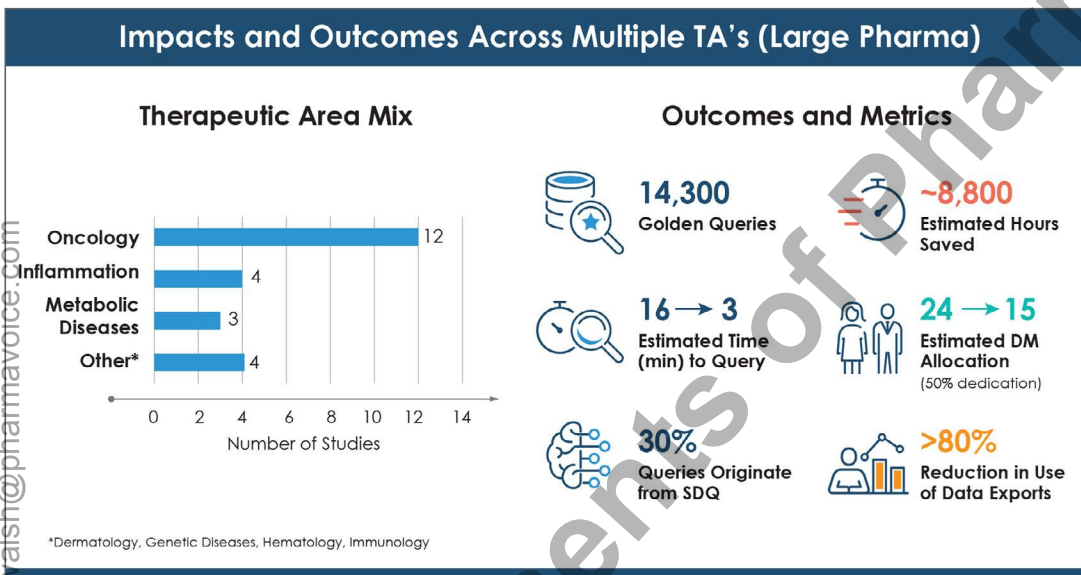
A Clean Slate

Thanks to the global pandemic, AI upended a clinical development process that had not changed dramatically for decades. Biopharma has taken note, and there is no going back. The industry is leveraging AI to architect a new era of drug development that will result in faster clinical trials, broader patient engagement, greater physician participation, and more rapid delivery of effective therapies. Welcome to the new drug development paradigm. **PV**

Impacts and Outcomes Across Multiple TA's (Large Pharma)

Therapeutic Area Mix

Oncology: 12
Inflammation: 4
Metabolic Diseases: 3
Other*: 4

Number of Studies (0, 2, 4, 6, 8, 10, 12, 14)

*Dermatology, Genetic Diseases, Hematology, Immunology

Outcomes and Metrics

- **14,300** Golden Queries
- **~8,800** Estimated Hours Saved
- **16 → 3** Estimated Time (min) to Query
- **24 → 15** Estimated DM Allocation (50% dedication)
- **30%** Queries Originate from SDQ
- **>80%** Reduction in Use of Data Exports

Where AI and Intelligent Automation will Impact Clinical Trials

Intelligent Protocol Design
Automated Specification Generation
Smarter Enrollment
Automated Database Creation
Intelligent Risk Management
Intelligent Interactive Monitoring and Data Review
Intelligent Data Cleaning
Intelligent Medical Coding
Automated SDTM Creation
Automated Analysis Creation
Automated Submission Creation

Protocol Design
Project Management
Clinical Trial Management
Logistics
Data Management
Biostatistics
Regulatory Submission

Saama is the No. 1 AI-driven intelligent clinical cloud company, enabling the life-sciences industry to conduct faster and safer clinical development and regulatory programs. Today, more than 50 biotech companies use Saama's award-winning Life Science Analytics Cloud (LSAC) platform on more than 1,500 studies, including many of the top 20 pharmaceutical companies. LSAC's rich applications facilitate an unprecedented, authoritative oversight of comprehensive clinical research data, enabling companies to file new drug applications (NDAs) more efficiently and bring drugs to market faster.
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