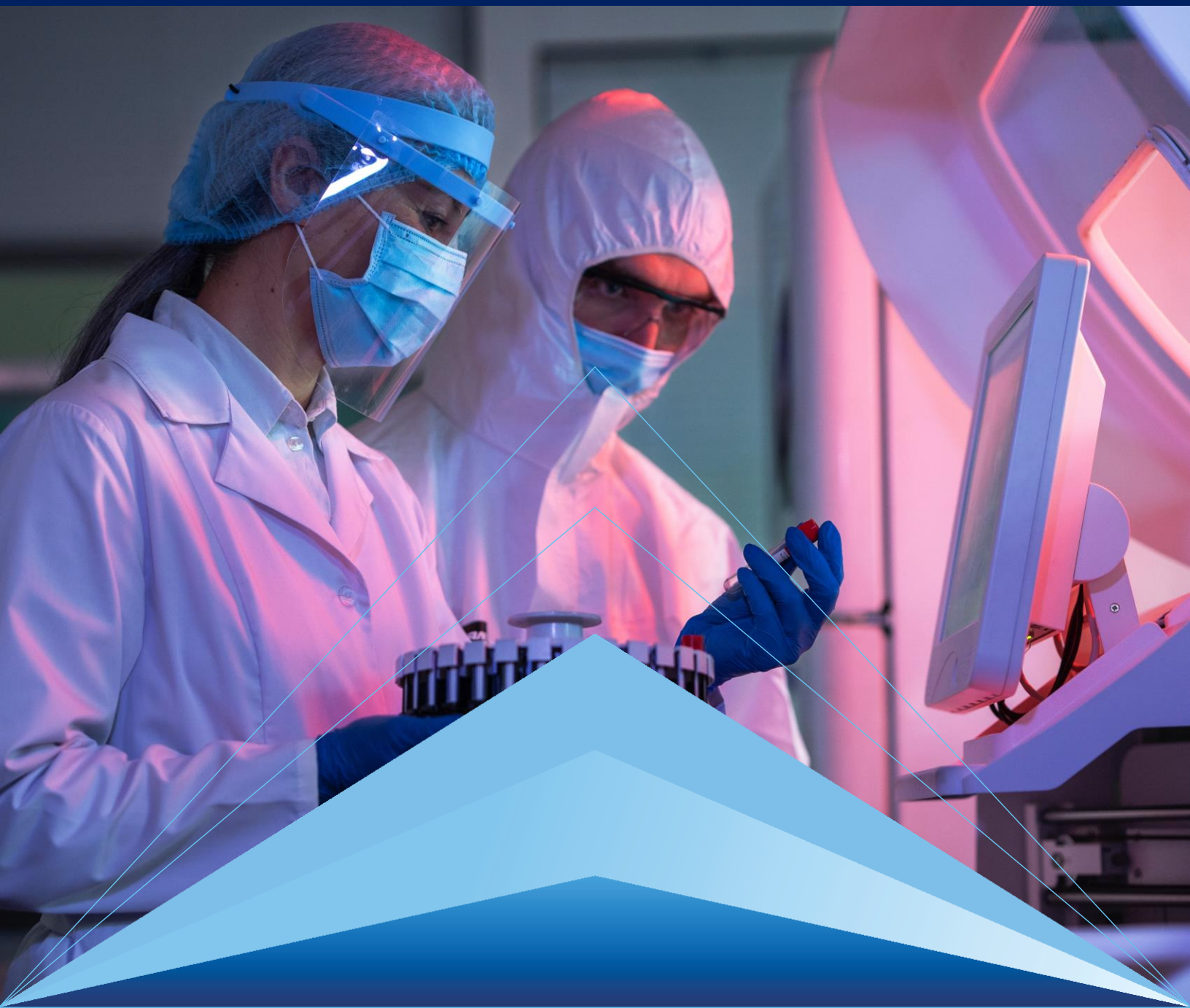
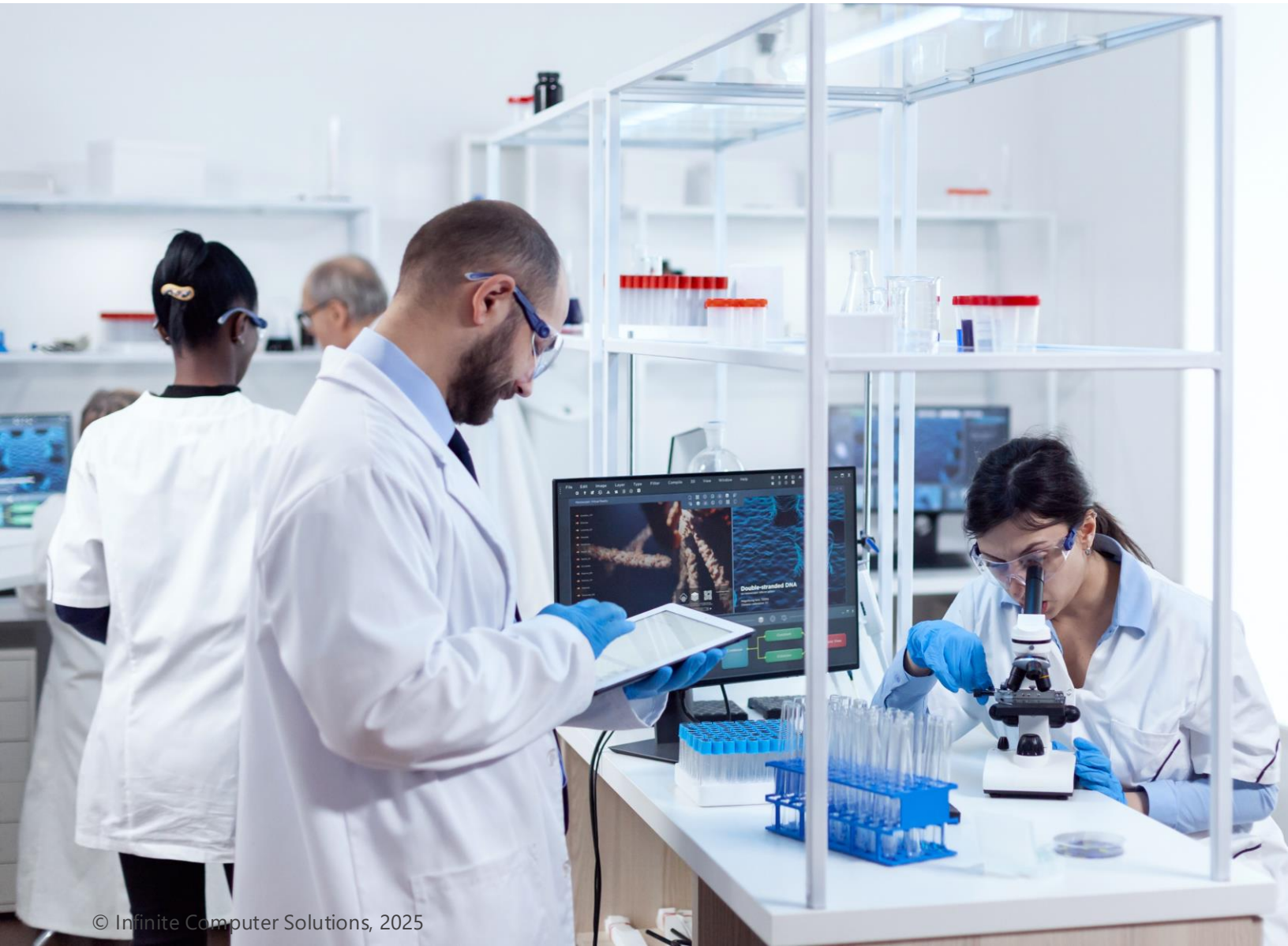
Case Study

# Accelerating Clinical Trials for a Leading Pharma Company



## Summary

A leading pharmaceutical company aimed to expedite the clinical trial process for a ground-breaking drug targeting a severe terminal infection in ICU settings. With a high mortality rate associated with the infection, rapid patient identification, enrollment, and real-time data collection were critical for evaluating the drug's efficacy and safety



## Challenges

- Delayed Patient Enrollment: Traditional processes slowed down patient identification and recruitment, impacting trial timelines.
- Data Fragmentation: Disparate data sources across multiple trial sites hindered comprehensive data analysis.
- Regulatory Complexity: Ensuring data compliance and generating FDA-ready datasets required meticulous data standardization.
- Manual Processes: High dependency on manual workflows led to inefficiencies and increased error rates.

## Key Focus Areas

- Accelerating patient identification, recruitment, and clinical trial processes using real-time data from devices and EMR applications
- Aggregating data from disparate sources (EMR, medical devices, administrative databases) across 100+ clinical trial sites
- Standardizing data through coding protocols for comprehensive analysis and interpretation

## Solution Approach

- Cloud-Based Analytical Platform: Developed a scalable data platform with deployable connectors and a one-click deployment strategy, reducing site onboarding time to less than a week.
- Customizable Clinical Trial Setup: Enabled site-specific protocols and workflows for seamless integration.AI-Driven Patient Identification: Implemented clinical decision support tools to identify eligible patients quickly.
- Automated Enrollment Alerts: Integrated alert systems for site coordinators to streamline patient enrollment.
- Digitized Consent Process: Introduced digital consent forms with decision support, integrated with EMR, ensuring informed patient consent.
- Real-Time Monitoring Tools: Built-in Clinical Quality Dashboard, Data Explorer, and Visualizations for continuous trial oversight.
- Adverse Event & Outcome Tracking: Monitored adverse events, treatment efficacy, and patient outcomes, including survival rates and treatment responses.AI-Powered Data Enrichment: Leveraged NLP and NER techniques to enhance data quality and aggregate clinical notes.
- Stakeholder Dashboards: Provided real-time dashboards for sponsors and site investigators to track trial progress.

## Results & Impact

- 50% automation of manual clinical trial processes60% reduction in site onboarding time40% faster patient enrollment ensuring timely access to investigational drugs
- Improved consent rates through digital tools and EMR integration
- Regulatory success with FDA-ready datasets enabling smooth submission and drug approval
- Enhanced data quality with reduced errors and improved accuracy

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