Transforming Pharma R&D/Drug Discovery with **mcube™**-powered solutions

Driving Innovation & Efficiency in Drug Discovery through Integrated AI Solutions for a Global Biopharmaceutical Leader.

About the Global Biopharma Company and Its Goals:

Founded in the 1800s, this global biopharmaceutical giant has a rich legacy in healthcare, with revenues of $58.5 billion and income of $9.88 billion. The company is committed to pioneering breakthroughs that enhance global health. With a vision to deliver innovative therapies that improve health and well-being at every stage of life, it is also accelerating the development of the next generation of cancer treatments.

To streamline operations and accelerate the delivery of new therapies, the company is focused on digitizing and integrating workflows. This approach aims to increase efficiency, accuracy, and speed in assay, genotyping analysis, and gene expression analysis processes—ultimately supporting its goal of delivering life-saving treatments faster.

Further, in alignment with its purpose to relentlessly innovate—particularly in the bioanalytical processes within its drug development lifecycle—the company is integrating AI to enhance efficiency, improve accuracy, and accelerate various workflows. As a result, the company is positioning itself to bring new therapies to market more swiftly, reinforcing its commitment to innovation and excellence in drug development.

Background: The Need for a Next-Generation Solution

The company identified a pressing need to modernize its pharmacokinetics (PK), genotyping, and gene expression workflows. Manual steps, fragmented systems, and compliance challenges were impeding efficiency and speed. It required an integrated, AI-powered solution that could drive automation, ensure regulatory compliance, and support high-throughput R&D operations.

The mcube™-Powered Transformation

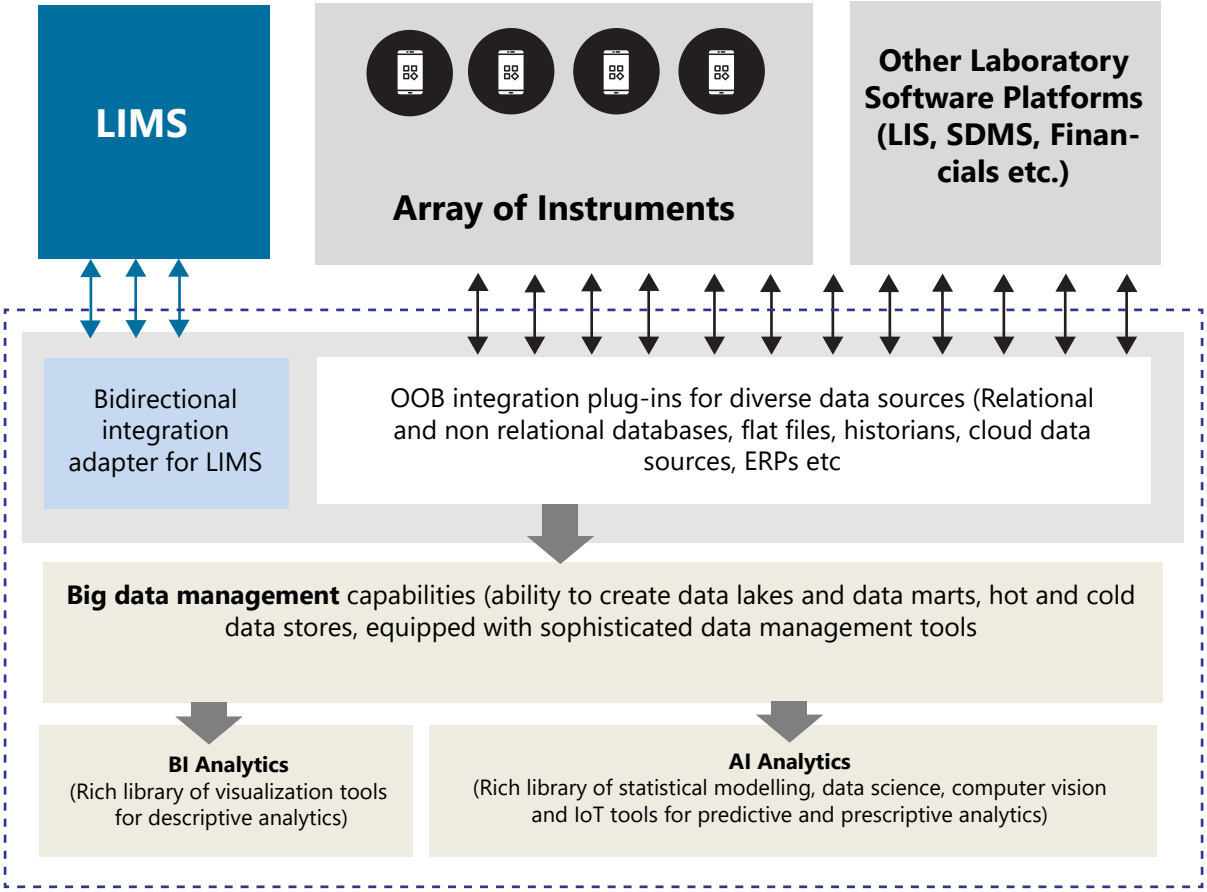
TCG Digital's integrated assay analytics solutions—built on its advanced analytics and AI platform, mcube™—have enabled the biopharma company to achieve a seamless and efficient workflow for R&D in drug discovery. The mcube™ platform integrates directly with the company's existing Laboratory Information Management Systems (LIMS), allowing data to be automatically written back to the LIMS after analysis. This integration reduces the risk of data manipulation and ensures a transparent audit trail, which is critical for maintaining compliance with regulatory standards. The platform supports a wide range of assay analytics, including pharmacokinetic (PK) and anti-drug antibody (ADA) assays, and offers robust capabilities for genotyping and gene expression analysis.

Scope and Implementation: TCG Digital's collaboration with the biopharma company began with the implementation of PK assay analytics, subsequently expanding to include PK assay analysis with multiplex, genotyping analysis, and gene expression analysis. Our team of subject matter experts worked closely with the client's R&D team to design a customized solution that integrated seamlessly with their existing workflows. By automating data analysis and reporting processes, the manual effort was significantly reduced, improving data accuracy, and ensuring better compliance with FDA and ICH regulations.

Why mcube™?

The company selected mcube™ for its:

- Ability to integrate directly with LIMS systems, allowing users to conduct analyses without leaving the LIMS environment, eliminating the risk of data manipulation and maintaining a transparent audit trail.
- Modular design, along with APIs and connectors to various LIMS systems, ensuring flexibility and scalability.
- Deep understanding of compliance regulations such as ICH and 21 CFR Part 11, enabling the design of a solution that meets industry standards and ultimately saves time and resources in the assay workflow.
- A unified platform that streamlines the entire assay analysis workflow, saving significant man-hours and reducing costs associated with errors and rework.



Solutions

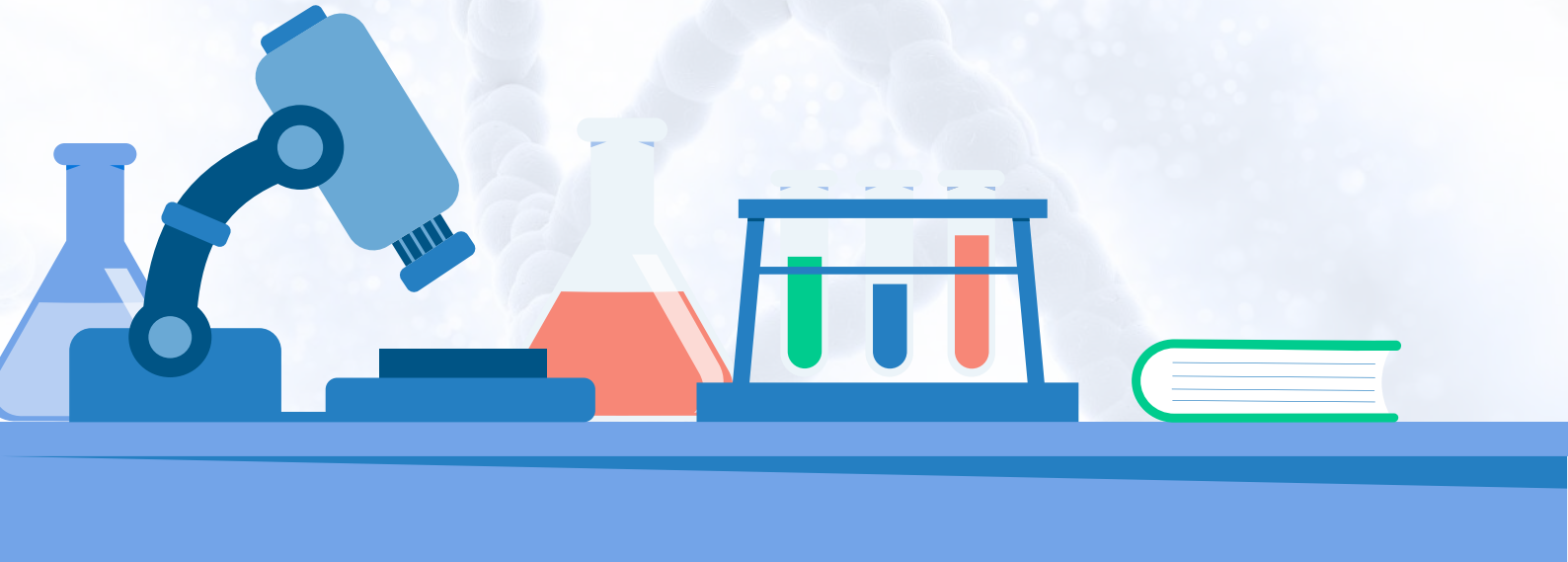
TCG Digital Solutions offered to the Biopharmaceutical Company:

01 PK Assay Analysis

02 PK Assay Analysis with multiplex

03 Genotyping Analysis

04 Gene Expression Analysis



01 PK Assay Analysis

The company wanted an integrated solution for PK Assay analysis to reduce manual steps and centralize the analysis approach. The goal was to optimize the accuracy, reliability, and efficiency of PK assay processes while reducing operational costs through streamlining of the entire analysis process.

The company aimed to achieve accurate data analysis that would help them study how a drug or substance is absorbed, distributed, metabolized, and excreted in the body. Further, the solution would provide actionable insights into determining the correct dosage, frequency, and duration of drug treatment to ensure efficacy while minimizing side effects

PK Assay Analysis solution: The solution developed for PK Assay Analysis was built on the mcube™ platform, a robust and versatile system designed to address the challenges associated with pharmacokinetic data analysis. The mcube™ platform provides a comprehensive suite of functionalities tailored for high-throughput and precision-driven PK assays.

Its key functionalities include:

- Seamless bidirectional integration and write-back facility with the existing LIMS
- Options to generate the best-fit calibration curve using known concentrations of the analyte being assayed
- Options for linear/non-linear regression algorithms with varying residual weightages
- Options to select/deselect standards for curve fitting
- Application of various method specifications
- Scenario-building capabilities
- Associated reports, such as assay precision analysis

Result

Cost Savings: The integrated solution led to an expected annual cost savings of $1.3 million. This financial benefit arises from increased manpower efficiency and a significant reduction in the costs associated with rework and manual data handling.

Enhanced Efficiency: The automation and centralization provided by mcube™ have streamlined the PK assay process, minimizing manual steps and reducing the potential for errors.

Improved Data Accuracy: With advanced calibration and regression capabilities, the platform enhanced the accuracy of PK assay results, leading to more reliable and actionable data.

The mcube™ PK Assay Analysis solution has proven to be a valuable asset for the global pharmaceutical company, driving cost efficiencies and enhancing the precision of pharmacokinetic analyses. By integrating mcube™'s advanced analytics & AI technology with its existing systems, the company has achieved significant operational improvements and continues to advance its drug development and clinical trial processes with greater confidence and efficiency.

02 PK Assay Analysis with multiplex

The company sought an integrated solution—particularly for the use of multiplexed assays in pharmacokinetics (PK)—to reduce manual steps and centralize its analysis approach.

The solution needed to simultaneously measure multiple analytes in a single sample, enabling the company to determine the concentration of various drugs, metabolites, or biomarkers in one analytical run.

PK Assay Analysis with multiplex: The solution was built on the mcube™ platform, which provided a robust framework for PK Assay Analysis with multiplex capabilities. This advanced analytics and AI platform was chosen for its comprehensive features designed to address the specific needs of the company. The mcube™ platform offers a comprehensive solution for PK Assay Analysis with multiplex.

Its key functionalities of the solution include:

- Seamless integration with the existing LIMS
- Options to generate the best-fit calibration curve for each analyte using known concentrations of the analyte
- Assortment of curve-fitting models (linear/non-linear)
- Ability to specify weights and select standards
- Options to select/deselect standards for curve fitting
- Application of various method specifications
- Scenario-building capabilities

Result

The implementation of the mcube™ -based PK Assay Analysis with multiplex solution yielded significant benefits:

Cost Savings: The company realized an estimated $0.8 million per year in cost savings. This was achieved through increased manpower efficiency and reduced costs associated with rework.

Enhanced Efficiency: Multiplexing allowed for the simultaneous measurement of multiple analytes in a single sample, drastically reducing the time and resources required compared to traditional, single-analyte assays.

Cost-Effectiveness: By minimizing the number of samples and reagents needed, the solution lowered overall operational costs.

Improved Data Integrity: The use of multiplexing minimized variations caused by handling and processing multiple samples, ensuring more reliable data.

Comprehensive Analysis: The ability to assess drug-drug interactions, multiple pathways affected by a drug, or different drugs in combination therapies provides a deeper understanding of drug behavior.

The mcube™-based PK Assay Analysis with multiplex solution revolutionized the company's approach to pharmacokinetic studies. By integrating advanced multiplexing techniques and streamlining processes, the solution delivered substantial cost savings, enhanced efficiency, and improved data integrity. This comprehensive approach not only supported better drug development but also contributed to more effective and safe therapeutic solutions.

03 Genotyping Analysis

The company recognized a need for an integrated solution to reduce the manual steps and centralize the analysis approach involved in its Genotyping analysis. The solution it sought would need to provide accurate data analysis to advance pharmacogenomics, which would enable it to focus on how genetic variations impact drug efficacy and safety. Further, the analysis provided by the solution was to allow for personalized medicine, where drug prescriptions would be tailored to an individual's genetic profile, enhancing therapeutic outcomes and minimizing adverse effects.

To address the challenges of manual data handling and the fragmented nature of existing systems, a comprehensive Genotyping Analysis Solution was built on the mcube™ platform. This solution aimed to centralize and automate the analysis approach, providing several key features.

Genotyping Analysis Solution built on mcube™: offers the following key features:

- Seamless integration with LIMS
- Data collection from Taqman, Copy Caller, Open Array, and Fragment Analyzer
- Relevant pre-processing for each type of instrument data
- Maintenance of consolidated mapping rules for each gene family and scenario creation with multiple rule files
- Application of the gene family rule on the consolidated data
- Generation of tabular outputs
- Write-back of results to LIMS

Result

The implementation of the mcube™-based Genotyping Analysis Solution yielded significant benefits:

Cost Savings: The company realized an expected annual cost saving of $0.5 million. These savings were attributed to improved manpower efficiency and a reduction in the costs associated with rework.

Operational Efficiency: The solution reduced manual steps and streamlined the genotyping process through its bidirectional integration and write-back feature, which enhanced overall operational efficiency.

Data Accuracy and Consistency: By integrating data from various instruments and applying consolidated mapping rules, the solution improved the accuracy and consistency of genotyping results.

Enhanced Research and Development: With a more efficient analysis system, the company was better equipped to conduct research, identify genetic markers associated with drug responses, and develop targeted therapies.

The mcube™-based Genotyping Analysis Solution has significantly advanced the pharmaceutical company's ability to conduct precise and efficient genotyping. By integrating various data sources, automating processes, and maintaining consolidated rules, the solution has not only optimized operational workflows but it has also contributed to substantial cost savings. This enhanced capability supports the company's broader goals in pharmacogenomics, including personalized medicine, drug development, and predictive analysis of adverse drug reactions, ultimately leading to more effective and safer medical treatments.

04 Gene Expression Analysis

In the dynamic and highly regulated world of global pharmaceuticals, efficient gene expression analysis is crucial for understanding disease mechanisms, advancing drug discovery, and personalizing patient treatments. To streamline and enhance their gene expression analysis process, the leading pharmaceutical company sought an integrated solution that would minimize manual steps and centralize their analysis approach for Gene Expression Analysis.

Gene Expression Analysis solution built on mcube™: The mcube™ platform offers an integrated solution for Gene Expression Analysis solution. Its salient features include:

- Seamless integration with LIMS
- Covers both qualitative and quantitative analysis
- Flexibility to omit the unwanted samples, select controls from housekeeping gene assays & select analysis parameters
- Analysis on CT data and sample normalization for each assay
- Standard curve fitting for quantitative analysis
- Results in a crosstab view
- Samples flagged based on CV acceptance criteria
- Write-back of the computed results to LIMS

Result

The implementation of the mcube™-based Gene Expression Analysis solution led to significant improvements:

Cost Savings: The company realized an expected annual cost saving of $0.5 million, attributed to enhanced manpower efficiency and reduced costs associated with rework.

Enhanced Efficiency: Automation of manual steps streamlined workflows, reduced errors, and accelerated the analysis process.

Mechanistic Insights: Understanding how drugs work at a molecular level through gene expression can lead to more targeted and effective therapies.

The mcube™-based Gene Expression Analysis solution has proven to be a transformative tool for the pharmaceutical company, enhancing efficiency, reducing costs, and providing valuable insights into gene activity. By integrating advanced analysis techniques and automating workflows, the solution supports ongoing research and development efforts, driving innovation and improving patient care.

Conclusion

By implementing mcube™-based solutions, the large biopharma company not only streamlined its R&D workflows but also realized substantial financial benefits through increased efficiency, reduced errors, and enhanced compliance.

Get in touch with us at **contact@tcgdigital.com** for a robust digital strategy and powerful demonstration of this easily deployable platform.

About TCG Digital

TCG Digital is the digital & AI arm of The Chatterjee Group (TCG), a multi-billion dollar conglomerate with a diverse portfolio in Aviation, Pharmaceuticals, Biotech, Petrochemicals, and Real Estate across the US, EU, and South Asia. Our umbrella includes companies such as LabVantage, Lummus Technology, and TCG LifeSciences. At TCG Digital, we are driven by our mantra of delivering "Velocity to Value", helping enterprises transform faster and smarter. Our AI Analytics platform mcube™ is at the heart of these transformations. We enable organizations unlock the full potential of their data, and by seamlessly integrating AI/ML capabilities into their business processes, we empower businesses to accelerate their digital transformation journey, enhancing agility and driving impactful results.

For more information please visit our website at www.tcgdigital.com

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