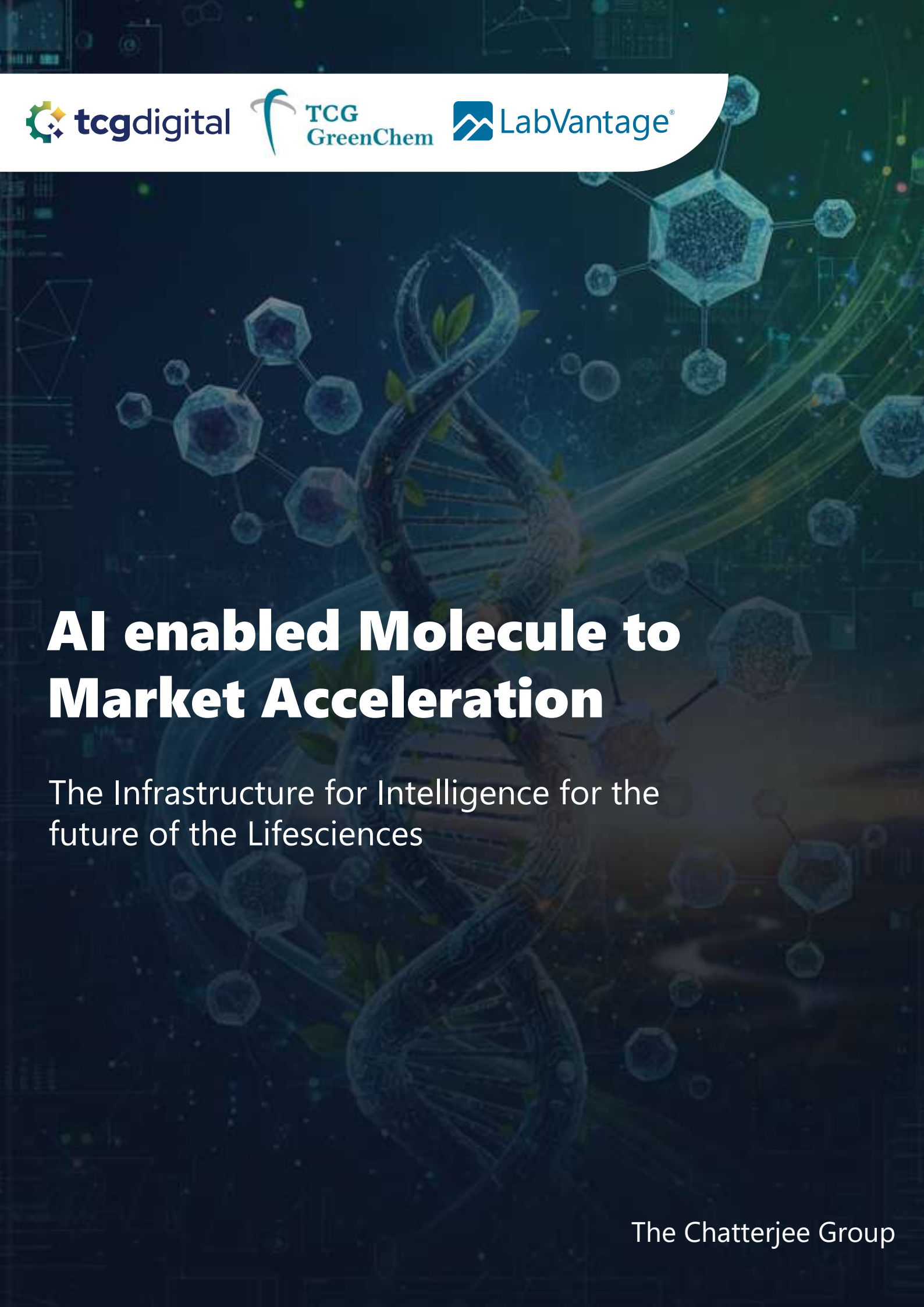

tcgdigital
TCG GreenChem
LabVantage®
AI enabled Molecule to Market Acceleration
The Infrastructure for Intelligence for the future of the Lifesciences
The Chatterjee Group

# CONTENT

# Accelerating Drug Development through Integrated Innovation

Drug development, from initial discovery of a promising target to the marketing of the final medication, is an expensive, lengthy and incremental process. On average, in the pharmaceutical industry, the journey from discovery to market takes around 7 years, while the timelines for some indications of medicine can be significantly longer.

Understandably, entities across the value chain make strenuous efforts to optimize speed and timelines. While clinical trials have historically been the focal point for optimizing time and cost, there is now a significant shift toward accelerating upstream stages: target identification, molecule selection, process development, and early-stage manufacturing. Organizations are increasingly investing in integrated, data-driven, and sustainable approaches to improve quality, speed, and efficiency across the drug development value chain.

The Chatterjee Group (TCG) through its group entities (please refer Annexure 2 for details of TCG) is putting forth a proposal aimed at accelerating the drug development process by around 6 months (delivering Phase 1 clinical material in 12 months vis-à-vis the traditional 18 months) as illustrated below. In addition, a Go/No-Go decision will ensure timely culling and prioritization and optimize the portfolio.

The above will be achieved through focus on accelerating the molecule to market journey via horizontal and vertical data integration across discovery, development and manufacturing enabling end-to-end insights, optimizing processes, accelerating timelines, and improving product quality and compliance.

We estimate, that the 6 months development acceleration will positively impact an equivalently earlier time to launch.

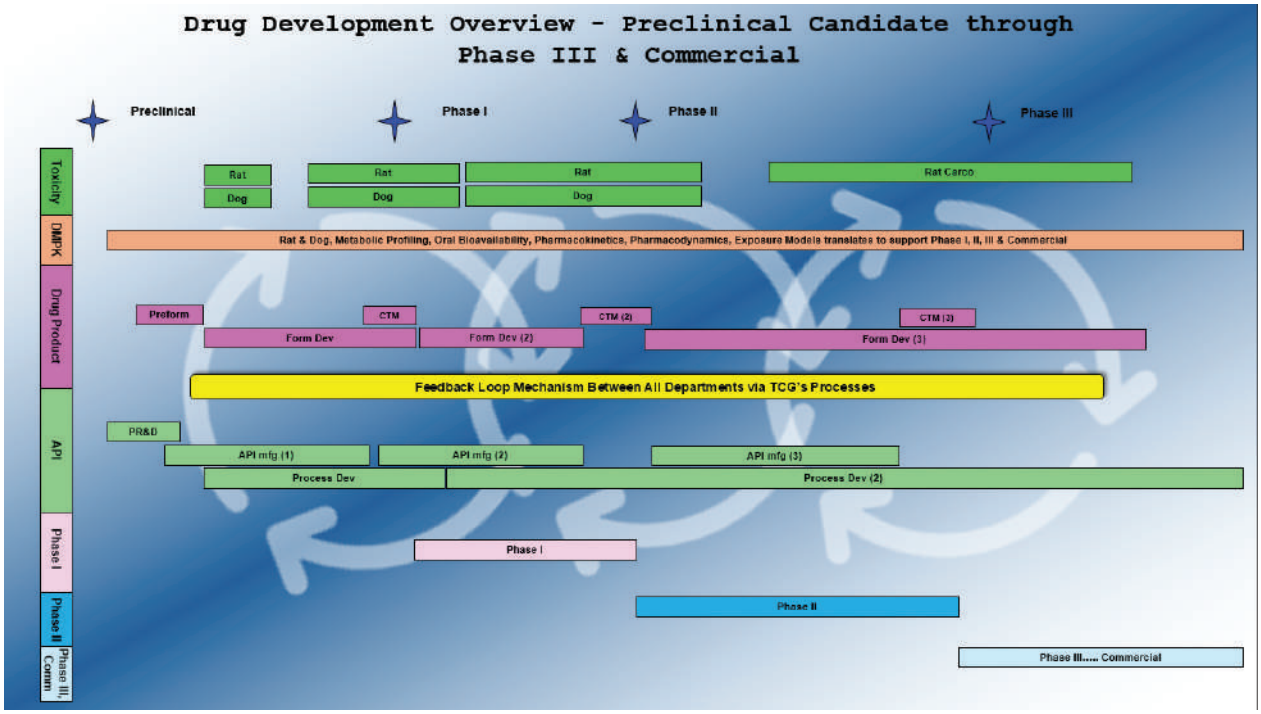

## Value Proposition

TCG's ecosystem is purpose-built to compress timelines from discovery to clinic, improve sustainability, and reduce development risks.

Committing to innovation and speed, TCG, proposes integrated offerings to significantly impact and accelerate the critical stages of drug development through Horizontal Optimization of Drug Development Processes and Horizontal data integration across discovery, development and manufacturing processes.

## Horizontal Optimization of Drug Development Processes:

- Utilizing novel technologies such as: catalysts, photochemistry, electrochemistry, continuous flow chemistry and crystal engineering processes. With excellence in synthesis of complex API, these technologies shorten the time for route design, and research and development and thus accelerate manufacturing under nonGMP and cGMP conditions for pre-clinical and clinical studies
- Characterizing the molecules and scaling up the processes in a safe and robust manner; transferring to kilo lab, pilot plant and commercial facilities
- Identifying polymorphic forms and developing robust crystal engineering supporting novel formulation developments and clinical trial manufacturing of drug products
- Engineering novel solutions for complex synthetic processes utilizing green and sustainable principles
- Accelerating development of synthetic processes for APIs
- Discovering and developing enabling technologies for increasing oral bioavailability of highly insoluble compounds
- Removing hazardous, dangerous, and expensive chemistry
- Rapid scale-up to pre-clinical and IND toxicology studies
- Developing scalable, practical, robust and economically feasible syntheses and formulations for manufacturing of complex small molecules from Phase I through Phase II to commercialization



**The above can be achieved primarily through:**

Vertically and Horizontally integrated Chemistry and Manufacturing Control (CMC), Drug Metabolism, Pharmacokinetics Pharmacodynamics, Animal Toxicity Studies, and Clinical Studies

- Vertical integration and real time knowledge sharing between the different functional groups which supports informed decision making at different stage gates
- Horizontal integration through applying late-stage development insights to early preclinical candidates accelerate pipeline progression
- Combined Drug Substance & Product teams to create greater synergy for decision making and execution
- Understanding of the parallel workflows above, highlights the Phase I complexity and enables acceleration of the drug development pathway
- Shared knowledge of combined "First Time Right with Line of Sight" for integrated Drug Substance with Drug Product development supports quicker and accurate decision-making. This minimizes post Phase I delays and bridges studies due to formulation changes
- Drug product miniaturization technology, with minimal material, allows preformulation and formulation development to occur in parallel workflows with less API
- Acceleration for the identified vehicle for animal toxicity studies for IND
- Shared analytical method development shortens the timeline for Drug Substance and Drug Product characterization
- Condensed timelines and less resources
- Eradication of duplication of analytical development
- Eradication of "wasted or excess" API and drug product batches
- Personalized formulation, eliminating one-for-all platform formulations
- cGMP manufacturing performed in parallel with formulation development so that clinical trial manufacturing can be initiated as soon as cGMP Drug Substance is provided

The value addition made in the CMC (Chemistry, Manufacturing, and Controls) section of and IND will strongly impact the late-stage manufacturing toward the commercial supplies of the drug substance. Furthermore, it positively impacts the following specific aspects of a late stage/ commercial manufacturing process.

- Drug substance quality and consistency
- Manufacturing process changes
- Late-stage regulatory submissions and approvals
- Risk management and risk mitigation
- Drug substance final cost and time efficiency

**Horizontal data** integration across discovery, development and manufacturing. This enables generating end-to-end insights, optimizing processes, accelerating timelines, and improving product quality and compliance. The goal will be to unify research-derived inputs with development and manufacturing workflows, structure data for traceability and reuse, and help accelerate decision-making across the journey to clinical readiness.

The benefits of this proposition are significant. Eventually it will lead to enhanced patient outcomes through better linkage of clinical trials data with drug development and production. Here are some examples of potential benefits derived from the integrated insights:

- Accelerated development decisions by linking biomarkers and mechanisms to clinical outcomes
- Facilitation of smoother tech transfer, with reduced cycle times, by feeding discovery & clinical data into scale-up processes during process development
- Early identification of critical process parameters (CPPs) informed by upstream experiments accelerating the process and reducing time and errors in CMC and scale-up phases
- Accelerated timelines and facilitating huge cost savings by running virtual simulations of process and outcomes on unified datasets; thereby reducing experimentation
- Accelerated timelines for submissions by leveraging a single source of truth across functions
- Improved safety and efficacy through tighter integration of post-market surveillance with early research and development (R&D)
- Improved R&D efficiency through in-silico simulations and model-based drug development and target validation using real-world and manufacturing data
- Real-time release testing (RTRT) with integrated quality and process data
- Quality support by Design and ICH Q12 principles through lifecycle data visibility

With the objective of implementing the above in a timely and cost-effective manner, we propose to leverage technology as a key enabler. A modular, scalable platform suite integrating data across discovery, development, and manufacturing will support optimizing traditional implementation challenges of volume, isolated workflows, siloed data, as well as resource intensive and human cognitive constraints.

## Key enablers for this integrated platform offering will include:

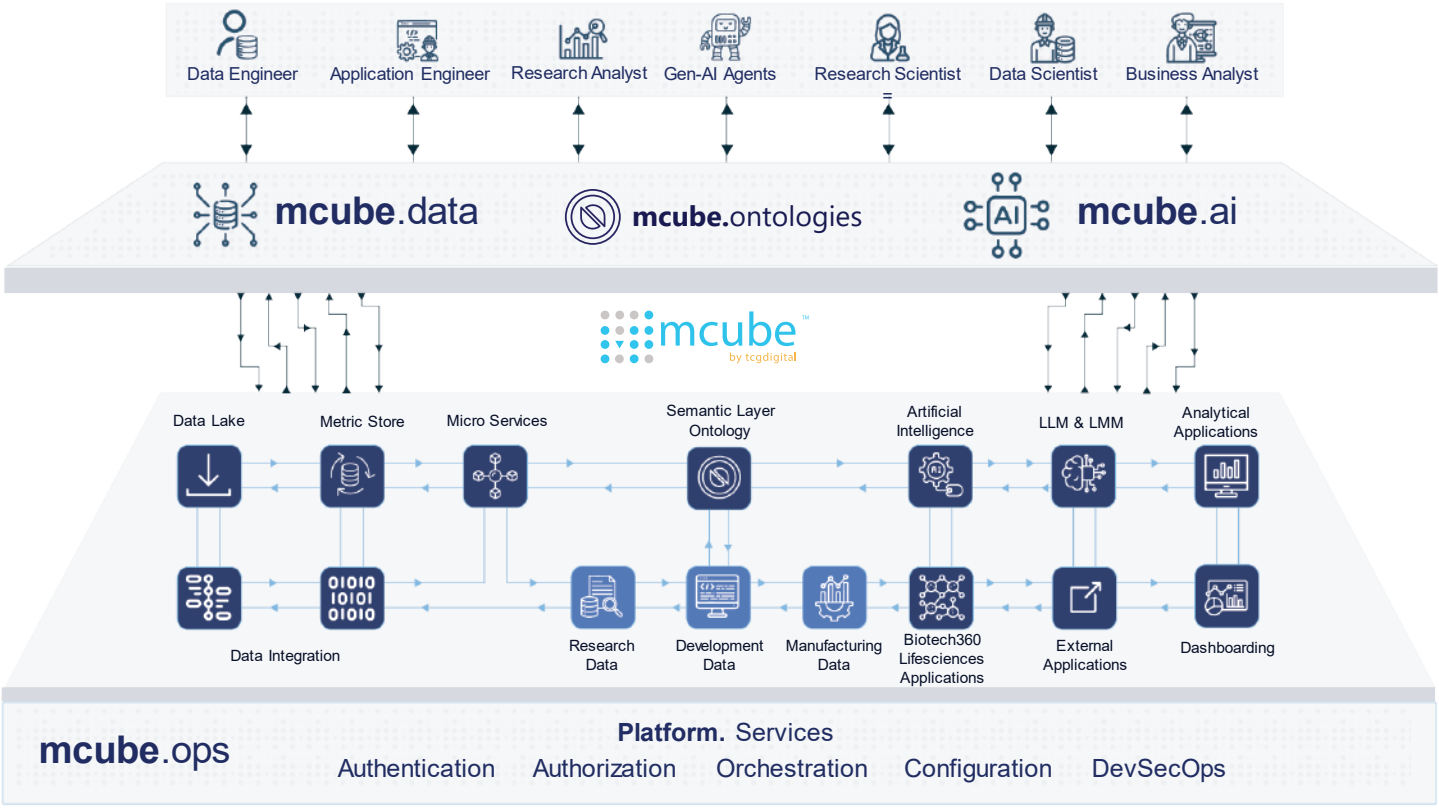
- A federated data lakehouse technology
- Pipelines to ingest and harmonize structured/unstructured data
- Knowledge Graphs to connect relationships across data types
- AI/ ML Models for predictive and prescriptive analytics
- Easy and efficient extraction of information in natural language combining Generative AI and Knowledge graph technologies
- Data Governance to ensure quality, security, and compliance
- Cross-functional Teams with domain, technology, and data science expertise

TCG brings together all these capabilities. The proprietary platform, mcube™, offers AI/GenAI, Data Management and Semantic Ontology powered by knowledge graphs on a single modular platform, bound by common platform services. This enables robust data management and the creation of a federated data lakehouse that makes data findable, accessible, interoperable, and reusable. Users can navigate through data based on relationships defined by the semantic ontology rather than relying on technical data dictionaries.

**Here are some of the core features of the mcube™ platform:**

- Pre-built connectors to various systems & instruments. The connectors support real time as well as batch ingestion, with features for data transformations at various stages. The semantic layer overlay enables data ingestion processes to utilize the semantic definitions.
- Robust data management leverages ontology management & knowledge modelling, making it “easy to extract data”.
- Traditional AI at scale with a wide assortment of capabilities including statistical, machine learning, deep learning, and optimization algorithms; comprehensive GenAI algorithms covering traditional LLM (private LLMs to mine text data), multimodal LLM (to mine image data) and referenceable RAG models for easy information retrieval as well as technology to create AI agents and agentic applications.
- Real-time AI and comprehensive model management.
- Insights dissemination layer with multiple, user interfaces - dashboards with easy business user.
- Deep data science expertise combined with the power of mcube™ can facilitate the creation of AI agents/ agentic applications that facilitate faster decision making and execution.
- Domain-specific ontologies, knowledge graphs, and metadata standards to contextualize scientific and operational data. Together they can semantically connect a broad range of scientific and operational entities—such as small molecules, antibodies, plasmids, strains, cell lines, genomic sequences, experimental data, and much more.
- Deep domain expertise in the area of process research, development and API manufacturing for chemistry, as well as wet lab expertise.
- Deep knowledge of laboratory data and technology (LIMS, ELN) across the Lifesciences value chain, tailored to support both research and GMP-grade operations.

The overall data flow in the platform has been illustrated below:




The above infrastructure and technology will operate as a single platform that will be configurable to the requirements of the different verticals and users. This platform approach ensures scalability, interoperability, and AI-powered decision-making.

As a proof of concept to the above stated proposition, we have built a use case leveraging our platform, mcube™, and the power of LLM to showcase a practical utility of the concept.

The use case focused on building support mechanisms for scientists in the lab, to find information easily and efficiently, from a repository of process research and development reports as well as public sources. Scientists in the lab will be able to query using natural language, and receive consolidated insights with references to source documents from where response has been generated. Scientists will also have access to the archive of all user queries and responses.

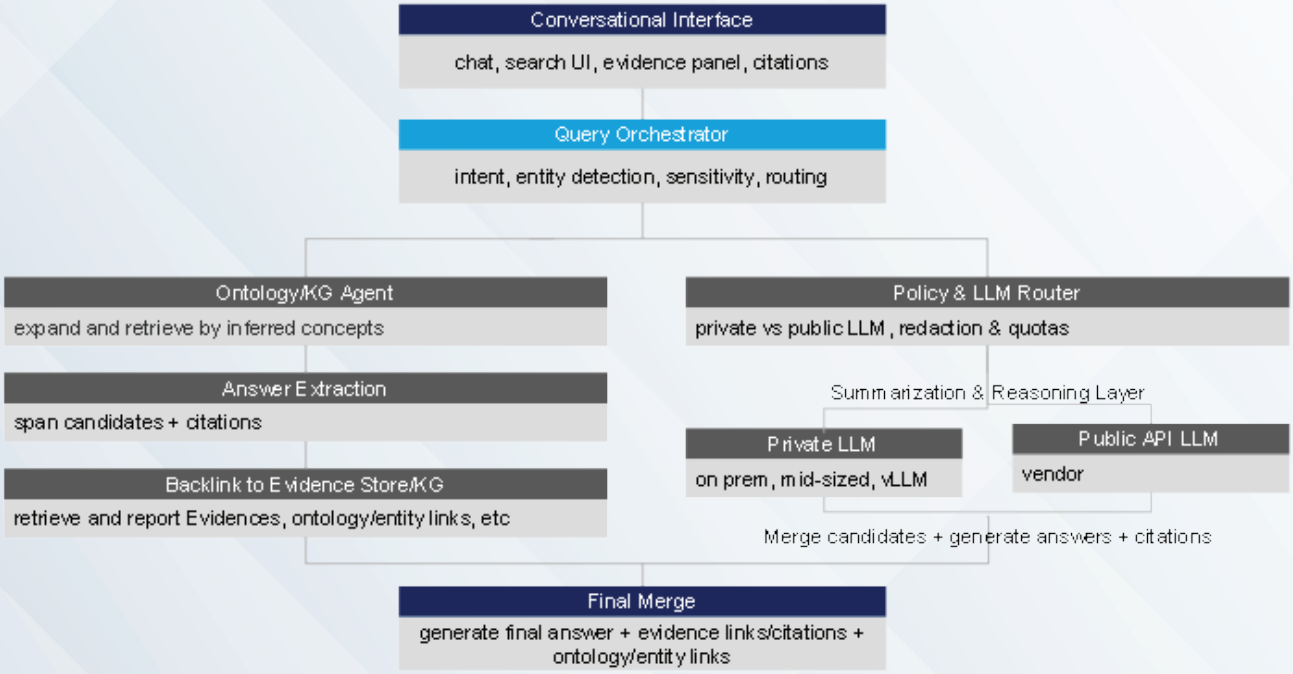
The questions can cover common parameters involved in screening a reaction - these include questions around reactants and equivalents, reagents and equivalents, solvents and volumes, temperature, pressure, reaction time, addition mode, addition rate, impurities and their ratios, catalysts and loading, ligand and loading, holding studies and specifications of starting materials, reagents, solvents and products.

In future, this repository can be extended to cover multiple documents as well as structured data, not only from process development but also from the entire value chain spanning R&D, process development, clinical trials and manufacturing.

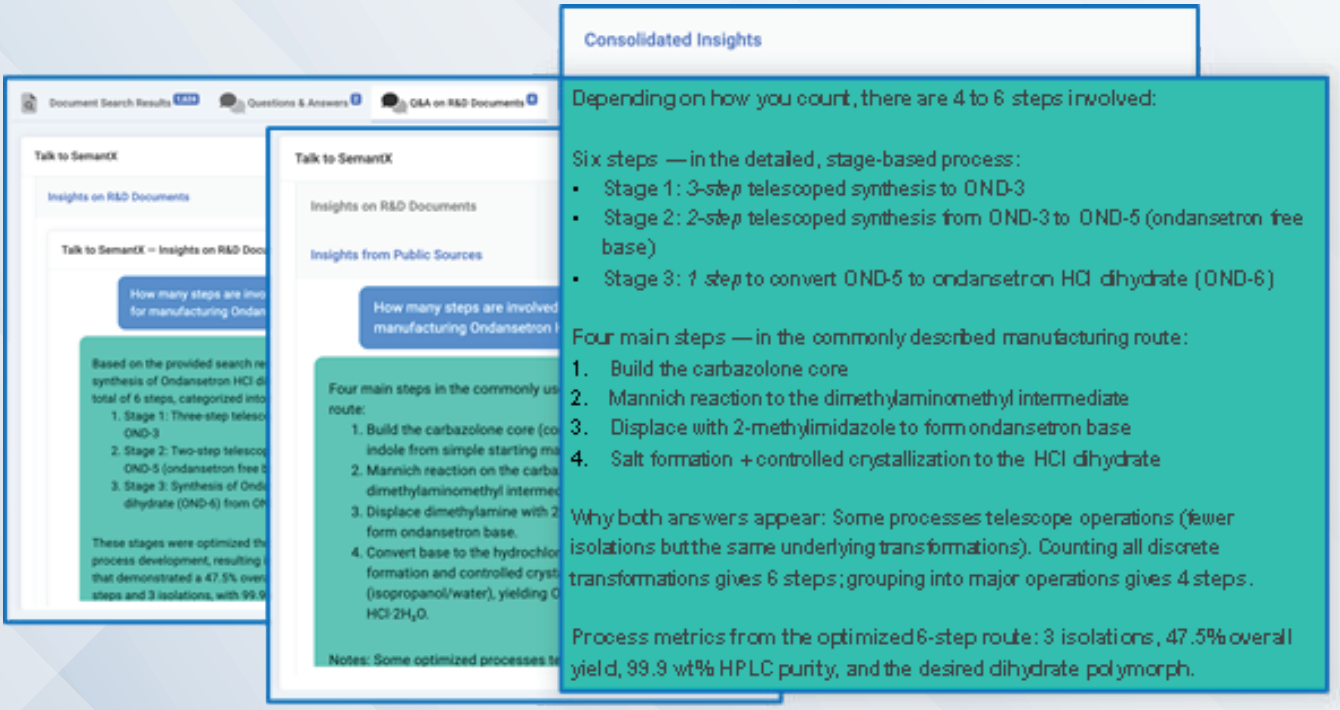
## The benefits will include:

- Efficient search and discovery of information
- Contextual response that is more actionable
- Huge time savings for personnel

An overview of the methodology adopted has been illustrated below:




A snapshot of a consolidated response to a user query is shared below:



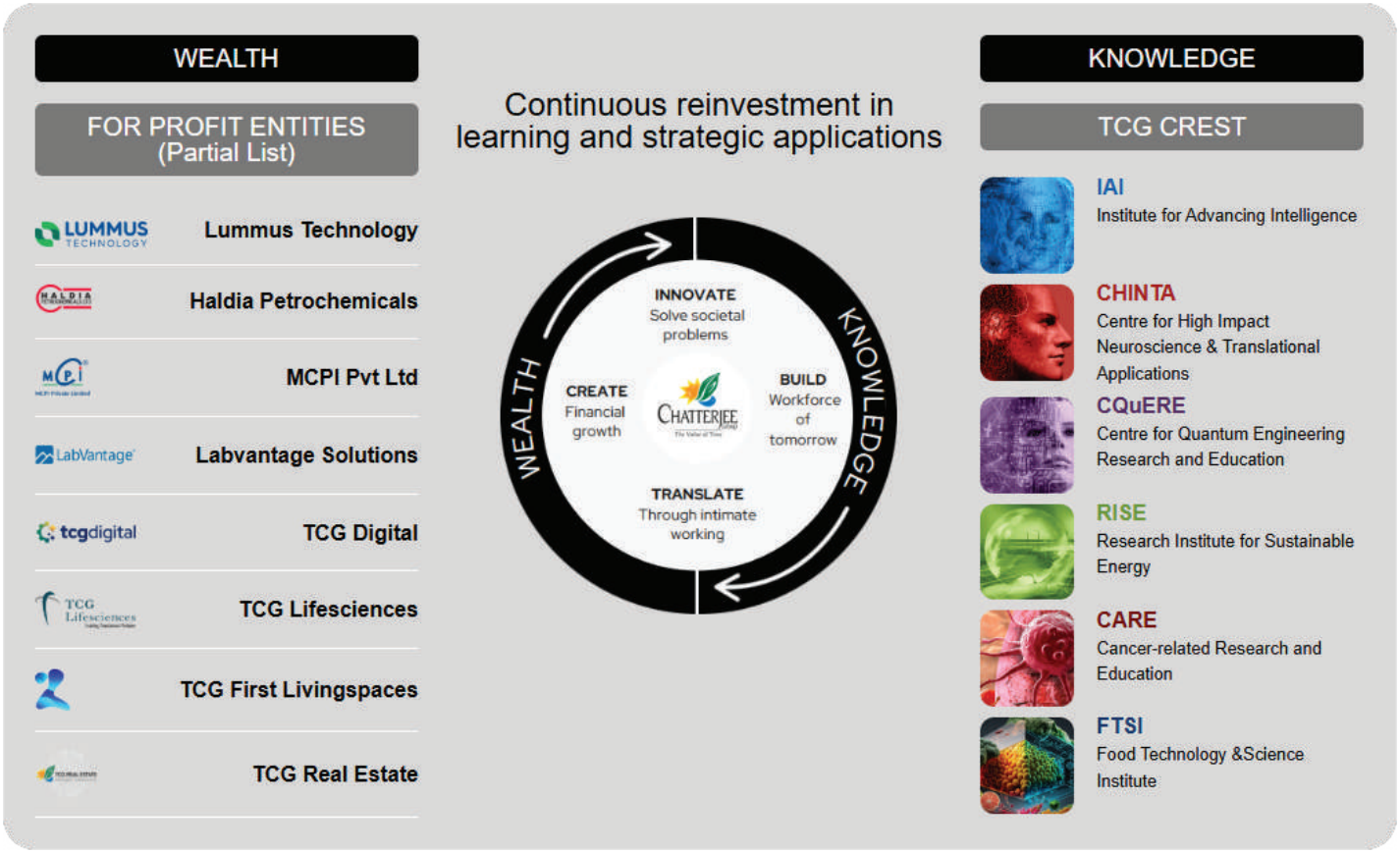
# Annexure 1: **Leveraging data across the pharma value chain**

| Data Domain | Typical Data Types | Primary use | AI Opportunity for Process Development |
|---|---|---|---|
| Research / Preclinical | Molecular structures, omics, physicochemical properties, cell-line performance, assay data | Identify targets, mechanisms, toxicity | Predict manufacturability and stability for API and DP, |
| Process Development (CMC) | Process parameters, equipment data, material attributes, lab/pilot run data, CQAs | Develop robust, scalable manufacturing processes | Learn from upstream & downstream manufacturing data to accelerate process characterization |
| Manufacturing / Operations | Sensor data, MES/LIMS/QMS records, yield, robustness, deviation | Execute production, ensure quality, assess facility fit, maximize yield | Feed real-world variability & performance back to PD, shrink tech transfer timelines |
| Clinical / Post-Market | Efficacy, safety, biomarkers, patient demographics, patient response | Demonstrate safety and efficacy for approval | Identify which attributes affect outcomes; refine CQAs |

# Annexure 2: **The Chatterjee Group (TCG)**

TCG is a multi-billion dollar portfolio of knowledge-based corporations specializing in Information Technology, Life Sciences, Petrochemicals, Real Estate, Fintech and more, across 45 countries. With over $3 Bn of strategic investments, TCG, since its inception, has an overriding focus on value creation through strategic long-term investments primarily in 'knowledge-based companies'.

A snapshot of the Group's portfolio and philosophy has been illustrated below:




TCG sets an ambitious vision, to generate wealth from knowledge and reinvest it deeper through the creation of the "Infrastructure for Intelligence (I4I)". The goal is to make siloed, vast, and often fragmented data interoperable and accessible. I4I will be leveraged to generate AI/ML driven improvements and innovation for accelerating research and development thereby enabling a molecule to market delivery for the industry.

Our collective and extensive expertise in pharmaceuticals, biotechnology, digital transformation, and advanced manufacturing through group entities like TCG GreenChem, Lummus Technologies, TCG Digital, and LabVantage, along with our translational research capabilities through TCG CREST, bring a converged ecosystem, where data, domain knowledge, manufacturing expertise and deep research capabilities in the biomedical sector coalesce. Key service/ product offerings of each of above-mentioned Group entities include:

TCG Digital is the AI & Digital arm of The Chatterjee Group (TCG). For 25 years, we've operated at the intersection of domain depth and digital excellence—partnering with global enterprises to embed AI into mission-critical operations, securely and at scale.

At the core is mcube™, our enterprise and agentic AI platform, built on strong domain-driven thinking and design. mcube™ unifies data, ontologies, and advanced AI models to navigate disparate data landscapes, accelerate decision-making, and deliver measurable RoI — with accelerated time-to-value! Driven by our mantra "Velocity to Value," we enable enterprises to transform smarter, and innovate with confidence. Operating from 11 global offices, TCG Digital serves enterprises across North America, Europe, Asia, Middle East & Africa.
www.tcgdigital.com

***https://www.tcgdigital.com/***

A global, innovative Contract Development and Manufacturing Organization (iCDMO), that partners with the pharmaceutical and biotechnology industries to deliver innovative, integrated, and accelerated process research and development for sustainable and green manufacturing of API under nonGMP/ cGMP conditions for preclinical and clinical materials. The application of different frontier technologies (e.g. catalysis, continuous flow chemistry, electrochemistry, photochemistry, novel crystal engineering), green chemistry principles, and a global talent pool, deliver efficient and economical processes for the acceleration of the drug development pipeline. Synergy of TCG GreenChem expertise and partnership with Lummus Technologies and its treasure trove of 160 proprietary technologies for continuous flow chemistry, creates an unparalleled collaboration for the manufacture of pharmaceuticals from the US stockpile.

https://tcggreenchem.com/

Frost & Sullivan ranks LabVantage #1 in global LIMS. Its SaaS 2.0 intelligent solution, which is highly configurable include LIMS, ELN, LES, SDMS, with advanced analytics, ontologies, and agentic AI, to enable smooth deployment in any environment. The BioTech360 suite offers preconfigured, interoperable applications and life-science specific semantic models that function as specialized registries and repositories for managing critical development-stage entities.

***https://www.labvantage.com/***

The Chatterjee Group (TCG) has an enviable track record as a strategic investor, with businesses in many sectors. Founded by Dr. Purnendu Chatterjee in 1989, the Group specializes in the Petrochemicals, Pharmaceuticals, Biotech, Financial Services, Real Estate and Technology sectors in the US, Europe and South Asia. It provides end-to-end product and service capabilities through its investments and companies in these sectors.