An era of better life expectancy, when the world faces the biggest health crisis of all times!

The Pharmaceutical Industry traditionally, deeply research driven, and compliance bound in nature, finds itself at the throes of making the choice – to accelerate the pace of introducing a new therapeutic entity vs. the risks it may entail to achieve this acceleration.

A paradigm shift seen on the **Research to Launch** timeframe during the COVID-19 pandemic, adds further optimism for this choice for the Pharmaceutical Industry.

Looking at the current state of the industry from an end market perspective, experts believe there has never been a better time to be in the drug delivery field!

Pipelines are at their largest, healthiest point in history, and **are more reliant than ever on enabling technologies to achieve desired patient outcomes**. This pipeline has been supported by strong industry R&D spend, which was estimated to be $270 billion for 2022-23 – almost four times the level of about 20 years ago.

More than 500 drugs are projected to be reaching registration stage over the next five years – clinical trial outcomes permitting. This along with the fillip to the newer approaches including biologics, biopharma, alternative and gene therapies, this era is poised **to significantly improve life expectancy with better Quality Adjusted Life Years (QALY)**.

What is enabling this strangely dichotomous situation – the worst health crisis vis-à-vis the highest life expectancy coexisting?

The Digital Shift

Within the stringent norms established globally, specifically with the US FDA (Food & Drug Administration) at the forefront and with local governance bodies like the CDSCO (Central Drugs Standard Control Organisation) in India, Pharmaceutical organizations are actively exploring leveraging the Digital ecosystem for **faster time to market** coupled with **better efficacy** by,

A. Accelerating pharma **discovery and synthesis planning** including prediction of reaction outcomes, conditions, and impurities; prediction of molecular properties; molecular representation, generation, and optimization (de novo design); and extraction and organization of chemical information,
B. Adopting Digital Twin approaches, specifically for the **product, production, and performance, including early approvals**,
C. Optimizing **the time for clinical trials** through a scientific approach for candidates' selection; compliance traceability; and outcome / adverse events tracking, and,
D. Accelerating **marketing authorization**, specifically from the focus of regulatory approval including best Pharmacovigilance approaches with automated auditing and reporting.

Industry and Academia consortiums have started working to leverage the opportunities provided by Artificial Intelligence, Machine Learning (ML) and Deep Neural Networks. A good example is the **MIT (Massachusetts Institute of Technology) partnership with Novartis and Pfizer** to transform the process of drug design and manufacturing with its ML for Pharma Discovery and Synthesis consortium. This will only see further acceleration with Generative AI

driven **Large Language Models** to enable complex correlations – a foundation for synthesis planning and better statistical coherence during clinical trials.

Adoption – A series of practical approached developed for Digital leverage.

A simple example of how Deep Learning can be employed in R&D is the use of the same technology that allows us to tag photos on social media platforms like Facebook or Instagram. This is being used to sort through and group a series of digitized images of cells treated with concoctions of different experimental compounds and their physical transformations. Thus, machine learning algorithms can classify compounds with the same visual effects on cells – and do it with incredible speeds. Not only does this reduce the time for deducing insights but also point us to new therapeutic possibilities with efficiency.

Another interesting initiative is the establishment of a **Digital Twin**, specifically for the product, production, and performance. As part of the greenfield approach for the production sites, the digital twin of a plant or production system created during the process and plant design phase ensures that this forms the basis for **early regulatory filing** thus, minimising delays during the approval process. It also, optimises the capex and brings in predictive planning and better operational cost management.

As a part of my engagements with the pharmaceuticals, life sciences and healthcare organizations, there are numerous such anecdotes of digital leverage. The aim is to outline a few significance ones, that made a wider impact, and demonstrate how incremental digital adoption can make a big difference and thus, delivering better health outcomes.

In 2015-16, had established a common health information aggregation platform providing a range of healthcare services. We leveraged clinical codification of master meta data using ICD 10, SNOWMED CT, LOINC Codification and Harmonized System for Procedure Codification. The aim was to use the anonymised real world clinical data – to better correlate with the drug development using patient cohorts based on drug resistance and toxicities. Specifically, this was used to fine tune patient recruitment in a clinical trial with imaging or other biomarkers. Another interesting applicability was the initiation into Personalized Medicines. While this was leveraged by the Pharma Companies, it also flowed into a Health Surveillance Platform for tracking efficacy of managing infectious diseases and related public health programs.

Worked on a **Blockchain based mobility driven cost-of-QALY solutions** for the Pharmaceutical Manufacturers – designed on a secure 'permissioned ledger' framework. Leveraging the platform during clinical trials, organisations can objectively track each Subject enrolled as a part of the Trials for capturing at source – reminders, adherence compliance, adverse event reporting, effectiveness tracking and quality of life impact. The design was to have a series of trusted IoT devices paired to the mobile and scheduled based collection of vital information post a visual capture of taking the Trial Medication.

2019, onwards have worked on digital solutions specifically from the focus of regulatory approval including best Pharmacovigilance approaches. Have used cloud-based solutions to integrate the entire PLM and Clinical Trial phases for a faster closure of Market Authorization with information integration and AI based approaches for root cause analysis and Non-Conformance closures. This is conjunction with RPA / eWorkers for enabling the manual tasks for data aggregation, digitization, quality checking and checklist compliance accelerating the authorization processes by over 20%.

Another interesting play is in the use of machine learning models for predicting a doctor's prescribing behaviour by synthesizing large volumes of data. This enables the optimization of efforts and better target doctors during the launch period.

Conclusion – Digitization in Pharma coupled with Digital Health re-emergence.

Driving on the post pandemic new wave of **Pharma 3.0 – doing digital health better**, a lot of the large Pharmaceutical organizations have invested in AI/ML/Digital HealthTech platforms. This **Value-Add era aims** to catalyse digitally optimised treatment options and pathways, while directly interacting with the patient. The focus is on enabling the core business (R&D, Digital Therapeutics, direct drug delivery); tracking drug efficacy; tracking prescriptions for deducing the return of investment on the launch of a new molecular entity; and the continuous feedback from the patient for enabling better products.

In addition, using digital assets to build patient trust and positive brand experiences / perceptions will create pathways for personalized medicines.

These are exciting times with a world of possibilities enabling the strangely dichotomous situation – the worst health crisis vis-à-vis the highest life expectancy!