Digital Health requirements in Pharmaceutical Industry

By Singh Abhijit Geetaben Yugal

INTRODUCTION

- What is Digital health?
  - Digital Health is broad term.
  - It is integration of Technology with Health.
  - Technology is uses for more effectively dealing with Health problem, conditions, etc.
  - For example: - Wearables, computing **platforms, connectivity, software, and sensors.**

- Digital Health Requirement in Pharmaceutical Industry
  - Nowadays technology is rapidly evolving as customer demand increase for quality product, companies need to be more efficient with minimal errors.
  - Like every other sector, digital transformation also reshaping the Pharmaceutical Industry also.
  - Digital transformation in the pharmaceutical industry led to improvements in various areas: -
  - Drug Discovery, Pharmacovigilance, Clinical Trails, Supply chain Management, Production, Factory automation.
  - Digital transformation is crucial for enhancing Patientcare, Cost-efficient, greater transparency, improving production and drug development.

OBJECTIVES OF INTERNSHIP

Research, analyse, the impact of digital health in the pharma industry.

Learn significance of electronic records (EMR & EHR) and how it can Revolutionize the Hospital and Pharma Industry.

Learn how the Digital Technologies can improvise products and services associated with pharmaceutical industry.

- Drug Development
- Better R&D in Drugs
- Achieving better patient outcomes and interaction
- Improved pharmaceutical distribution
- Enhancing the transparency in supply chain

To find out the digital trends in Pharmaceutical Industry

Usage of Machine Learning to make prediction-based data collected from previous works

What are different rules and regulations related to digital healthcare?

To learn about legal and regulatory framework related to digital such as Anti-kickback law, HIPAA, HITECH ACT, Stark Law, etc.

To know about Top operational digital platform across India, North America, Europe.

Learn how the digital technologies can improve clinical trial efficiency and clinical research for drug discovery.

ORGANIZATIONAL PROFILE OF TATA ELXSI

It was founded 1979 in 1979 in San Francisco Bay Area, California, United States by Joe Rizzi Thampy Thomas

It was acquired by Tata Group in March 30th 1989, Bengaluru

Tata Elxsi is one of world's leading providers for design and technology services across numerous area that include Automotive, Media, Communications, Rail, Medical devices, Pharmaceuticals and Healthcare.

Tata Elxsi deliver integrated services from research & strategy to electronics and mechanical design, software development, validation, and deployment. Tata Elxsi has over 30 years of technology and product development experience with deep domain expertise.

Tata Elxsi provide products and services through design thinking and application of digital technologies such as IoT (Internet of Things), Virtual Reality, and Artificial Intelligence, Machine Learning.

Mission & Values

Mission: - We are the preferred design, technology, and innovation partner, creating differentiated products and services that delight customers and drive business

Values: -

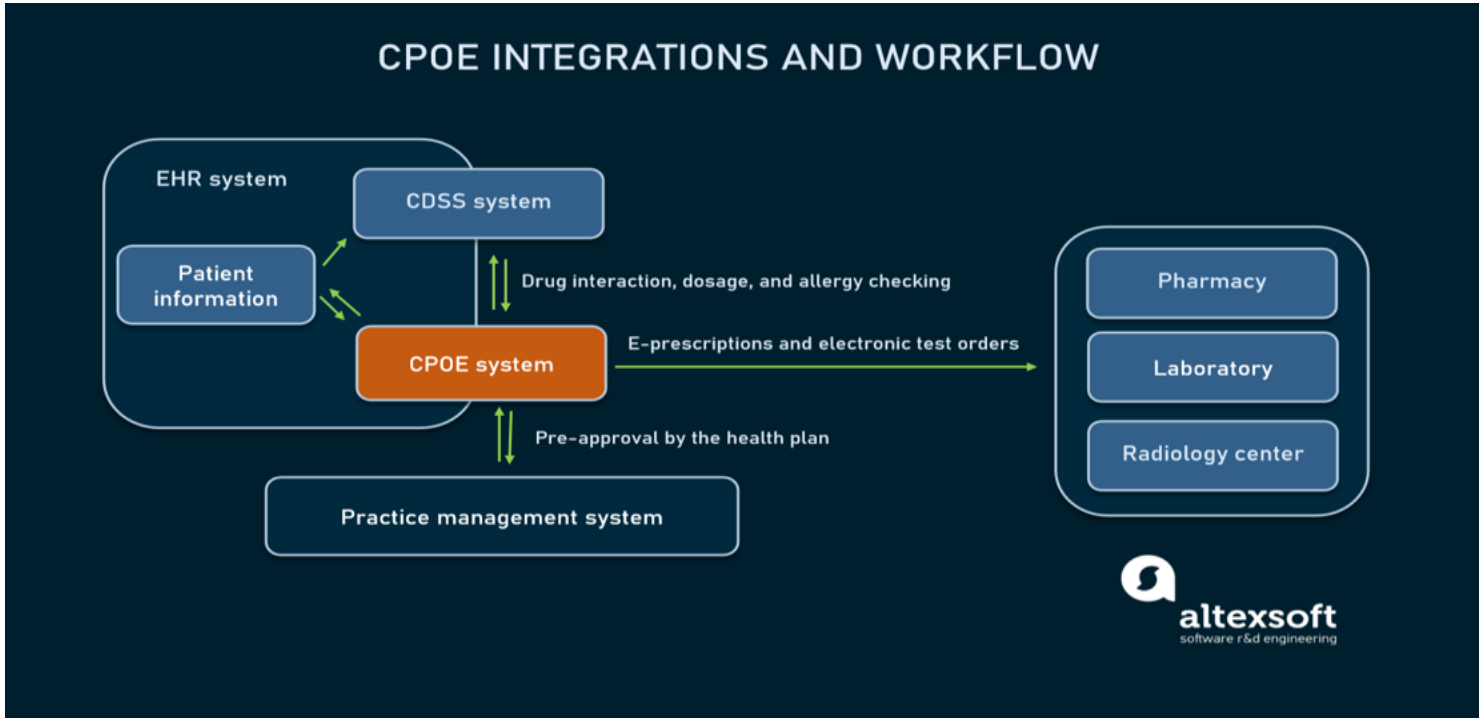
Agility	- Speed of actions, speed of decision-making
Confidence	- to take on the world - Thinking big, taking risks
Transparency	- Building trust through openness and sharing
Improve Collaboration	- We win when we work together
Ownership	- Commitment, make it happen, do it well nurture continuous learning

E- Prescription in North America

What is E-Prescription?

- It is computerized form or digital form of paper prescriptions.
- Health-care provider enter prescription into a computer device like laptop, tablet or desktop computer and transmit prescriptions to pharmacy stores using a software program and connectivity to a transmission network.

E-Prescriptions End to End Process



Component of E-prescription End to End Process

- **CPOE System**

It enables Physicians to place orders for Prescription electronically rather than writing prescriptions by hands.

- **CDSS System**

Modern CPOE system includes clinical decision support system (CDSS) that uses for dosage verification, check prescription for drug allergies and drug-drug interactions.

- **Patient management Component**

It uses for patient registration, admission, discharge.

Registration includes patient information such as contact details, demographics, and insurance data.

During registration in electronic records software, given with Unique ID known as Medical Record Number.

EMR Versus EHR

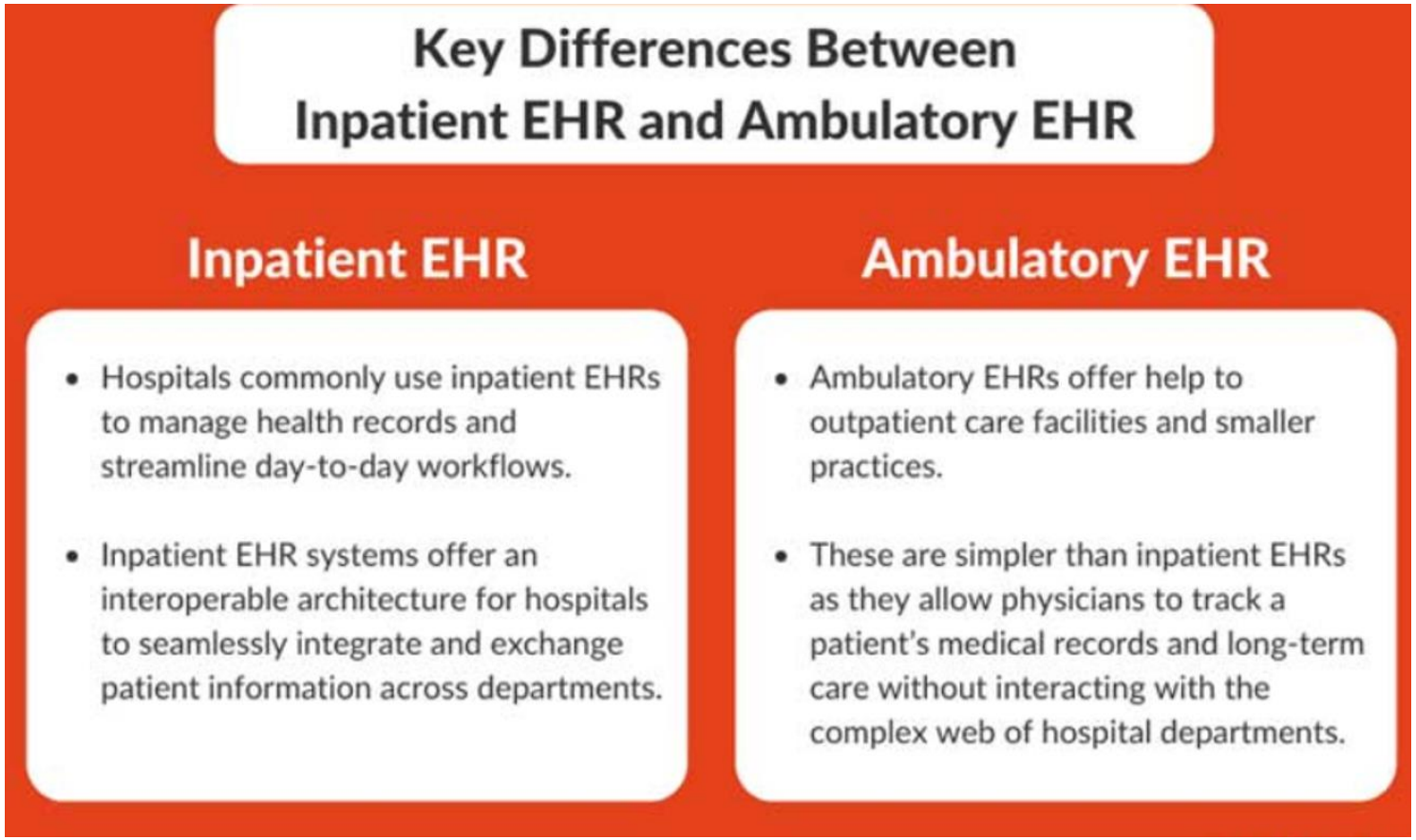
Table 3.1

EMR and EHR Comparison

EMR	EHR
A record of medical care created, managed, and maintained by one health care organization (intra-organizational)	A repository of individual health records that reside in numerous information systems and locations (inter-organizational)
Integration of health care data from a participating collection of systems from one health care organization	Aggregation of health-related information into one record focused around a person's health history, i.e., a comprehensive, longitudinal record
Consulted by authorized clinicians and staff within one health care organization.	Consulted by authorized clinicians and staff across more than one health care organization
Data continuity throughout one health care organization	Data interoperability across different organizations

EMR – Electronic Medical Records

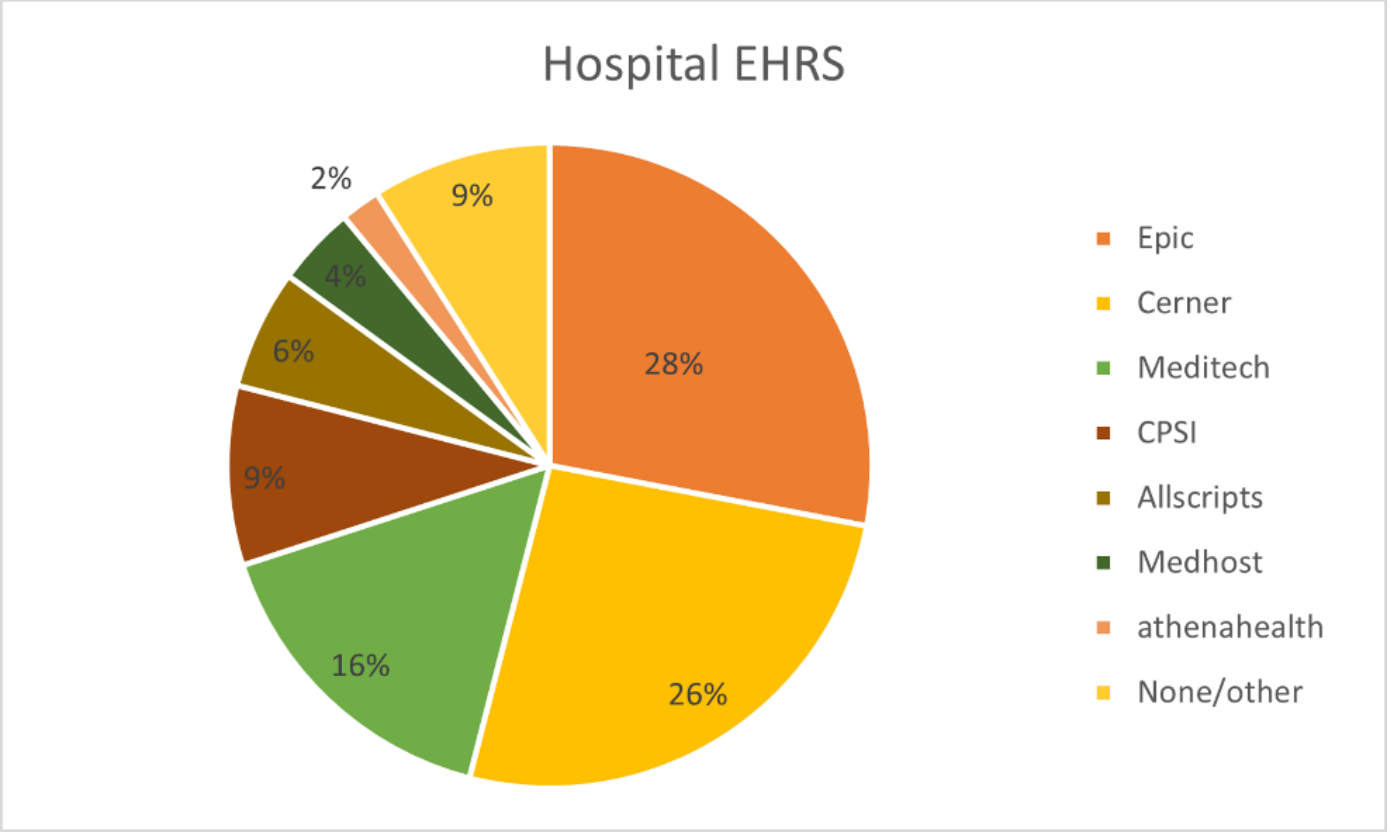
EHR – Electronic Health Records



Inpatient EHR = Hospital EHR

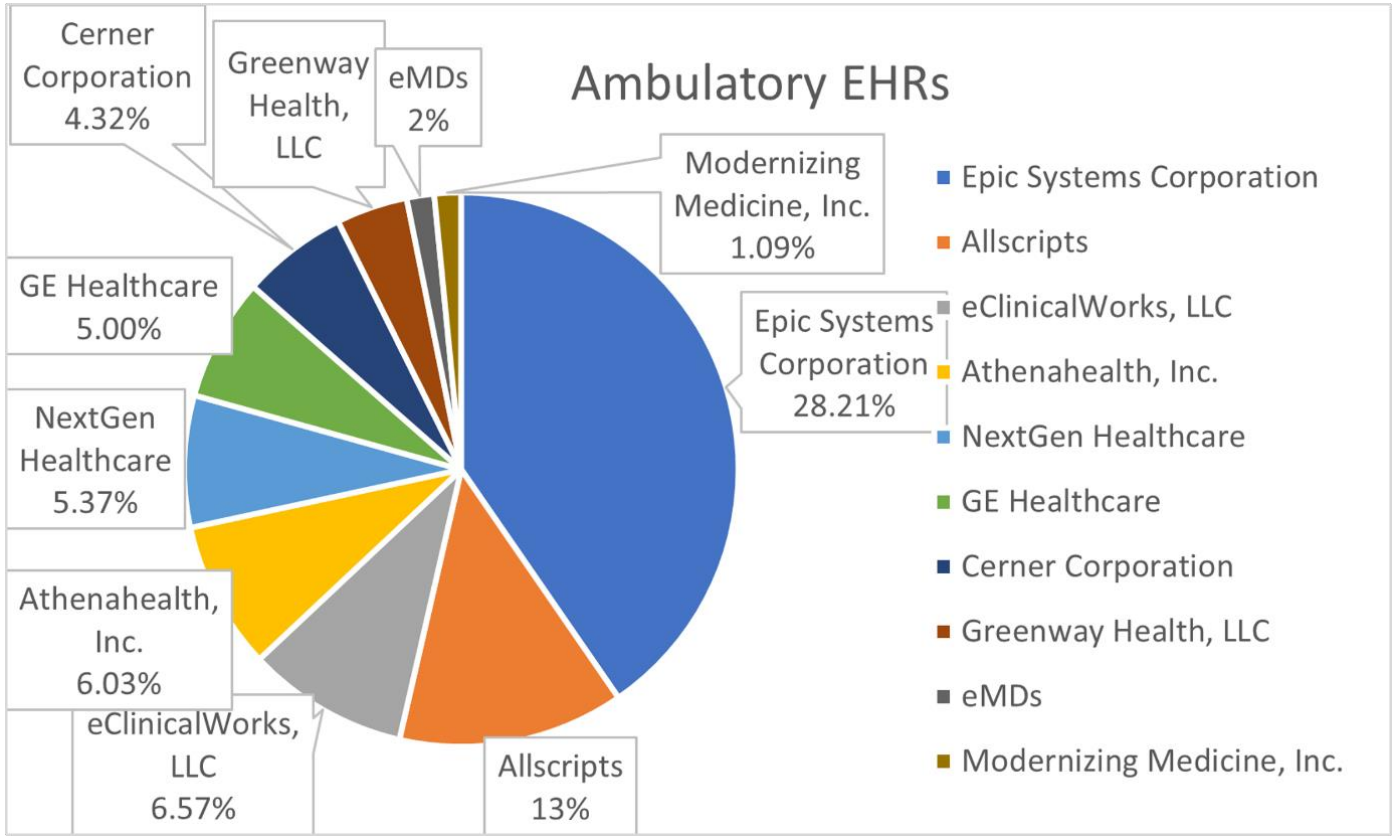
Market Share of Hospital EHR

- As per KLAS report, Epic EHR and Cerner have major share in acute care hospital EHR market.
- Report name - U.S. Hospital EMR Market Share 2019 **report.**
- They examine nearly 5400 acute care hospital in US.
- Market share given in charts form



Market Share of Ambulatory EHR

- In 2018, KPMG analyzed 4.85 lakh healthcare Provider based on ambulatory EHR products to determine the company's market share in ambulatory EHR.
- KPMG find out that 15 EHR vendors has **73%** market share, whereas top 4 vendors has more than **50%** market share.



Top EHR Solutions

Acumen EHR – A market leading for providing EHR solutions in nephrology.

Allscripts EHR – An “Open-platform solution” that drives care & coordination and allow user to work smarter.

Athenahealth EHR – They use a patented Billing Rules Engine that gets claims paid faster and increase revenue. They are recognized by KLAS as #1 for ease of use.

Meditech EHR – Meditech Expanse is a mobile, web-based EHR.

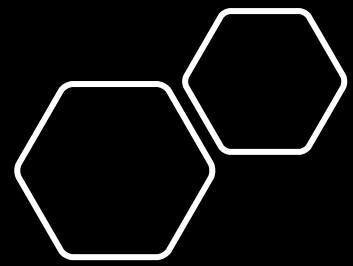
Cerner EHR – An ambulatory EHR used to “minimize clicks, provide comprehensive yet flexible documentation, and automate reporting processes for your business.”

DrChrono – An EHR solution that let’s you focus on practicing medicine, not administration.

eClinicalWorks EHR – They offer improved workflow, and it is customizable by physician. They also offer a practice management solution to streamline the entire process.

Elation Health – With a focus on primary care, Elation Health boasts great reviews and is competitively priced.

Epic EHR – The most widely used EHR and it is the “information backbone” for many large healthcare systems. But Epic can also used by small to mid-sized practices too.



EHR Software

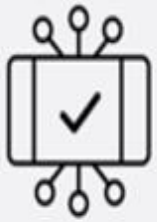
Integrated Systems

Best Of Breed

Latest Trends

Use of Artificial Intelligence:
Artificial Intelligence assisting doctors and recognizing historical trends have already shown signs of success.

Influence of 5G:
Increased speed of 5G when incorporated in health systems will have an impact on the overall dimensions of the quality and application of care delivery.

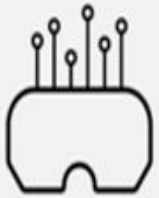


Blockchain and EHR:
Blockchain Technology establishes security as it prevents insurance fraud, confidentiality, and scalability. It also reduces human involvement by taking actions based on predetermined results.

Push for Interoperability:
Interoperable systems can eradicate time-consuming and redundant tasks. Implementing interoperability can improve communication with other medical facilities. Medical errors such as misdiagnosis can be prevented if providers can gather and analyze necessary information in time with the help of interoperable systems.

Enhanced Patient Access:
As the healthcare industry shifts to electronic records, secure access for patients to their own health data is becoming increasingly important. By accessing their medical records, patients become more informed and engaged in their healthcare journey. This leads to greater health outcomes and increased trust with their provider.

Internet of Medical Things:
IoMT (Internet of Medical Things) allows clinicians to supervise their patients from any part of the world. Other connected devices make sure patients are taking medication as prescribed, monitor blood pressure, oxygen levels, keep track of fitness and weight, and more.



Virtual Reality:
The healthcare industry is among the Top 3 industries that have adopted virtual reality. According to Accenture, pieces of evidence state that 82% of healthcare professionals believe that virtual reality makes it convenient to access and learn information for medical students and practicing healthcare professionals.

Digital Therapeutics:
Digital therapeutics is software that uses interventions to bring about behavioral changes in patients, to help treat their conditions. DTx usually are done over smartphones and tablets. These products aim to be patient-centric and are growing in popularity as they meet industry requirements, publish clinical trial results in peer-reviewed journals.

HIPAA Rules

- The Health Insurance Portability and Accountability Act (HIPAA), which was passed in 1996 by congress.
- It specifies who can access / retrieve a Patient's Medical records.
- It determined the series of privacy and security obligations for healthcare providers on the use and release of medical records
- HIPAA privacy and security rights requires medical records must retained by healthcare providers for at least 6 years after either the later of date of creation or the date when last in effect.
- It limits on disclose or release of patient medical records to third parties without patient consent.

Competitive Analysis of digital health platform

Digital Health Requirements for Pharma Industry

- Pharmaceutical Industry play significant role in patient wellbeing by providing them medications. Pharmaceutical industry discover, develop, manufacture, market medications.
- India ranks 3rd worldwide for pharmaceutical production by volume and 14th by value
- US ranks 1st by value worldwide

TOP 4 Pharmaceutical companies in 2021

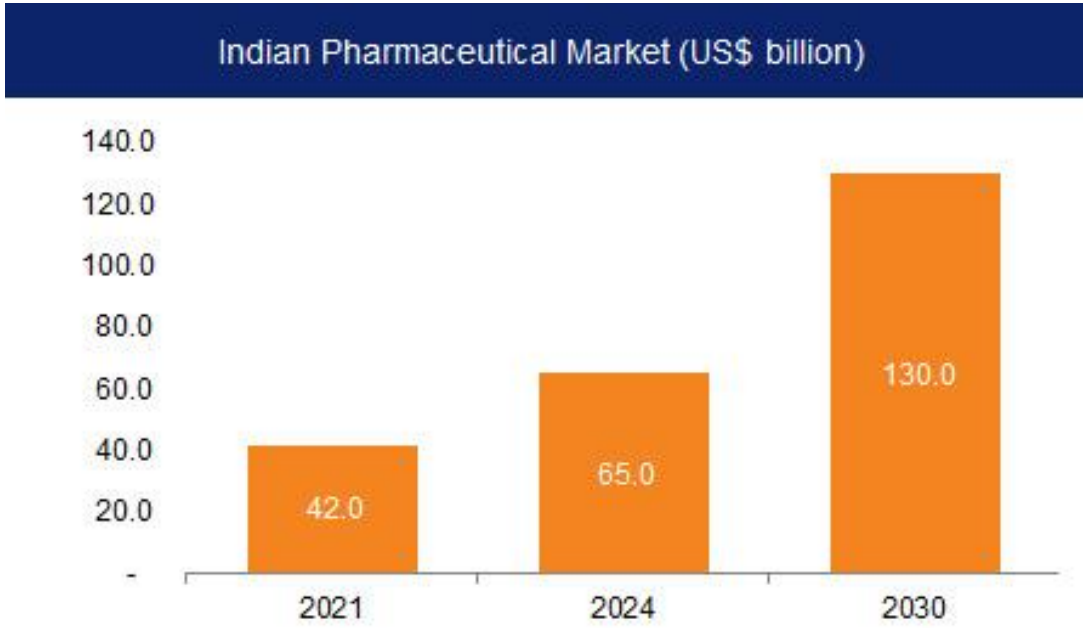
1. Pfizer
Revenue: USD 81.3 billion

2. Roche
Revenue: USD 68.1 USD

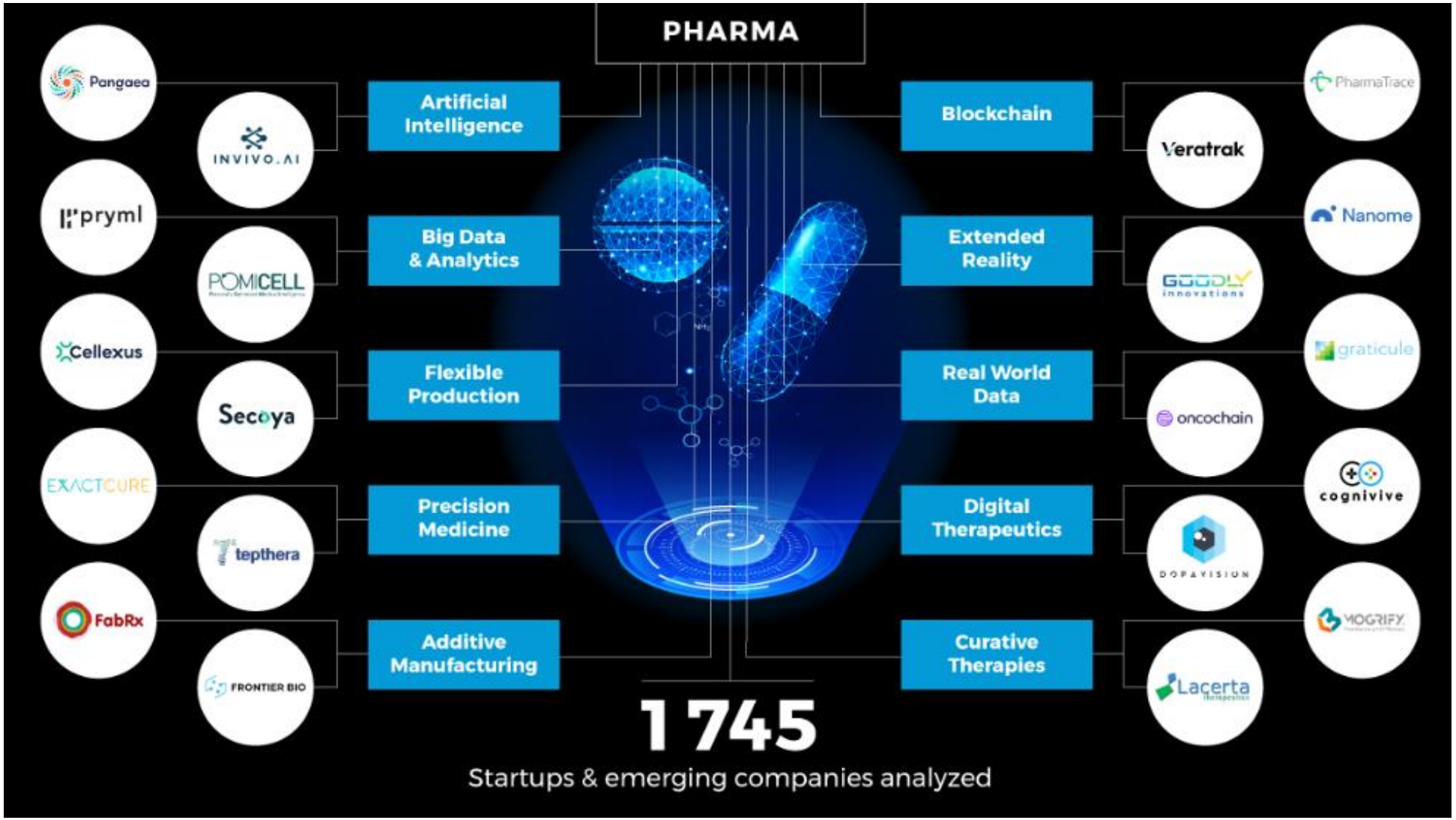
3. Abbvie
Revenue: USD 56.1 billion

4. Johnson & Johnson (Janssen)
Revenue: USD 52.1 billion

- The Global Pharmaceutical market is set to exceed US$ 1.5 trillion by 2023
- As per Indian Economic Survey 2021, the domestic market size is expected increased by 3x in next 10 years. In 2021, Indian pharmaceutical market was at **$42 billion** and is expected to reach US$ 65 billion by 2024 and 2030 by US$ 120-130 billion



Digital Trends in US pharmaceutical industry



Digital Trends in Indian Pharmaceutical industry

E-Pharmacy - It provides simple and affordable medicines to people at their doorstep in just one click and give information about medicinal remedies awareness to the purchaser.

E.g., PharmEasy, Tata 1mg Technologies Pvt.ltd , Apollo Pharmacy Pvt. Ltd. Netmeds Ltd.

Digitization with AI and ML: The use of AI & ML has changed towards patient centricity customers medical consultations sitting back at home,

Digital Records

Cloud Computing: Pharmaceutical companies depend specifically on cloud security and Cloud scalability keeps thousands of records remotely monitored patients

Digital Trainings: Offered anytime, anywhere, and cost-effective. Online training courses for new technologies in the pharmaceutical sector will be further expanded in 2022 to improve operations and compliance

Blockchain Technology and Big Data: Blockchain technology will further revolutionize the pharmaceutical sector, by helping them secure data and increase visibility, compliance, improved traceability of drugs, and simplified transactions.

Key Elements driving the need of digital health in Pharmaceutical Industry

- Telehealth, Telemedicine & E-detailing
- Drug Development Process
- Drug Discovery
- Clinical Trials
- Supply chain Managements

Telehealth, Telemedicine & E-detailing

Telehealth & Telemedicine provides easy to customer by creating various options for Customer

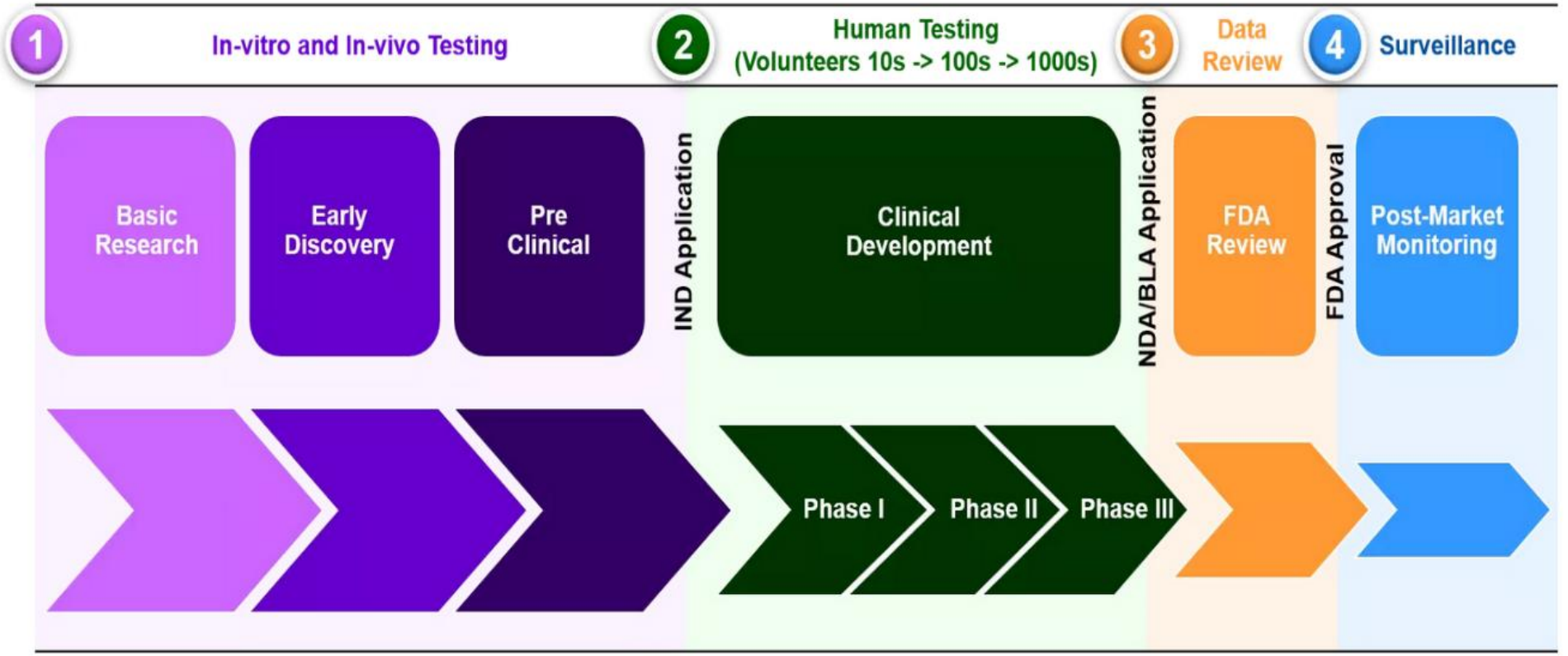
Telehealth also provide help for disabled patients by Virtual meeting with them.

Telemedicine gave various option for middle-class and low-class choose the different brand due to price issue

E-Detailing gave medical representative advantage as doctor sole focus on Medical Representative Detailing E.g., In-Contro MR

All these are example of patient-centricity

Drug Development Process



Drug Discovery

AI Platforms for Drug Design using Chemical Principles

Exscientia: - Exscientia established strategic research collaboration with Sanofi to develop AI-driven pipeline of **precision-engineered medicines**

Exscientia is an **AI-driven Pharmatech company** that discovering, designing and developing the best feasible drugs in effective and fastest manner.

Exscientia developed the **first-ever functional precision oncology platform** to successfully guide treatment selection and improve patient outcomes in a prospective interventional clinical study, as well as to progress AI-designed small molecules into the clinical setting. Our pipeline included with more than 25 projects advancing, including first three AI-designed drug candidates to enter Phase 1 clinical trials.

PostEra: -AI Platforms for Drug Design from First Principles

ROIVANT Sciences

Insitro is a data-driven drug discovery

XtalPI: - Drug R&D, such as new binding pocket discovery, new drug scaffold design, activity and ADMET predictions, among others, and provides access libraries containing tens of billions of molecules to facilitate development of new models. The platform also provides visualization of calculation results and supports deployment of cloud computing resources to perform data analysis, feature engineering, and AI model construction within days.

Advantage vs disadvantage of AI in drug discovery

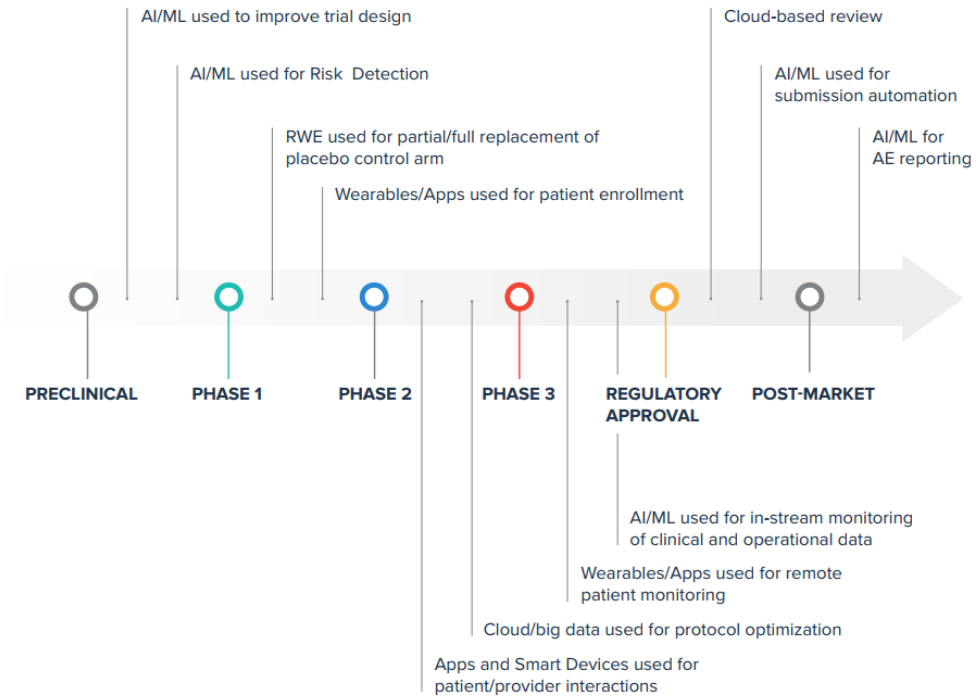
- Advantages
  - Error Minimization
  - Difficult exploration
  - Digital Assistants
  - Repetitive Tasks
  - Medical uses
  - No breaks
  - Limitless functions
- Disadvantages
  - Expensive
  - No replicating humans
  - No improvements with experience
  - No original creativity
  - Unemployment

Virtual Clinical Trials Market Share

- In 2021, global virtual clinical trials market size was at $7.8 billion.
- Market size in 2022 is at $8.3 billion is expected to reach $12.9 billion with CAGR of 5.7%.
- The COVID-19 pandemic has significantly affected the market.
- The market major-driven factors are a rise in R&D activities, rising **healthcare digitization, as well as adoption of telehealth**.
- This are also some driving factors such as alliances between clinical research organizations and pharmaceutical, biotechnology companies as well as supportive government initiatives.

Virtual Clinical Trials

- Digital health technologies adopted by pharmaceutical companies for clinical trials:
- Digital medicine, Telemedicine, Electronic informed consent (eConsent), Digital data collection tools, Remote site monitoring, Direct to patient shipping (DtP), Medication reminders



How Pharmaceutical Companies using Analytics

1. Accelerate Drug Discovery and Development

The cost to introduce a new drug into the market is skyrocketing and with the patents for blockbuster drugs expiring, the pharmaceutical industry is looking towards accelerate this process of bringing a drug to market.

Blockbuster drugs are drugs used to treat chronic or long-term medical problems.

By filtering through vast datasets such as **scientific publications, academic research papers, control group data, and by running predictive algorithms** through these immense data, pharmaceutical analytics can help company make more intelligent decisions to increase pace for process of data discovery.

2. Increase the Efficacy of Clinical Trials

Pharmaceutical analytics by identifying and analyzing various data points like **participants' demographic and historical data, remote patient monitoring data, and by examining past clinical trial events data** can help pharmaceutical businesses to reduce cost and pace up clinical trials lead to optimizing this whole process

3.Personalize & Create Targeted Market

Problem- Using present biology and biotechnology can’t handle complex data that are used for effective and personalized medicine.

Pharmaceutical analytics in pharmaceutical industry can solve the problem of personalized medicine by combing of **data of genomic sequencing**, **patient’s medical sensor data** and **electronic medical records**.

By effectively utilizing big data technologies to sift through unstructured genomic data, pharma companies can spot patterns to help create a more effective and personalized medication for their patients.

4. Reduce Cost and Increase Drug Utilization

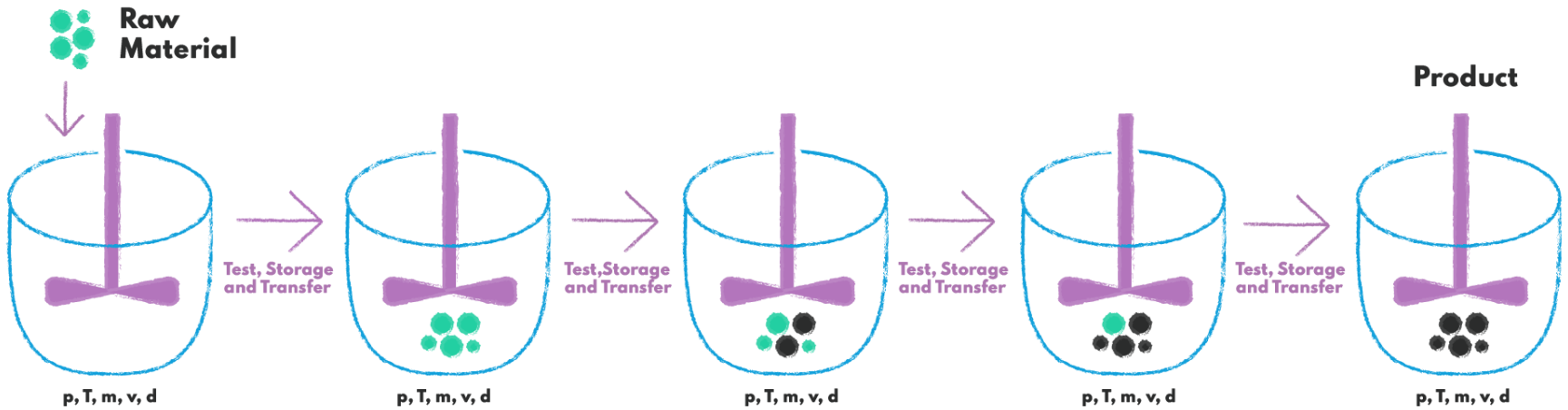
Pharmaceutical analytics can help pharmaceutical companies by granular analysis of key metrics such as **average ingredient cost per prescription, rebate as a percentage of total drug spending, drug utilization review savings per member per year**, to make smarter decisions, to increase revenue, reduce costs & essential to increase efficiency of whole process.

5. Improving Operations & Employee Training

Pharma companies can significantly reduce their costs by improving their existing operations & processes with pharmaceutical analytics and data insights. Advanced analytics can help pharmaceutical firm to understand how **machine settings, operator training levels, or raw material inputs** are going to affect the output quality.

It can reduce cost by optimizing operations and whole process & also predict risk such as machine failures, quality issues or substantial changes in demand.

Predictive manufacturing in Production



Historical data

pressure
temperature
batch process control records
production floor data
time
sales data
maintenance data, etc.

Predictive Analytics Model

- customized model trained to identify key attributes (insights) and generate predictions

Forecasts Visualisation

- forecasts are visualised for further analysis to build actionable prescriptions

Custom Integrated Analytics

- model outcomes are used further to in custom applications and integrated into wider processes

Aids

Predictive analytics helps manufacturers create manufacturing intelligence solutions to discover unexpected behaviors, notice early warning signs of quality issues, and develop reliable alarms for process engineers.

Benefits

Intelligent manufacturing with more accurate forecasts for improved production monitoring and planning, early warnings systems, less unplanned downtime due to fixable equipment settings – all leading to a better bottom line in terms of quality, consistency, reduced wastes, efficiency, and productivity

Predictive Maintenance for Pharmaceutical Production Line

Predictive analytics help manufacturers indicate when equipment needs cleaning or maintenance or is about to fail, **eliminating costly manufacturing disruptions and prolonging service life.**

Building-management systems capture air pressure, temperature, and other readings in multiple locations at each plant, sampling

minute that are transferred to digital format and analyzed with predictive technologies

applied to central equipment such as air and centrifugal compressors, boilers, pumps, and water purification systems

Data driven insights for Rx & R&D

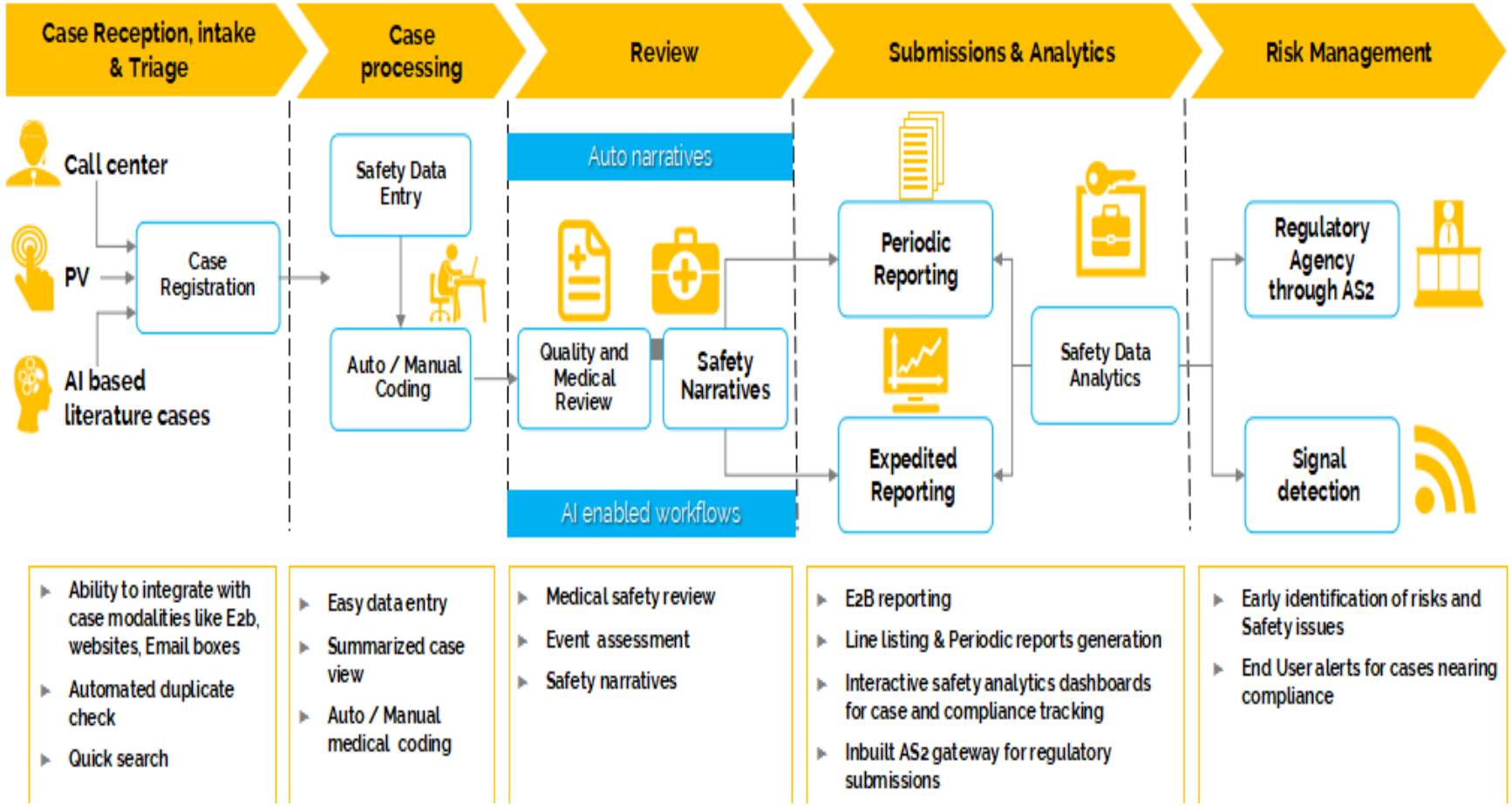
Prescription transaction data, Supply chain data, Therapeutic clinical data, Insurance data, External marketplace data

This data can be housed in various databases including pharmacy management systems, category product systems, and supply chain systems, EHR Systems

Aventis Pharma, part of the Sanofi Group, relies on Informatica’s data integration technology to automate the gathering of research data, standardize this data, and speed distribution of reports and metrics to support faster science

Clinevo Technologies – Pharmacovigilance & Drug Safety

- It is an Indian Startup, which is providing the cloud-based solutions with help of advanced analytics & AI to monitor the quality issues to meet with Global standards & real time tracking of various drug protocols.



INDEGENE

Indegene is an Indian startup, which is using AI & machine learning (ML) to address the issue which is drug safety. AI with human interventions for pharmacovigilance.

Their Core Agenda for healthcare and customer engagement is cost-cutting

NAVRO TECHNOLOGY SOLUTIONS

It is an Indian startup which provide pharmacovigilance with help of deep learning and AI to enables quicker reporting and to reduce the time taken to report the adverse drug reaction.

It improves the productivity of data reporting and efficiency of drug development as a process.

Natural Language processing and speech & text recognition to provide error free reporting of several clinical and regulatory information.

ELECTROSAN TECHNOLOGIES – PROCESS & FACTORY AUTOMATION

- It is an Indian startup which render solutions related to process and factory automation via Internet of things enabled sensors and predictive function.
- To allow manufacturers prudently monitor production costs, operational efficiency, and downtimes.
- It also has compliant with **21 CFR** (Code of Federal Regulations) and **GAMP 5** (Good Automated Manufacturing Processes) standards.

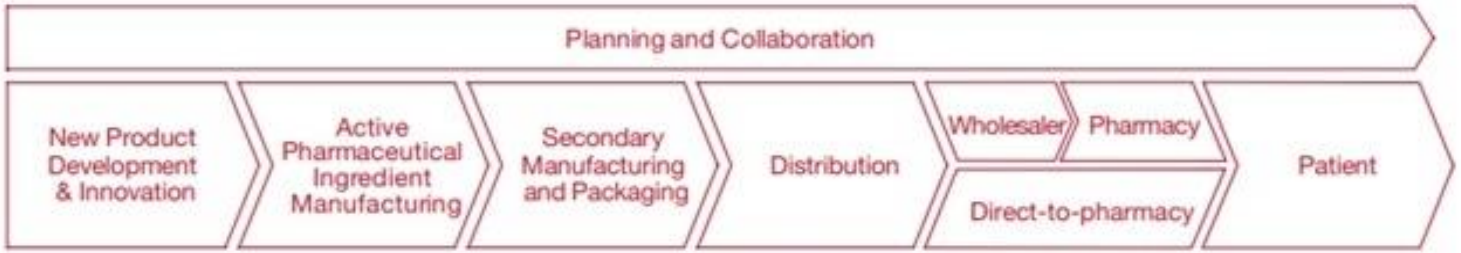
GOODLY INNOVATIONS

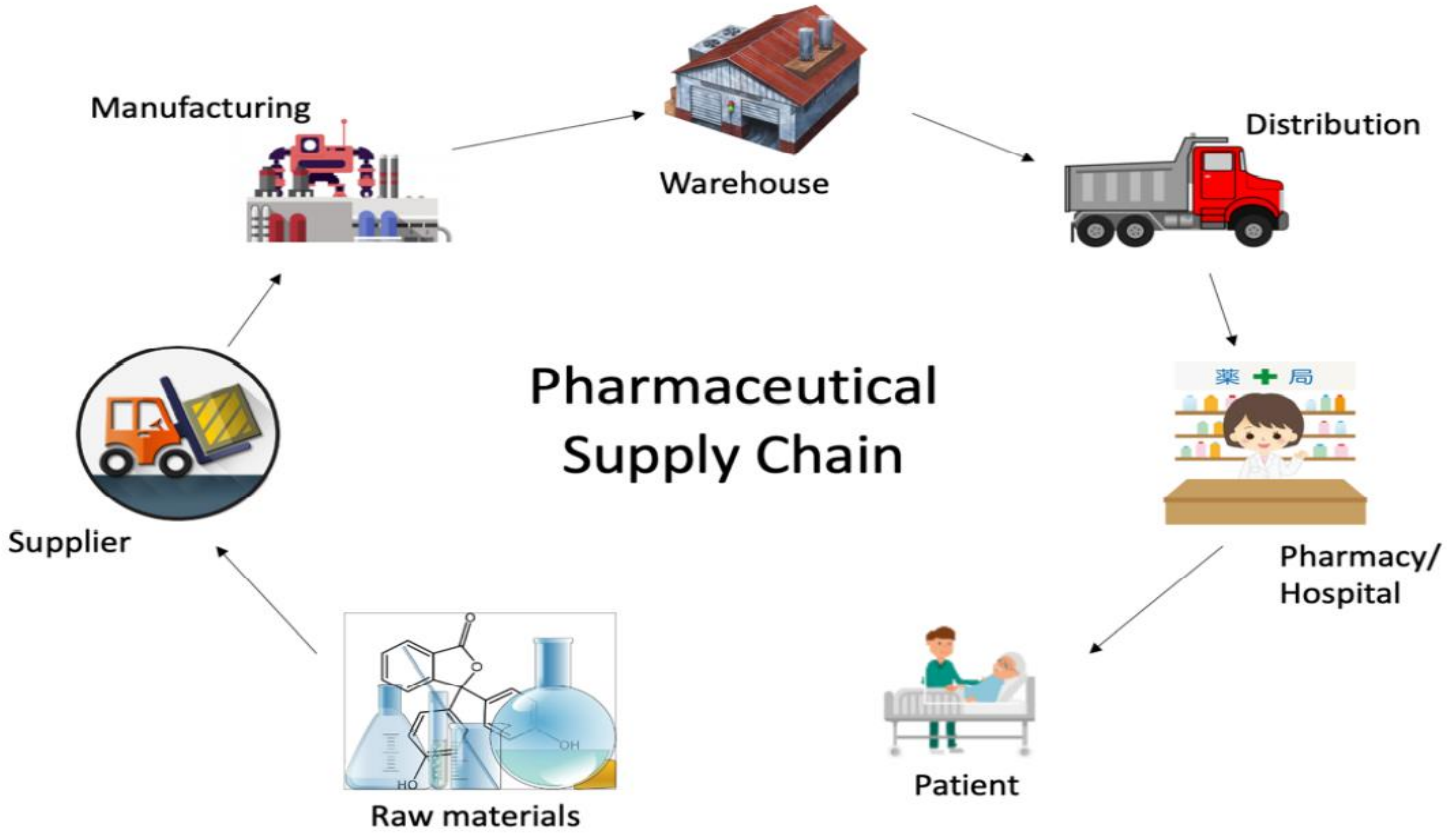
It is a German startup develop AR suite, OptiworX which enables technician and line operators to increase their productivity and efficiency .

It allows standalone systems and connected systems with two ways data flow.

This Suite also supports floor processes like manufacturing, filling, primary packaging and secondary packaging.

Supply Chain Management





C&F – Carrying and Forwarding

C&F agent transfer pharmaceutical products from warehouse to stockists plus they also import the raw materials from suppliers

C&F agents are required because of India taxation systems. Pharmaceutical firms have one C&F agent in every state but not necessarily. C&F agents Margin - 2%–10% depending upon the turnover.

Stockiest

Stockiest exist as a link between pharmaceutical Companies and Retailers.

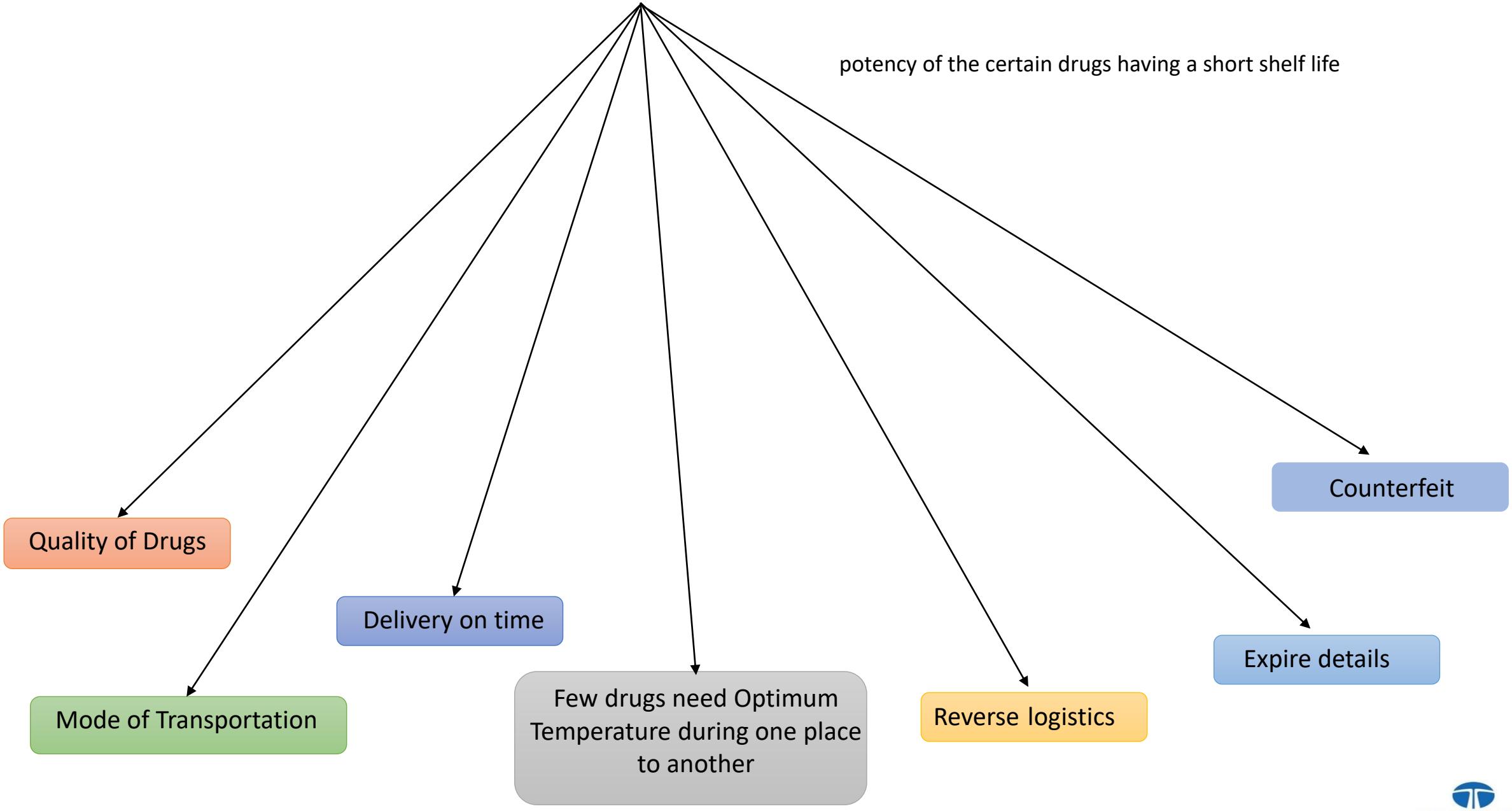
Stockiest margins - 8%–10%.

Retailers

The retailers provide the pharmaceutical products to customers

Retailers include small pharmacist store to large pharmacist retail stores. Retailers take margins of 16%–20%. Usually depending upon which they are more sold.

Challenges in SCM



Problem Statement

Does the Quality of drugs deteriorate during transportation?

Did the Counterfeit drugs tarnish the image of company?

Key Pillars

1. AI
2. ML
3. Sensor Technologies
4. Blockchain

Cold chain logistics Market Share

In 2018, Globally cold chain logistics was at $159.98 billion in valuations

It is expected to reach $585.105 billion by 2026 with CAGR of 17.9% from 2019 to 2026

Solutions

Blockchain

Supply chain visibility, speed and coordination are focal for the delivery of safe & effective product in pharmaceutical industry, blockchain is essential.

Blockchain can help to prevent **information leakages, help identify counterfeit items and fraud,** and pinpoint at-risk suppliers in order to demonstrate regulatory requirements are being met.

Blockchain can offer End-to-end tracking and monitoring of drugs via supply chain

AI & ML

Leveraging AI In Pharmaceutical Supply Chain

There are 2 distinct types of AI solutions that facilitate pharmaceutical Supply Chain Management:

Augmentation- Assisting technology to workforce, boosting efficiency, reducing human error.

Automation- AI has no human intervention and works completely autonomously.

Examples of AI Implementation

DataRobot – It is an AI platform powered by open-source algorithms that are able to model automation by using historical drug delivery data.

OptumRx- It uses AI/ML to manage data collected from healthcare setting to reduce number of shortages or excess inventory of drugs.

Supply chain Management

- Theft, diversion, and counterfeiting are rampant worldwide in the pharmaceutical industry.
- Vu 360 Solutions

Inventory Control, AI based Warehouse Management Solutions.

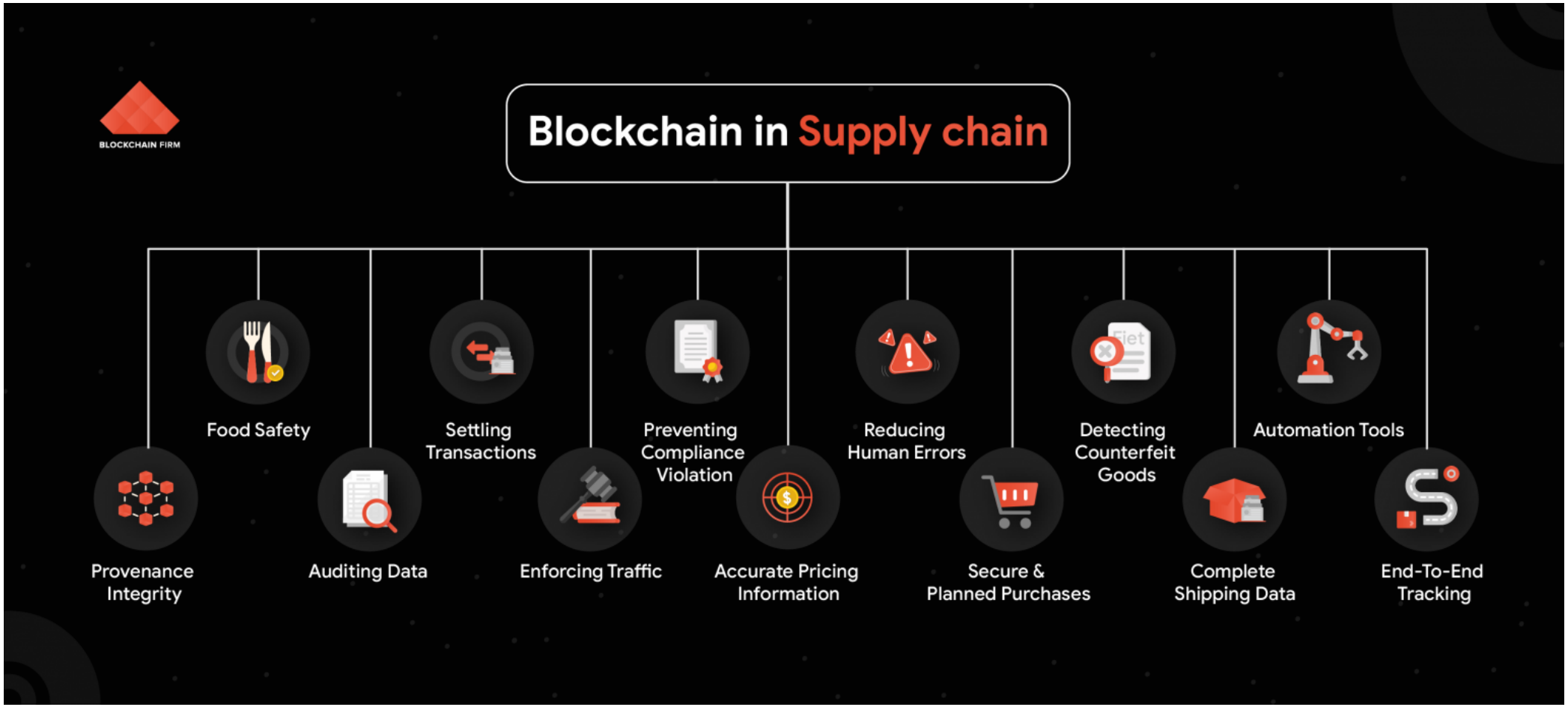
- Products
- Vu360's Automated Track & Trace Solution
- Vu360 Cold Chain Solutions
- Vu360 Supply chain Security Management

- Advantage
- Vu360 Solutions Seamlessly associates with GS-1 codes

where those materials and products are within the entire supply chain at any given point in time and what characteristics the products possess.

lose efficacy & become ineffective. Automated active real-time temperature monitoring system utilizes **IoT, RFID and nano marker technologies that integrate 3D thermal imaging**. Monitoring the temperature of your products and ensuring consumers. (Radio frequency identification).

Security management include tracking product with RFID enabled multi-level unique identification codes, validating transporter credentials, interfacing shipper **TMS systems** with transporter ELD systems for complete visibility, and securing cargo in transit with real-time monitoring incorporating cameras and sensors.



nVipani

It is an Indian startup that provides solutions for procuring day to day material for pharma companies, uses real-time data for analyzing various stages of the supply chain such as inventory consumption, raw material procurement and other inventory-related issues. As technological progress steadily increases, AI will revolutionize pharmaceutical companies.

Blockchainfirm

Blockchain technology's true potential lies in maintaining a decentralized, tamper-proof, and transparent record of data. These features make blockchain a technological rife for security-based apps.

Inventory Management as Part of Supply Chain Management:

AI-based inventory management can determine which product is most frequently required (and how often), track when exactly delivered to a Stockiest or wholesaler, and provide delivery time and delays or incidents that might trigger replacement shipment within hours.

Benefits Of AI In Pharmaceutical Supply Chain

Forecasting Demand**:** AI-based software helps in analyzing big data related to diseases and drugs consumption to drive patterns and forecast demand.

Fake Drug Detection: Serialization of drugs coupled with AI/ML capabilities helps in tracking drugs around the globe and detecting fake drugs. This imposes safety of consumers.

How To Implement AI In Pharmaceutical SCM?

AI can be used to power solutions for managing these disruptions in following ways:

Chatbots: Chatbots can be used for operational procurements such as talking to suppliers during trivial conversations, setting & sending actions to suppliers regarding compliance material, placing purchase orders, receiving/filing/documenting invoices, etc.

ML For Supply Chain Planning: It could help the SCP professionals in providing best solutions based upon intelligent algorithms and machine-to-machine analysis of big data. This facilitates optimized delivery of goods while balancing supply & demand.

NLP For Data Cleansing & Building Data Robustness: Natural Language Processing deciphers large amounts of foreign language data in streamlined manner. It drops the language barrier to **build supplier data sets** and streamline auditing/ compliance actions.

Legal & Regulatory Framework

Core legislation in digital health

Health Insurance Portability and Accountability Act of 1996 (Hipaa), the California Consumer Privacy Act (ccpa), and the federal Health Information Technology for Economic and Clinical Health Act (Hitech Act). This are core digital health laws.

Federal Food, Drug and Cosmetic Act also includes medical devices.

FDA regulations and programme related to digital health include

- 510(k) certification,
- Premarket Approval (PMA),
- Software as a Medical Device (SaMD),
- Digital Health Software Pre-Certification Program (Pre-Cert Program),
- Laboratory Developed Test (LDT) regulated under CLIA (Clinical Laboratory Improvement Amendments) programme.

Stark Law and Anti-Kickback Statutes that apply to telemedicine and virtual health providers. Anti-kickback statutes dealing with any individual including doctors or pharmaceutical companies who try to give referrals for products & services for incentives. whereas stark law dealing with only doctors.

HIPAA sets forth the federal privacy and security requirements for how certain entities must safeguard protected health information (PHI) (inclusive of electronic PHI or ePHI) and how to handle security breaches of PHI or ePHI

Regulatory schemes apply to consumer healthcare devices or software

The device are regulated under FDCA

- Class I (general controls)
- Class II (general contracts and special controls)
- Class III (general controls and premarket approval (PMA)

The level of risk that medical device poses to user or patient is substantial factor in determining permission.

Regulations apply to Software as a Medical Device and its approval for clinical use

Digital health center of excellence is a part of U.S. Food and drug administration. It supports the FDA, to enhance capabilities in digital field. It also gives regulatory advice to FDA & to assist FDA in regulatory review related to digital health technology.

Telemedicine/Virtual Care

- State-specific practice of medicine licensing laws and requirements.
- Data privacy laws including HIPAA, CCPA and HITECH Act with respect to health data that is collected from patients during consultation.
- Data rights to health data collected from patients during consultation.
- FDA regulatory issues such as SaMD, 510k certification and PMA.
- Stark Law and Anti-Kickback Statutes.

Software as a Medical Device

- FDA regulatory issues such as SaMD, 510k and PMA if manufacture makes diagnostic or therapeutics claims for the software. Unique issues with evaluating safety and efficacy of software used to diagnose or treat patients
- Issues related to patentability of software of diagnostics inventions.

KEY LEARNING FROM INTERNSHIP

Learn how the Digital Technologies can improvise products and services associated with pharmaceutical industry.

- Drug Development
- Better R&D in Drugs
- Achieving better patient outcomes and interaction
- Improved pharmaceutical distribution
- Enhancing the transparency in supply chain

Usage of Machine Learning to make prediction-based data collected from previous works

To know about Top operational digital platform across India, North America, Europe.

Learn how the digital technologies can improve clinical trial efficiency and clinical research for drug discovery.

Learn how to digital technologies use in Supply chain management for safe & secure supply

Learn about the digital Health rule & regulation & applicability.

To learn about different legal and regulatory framework related to digital such as Anti-kickback law, HIPAA, HITECH ACT, Stark Law, etc.

Thank you