

Digital Health Requirements in Pharmaceutical Industry

Dissertation Submitted to



The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree

of Master of Business Administration (MBA)

in

Pharmaceutical Management

by

Singh Abhijit Geetaben Yugal

Under the Supervision and Guidance of

Dr. Sudhinder Singh Chowhan

Associate Professor

School of Pharmaceutical Management

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Digital Health Requirements in Pharmaceutical Industry** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Singh Abhijit Geetaben Yugal

01-07-2022

CERTIFICATE

This is to certify that (Name of Student) in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management)/MBA (Pharmaceutical Management)/MBA (Rural Management) from the IIHMR University, Jaipur has successfully completed her/his internship at (name of the organization) during March 22, 2022 to June 19, 2022.

Place: kalol
Date: 1-07-2022

Reporting Manager: - Manish Agrawal/Ajay sir
Name of the organization: - Tata Elxsi

Abstract

Digital Health is boom after Covid-19 hit the world. Digital health is basically a integration of digital and healthcare sector. Digital is gaining pace in various areas which includes clinical trials, drug discovery, e-prescription, pharmacovigilance, supply chain, digital health platforms, etc.

E-prescription in north America is in rapid pace. EHR and EMR software used by both local physician and Hospital. EMR store data locally either hosted locally or used software as a service. In EHR also, there are two different types – Hospital EHRs and Ambulatory EHR. In Hospital EHR, two are Major market share – Epic EHR and Cerner EHR. Latest Trends in E-prescription is 5G, Blockchain, AI, Virtual Reality, Digital Therapeutics, Internet of things.

Digital Health platform is a platform. It **provides a vital central hub**, linking together disparate and unconnected systems and applications, enabling faster, more efficient, and more reliable information exchange, and promoting increased access to health data across a range of devices. In this report, comparative analysis of different digital health platform which includes Karexper, GE Edison Healthcare, Philips Suite, Airstrips Technologies, Athenahealth, Innovaccer & Siemens Healthineers.

Digitalization in Pharmaceutical Industry

Supply chain management is crucial in pharmaceutical industry. Theft, counterfeiting is rampant throughout world. Digitalization helps in countering this challenge and for safe and secure delivery. It includes blockchain which provide more security, thermal Sensors with radio frequency identification which provide for drugs which become less potent or deteriorate due to temperature fluctuation & AI & ML based inventory provide to predict when product finished in warehouse & delivery on time or get delay.

Acknowledgement

I would like to express my heartfelt gratitude to IHMR placements for providing me with this wonderful opportunity to work with Tata Elxsi. I have completed my internship program from Tata Elxsi.

This internship is a result of valuable insights, facts and Experiences I had during my program from Tata Elxsi. The Experience which I have earned was Informative and educative and lead to understand different concept.

Also, I would like thank Manish Agrawal, Business Analyst (industry mentor) & Dr Sudhinder Singh Chowhan, Associate Professor (Faculty Mentor) for given support throughout my journey at Tata Elxsi

Singh Abhijit Geetaben Yugal

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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 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.

Industries served



Automotive

Passenger experience, connected and autonomous, shared and electric



Broadcast & Media

OTT streaming, RDK, Android TV, CPE, QoS, QoE, customer experience



Medical Devices

Product design, system engineering, regulatory compliance



Communications

5G, SDWAN, network transformation, digital transformation



Pharmaceuticals

Clinical trials, packaging and labeling, pharmacovigilance



Rail

Industrial, service design, rolling stock



CONSUMER ELECTRONICS

Sustainability is at the center of our consumer research and product design & strategy, which guides us in developing solutions for digitalisation of home appliances for our customers. Our intelligent energy monitoring systems and circular product designs help consumers choose products that are energy-efficient and sustainable.



OFF-HIGHWAY EQUIPMENT

Our C.A.S.E. (Connected – Autonomous – Shared – Electric) solutions for off-highway vehicles help our customers bring cutting-edge technologies to the market and maintain leadership in a fast evolving market.



SEMICONDUCTOR

Our expertise in AI Tools & Frameworks and SDK & Reference Design solutions is helping our partners harness opportunities by adopting hardware platforms in the semiconductor and electronic product market space.

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

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

SERVICES PROVIDED BY ORGANIZATION

Assignment – 1

E-prescription in North America. Example :- Dosespot

Assignment – 2

Competitive Analysis of digital health platform across the US, Europe, and India.

Example :- Health suite digital Platform, Edison digital Platform.

Assignment – 3

Project Goal:

Research, analyze, and evaluate the impact of digital health in the pharma industry, and create a detailed report on digital health requirements for pharma industry across major geographies such as NA, India, Australia, & Europe.

Milestones:

Week 1 and 2 (Introduction and setting up the context)

- Executive summary,
- key elements driving the success of digital health,
- trends in the market,
- emergence of digital technologies into the pharma traditional value chain,
- enablers of patient centricity & shift from patient engagement to patient centricity in pharma industry,
- challenges in adopting digital technology across major markets, and digital health ecosystem look like post-COVID

Week 3, 4 and 5 (Applications of digital health)

- Application of digital health in pharma industry, including
- personalized (precision) medicine, personalized care, data analytics for process improvement, predictive manufacturing, drug filing and refilling, patient support programs, patient assistance programs, e-prescription, in-home Rx delivery, virtual clinical trials, data driven insights for Rx R&D, AI for drug discovery, VR for remote training and assistance, and emerging products and platforms for digital pharma workflows

Week 6 and 7 (Creating a digital transformation strategy)

- Strategies to improve patient centricity,
- digital transformation of pharmaceuticals,
- creating the digital pharma company,
- drivers and potential threats for digital health in pharma industry,
- competition analysis, national digital health strategies

Week 8 and Week 9 (Evaluating cross functional operations)

- Investment strategies, legal and regulatory framework, data protection guidelines, IP, recommendations & Conclusions.

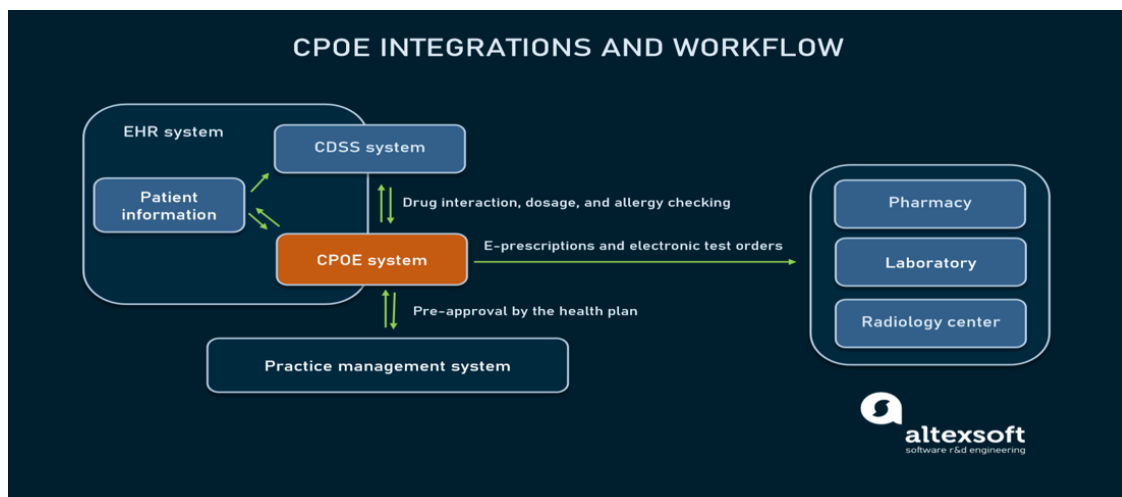
KEY ACTIVITIES/ PROJECTS UNDERTAKEN OTHER THAN DISSERTATION

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

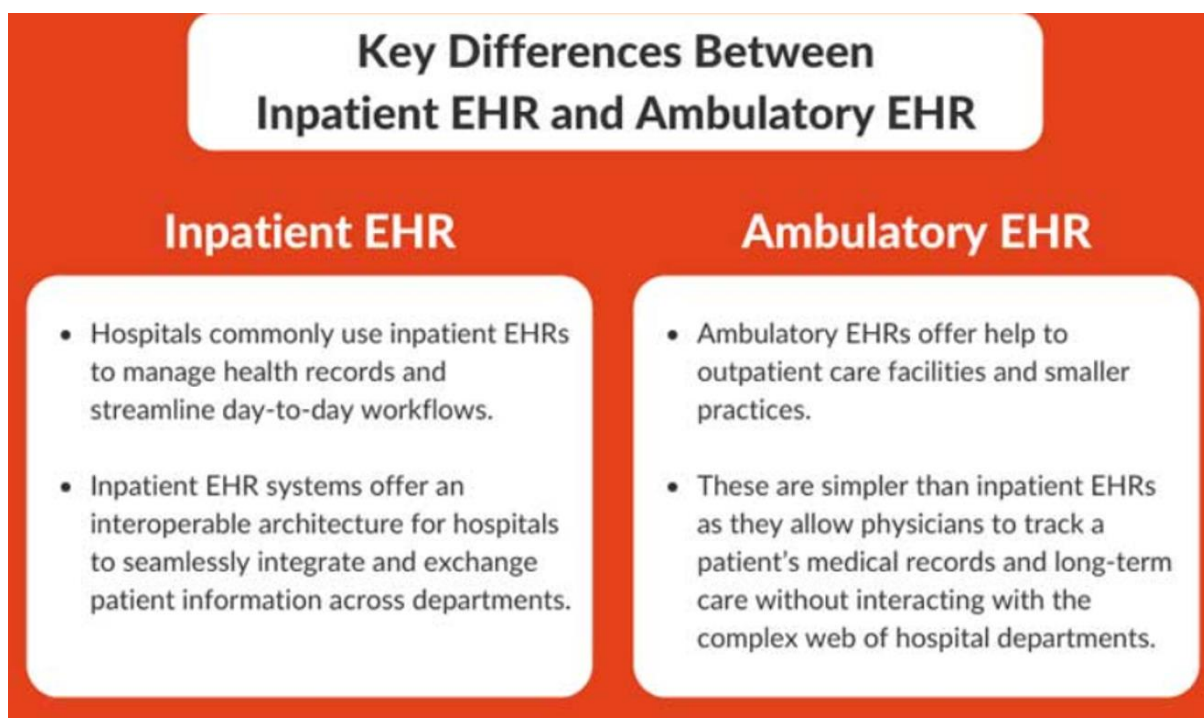
Table 3.1

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

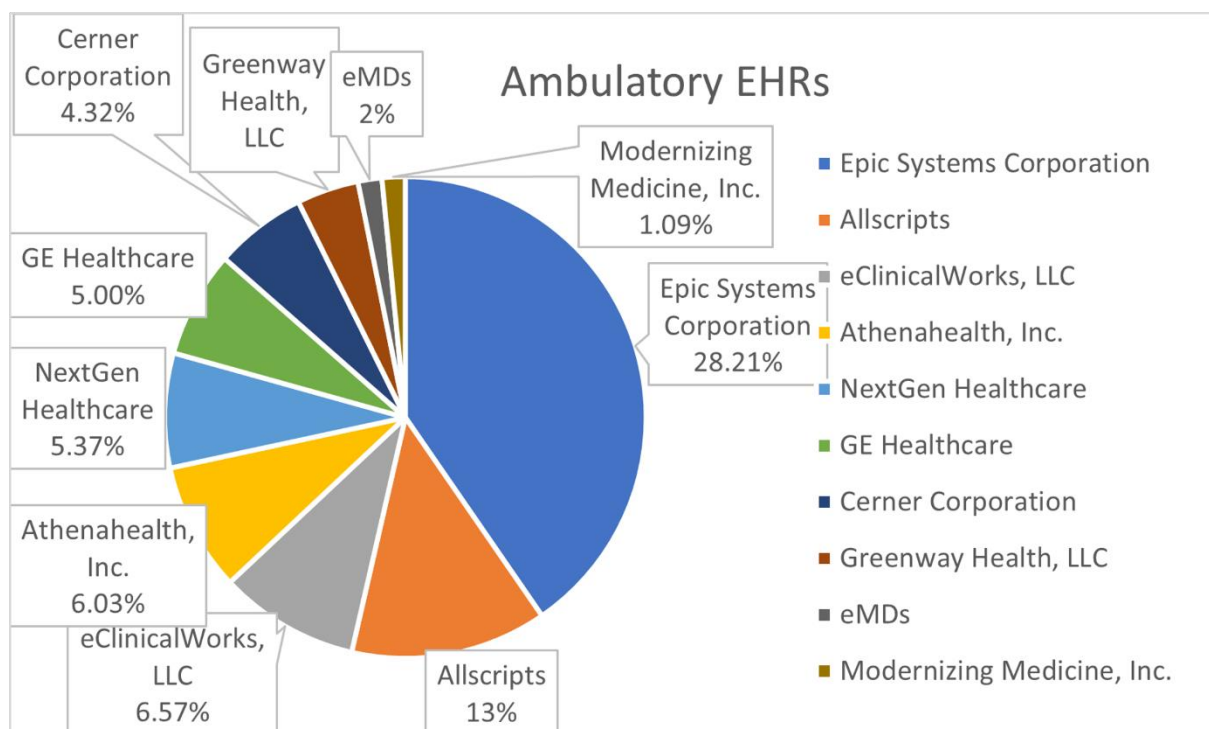
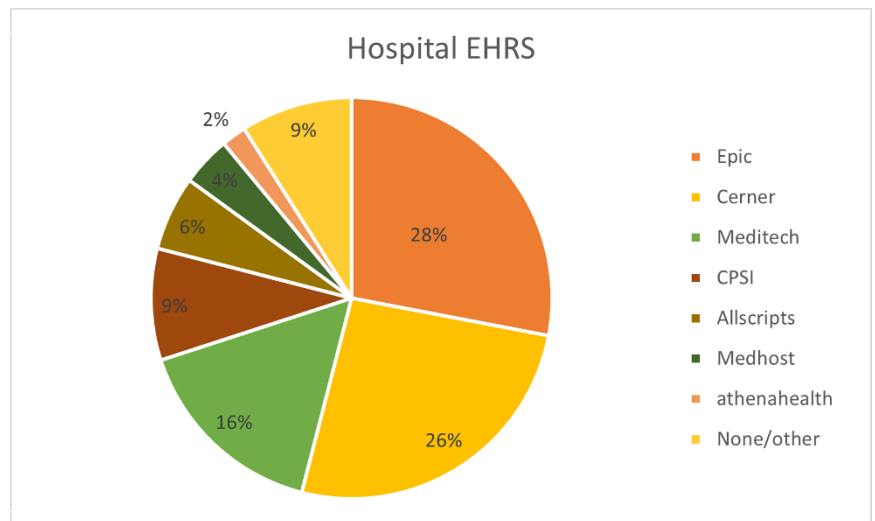
Market Share of Hospital EHR & Ambulatory EHR

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



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



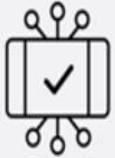
Latest Trends

**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.

1. Competitive Analysis of digital health platform.

Region: - U.S.

Motto/Mission	incorporating hospitals to provide quality healthcare solutions to their patients anywhere, anytime by digitizing their end-to-end operations	We connect and curate the world's healthcare data and make it accessible and useful.
U.S.P.	USP lies in its integrated, SaaS-based, and platform-based approach that enables seamless digitalization of hospitals	
Product & Services	Advanced HIMS, EMR / EHR Virtual Care, LIMS, RIS/PACS, Pharmacy, Connected Ambulance, AI Healthcare, Advanced Business Intelligence, Medical IoT Solution	Population Health Management, Accountable Care, Revenue Cycle Management, Value Based Care, Clinical Integration, Big Data analytics, Quality Reporting, Interoperable Data Lake, Drilled Down Contract Performance, and healthcare data platform
Pros	Clouds based technology; AI led Digital Healthcare startup	
Cons		
Available	Desktop Platforms Web App, Windows, Mac KareXpert EMR/EHR supports the following devices: IOS, Android	
CARE Categories	Ophthalmology, Cardiology, neurology, Critical Care	
News	This Reliance-funded startup KareXpert is aimed at digitally transforming one lakh hospitals by 2026	Innovaccer Showcases the #1 Healthcare Data Platform at HIMSS22
	KareXpert plans to digitally transform 100,000 hospitals globally	Innovaccer Inc., the Health Cloud company, announced that its Patient Relationship Management (PRM) solution has been recognized by providers as a high-performance Customer Relationship

Pros	Save money via workflow and communication improvements- decreased risk of miscommunication. It can Integrate with EHR or EMR System	Connected: allowing for easy access to data across care pathways with purpose-built ecosystem services, such as integration with third-party partners. Protected: secure by design, meeting privacy and security requirements and ensuring systems are always up to date with continuous vigilance. Future-Ready: enabling faster adoption of innovation, allowing health systems to scale solutions within the enterprise and to add solutions according to need. Predictable: the adoption of new innovations requires less initial investment and creates a transparent total cost of ownership. Philips is responsible for all updates and upgrades, allowing IT to focus on new strategic initiatives rather than maintaining the life cycle of software products.
Cons	It didn't provide Telehealth and Telemedicine	
Available	AirStrip ONE is used by care teams on mobile devices, laptops and desktops to monitor patients throughout the care delivery system	Mhealth
CARE Categories	Labor and Delivery, Cardiology, Telemetry, Critical Care, Operating Room, Procedural anesthesia	
News	AirStrip® Adds Unique and Powerful Analytics Capabilities to Enrich Virtual Acute Care Platform via Partnership with Fifth Eye™	Philips signs long-term strategic partnership with Oulu University Hospital Finland to deliver advanced image-guided specialist care
	AirStrip Integrates BioIntelliSense Medical Wearable Devices	Philips adds to its cardiology suite of solutions at ACC 2022 with innovations to help improve patient outcomes, experiences, and care pathway effectiveness

Companies	Airstrips Technologies	GE Edison Healthcare
		
Introduction	Athena One—our suite of integrated, network-enabled services—works to deliver ROI healthcare	GE Healthcare announced its intention to bring to market, a digital

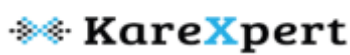
	solutions for our clients. athenahealth is a committed partner that continues to add value because your financial success drives ours.	health platform to be called Edison Digital Health Platform March 15, 2022
Motto/Mission	To create a thriving ecosystem that delivers accessible, high-quality, and sustainable healthcare for all,	
U.S.P.	our integrated suite of services	
Product & Services	Electronic health records, medical billing, Revenue Cycle Management, Patient Engagement, Advisory Services, Care Coordination, Telehealth	
Pros	It offers both EHR system and EMR system. It also has mhealth app. it offers 3rd party solutions that integrate into their EHR solution.	
Cons	The pricing of the software is a bit on the higher side and is difficult to afford for the smaller businesses.	
Available	Athenas Health is available on mobile devices, laptops and desktops	
CARE Categories	Orthopedics, Pediatrics, Cardiology, Urgent Care, Gastroenterology, Internal and Family Medicine, Obstetrics, and gynecology	
News	MedWise Urgent Care Partners with athenahealth to Support its Growing Network of Clinics	
	athenahealth and AllianceChicago Partner to Provide Comprehensive Solution to Nationwide Network of Community Health Centers	

Region: - Europe

Companies	Siemens Healthcare	Babylon health
		
Introduction	Siemens Healthineers AG is a German medical device company. It is the parent company for several medical technology companies and is headquartered in Erlangen, Germany.	Babylon Health is the most prominent of the new private companies seeking to develop digital technology in the NHS
Motto/Mission	To enable healthcare providers to increase their value by equipping them with our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics and molecular medicine as well as digital health and enterprise services.	We want to make high-quality healthcare accessible and affordable for everyone on Earth.

U.S.P.	Siemens USP lies in being the largest digital healthcare platform in Europe	
Product & Services	Medical Imaging, Laboratory Diagnostic, Clinical Fields, Point of Care testing, Digital health Solutions, Accessories, OEM & Electronics	Health check, virtual connect with doctor, Digital Appointment, Tele Home & M-Health and Tele Hospital
Pros	Siemens can strength leadership in digitization by combining software, platform & services. Increase in smart city projects globally spur demand of next-gen technology which can drive siemens growth	Collaborate with NHS, data availability
Cons	Reliance on Third party vendors, Threats from Competitor like GE Healthcare	Third Party devices/app
Available	Mobile apps help your staff by shortening the time needed for clinical documentation and by keeping patient data secure ¹ and up to date. Patient Consent Visual Capture	Available on Mobile
CARE Categories		
News	Proscia and Siemens Healthineers Ink Agreement to Expand Global Reach of Digital Pathology	Babylon selects Google Cloud to help speed up access to patient data
	Siemens Healthineers announces market introduction of the teamplay digital health platform on 11/03/2020	

Region: - India

	KareXpert	Innovaccer
Companies		
Introduction	Asia's first AI-enabled Integrated Healthcare Platform KareXpert digital healthcare platform is a SaaS-based and integrated solution that enables exponential growth in healthcare organizations HIMS EMR LIMS RIS.	largest healthcare organizations are connecting their care ecosystems on the Innovaccer Health Cloud

Motto/Mission	incorporating hospitals to provide quality healthcare solutions to their patients anywhere, anytime by digitizing their end-to-end operations	We connect and curate the world's healthcare data and make it accessible and useful.
U.S.P.	USP lies in its integrated, SaaS-based, and platform-based approach that enables seamless digitalization of hospitals	
Product & Services	Advanced HIMS, EMR / EHR Virtual Care, LIMS, RIS/PACS, Pharmacy, Connected Ambulance, AI Healthcare, Advanced Business Intelligence, Medical IoT Solution	Population Health Management, Accountable Care, Revenue Cycle Management, Value Based Care, Clinical Integration, Big Data analytics, Quality Reporting, Interoperable Data Lake, Drilled Down Contract Performance, and healthcare data platform
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Assignment 3:- Digital Health Requirements for Pharma Industry

Introduction

- Pharmaceutical Industry play significant role in patient wellbeing by providing them medications. Pharmaceutical industry discovers, develop, manufacture, market medications.
- India ranks 3rd by volume and 14th by value worldwide.
- 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)

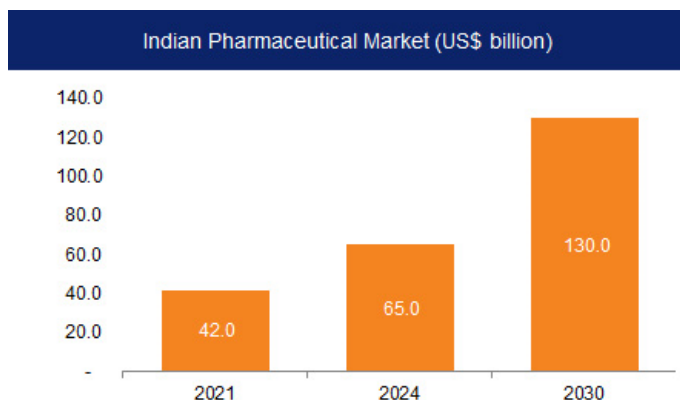
Revenue: USD 52.1 billion



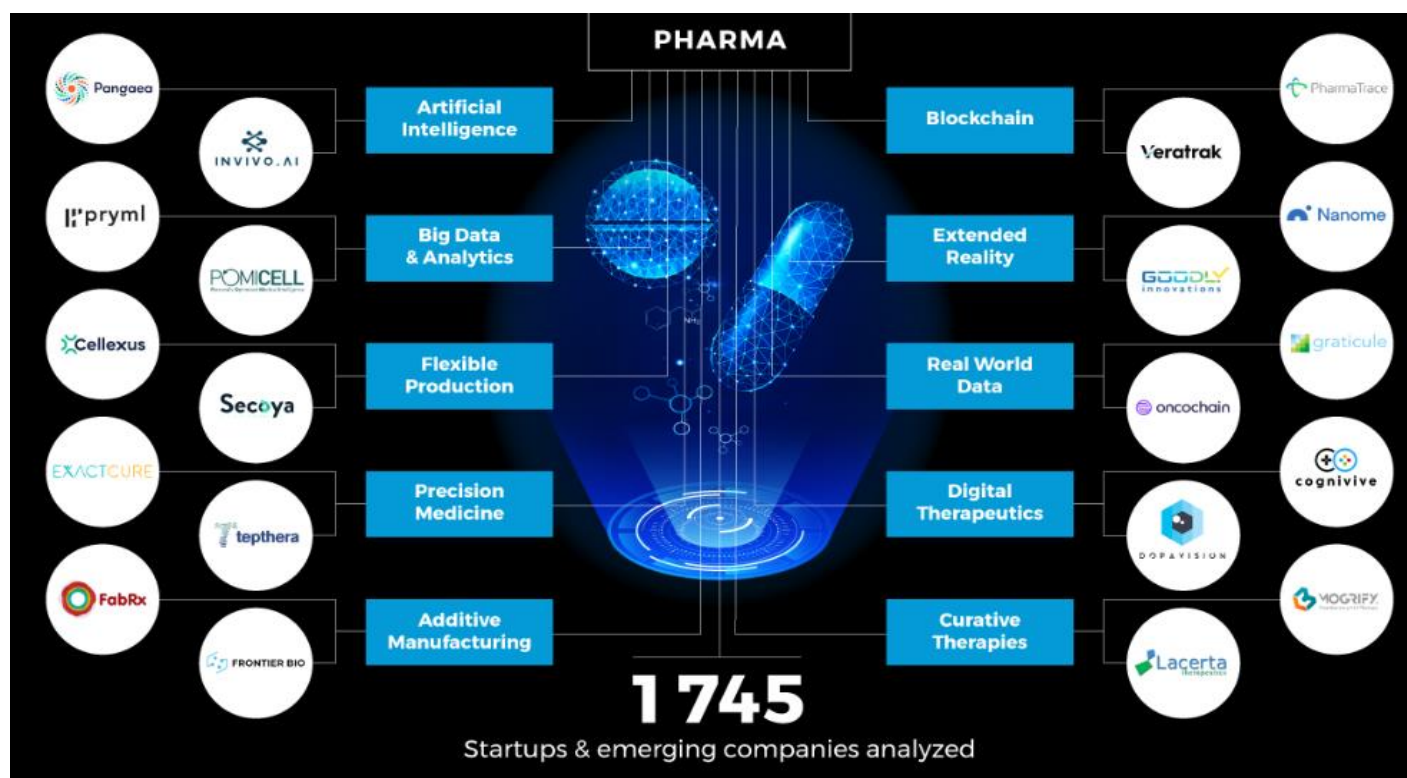
- The global pharmaceutical market is set to exceed US\$ 1.5 trillion by 2023

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.

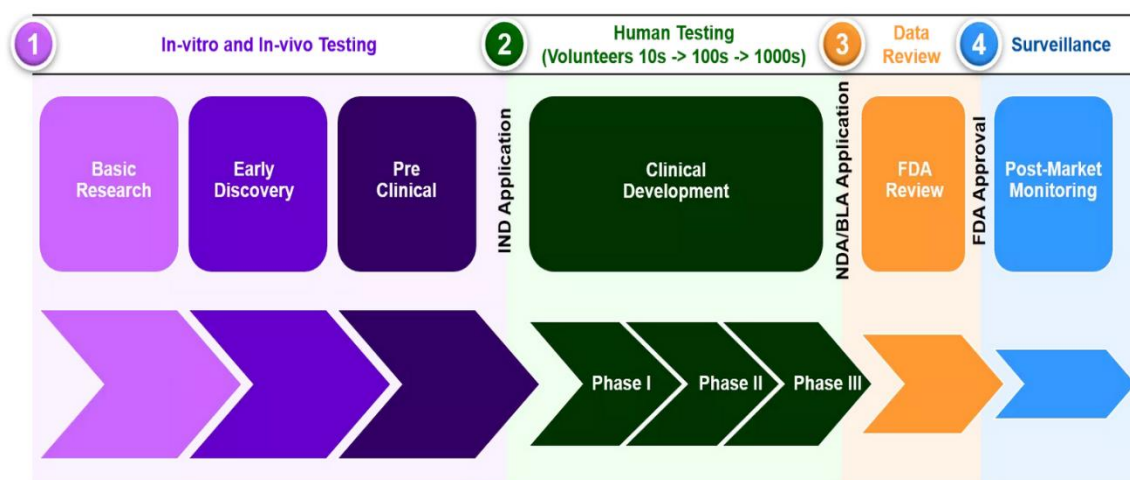
Key Elements driving the need of digital health in Pharmaceutical Industry

- ❖ 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

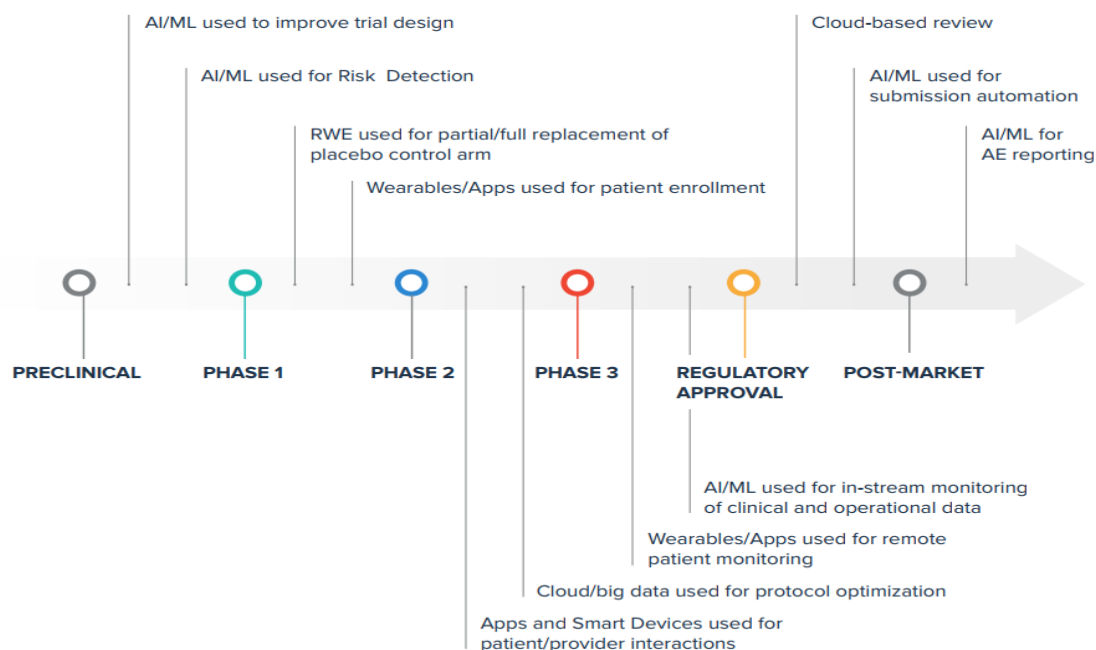
Advantage	Disadvantage
Error Minimization	Expensive
Difficult exploration	No replicating humans
Digital Assistants	No improvements with experience
Repetitive Tasks	No original creativity
Medical uses	Unemployment
No breaks	Expensive
Limitless functions	

Virtual Clinical Trials

- 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 Medications

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 combining 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.

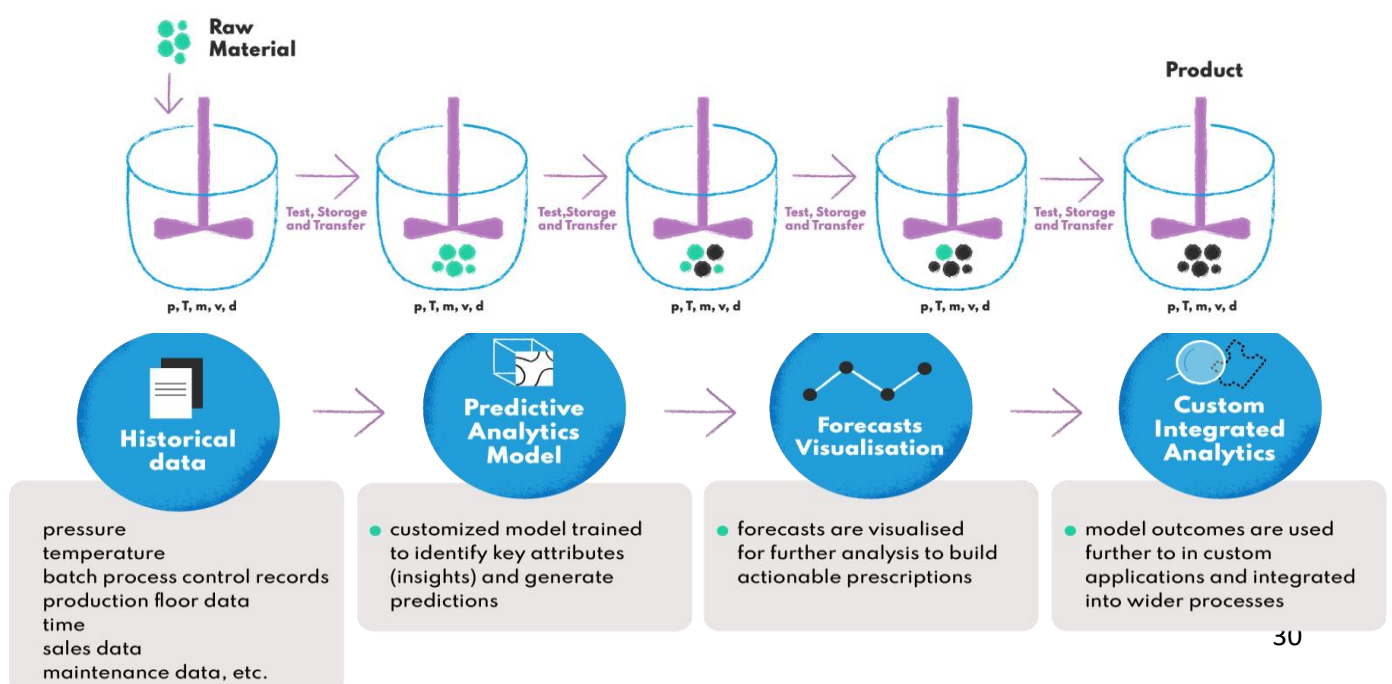
4. Reduce Cost and Increase Drug Utilization

- 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



Predictive Analytics helps pharmaceutical manufacturers to create manufacturing intelligence solutions to discover unexpected behaviours, notice early warning signs of quality issues.

It helps to improved production monitoring and planning, 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 pharmaceutical manufacturers indicate when equipment needs **maintenance or cleaning 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

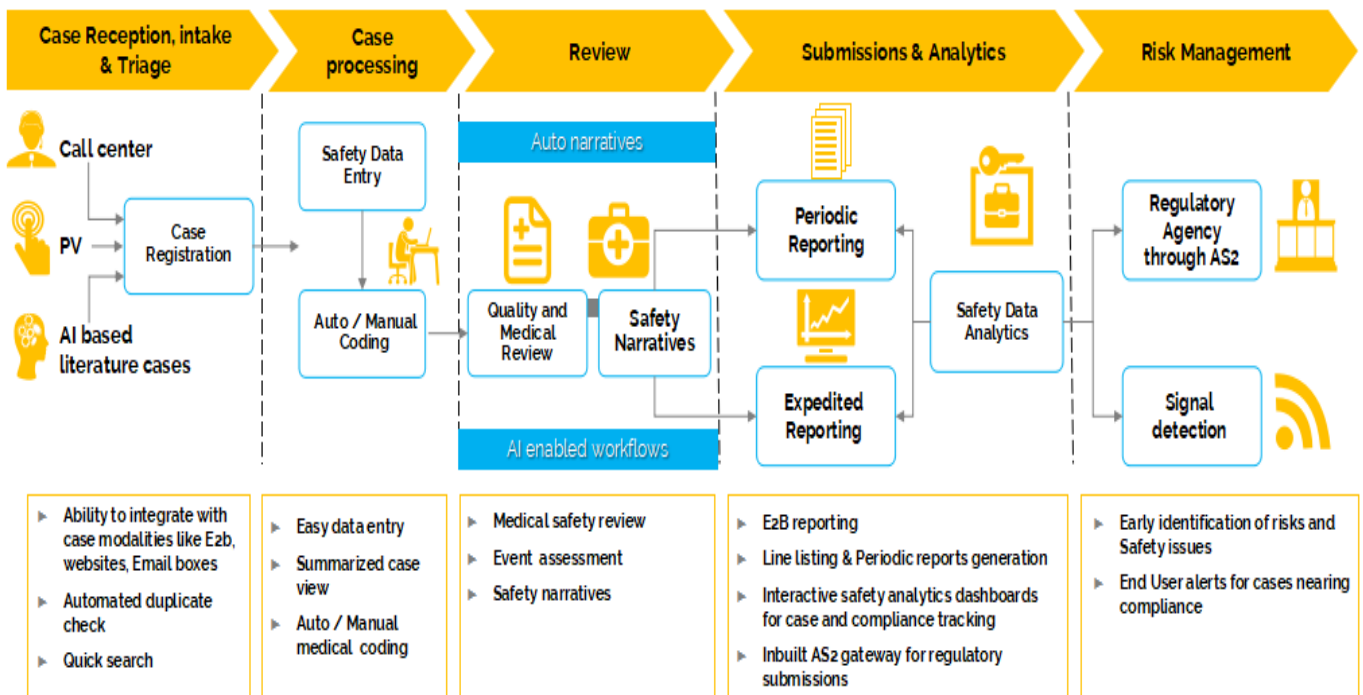
Data driven insights for Rx & R&D

- 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

Startup related to Pharmaceutical Industry

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.

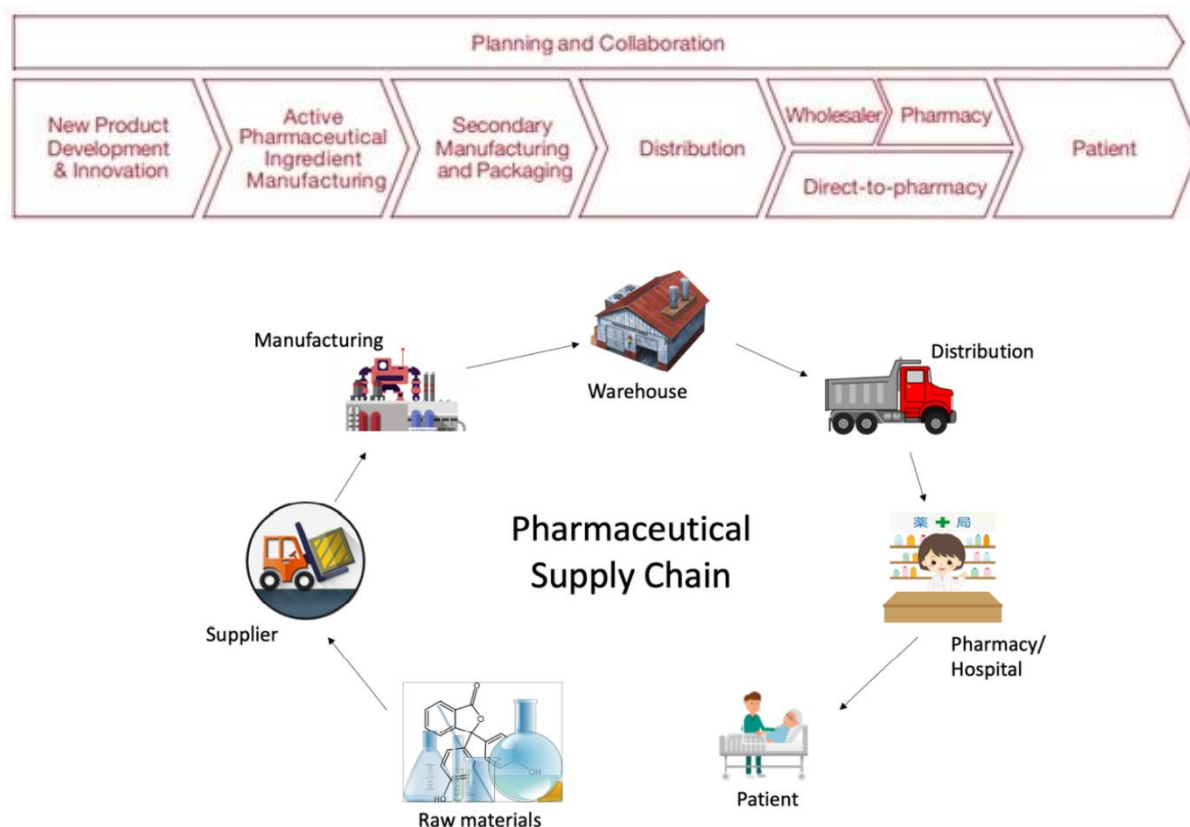
ELECTROSAN TECHNOLOGIES – PROCESS & FACTORY AUTOMATION

- 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 connects 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.

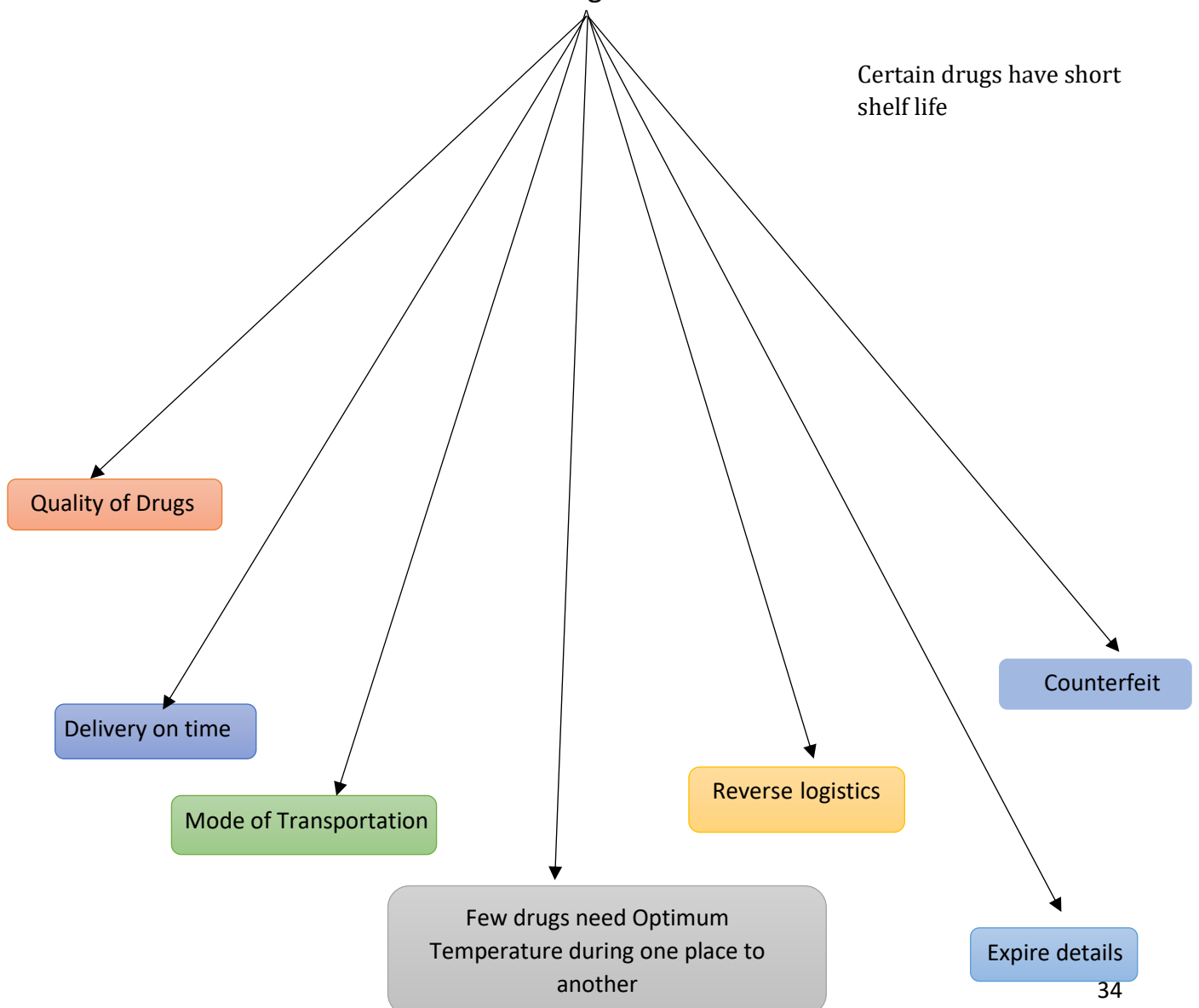
Stockiest

- 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 open-source algorithms, AI platform that 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.

Startup related to Supply chain

Example: -Vu 360 Solutions, nVipani, Blockchain firm, Better Sense

Theft, diversion, and counterfeiting are rampant worldwide in the pharmaceutical industry.

Vu 360 Solutions: - It is Inventory Control, AI based Warehouse Management Solutions.

Vu360's Automated Track & Trace Solution

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

Vu360 Cold Chain Solutions

- lose efficacy & become ineffective. Automated active real-time temperature monitoring system utilizes IoT (Internet of Things), RFID (radio frequency identification) and nano marker technologies that combine with 3D thermal imaging. Monitoring the temperature of company's products and ensuring consumers.

Vu360 Supply chain Security Management

- 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.
- **Advantage**

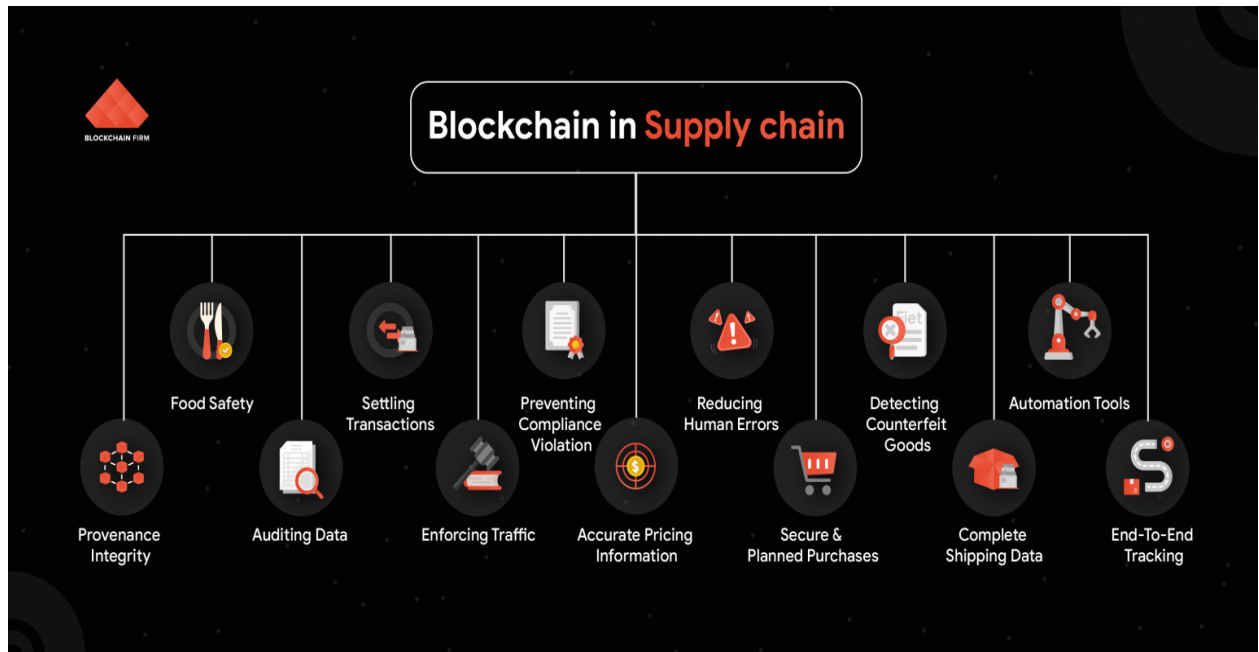
Vu360 Solutions Seamlessly associates with GS-1 codes

nVipani

- 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.

Blockchain firm

- Blockchain technology's true potential lies in maintaining a decentralized, tamper-proof, and transparent record of data. These features make blockchain a technological ripe 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 (Hipa), 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 is regulated under FDCA

Class I (general controls)

Class II (general controls 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 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 manufacturer 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.

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