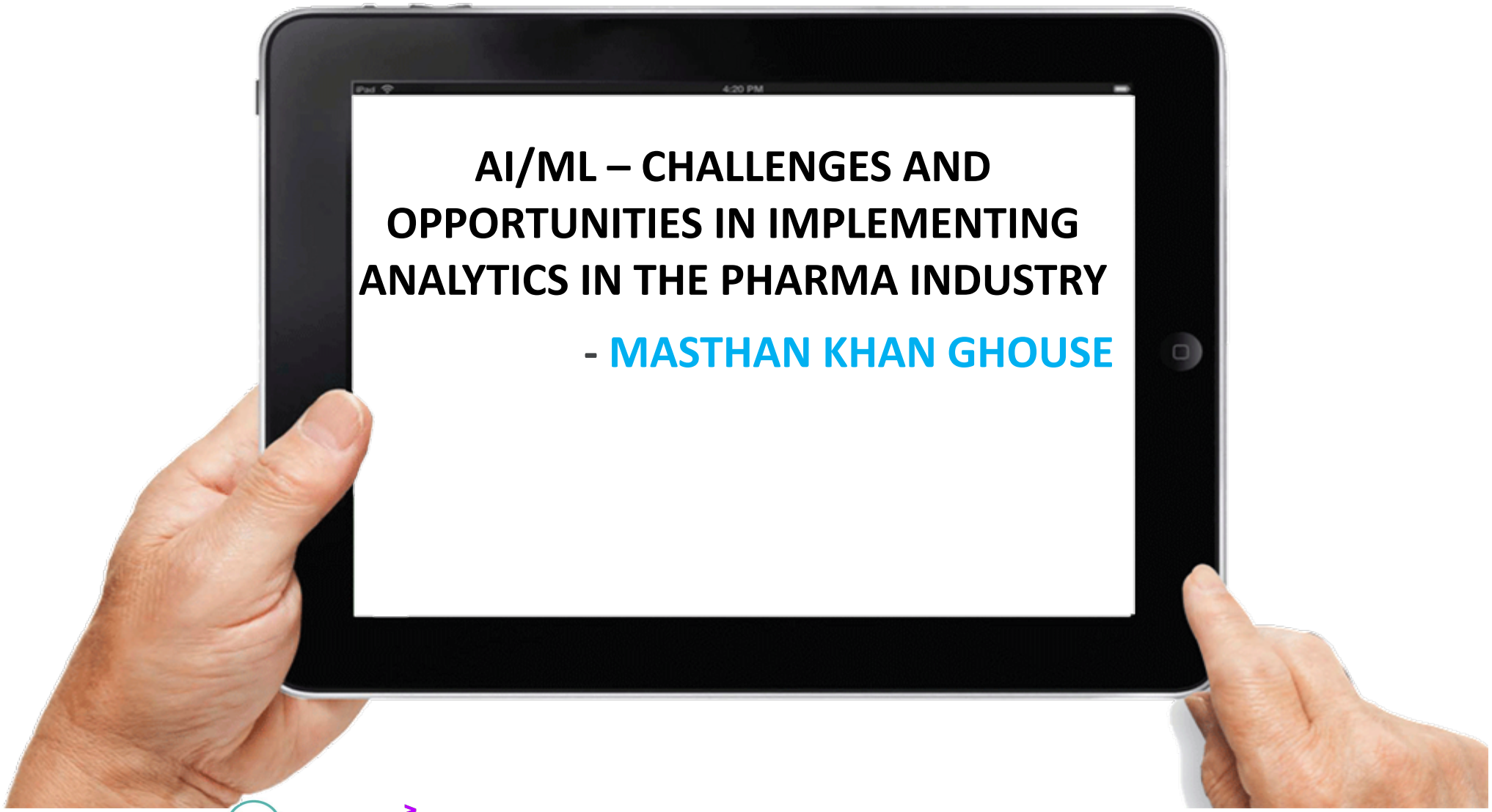


AGENDA

- GLOBAL LS BPO MARKET & STRATEGIES
- PHARMA INDUSTRY TRENDS & FOCUS
- AI & ML
- HOW ORGANIZATION ADOPT TECHNOLOGY
- APPLICABILITY OF DIGITAL IN LIFE SCIENCES
- TRANSITIONING TO FUTURE OF CLINICAL TRIALS
- AI IN CLINICAL DATA FLOW
- CHALLENGES WITH IMPLEMENTING AI
- HOW TO PREPARE FOR BETTER AI OR WHAT MAKES AI SUCCESSFUL
- Q&A

GLOBAL LS BPO MARKET & STRATEGIES

(2019 - 2027)

Market Volume 2027

US$ *400 Bn*

"Nearly 50% of global healthcare companies will implement artificial intelligence strategies and by 2025 and some experts believe it is crucial for how businesses operate down the line."

pharmanewsintel

2018

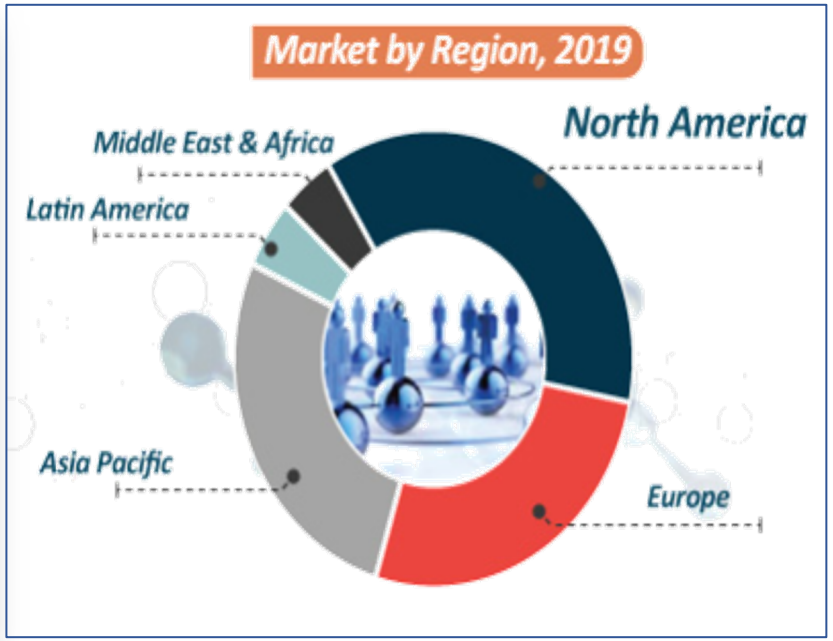
$218B

Rise in demand for low-cost drugs, patent expirations, and uncertain economic conditions have compelled the pharmaceutical players to take support of various outsourcing services.

2027

$400B

TransparencyMarketresearch

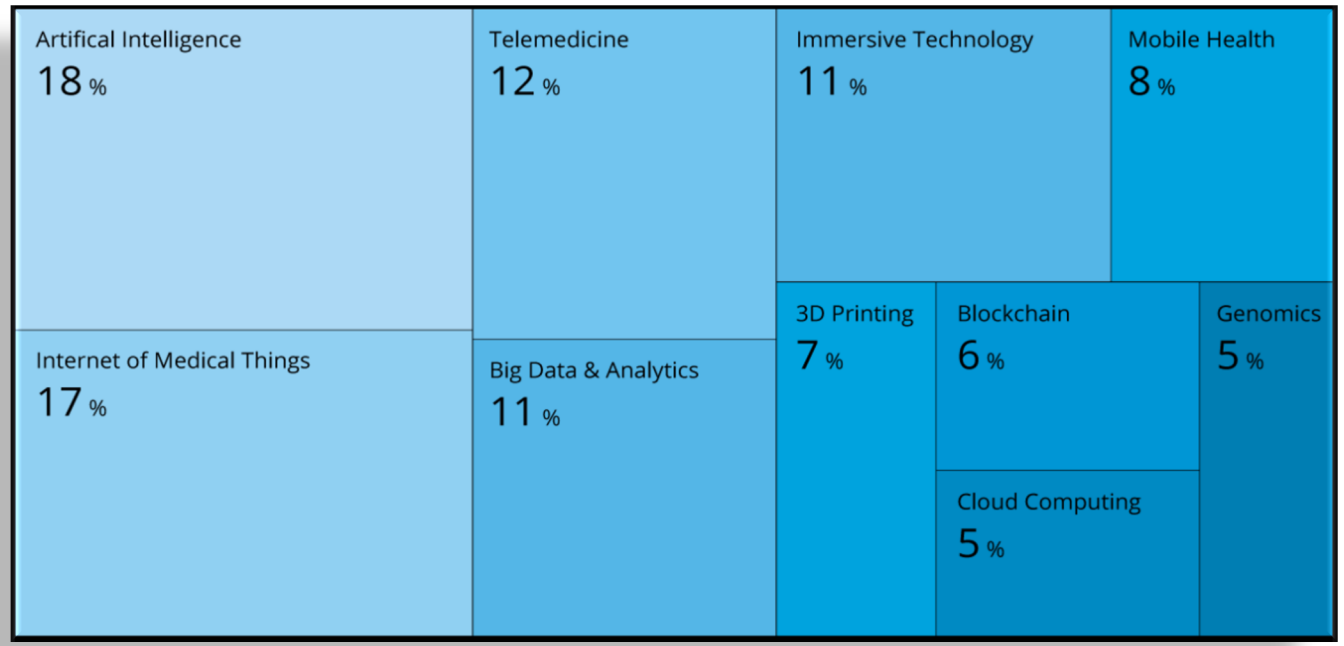


PHARMA INDUSTRY TREND & FOCUS

TRANSFORM THE ENGINE OF BUSINESS OPERATIONS

Enterprises are looking to act quicky with intelligence, insight and confidence to adapt to the changes in the competitive and customer landscape.

TOP 10 TRENDS OF 2021



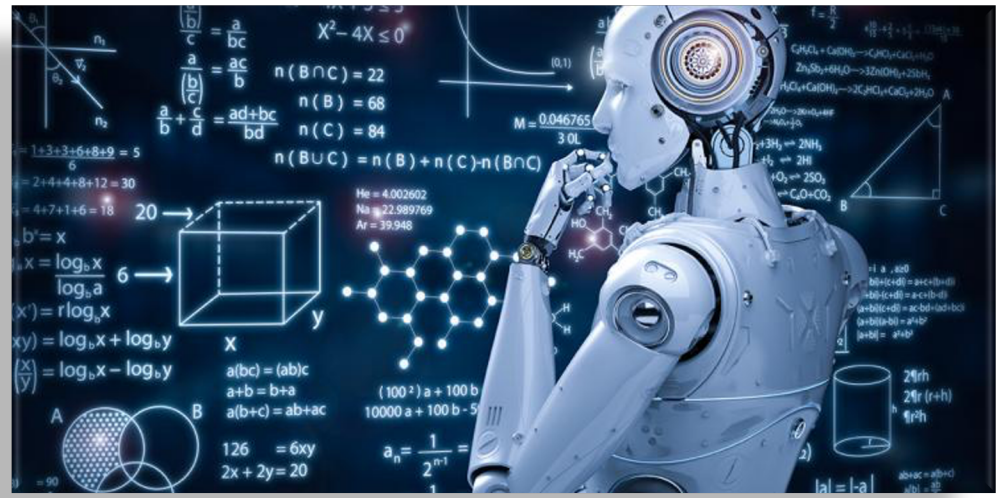
startus-insights

FOCUS OF FUTURE

- **Drive** speed, agility and scale
- **Enhance** site & patient experience
- **Improve** people's lives
- **Reduce** transactional Errors and **Operational** Cost
- **Drive** intelligence and insights

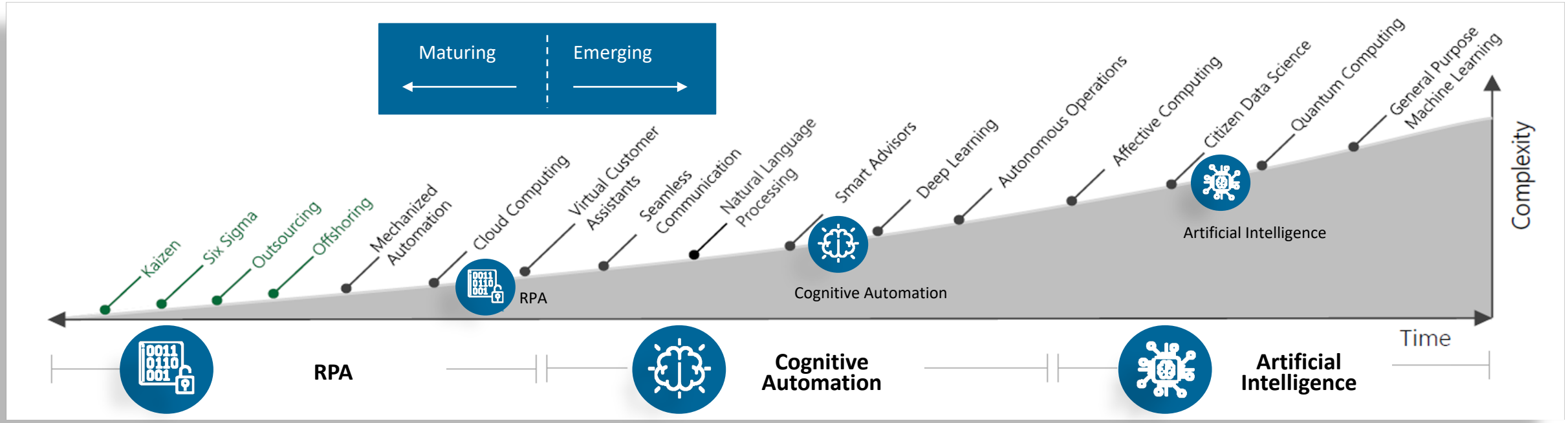
AI & ML

Artificial Intelligence (AI) is the ability of a computer or computer-controlled robot to perform tasks commonly associated with human intelligence. The term is frequently applied to the project of developing systems endowed with the intellectual processes characteristic of humans, such as the ability to reason, discover meaning, generalize, or learn from Past experience.



- **Machine Learning (ML)** is a branch of artificial intelligence (AI) based on the idea that systems can learn from data, identify patterns and make decisions with minimal human intervention. It is the scientific study of algorithms and statistical models that computer systems use to progressively improve their performance on a specific task.
- While AI is the broad science of mimicking human abilities, ML is subset of AI that trains machines how to learn.

HOW ORGANIZATIONS ARE ADOPTING AUTOMATION TECHNOLOGIES TO TRANSFORM THEIR OPERATIONS



MIMICS HUMAN ACTIONS

- Screen scraping data collection
- Rules based business process management
- Tactical toolset to automate repetitive tasks
- Cheaper and faster step towards process efficiency

MIMICS HUMAN JUDGEMENT

- Data input and output in any format
- Pattern recognition with unstructured data
- Replication of judgement-based tasks
- Basic learning capabilities for continuous improvement for quality and speed

AUGMENTS HUMAN INTELLIGENCE

- Natural language recognition and processing
- Dealing with unstructured super data sets
- Hypothesis based predictive analysis
- Self-learning rules continuously rewritten to improve performance

APPLICABILITY OF DIGITAL IN LIFE SCIENCES

Drug Discovery

- **Real World Data (RWD) for disease identification:** RWD refers to data procured outside clinical trials medical records, billing which includes patient electronic and prescription data and insurance claims
- **Use of AR-VR to accelerate drug discovery:** Augmented reality **(AR)** and virtual reality **(VR)** allow for immersive experiences, offering untapped opportunities for research
- Moving Away from Blockbuster drug model to Personalized Medicines to improve Clinical Outcomes
- **New drug discovery areas**

  Protein Degraders (protein degradation, has deals worth USD 2bn with Pfizer, Merck and Roche),

  Human Microbiome (USD 4bn industry by 2030)

Pre-clinical Trials

- **Organ-on-a-chip (IoT based) to fast-track Pre-clinical Trials**:

  OOC trials on chips rather than animals can help increase trial success rate and potentially replace animal testing
- **In silico Trials to experiment with simulations on computers**

  No animals or humans or even a single cell is required

  Modeling, simulation and visualization of biological and medical processes can instead be done on computers

Clinical Trials

- **Patient Acquisition and Retention**:

  50% of sites fail to meet enrolment targets

  30% of Clinical Trial Patients Drop Out

Various startups are using AI and ML to recruit and onboard eligible candidates in clinical trials

- **Virtual trials:** Helps overcome geographic limitations
- **Flexible Trial Designs:**

  Adaptive trials: Enable Amendment based on patients' response during trial
- **Clinical Data Management:**

  AI: Data-driven protocols, powered by advanced AI algorithms

  Blockchain: network platform that enables multiple databases to store time-stamped records
- **Remote Patient Monitoring**

  Wearables: At present, about 10-15% of trials incorporate wearables to collect data

  Ingestible Sensors: Higher adherence can be achieved through ingestible sensors. Eg: Abilify MyCite

Regulatory Approvals

- **Process Automation in Compliance**
- AI technology can expedite CSR writing by taking information from previously authored study documents and help in creating the templates which can be reused or auto populate. Then, the writers only must complete the final 10 to 20 percent of effort.
- AI technology is also being leveraged for redacting sensitive information from clinical trial documents. This technology understands the context of **the sensitive information in clinical documents** as well as business rules to identify and redact PPD as well as support the process to redact company confidential information

APPLICATIONS OF AI

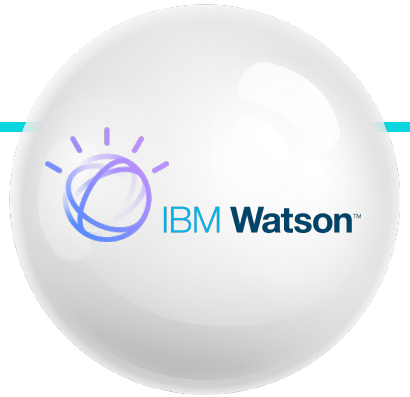
• GOOGLE'S DEEP MIND HEALTH

SCOPE

- Radiology & Radiotherapy

USAGE

- Detect differences between healthy and cancerous tissues.
- To improve the accuracy of radiotherapy planning while minimizing damage to health organs at risk



• IBM WATSON

SCOPE

- Personalized Medicine & Rare Disease Identification

USAGE

- AI for personalized treatment decisions in the oncology space.
- It uses each patient medical information and history to optimize the treatment decision-making.
- Recently Watson correctly Diagnoses a rare form of leukemia in a patient originally thought to have acute myeloid leukemia.
- It reported examined millions of oncology research papers in 10 min after which is successfully diagnosed the patent and recommended a personalized treatment plan

• ACORN-MEDIDATA

SCOPE

- To develop new insights across all phases of drug development.

USAGE

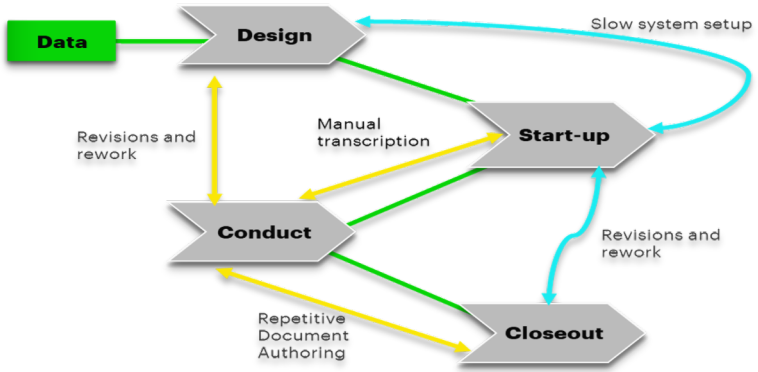
- AI aim is to make data 'liquid' across the end-to-end life cycle of a biopharma company.
- They take medical data from many structured and unstructured data sets and turn these into data digitized patient journeys aligned to specific treatments.
- its algorithm can segment patient populations by their demographic

TRANSITIONING TO FUTURE OF CLINICAL TRIALS

Study published by the Massachusetts Institute of Technology (MIT) has found that only 13.8% of drugs successfully pass clinical trials company can expect to pay between $161 million to $2 billion for any drug to complete the entire clinical trials. This Artificial Intelligence has the potential to Significantly reduce clinical cycle time and cost while helping to improve the outcome of clinical development.

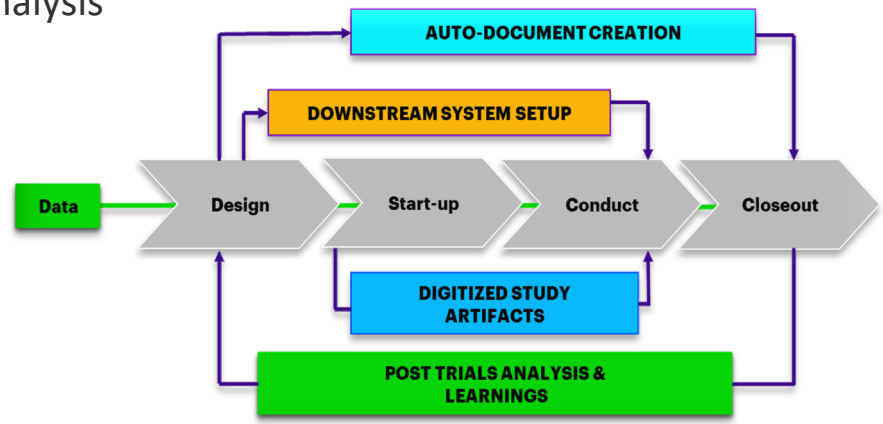
Traditional clinical trail data flow

A Non-linear maze of manual effort, rework Inefficiency



The future state vision

Streamline interoperability of trial artifacts enabled through the standardization of data/vocabulary learnings from AI & ML analysis



FUTURE STATE BENEFITS

- **Reduced manual** Effort & rework.
- **Increased interoperability** Across Multiple systems
- **Improved Trial** Cycle time.
- **Optimized Use of Insights** To Improve the Next Trial
- **Reduced Errors in** Trial artifacts.

phuse + accenture

AI IN CLINICAL DATA FLOW

CLINICAL OPERATIONS INNOVATION

CLINICAL SERVICES

STUDY DESIGN & PLANNING

- Support Study Plan Creation
- Study Specific Documents Creation

STUDY SETUP & EXECUTION

- Study Setup
- Build Study DB and eCRFs
- Site Identification and Qualification
- Study Initiation Setup
- Site Initiation
- Study Tracking

CLINICAL DATA MANAGEMENT

- Data Aggregation & Transformation
- Data Entry (Paper Studies Only)
- Preparation for Database lock
- Data Validation
- Discrepancy and Query Management
- External data reconciliation
- Medical coding

STUDY ANALYSIS & CLOSURE

- Database Lock
- Closeout Study , Countries and Sites
- Statistical Programming
- Medical Writing-Clinical Study Report
- Prepare Clinical data for Submission
- Publications and Posting of Results

APPLIED ARTIFICIAL INTELIGENCE

PROTOCOL BUILDER

Use AI/ML and Biomedical Concepts in conjunction with the Common Protocol Template to enable Creation of digitized protocol and traceability of Common elements from protocol to CSR.

DATABASE DESIGN

Use metadata collected for each visit as defined in the study builder to generate an ODM/ALS import file to automate CRF build in EDC System.

DATA CLEANING

Data Review and cleaning automated With Machine Learning. Queries auto proposed for Human Evaluation.

SDTM CONVERSION

Automate data quality checks and mapping from source clinical/non-clinical data(CRF, device, ePRO etc.) to SDTM and SEND, and analysis routines to drive automation.

AS AI ACCELERATES, UNIQUE ETHICAL CONCERNS COME IN PLAY

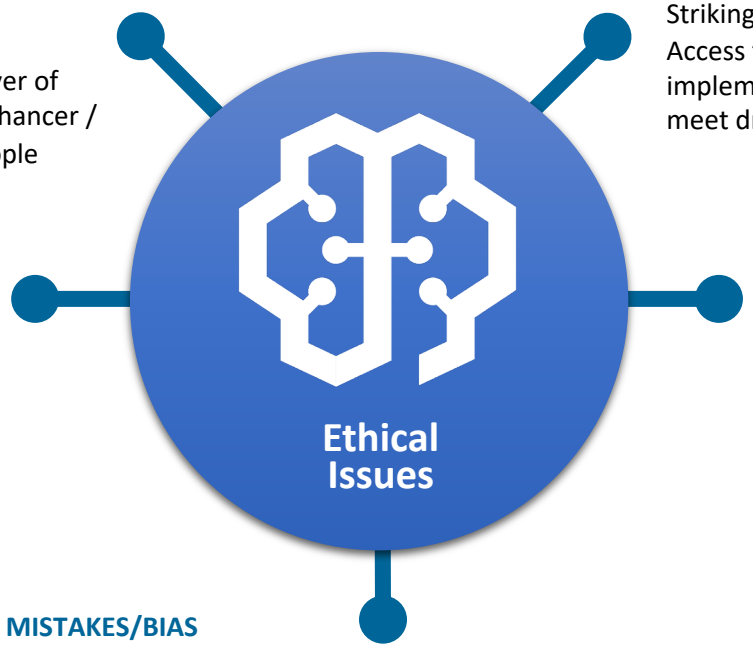
AI is progressing rapidly, but the topic around AI governance is still in its infancy with no industry consensus on standards and guidance from Health Authorities are also evolving

FIXED (VS. GROWTH) MINDSET
Shift mentality from:

Increased automation and its displacement of current jobs → Seeing AI as a driver of growth and an enhancer / augmenter of people

TRUST & TRANSPARENCY
Build trust through:

- Increased transparency, communication and explain-ability
- Ability to speak to how and why decisions were made, and actions were taken



PRIVACY & REGULATIONS
Striking the right balance between privacy and entitlements on Access to Data is crucial to the broader development and implementation of AI. The need for transparent algorithms to meet drug development regulations.

INCLUSION & DIVERSITY
Strive for diversity in developing and training AI systems by seeking a wide range of AI talent and data.

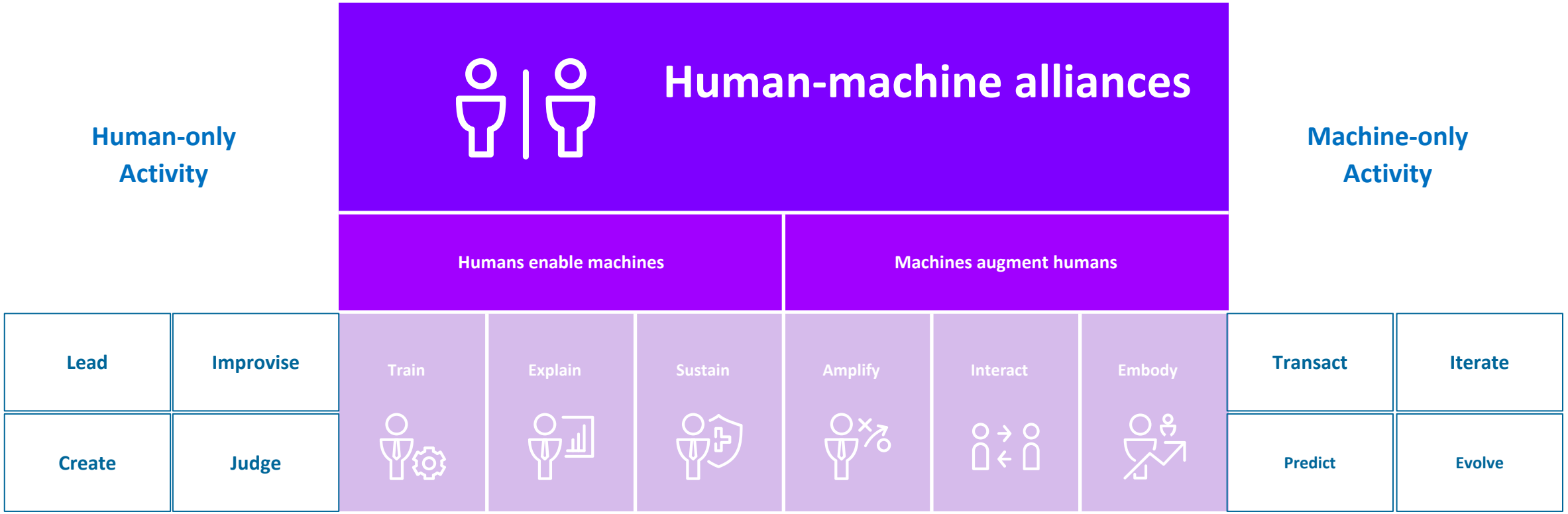
AI is not in the hands of the few.

AI MISTAKES/BIAS
Take into consideration, AI design and governance …
… that might impact AI performance or corporate brand

HUMAN + MACHINE DELIVERING TOGETHER

RESPONSIBLE HUMAN & SENSIBLE AI

The advent Of AI introduces New Intersections between Humans and Machines, reshaping the activities that each has traditionally been known to do in a way that Unlocks Greater Value



Our workforce will need to prepare to work alongside AI in these new ways

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THANK YOU