

IT SOLUTIONS FOR CLINICAL CHALLENGES ENCOUNTERED BY PHARMACEUTICAL COMPANIES

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CLINICAL DATA ECO-SYSTEM

Key Asks

Ability to deliver comprehensive information from insights to foresight

Scalability to handle big data and deliver more

Data Quality & Governance

AI/ ML enabled operations & Analytical workbench

Performance benchmarking and tools for site selection

Trial design optimization and reduce trial timeline / costs



Data Challenges

Data Quality Issues - Check for

- **Completeness**
- **Conformance**
- **Uniqueness Plausibility**
- **Atemporal Plausibility**
- **Temporal Plausibility**
- **Data inconsistency**
- **Misconduct** – Made up data at sites because of neglect & forgetfulness
- **Checks for unusual distribution of data within & between study sites**

Data collect

Clinical Data

- Electronic Health Records
- Administrative data
- Claims
- Patient / Disease registries
- Health surveys
- Clinical Trials Data

Study Design Data

- Treatment study
 - Randomized control
 - Adaptive clinical
 - Nonrandomized
- Observational study
 - Descriptive
 - Analytical

Device & Logistics

- Device
 - Mobile Test device
 - Lab Kits (etc.)
- Logistics
 - Import / Export regulation
 - To site / Direct Patient
 - Enrollment forecast

Other Data

- Imaging data
- Laboratory data
- Operations data
- IoT data
- Safety data

Data Stakeholders



Patient



Investigator



Clinical Research Coordinator



Care Provider



Ethics Committee



Sponsor



CRO



Regulatory Authority



Bio-Statistician



Social Media

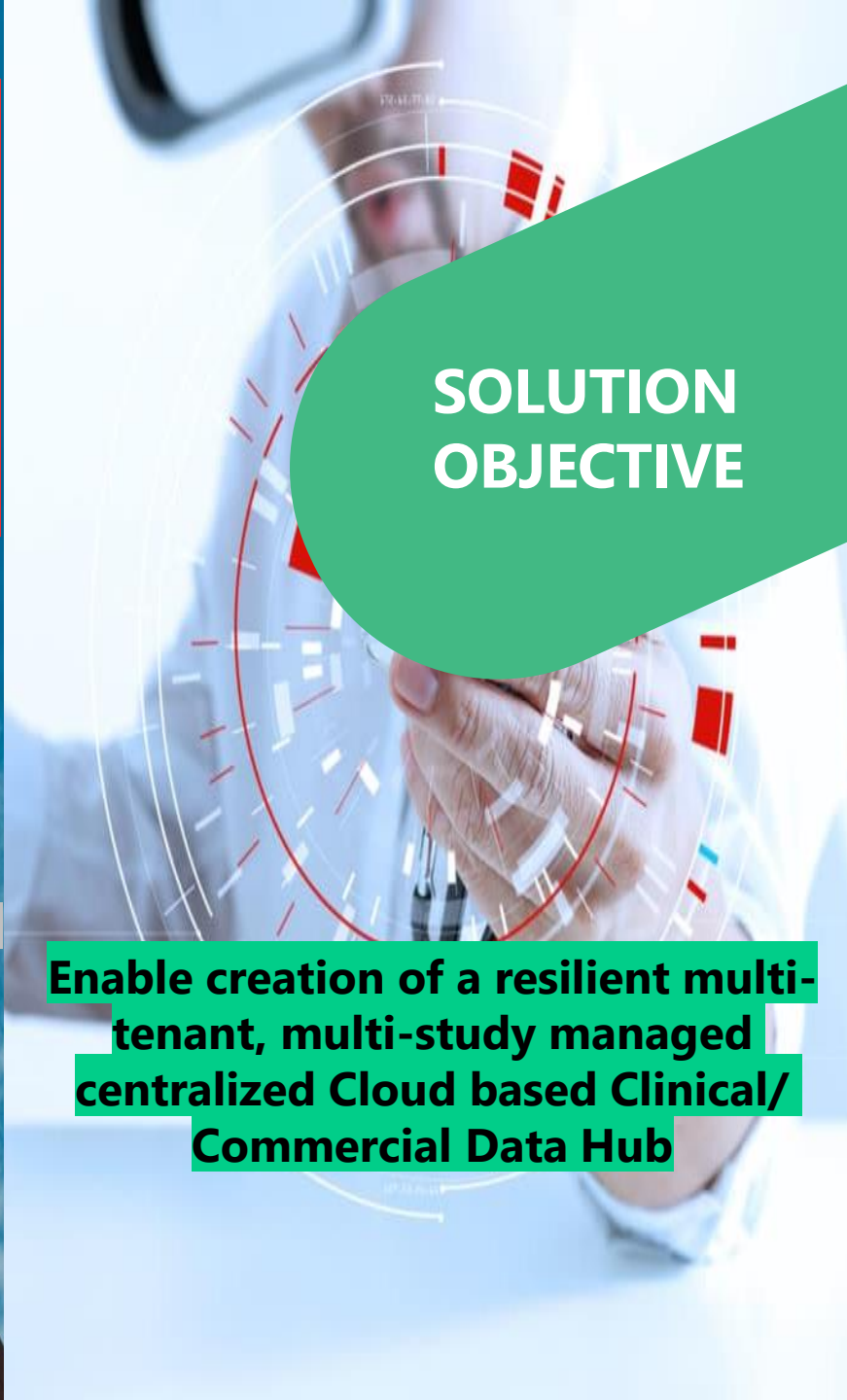


Wearable



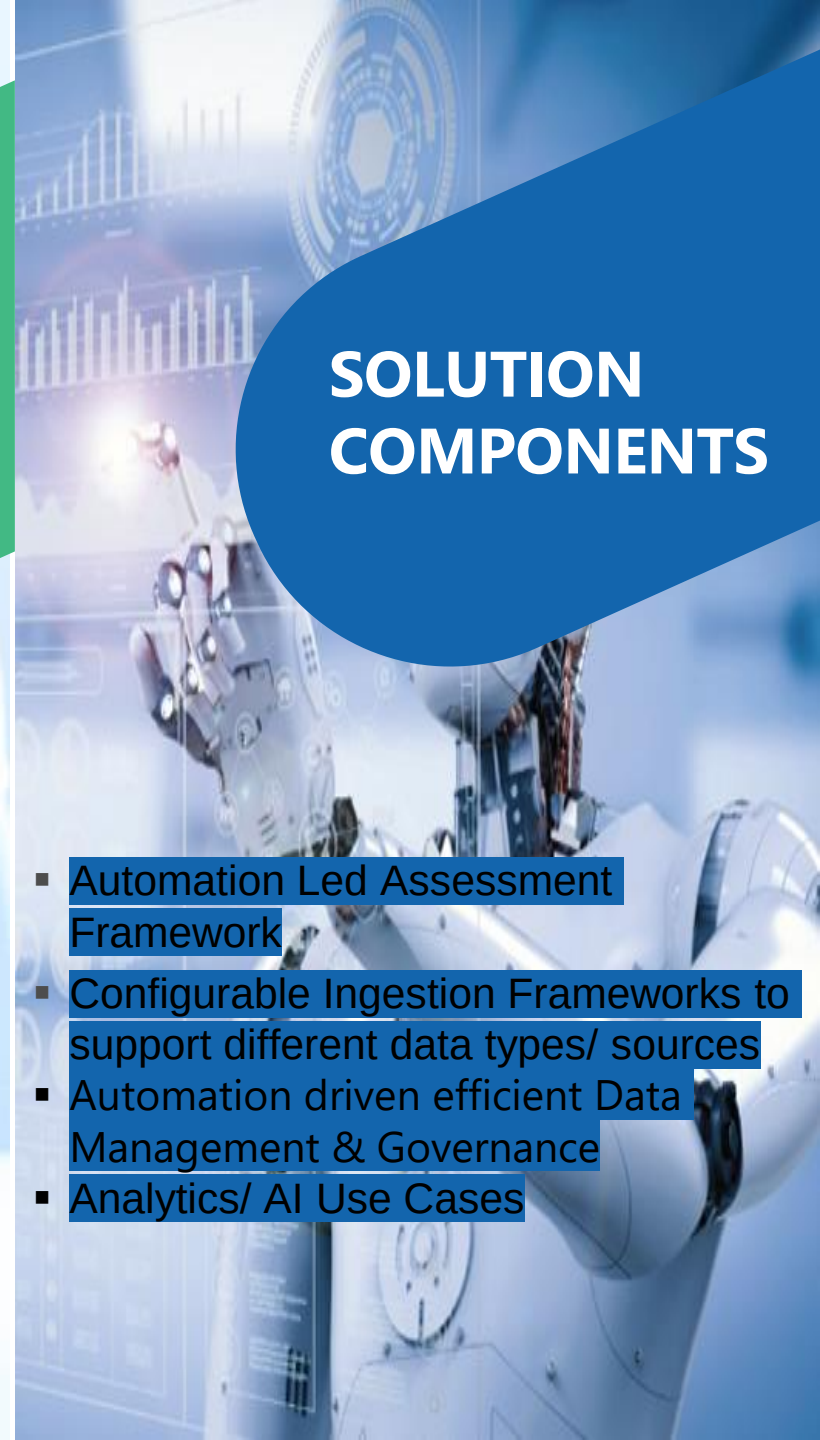
MARKET CHALLENGES/ OPPORTUNITIES

- Manual clinical trial data management
- Lack of real-time & timely access to clinical trial data
- Data governance is the #1 issue for regulatory compliance
- Enable distributed and global operations
- Move towards more Automated increasingly low-touch business processes
- eSource data is the future



SOLUTION OBJECTIVE

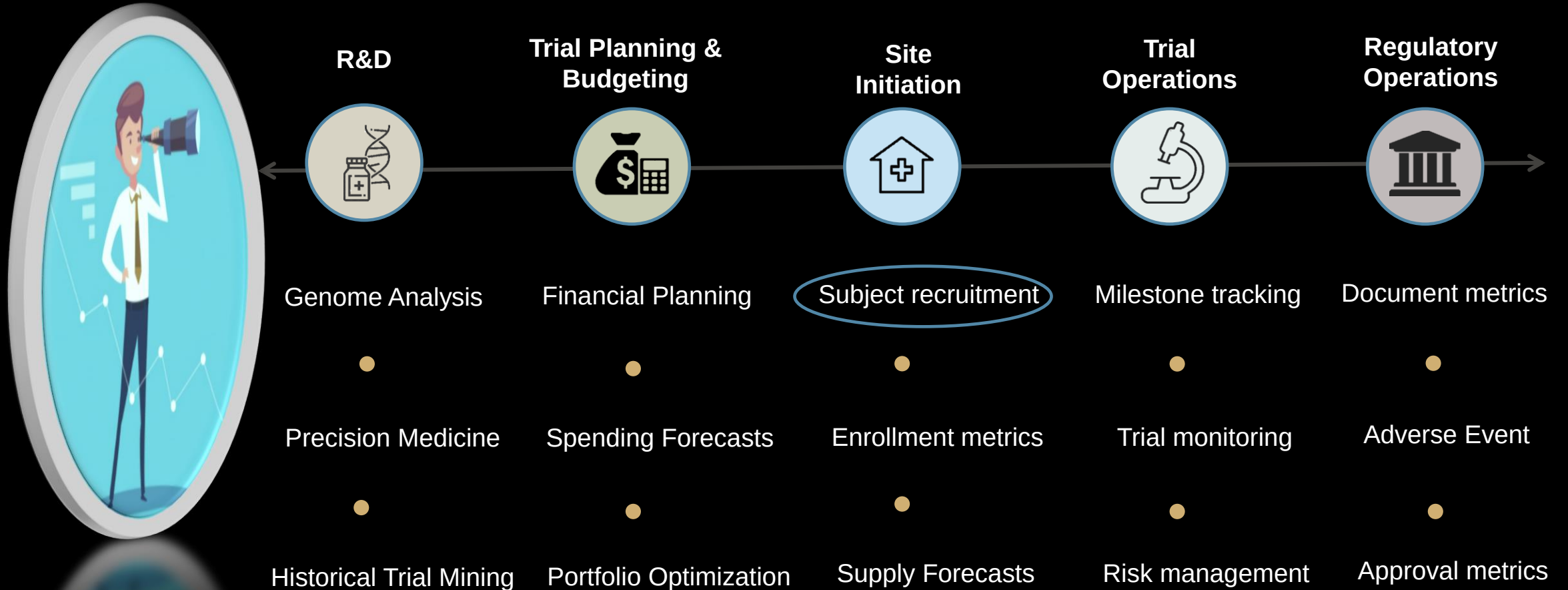
Enable creation of a resilient multi-tenant, multi-study managed centralized Cloud based Clinical/ Commercial Data Hub



SOLUTION COMPONENTS

- Automation Led Assessment Framework
- Configurable Ingestion Frameworks to support different data types/ sources
- Automation driven efficient Data Management & Governance
- Analytics/ AI Use Cases

INNOVATING ACROSS CLINICAL TRIAL LIFECYCLE



ENROLMENT CHALLENGES



48%

of sites under-enroll study volunteers



9 out of 10

trials meet enrollment goals if original timelines are doubled; patient recruitment alone accounting to 1/3rd of overall trial duration



10-15%

increase in volume of studies registered



11%

of sites are failing to enroll single patient



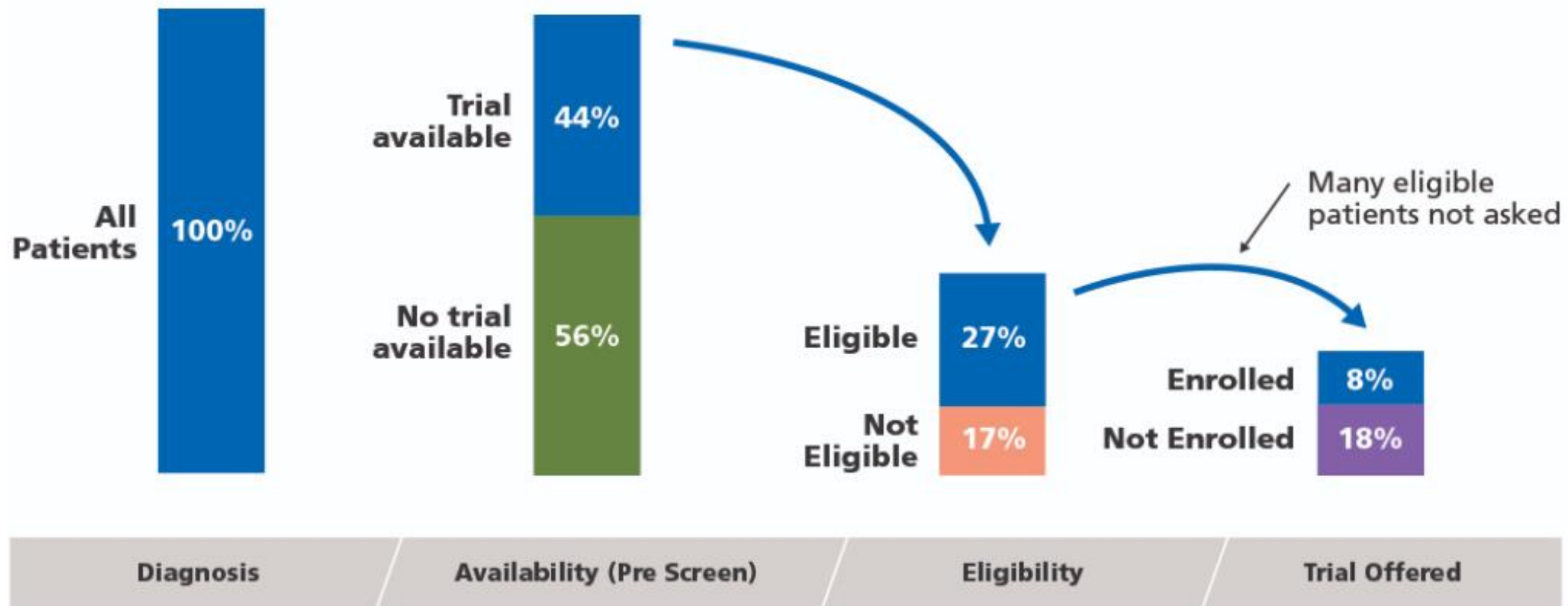
32% Phase 3 enrolment failure

Phase 3 being the largest cohort owing to 60% of trial cost



10 min to <2hrs

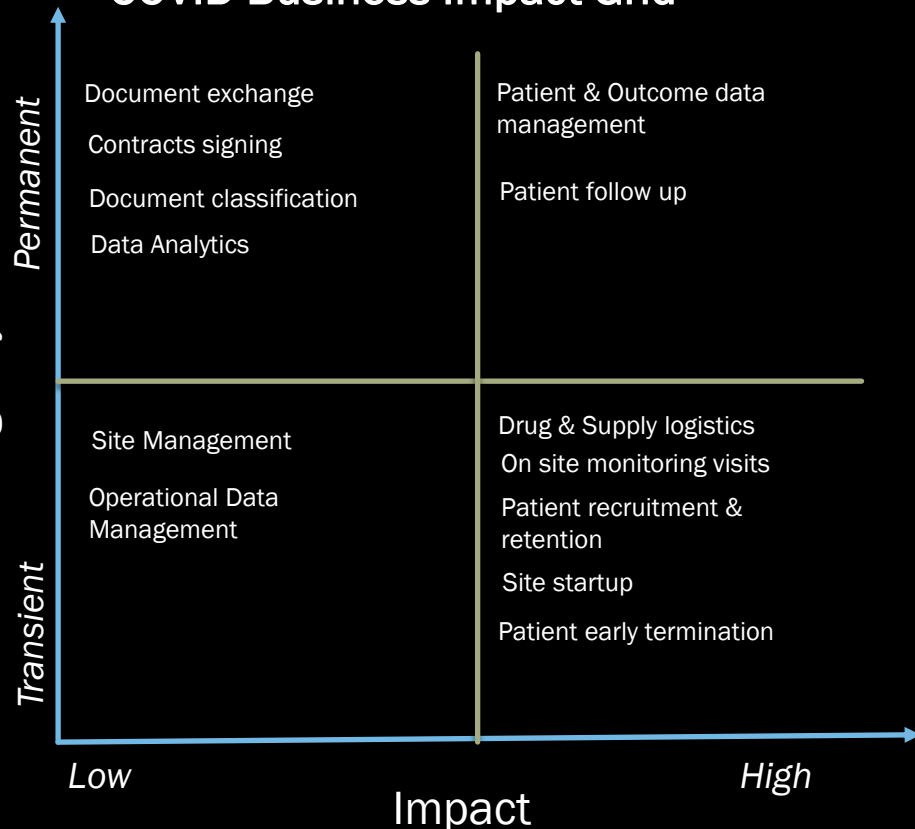
for patient eligibility screening with minimal to highly complex matching



Current landscape and what perpetuates status quo

In Covid-19 scenario – this has become a bigger problem with the global data showing a 65% decrease in the average number of new patients entering trials per study-site YoY during March

COVID Business Impact Grid



Post COVID Priorities

01

Low touch business processes

Enabled by



02

'Digital Leapfrogging' & Resilience on Cloud

and



03

Automation - led Sustainable Cost Takeout



CLINICAL KEY SOLUTIONS

Classify Documents :

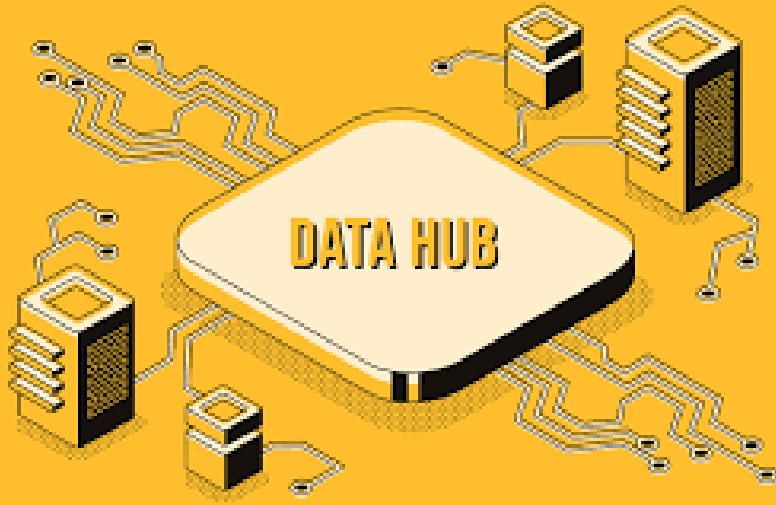
Automation of classification and packaging of documents generated from clinical studies (reducing it from 20 mins to 5mins)



Patient Recruitment:

Patient match based on Protocol criteria

Enabling creation of a resilient multi-tenant, multi-study managed centralized Cloud based Clinical Data Hub



The attributes of Data Hub are:

Clinical content management: Providing complete support for clinical data types required by ambulatory and in-patient systems

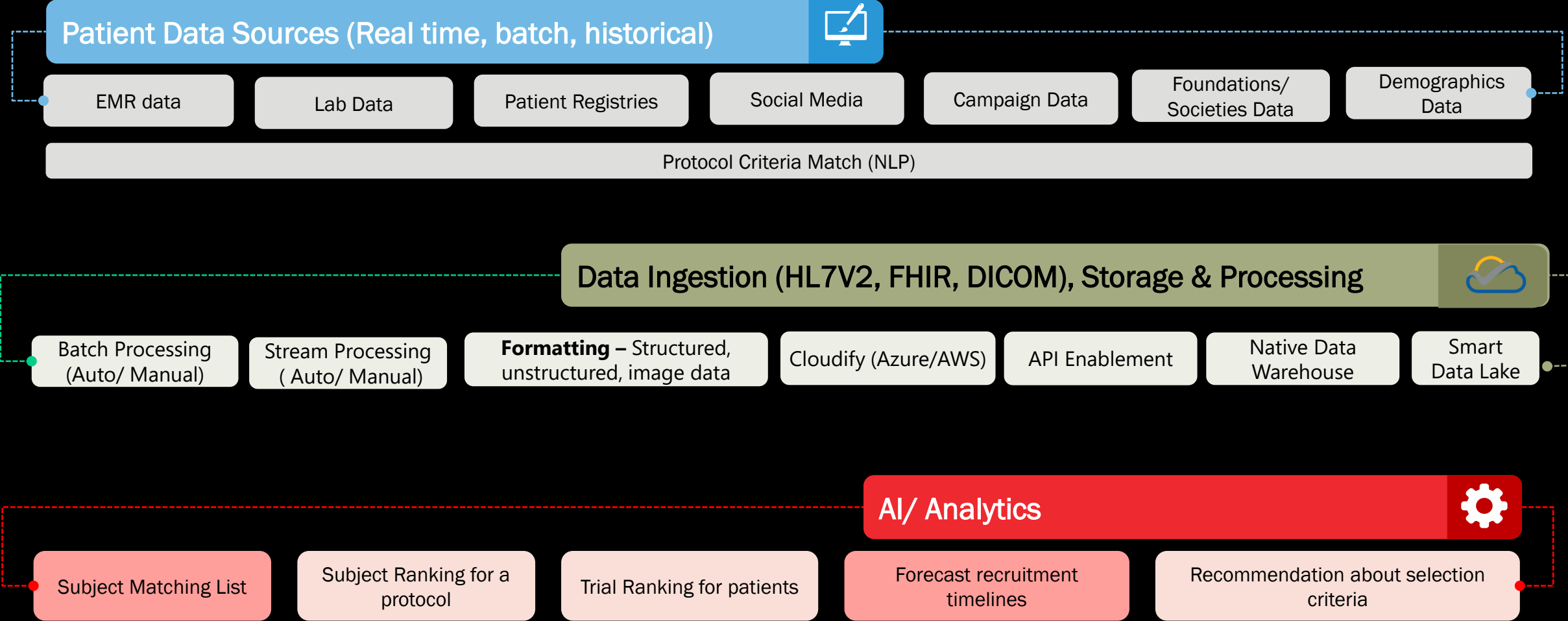
API: Enabling complete data access and enhanced system integration points

User portal: A user-accessible front-end for the display and management of patient data

Consent & data protection: Secure patient data management for sharing and access permissions

Cloud-hosting: Completely managed and uninterruptedly delivered solution leveraging Amazon Web Services (AWS), Azure and other available platforms

Patient Recruitment- (Data Ingestion, Storage & Decision Making)

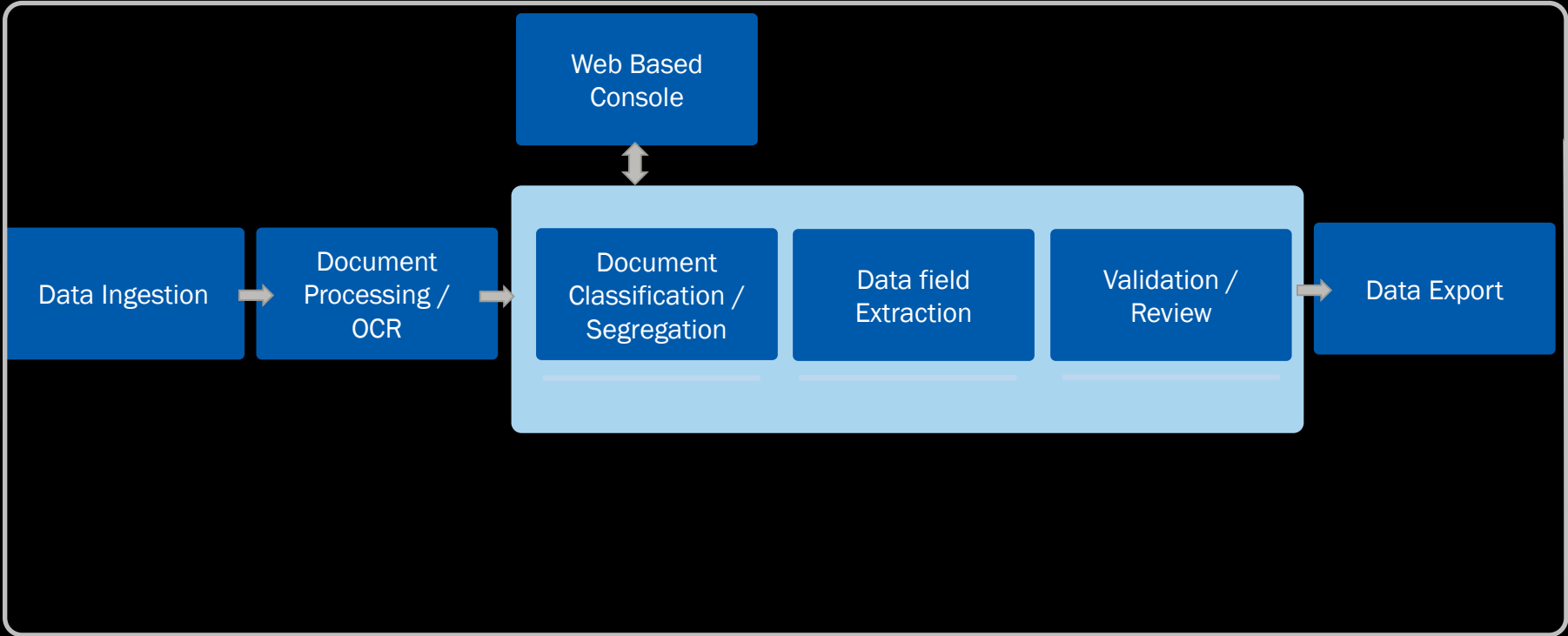


Classify Documents: Automation of Clinical Document Classification

Solution

Inputs ✓

Unstructured data across various document types – drug investigation report patient reports, investigator CV, subject enrollment reports etc. File formats – mail, pdf, word



Output ✓

Data classified per document types and structured data available in key value pairs for each input document

CONCLUSION

OFFERINGS FOR CLINICAL DATA ECOSYSTEM

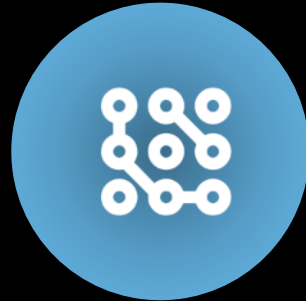


OFFERINGS



❑ Patient Recruitment

- AI/ML workbench for right patient recruitment
- Structured, semi-structured and unstructured data analysis of patient data
- Structured and computable protocol criteria format using natural language processing (NLP)



❑ Clinical Data Analysis

- Easily access to siloed historical data
- Data cleaning & harmonization across trials/ sources for Meta-analysis
- Upload and analyze large volume Real World datasets
- Pattern recognition and analysis of image/ text data



❑ Study Design & Startup

- Mine structured/ unstructured data to identify and match patient/ sites with trials
- Predict feasibility of clinical trials and forecast recruitment timelines
- Perform iterative Insilco clinical trial simulations



❑ Trial Execution

- Global trial execution with secure data sharing
- Oversight and Monitoring of incoming data
- AI/ML/DL with enhanced self service capabilities
- Authenticity, integrity, security, and confidentiality of data
- Support for newer data sources



Thank you