Integrating Real-World Evidence and Digital Health with AI

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CHAPTER 1

The Data Tsunami Challenge

Modern clinical trials now collect an average of average of **3.6 million data points**—three times three times the volume of a decade ago. Yet Yet traditional reactive methods fall short.

- Over 90% of adverse drug events go unreported through official channels
- Manual case processing consumes up to to two-thirds of PV budgets
- Traditional workflows take weeks or months to detect safety signals

3.6M

Data Points
Per clinical trial today

90%

Unreported
Adverse drug events

Real-World Evidence: Beyond Clinical Trials

RCTs suffer from limited generalizability due to stringent criteria that exclude vulnerable populations. RWE reflects actual clinical performance across diverse demographics and real-world conditions.

Electronic Health Records

Longitudinal patient tracking, phenotype identification, and clinical endpoint validation from clinical notes and lab results.

Digital Health Technologies

Real-time monitoring through wearables wearables capturing continuous physiological physiological streams and patient-reported reported outcomes.

Patient Registries & Omics

Disease-specific cohorts and genomic profiles profiles enabling precision medicine and and patient stratification.

CHAPTER 2

AI Architectures for Healthcare Data

Advanced Deep Learning Models

Graph Neural Networks (GNNs) represent healthcare claims and clinical networks as interconnected nodes, improving accuracy by 10-20 percentage points over traditional models.

Transformer Models process dense sensor data from DHTs, creating creating deep latent representations that excel at estimating blood blood pressure and arterial stiffness.

GNNs

Complex dependency identification in clinical networks

Transformers

Long-range pattern recognition in sensor data

Five-Layer AI Platform Architecture

Hospital systems are adopting scalable architectures that transition from batched updates to intelligent, real-time data pipelines with unified governance. governance.

Data Ingestion

Real-time streams and batched EHR data through unified pipelines and IoT gateways

Storage & Lakehouse

Centralized raw, curated, and enriched data in FHIR-compliant distributed systems

Processing & Vectorization

Converting data into AI-intelligible formats using vector databases and embeddings

Security & Fabric

Data consistency and privacy through intelligent fabric and encryption

Clinical Integration

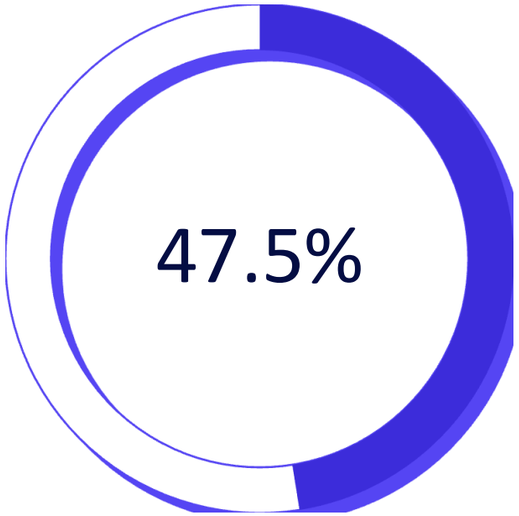
Embedded predictive alerts and decision support within existing workflows

CHAPTER 3

Revolutionizing Clinical Trials

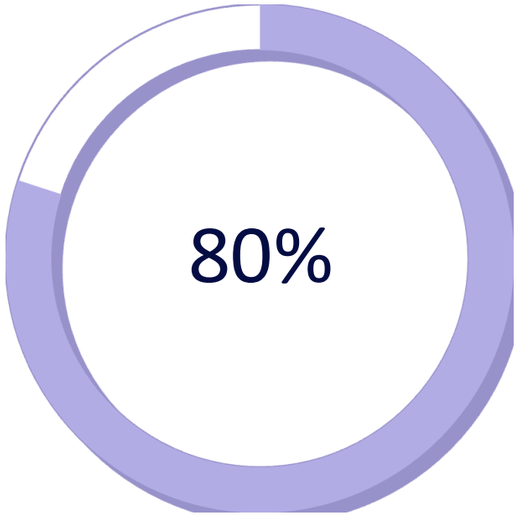
Synthetic Control Arms Transform Research

SCAs leverage RWD and historical trial data to create virtual comparator groups, reducing or eliminating traditional placebo groups—critical in oncology and rare diseases where placebos raise ethical concerns.



Oncology Share

Of SCA market in 2024



Workload Reduction

In recruitment screening

AI uses NLP to parse massive EHR datasets, identifying eligible participants based on complex phenotypes and accelerating recruitment timelines dramatically. dramatically.

Personalized Treatment & Digital Twins

Cardiovascular Digital Twins

Real-time data from wearable IoT devices feeds personalized virtual personalized virtual replicas that simulate different treatment treatment scenarios before clinical application.

Systems utilize Bayesian estimation and Kalman filters to manage uncertainty, ensuring virtual models accurately reflect physiological reality.

ALS Monitoring

AI-enhanced video analysis identifies visual visual biomarkers for remote progression progression tracking

Mental Health

Automated speech latency analysis correlates with schizophrenia and depression severity

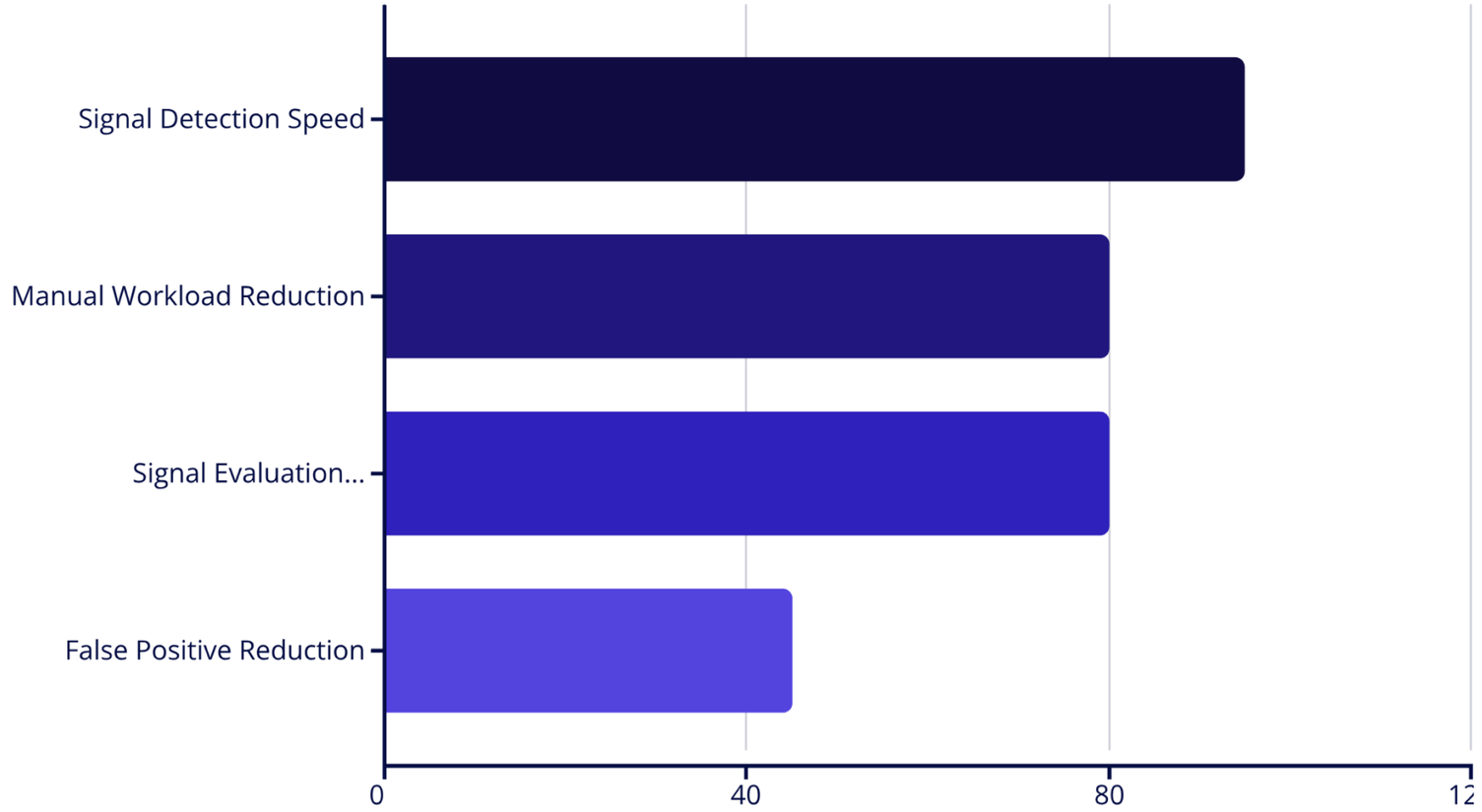
Cancer Diagnostics

AI examination of radiology and pathology pathology images improves detection rates rates

CHAPTER 4

AI-Driven Pharmacovigilance Revolution

Post-market surveillance is transitioning from reactive spontaneous reporting to proactive, real-time monitoring across EHRs, claims, social media, and wearables.



AI platforms detect safety signals in under 24 hours versus weeks with traditional methods. NLP extracts critical information from unstructured reports, reducing data entry workload by up to 80%.

FDA's 7-Step AI Credibility Framework

The FDA's January 2025 guidance establishes a risk-based process for validating AI models used in regulatory decisions, defining "credibility" as trust through performance evidence.

01

Define Question

Articulate the regulatory question the AI model addresses

02

Context of Use

Specify model role, scope, data inputs/outputs, and decision-making authority

03

Assess Risk

Evaluate model influence and decision consequence consequence severity

04

Credibility Plan

Develop validation strategy with performance metrics metrics and uncertainty quantification

05

Execute Plan

Conduct validation experiments and stress tests across tests across diverse cohorts

06

Document Results

Compile credibility report with outcomes and deviations explained

07

Determine Adequacy

Holistic assessment of model fitness for specified use

The Future: Collaborative Healthcare Transformation

Strategic Priorities for Success

High-Quality RWD

Prioritize completeness, standardization, and standardization, and clinical relevance of real-of real-world data sources

Risk-Based Frameworks

Adopt FDA credibility assessments and integrated evidence plans proactively

Algorithmic Transparency

Move toward explainable AI architectures that provide clear clinical rationales

Equitable Access

Ensure DHTs and AI interventions are accessible and validated for diverse populations

> "The convergence of RWE, DHTs, and AI provides the tools to transition from episodic, reactive evidence models to continuous, models to continuous, predictive, patient-centered precision medicine—redefining the boundaries of clinical research and research and therapeutic delivery."

Thank You

Please direct all inquiries to varuns8@hexaware.com

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