Leveraging Artificial Intelligence (AI) and Generative AI (GenAI) for Transforming Real-World Evidence (RWE) Across the Product Value Chain and Industry Functions

MSR40

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Select RWE Use Cases Across Value Chain

RWE Use Cases Across The Pharma Value Chain

Research & Discovery

- Biomarker Development
- Portfolio Planning
- Rare Disease Targeted Treatment
- Identification of Biological Pathway Insights

Drug Development & Regulatory Decisions

- Support Trial Design
- Identify Patient Cohort Design
- Patient Recruitment and Enrolment
- External Control Arm development
- Pragmatic Trials
- Develop Patient/ Disease Registries
- Supplement Clinical Trial Evidence for regulatory submissions

Post Market Safety and Surveillance

- Pharmacovigilance & drug safety through signal detection and analysis
- Label Extension
- Treatment adherence
- Inputs for Safety Reporting – Risk Management Plan, Risk Benefit Analysis, Aggregate Reports, Adverse Event Reports

Market Access & Reimbursement

- Health Economics & Outcomes Research, Support value story , reimbursement model & budget impact models for payers, HTA and Reimbursement Agencies
- Optimal Dosing by patient response and cohort analysis
- Optimize Commercial activities – field force, brand planning, commercial support
- Improve patient targeting by identifying underdiagnosis, misdiagnosis and undiagnosed

RWE Facts and Figures

Potential of Unlocking $300Mn by adopting RWE across value chain by a pharma [1]

92% FDA approval included RWE for NDA Type 1, Type 9 and BLA from 2021-2022 [2]

More than 40 regulatory & HTA guidance & frameworks released across US, UK, Europe, Mid East & Asia Pacific [3]

New ICH Topic Proposal in Dec 2024 for harmonizing RWD/RWE Terminology, metadata, and assessment principles [4]

Value and Volume | **Increased Regulatory Adoption**

100% of pharma & biotech with varying scale of RWE Initiatives [5]

$300Mn average RWE spend by top 10 pharma [6]

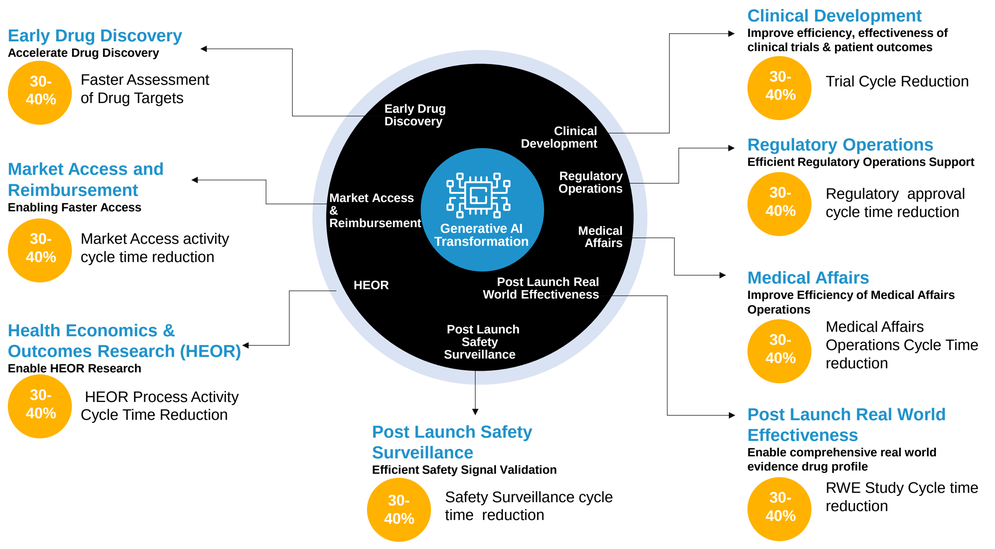
100% of Regulators, HTA, Reimbursement Agencies & Payers encourage RWE dimension for key approvals [7]

>15 Entities collaborate to develop robust RWE Ecosystem [8]

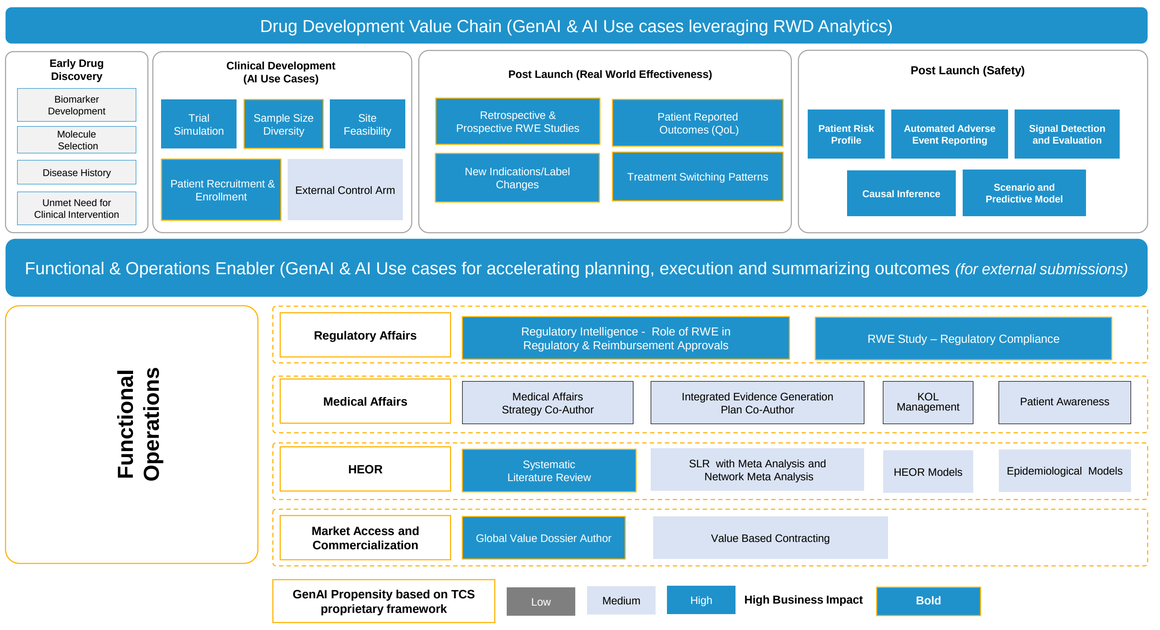
Industry | **Ecosystem**

AI & GenAI Potential for Enabling "Transformation of RWE Generation" Across Value Chain and Functions

Generative AI Transformation



AI & GenAI Propensity Framework for RWE Use Cases



Select RWE Use Cases Enabled by GenAI & AI, Across Value Chain

Research and Discovery

Drug Target Identification and Validation

Disease History & Unmet Need for Clinical Intervention

Biomarker Development

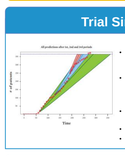
Role of RWD:
Analysis of Large-scale genomic datasets, EHR,EMR and Registry Databases.

Role of GenAI Enablement:

- Aid in structured analysis of RWD Data Sets
- Hypothesis Generation
- Generating Analysis ready data sets
- Generating analysis codes
- Generating visualization codes
- Summarizing analytical outcomes

Clinical Development

Trial Simulation



- Simulate Phase 1, 2a, 2b and 3 simulations with help of RWD analysis
- Simulate drug effects with LLM Models consisting of virtual patient data, physiological data, dose response relationships,
- Assessment of drug metabolism in special patient populations
- Validate statistical analysis
- Patient Recruitment, Enrollment

Sample Size Diversity Feasibility

- 2020 FDA Guidance Compliance for inclusive trials and broad eligibility
- Include patient population with diverse demographics , to map the trial outcomes with general population
- Site Patient Population Analytics with trial specific diversity

Patient Recruitment and Enrollment

- Feasibility of patient match with multiple trials
- Analysis Site Patient Data with a lens of trial inclusion criteria
- Faster recruitment & Enrollment
- Enabling Reanalyze eligibility criteria,

Site Feasibility

- Historical Insights about Site Performance correlated with specific trials & disease areas
- Analysis of patient pool and other demographics
- Investigator and Site Infrastructure

External Control Arm

- Serve as a placebo or comparator arm
- Retrospective Data Sets from past Trials or RWD which align with single arm trial inclusion criteria

Role of RWD:
Multimodal Retrospective RWD Analysis

Medical Affairs Operations

Medical Affairs Strategy Co-Author

Challenges:

- Manual & Disparate Medical Affairs Strategy Development Process
- Absence of single source of truth
- Challenges in global roll out

Role of GenAI Enablement:

- GenAI enabled content summarization of product specific Medical Affairs Strategy
- Summarizes the outcomes of multiple clinical, safety, patient reported and real-world researches for product specific MAS
- Auto update of the MAS

Integrated Evidence Generation Plan Co-Author

Challenges:

- Manual & Disparate Integrated Evidence Generation Process
- Absence of single source of truth
- Challenges in global replication, updating, retiring and integrating evidence generation plans
- Complex and Niche Resource Intensive process

Role of GenAI Enablement:

- Drug specific IEGP draft
- Integration of historical IEGP
- Summarize evidence generation plan linked with Medical Affairs Strategy

KOL Management

Challenges:

- Barriers in strategic planning
- Scientific communication based on clinical trial insights
- Absence of real-world data and patient voice in KOL Communications

Role of GenAI Enablement:

- Summarize RWE and RWI generated as a results of MAS and IEGP driven pivotal RWE studies

RWE Study Regulatory Operations

Regulatory Intelligence – Role of RWE in NDA and Reimbursement Submissions

Objective:

- Generate Regulatory Intelligence about historical landscape of role of RWE in influencing NDA and HTA/Reimbursement approvals
- Define an RWE strategy that regulators and HTA, Reimbursement agency & payers are more likely to accept

Challenges:

- Manual Process
- Complexity of synthesizing Global Regulatory Intelligence

Role of GenAI Enablement:

- Therapeutic Area specific regulatory, HTA, Reimbursement Agency & payer approval and rejection intelligence
- Scan and analyze through multiple regulators & agencies across globe in real time
- Create custom intelligence and dashboards for internal stakeholders

RWE Study – Regulatory Compliance

Objective:

- Generate Regulatory Obligations and SOP checklists specific to RWE studies as per the RWE regulatory guidance
- Corelate with clinical and safety mandates and guidance

Challenges:

- High Risk of Non-Compliance
- More than 40 guidance from Regulatory and HTA Agencies related to RWE.
- Lack of harmonization of guidance and terminologies.
- Interpretation & alignment complexities for regional and global RWE studies
- Resource Intensive Semi Automated Process

Role of GenAI Enablement:

- Focus on RWE Study Regulatory Compliance
- Consolidate all the applicable regulatory guidance by triaging RWE study execution country, disease area, RWE study type, RWD Sources, Reporting Stakeholder
- Generate Regulatory Obligations for compliance
- Generate SOP Checklist for the RWE Study

End to End RWE Study

Study Design	Study Conduct	Study Analysis	Study Closure
Regulatory Intelligence – Role Of RWE	RWE Study Data Transformation & Management	TLF Code Generation	Study Report
"Fit for Purpose Data " Feasibility	Informed Consent*	Analysis Outcomes Visualization Codes Generation	Manuscript
RWE Study Design	Site Contracting and Management*		
Regulatory Compliance – Regulatory Obligations and SOP Check List	Risk based Monitoring*		
Protocol & SAP Authoring			

* **Prospective RWE Studies**

Select RWE Study Phasewise Use Cases

RWE Study Design

Objective:

- Optimize the RWE Study Design process

Role of GenAI Enablement:

- Workflow including specific disease area with country specifications
- Generate a first draft of study design
- Generate references of published study designs of relevant disease

TLF Code generation and Visualization

Objective:
Optimize the Real-World Data analysis and generate TLF (Table, Listing and Figures) Codes

Role of GenAI Enablement:

- Generate List of analysis
- Mock shells for TLFs
- Generate and execute SAS/ R/Python programming code
- Review

Real World Data Transformation & Management

Objective:

- Optimize the Real-World Data Curation and Transformation to generate analysis ready Real World Data Sets.

Role of GenAI Enablement:

- Clean and normalize RWD and correct any inconsistencies or missing values. Common scale and format from various sources
- Map data fields from different RWD sources to a unified schema
- Map different coding systems (e.g., ICD-10, SNOMED CT) to a common terminology
- Entity resolution techniques merge records referring to the same patient across different data sources, ensuring a single, comprehensive patient profile.
- Enrich data by adding demographic and socioeconomic information and create longitudinal datasets

Post Launch Safety Surveillance

Patient Risk Profiling

- Generate detailed risk profiles for individual patients Generate personalizing treatment plans and monitoring strategies to minimize the risk of adverse events.

Benefits: **Personalized Safety**

Automated Adverse Event Reporting

- Automate the extraction and summarization of adverse event reports from diverse sources such as EHRs, patient forums, social media, and online health communities.
- Natural language processing (NLP) to be used to interpret unstructured text data and generate structured reports.

Benefits: **Comprehensive Safety Reporting**

Signal Detection

- Enhance signal detection by identifying correlations and patterns in large datasets that may indicate potential safety issues.
- Generate hypotheses about potential drug-AE relationships and prioritize signals for further investigation.

Benefits: **Reduced cycle time of signal detection & analysis**

Predictive Modeling & Scenario Simulation

- Predictive models that forecast the likelihood of adverse events based on patient characteristics, drug usage patterns, and historical data.
- Simulate different scenarios and predict the impact of various factors on drug safety. For example, model the effects of dose variations, drug interactions, or demographic changes on adverse event rates.

Benefits: **Proactive understanding of potential risks and planning mitigation strategies.**

Causal Inference

- Infer causal relationships between drugs and adverse events by generating counterfactual scenarios and analyzing the differences.

Benefits: **Strengthen the evidence for causality in situations where traditional statistical methods may fall short.**

Signal Evaluation

- **Clinical Assessment:** expert review of potential signals to determine clinical relevance.
- **Case Studies:** Detailed review of individual cases to understand the context and possible causality.
- **Comparative Analysis:** Comparing incidence rates with other drugs in the same class or with historical controls

Benefits: **Enabling compliance with regulatory reporting and support risk minimization strategies**

HEOR (Qualitative and Quantitative)

E2E Systematic Literature Reviews (SLR) - Qualitative

Objective: leverage AI & GenAI to automate and simplify manual, complex tasks and workflows of end-to-end systematic literature review

Role of GenAI Enablement:

- Protocol Generation
- Search Strategy Generation & Execution
- PICOS development
- Deduplication
- Abstract Review and Full Text Screening
- Data Extraction Grid Generation
- Critical Appraisal with relevant checklist
- Population of Data Extraction Grid
- Report Authoring
- Reference Generation
- Improving Search Efficiency
- Use AI-driven semantic search algorithms
- Advanced Synthesis and Summarization
- Continuous Update

E2E - Health Economics Model - Quantitative

Objective: Assist and Augment the model development process for helping evaluation of the economic impact of healthcare interventions, treatments, and policies. They help stakeholders understand the cost-effectiveness, efficiency, and value of different healthcare options.
HEOR models which can be assisted and augmented leveraging statistical techniques like decision tree, Monte Carlo, Markov etc.

- Cost Effectiveness (CEA) models
- Cost Utility Analysis (CUA) models
- Cost Benefit Analysis (CBA) models
- Cost Minimization Analysis (CMA) models
- Budget Impact Models (BIM)

Role of GenAI Enablement:

- Data Collection and Preprocessing
- Model Selection and Training
- Scenario Generation
- Analysis and Interpretation
- Validation and Refinement

Market Access & Reimbursement

E2E Global Value Dossier Author

Objective:
Optimize the E2E global value dossier authoring process

Role of GenAI Enablement:

- Automated Content Creation & Extraction:
- Data Integration:
- Section Drafting :
- Summarization:
- Regional Adaptation:
- Stakeholder-Specific Versions:
- Integrated Summary of Systematic Literature Review, Health Economic Analysis Models
- Automated Chart Generation:
- Interactive Dashboards:.
- Consistency Checks:

E2E Value Based Contracting Author

Objective:
Optimize the E2E value-based contracting

Role of GenAI Enablement:

- Contract Generation and Customization
- Predictive Analytics:
- Risk Stratification :.
- Financial Risk Modeling Negotiation Scenario Simulation
- Insight Generation

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