Need for Adoption of Patient Centric Evidence Generation Management Best Practices

RWD91

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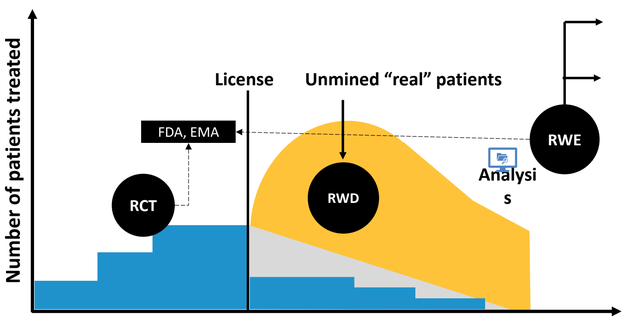
Real Word Evidence – Augmenting Patient Centricity[1]



Patients treated, no active surveillance

Patients in observational studies, registries, etc

Patients in RCTs (or other interventional studies)

Key Post Launch Real World Evidence Objectives

- Epidemiological Analysis
- Disease Progression
- Clinical Trial Design Insights for new Phase 3 trials
- Real World Effectiveness in a specific population subgroup
- Head-to-Head Comparison of effectiveness and/or safety
- Cost Effectiveness
- Treatment Burden
- Patient Reported Outcomes
- Treatment Adherence/Switching Pattern
- Label Extension (Secondary Indication)
- Long Term Safety Surveillance

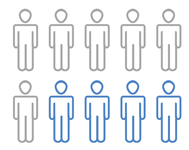
* Adaptation from How real-world evidence transforms the entire healthcare ecosystem. (n.d.). DXC Technology. https://dxc.com/us/en/insights/perspectives/paper/how-real-world-evidence-transforms-the-entire-healthcare-ecosystem

Patient Centric Real World Evidence Generation Life Cycle Management: Industry Observations & Challenges [2]

Evidence Planning Challenges

1. Evidence Planning
2. Project Tracking
3. Global Dashboard

1 Evidence Generation Gaps - Global, Regional, Local , process variation



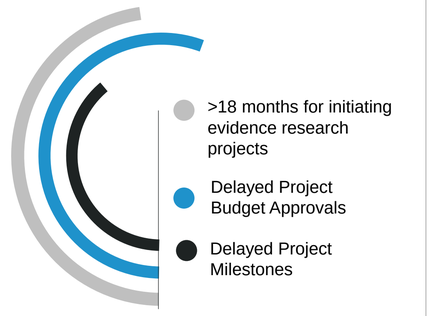
6 out of **10**

Evidence Generation Leads experience challenges related global evidence planning

- Lack of adoption of Integrated Evidence Plans for evidence requirements of external & Internal stakeholders, internal functions and regional stakeholders across the product life cycle

>83% Evidence Generation Process lack global integrations

2 Significant delay in starting Evidence Projects

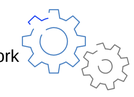


More than 50%

Time spent on entering data rather than qualitative evidence evaluation

3 Lack of Comprehensive Return of Investment on Evidence Generation

Low Maturity of adopting Comprehensive framework for EvidenceGeneration RoI Framework



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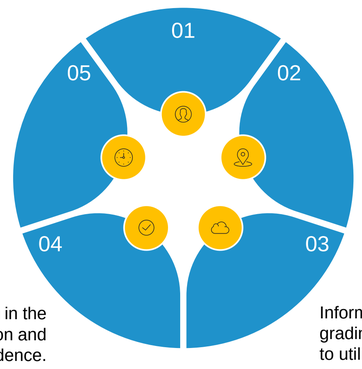
Lack of Investment Optimization due to inability to prioritize decision making

>65%

Evidence Generation Activities lack Standard measure of Evidence Impact

Key Challenges in Demonstrating Tangible Patient Centric Outcomes

Lack of adopting Integrated Evidence Generation as Patient Centric approach rather than an innovation adoption



Lack of Adoption of best practices in Integrated Evidence Generation & Evidence Generation management, can save patient lives by prioritizing and demonstrating key evidences earlier in the lifecycle

Informal mechanisms for evidence grading. The grading needs to be linked to utility, role and contribution in decision scenarios across the product life cycle.

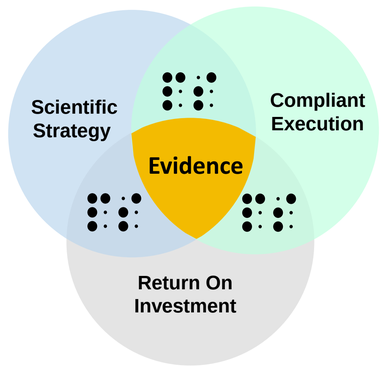
Significant variation in the adoption, impact calculation and governance of the evidence.

Significant variation in designing and applying comprehensive definitions of the evidence metrics.

Best Practices in Strategy Development for patient centric evidence generation life cycle management

Collaborative development of a comprehensive framework demonstrating tangible role & utility of all the evidence generated across the life cycle and linkage with patient centric outcomes.

The framework needs to be adopted for all the evidence generated for each product across the product life cycle.



The investment for evidence generation management activities across life needs to be linked with patient centric objectives

The framework involves a tangible scoring for each evidence by evaluating the value and impact of evidence Additionally, weightages with respect to scientific strength of the evidence, to be applied as per NCCN[3] evidence scoring guidelines (Oncology) and for RWE studies include ISPOR[4], STROBE[5], PCORI[6],ENCePP[7], GRACE[8] and others.

Best Practices for Adoption of Digital Transformation for Global Evidence Generation

Strategic Evidence Leadership

Collaborative Workflow to enable global evidence generation journey

Inclusive Harmony

Global harmonized processes with inclusive flexibility of global regional & local variation

Single Source Of Truth

Centralized repository for all the evidences

Project Dashboard & Monitor

Global View of evidence generation project status

Embedded Innovation to drive Agility

GenAI & AI driven functionalities

Return on Investment Scorecard for Evidences

Tangible and metrics driven utility of all evidence types

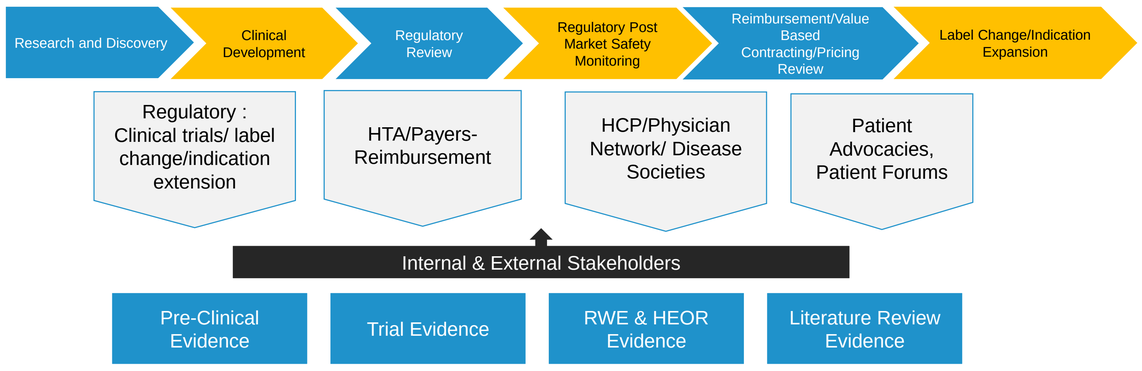
Accelerate & Optimize Evidence Generation

>40 % reduction in time and cost of evidence generation cycle

Strategic Focus on Evidence Value

Tangible Outcomes Framework – Return on Investment of Evidences Across Product Life Cycle

- Development and implementation of a 360° Value Score Framework for all the evidences (Research and Discovery, Randomized Control Trial, RWE, Health Economics and Outcomes Research, Systematic Literature Review & Market Access – Value Based Contracting) generated across product life cycle
- Eliminate Informal & inefficient mechanisms of grading evidences by linking scientific & commercial utility of evidence, role and contribution with context specific decision instances across the product life cycle .
- Efficient management of the evidence utility, governance and impact of evidences generated through out the product lifecycle.
- Mitigate the challenge of variation of evidence impact measurement metrics across regions.



Illustrative Product Specific Evidence Scoring Framework Across Life Cycle

Evidence Methodology Category	Illustrative KPI	Tangible Decision-Making Impact for respective stakeholders						
		Revenue ($)	Internal	Regulatory Agency	Reimbursement	Patient	Cost	No of references
Pre-Clinical	• % contribution of PK/PD/ADME/Toxicology Outcomes to Phase 1 • % of publication referencing specific evidence • Cost of evidence generation	NA XX XX	X NA NA	NA NA NA	NA NA NA	NA NA NA	NA NA $	NA X NA
Clinical & Safety	• % clinical trial failure rates • Number of clinical trial approvals • % of submissions (including label expansions) where evidence is considered "substantial" evidence for positive regulatory opinion/topic closure • %. of ODA/PIP* acceptance • % of post marketing regulatory commitments approvals • % of publication referencing specific evidence • Cost of evidence generation	XX XXY XXY XX XX XX XX	XX XXY XXY XX XX NA NA	XX XXY XXY XX XX NA NA	NA XX XX XX XX NA NA	XX XXY XXY XX XXY NA NA	NA NA NA NA NA NA $	NA NA NA NA NA XX NA
HTA (RWE &, HEOR)	• % of HTA submissions with positive outcome • % of HTA submissions where RWE is considered substantial part for positive HTA decision • % of HTA submissions where clinical evidence is considered substantial part for positive HTA decision • Time to access decision - faster • % instances to support positive outcome of substantial part of price negotiations • % managed entry agreements/value-based contracts with positive outcomes • % of improved pricing/premium pricing decisions with positive outcome • % of formulary inclusions with positive outcome • % of publication referencing specific evidence • Cost of evidence generation	XX XX XX XX XX XX XX XX XX XX NA XX	X X XX XX XX XX XX XX XX XX NA NA	NA NA NA XX XX XX XX XX XX XX NA NA	XX XX XX XX XX XX XX XX XX XX NA NA	XX XX XX XX XX XX XX XX XX XX NA NA	NA NA NA NA NA NA NA NA NA NA $	NA NA NA NA NA NA NA NA NA X NA
Systematic Literature Review along Meta Analysis or Network Meta Analysis (as a supportive evidence)	• % clinical trial failure rates • $ clinical trial approvals • % of submissions (including label expansions) where evidence is considered "substantial" evidence for positive regulatory opinion/topic closure • %. of ODA/PIP acceptance • % of post marketing regulatory commitments approvals • % of publication referencing specific evidence • Cost of evidence generation	XX XXY XXY XX XXX NA XX	XX XXY XXY XX XXY NA NA	XX XXY XXY XX XXY NA NA	NA NA NA NA NA NA NA	XX XXY XXY XX XXY NA NA	NA NA NA NA NA NA $	NA NA NA NA NA X X NA