NEXT GENERATION RWE: WHAT FACTORS ARE ESSENTIAL TO FULLY FEDERATED AND AI-ENABLED RWE AND OUTCOMES RESEARCH?

RWD12

SCAN ME

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BACKGROUND

Despite progress in RWE research, significant challenges remain to advance data assembly and analysis. Issues like limited patient numbers, data silos, privacy concerns, adaptive study design acceptance, AI utility, data restrictions, and methodological barriers hinder data access and evidence generation, especially in rare diseases and niche oncology. This analysis examines these factors and identifies needed advancements to drive the next generation of RWE research.

METHODOLOGY

The analysis reviewed peer-reviewed (PubMed) and grey literature and evaluated next-generation RWE solutions for key challenges. Out of 9,689 abstracts, 34 articles met criteria, and 44 AI-enabled companies were identified, focusing on real-world evidence and outcomes research. The study assessed current methodological and practical solutions, highlighting areas for further RWE development.

RESULTS

Literature suggests most AI solutions focus on supporting R&D, de-risking clinical trials, predictive modeling, or commercial optimization. Fewer address HEOR, HTA, market access, or AI applications for mining large datasets, and only a small number focus on federated data networks and full interoperability.

The analysis identified core areas where AI companies develop solutions for generating regulatory and HTA evidence, forming the basis for a detailed evaluation of AI-enabled companies. Overall, the literature does not yet fully capture the scope of AI solutions currently deployed in healthcare and RWE research.

FIGURE 1: CORE PROBLEM AREAS WHERE AI-ENABLEMENT IS ADVANCING SOLUTIONS

- Difficulty finding new patients/ enriching patient data
- Data protection is complex & resource intensive
- Reducing site burden is crucial to scalable, quality solutions
- Data islands limit stakeholder collaboration
- Strict data privacy regulations limit access to valuable data
- Mining data is inefficient and increases timelines
- Data challenges impact study design
- Limited interoperability among commercial data handling solutions
- Limited advancement of virtual solutions that solve for traditional model limitations

CONCLUSIONS

As RWE evolves in an AI-enabled, interconnected world, addressing data access, interoperability, and secure data sharing is key to enhancing research reliability and output. Here are the main conclusions from this analysis:

- Although health tech and AI in healthcare are progressing, there is still a long way to reach an optimal state, potentially advancing faster than regulators and decision-makers can track.
- The AI-enabled research environment is fragmented, with most providers focusing on niche solutions. Researchers may need a toolkit of solutions for broader challenges, and integration of these tools could maximize the use of global, disparate data sources.
- Data ownership and sharing incentives limit fully federated healthcare research. Shifting views on data ownership is crucial, though some providers are advancing non-movement data sharing solutions.
- Most AI solutions focus on predictive models and analytics (e.g., de-risking trials, patient finding), while fewer rethink data federation and patient integration for more robust AI application.
- Solutions that advance RWE will address practical challenges identified here and others yet to be considered.

As AI-driven healthcare tools evolve, there is an opportunity to tackle long-standing research limitations, requiring fresh perspectives and adaptive practices.

FIGURE 2: PERCENT OF HEALTH TECH COMPANIES ADDRESSING CURRENT DATA LIMITS

FIGURE 3: PERCENT OF COMPANIES ADDRESSING DATA INTEGRATION & ANALYTICS CHALLENGES

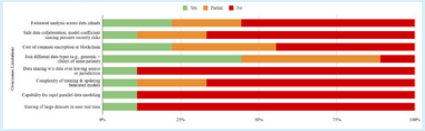

FIGURE 4: PERCENT OF HEALTH TECH COMPANIES ADDRESSING KEY AI CHALLENGES

FIGURE 5: PERCENT OF COMPANIES ADDRESSING DATA INTEGRATION & ANALYTICS CHALLENGES

REFERENCES - SEE QR CODE

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