The Evolution and Future of Integrated Evidence Planning

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Introduction

The healthcare landscape is constantly evolving, with emerging treatments and therapies that promise to improve patient outcomes. However, bringing these treatments to market and delivering them to patients is complex and time-consuming. In recent years, the value of adopting an integrated approach to planning, generating, and managing evidence that demonstrates the value of innovations is becoming more widely accepted. This approach expedites patient access to treatment.

Even though integrated evidence planning (IEP) has been known to industry leaders for over 20 years, many companies still face barriers to efficiently and effectively implementing it. Only a few pioneering life science companies have adopted IEPs enterprise-wide to cover the activities of multiple evidence-generating functions, including clinical development, medical affairs, real-world evidence, health outcomes, epidemiology, etc. Some life science companies have established a dedicated IEP function that centralizes planning and focuses on the needs of all external customers, such as patients, payers, HCPs, and regulators, irrespective of the type of evidence required (e.g., real-world evidence, patient surveys, interventional studies, etc.).[1]

Axtria hosted a webinar titled *"Evidence Generation: Evolution and Future of Integrated Evidence Planning,"* (please click the link to watch the live video) where a panel of industry leaders from top pharmaceutical companies in the IEP space discussed the past, present, and future of IEP and answered the following questions:

- How has IEP evolved up until this point?
- How do organizations harness all available and emerging evidence-generation methods across product lifecycles?
- What are the emerging and innovative trends in IEP?

This white paper summarizes the evolution of IEP and highlights the emerging trends rather than the execution of evidence generation, which is another broad topic in and of itself. Starting with a brief overview of the benefits of IEP (Section 1), followed by the barriers associated with implementing IEPs (Section 2), we discuss how life science companies' maturity evolves in terms of the four pillars of IEP, people, platform, process, and analytics (Section 3). Section 4 describes the current, emerging, and innovative trends in IEP. The white paper concludes by providing a concise summary of the key points and highlighting the forward-looking global trends that will shape the future of evidence generation within life science companies.

Executive Summary

- In recent years, the life sciences industry has increasingly acknowledged the significance of adopting an integrated approach to planning, generating, and managing evidence to demonstrate the value of innovations. This approach aims to expedite patient access to treatment.
- IEP is a comprehensive planning process that aims to incorporate the needs of all customer groups in the planning of evidence needed for successful approval, launch, and post-launch. As part of the IEP discussion, different types of data, scientific methods, and cross-functional expertise are required across a product's lifecycle to generate key information about its benefits, safety, and value in the most efficient way. A properly designed and executed IEP leads to the efficient use of limited resources and generates holistic evidence that meets the requirements of key stakeholders, including patients, regulatory authorities, health technology assessment (HTA) bodies, payers, healthcare professionals, healthcare providers, and policymakers.

- To effectively implement IEP, a comprehensive, multifaceted approach should be adopted, which involves engaging skilled individuals, optimizing processes, leveraging platforms, and potentially industrializing analytics in the future.
- Some barriers to implementing IEP include the capabilities of those in key roles for achieving cross-functional alignment and coordination, a comprehensive and aligned understanding of customer needs across the team, awareness of the existing evidence, and resource allocation and prioritization. Finally, a cultural shift toward cross-functional planning and leadership buy-in is essential for successful IEP adoption.
- Different companies are at varying levels of IEP maturity regarding people, processes, platforms, and analytics.
- Regardless of where a company is in its journey of building integrated evidence plans, in the coming years, evidence generation will likely see increased technology adoption and the use of patient-reported data combined with advanced analytics, including artificial intelligence/machine learning (AI/ML) and natural language processing (NLP). The concept of "whole patient health" could also play a pivotal role in formulating integrated evidence generation (IEG) plans. A constantly changing regulatory landscape that includes laws like the Inflation Reduction Act (IRA) in the US can potentially change the dynamics of evidence generation. Integrating different analytical approaches for well-organized evidence generation will be important. The approaches vary from fundamental descriptive analysis to predictive machine learning to a counterfactual causal inference analysis that is now gaining more traction from regulatory bodies around the world. Combining rapid cycle analytics with generative AI to generate on-demand insights could also become a new trend.

Integrated Evidence Planning: What is it?

Integrated evidence planning is a comprehensive process that aims to incorporate the needs of all customer groups in planning the evidence needed for successful approval, access, and uptake in launch and post-launch periods for each market. The team considers these needs alongside the target product profile (TPP) to shape specific objectives on what the product can realistically deliver to customers in terms of efficacy, effectiveness, safety, value, etc. These objectives serve as the anchor to review the existing evidence base within and outside the company, determine evidence gaps, and discuss how these should be filled.

As part of the IEP discussion, different types of data, scientific methods, and cross-functional expertise are required across a product's lifecycle to generate essential information about its benefits, safety, and value in the most efficient way. Integrated evidence plans often leverage diverse but complementary methods across the product's lifecycle, including randomized clinical trials (RCTs), economic models, and observational studies using real-world data (RWD).

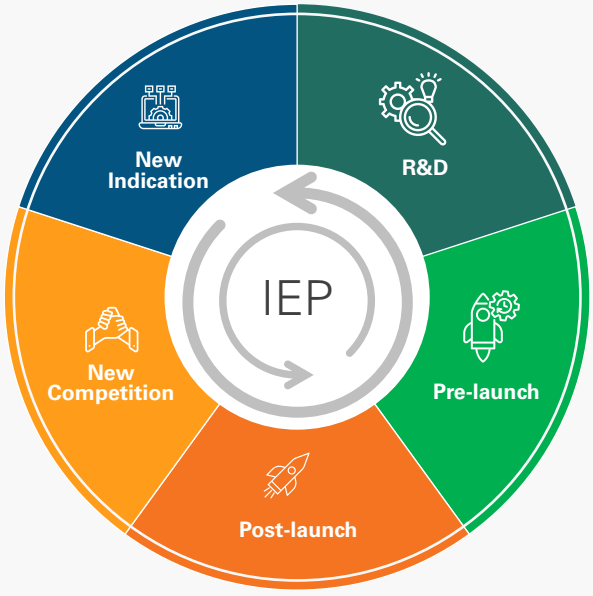
Using an IEP early creates an iterative, cross-functional process throughout the drug development life cycle.[2] Integrated evidence plans can be developed as soon as customer needs are identified and TPPs are available – as early as Phase 1 study planning, all the way through post-launch. They should be updated frequently and reprioritized based on data readouts, competitor landscape, and evolving requirements of evidence generation from customer needs.

Integrated Evidence Planning: Why is it needed?

Integrated evidence plans driven by the ability to provide relevant evidence that meets each customer's specific needs can lead to faster approval, reimbursement, and access to care and improve decision-making by considering multiple needs in the treatment landscape and a wide breadth of evidence types to address these. Most importantly, a meticulously designed and executed IEP uses limited resources and time efficiently, reducing duplication and fostering communication and cooperation across different functions within a company. It generates holistic evidence that meets key stakeholder requirements, including patients, regulatory authorities, HTA bodies, payers, healthcare professionals, providers, and policymakers (Figure 1).[3]

In addition, drug development is becoming more circular, allowing us to anticipate post-launch real-world evidence (RWE), studies during research and development (R&D), and clinical development. Post-launch, insights from interactions with HCPs can inform new clinical developments, including potential new indications.

Figure 1: Drug development is becoming more circular



RWE plays a crucial role in informing RCTs and their outcomes, informing more RWE

Source: Axtria Inc.

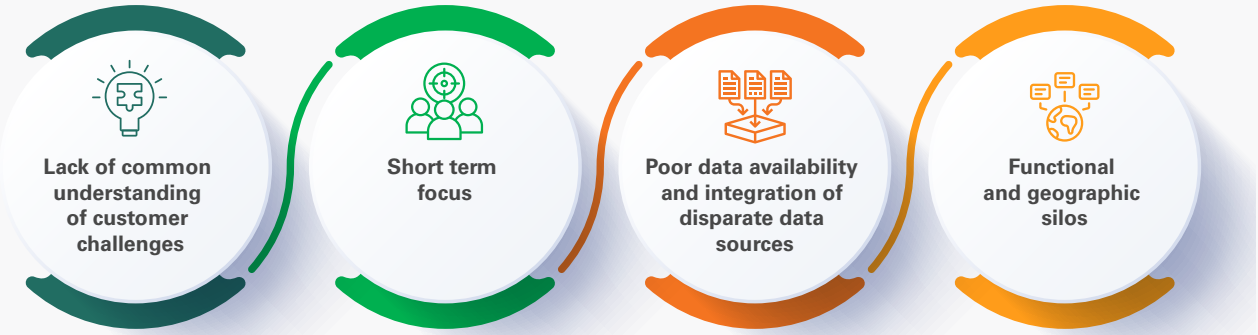
The demand for evidence amongst regulators, payers, providers, and patients changes constantly. Regulators are increasingly considering evidence beyond clinical trials (CTs), including the use of RWE, to support market authorization. Examples of such uses include revising or augmenting product labels, highlighting or alleviating safety concerns, and using external/synthetic control arms when RCTs are infeasible, as in rare diseases, ethical concerns, and issues related to treatment switching and crossover.[4, 5] Incorporating multiple types of evidence into clinical practice guidelines can also increase transparency in the drug development process and lead providers to make more informed decisions, thus providing stakeholders with a more complete understanding of the value of new therapies.

Coverage and reimbursement are two areas where payers need to make increasingly complex decisions, incorporating a variety of criteria, including efficacy, costs, side effects, and patient preferences, and adopting a long-term view of value across jurisdictions.[6] With the additional RWE generated post-launch, manufacturers can renegotiate the positioning and pricing of their products during the reimbursement decisions. Healthcare providers need RWE to inform guidelines that can improve clinical practice. More importantly, patient centricity is growing with increasing focus on the whole patient's health. Companies can harness even more capabilities to generate a comprehensive and objective picture of a product's value through the growing availability of data collected through wearable devices, social media, patient surveys linked to claims or electronic health records (EHRs), and novel analytic methods.

Integrated Evidence Planning: What are the current and emerging barriers to implementing IEP?

Evidence generation involves risks, challenges, and costs, which life science companies must balance against expected benefits. Several emerging barriers hinder the development and implementation of IEPs in the biopharmaceutical industry. Historically, IEP implementation faces four persistent challenges (Figure 2).

Figure 2: IEP barriers



Source: Axtria Inc.

There is a lack of shared understanding of customer needs within the cross-functional team and across relevant geographical units. The wide variety and large volume of customer data from different sources, like medical science liaisons, regulatory discussions, payer advice, patient market research, and physician market research, can make management and alignment challenging, leading to a singular focus from each function on addressing only the needs that they are aware of.[7]

Short-term focus, which often is the case for small biopharma companies, refers to how they predominantly focus on producing evidence through CTs to obtain regulatory approval rather than generating wide-ranging evidence that enables successful launch and utilization throughout the product life cycle.

A system for collating all available internal evidence and external studies is often missing, which poses difficulties in determining the existing accessible evidence and the potential need for additional data.[8] As a result, gaining a complete, cross-functional perspective becomes difficult. Finally, information on customer needs and available evidence is not optimally shared across functions or geographies. And companies often overlook geographic coordination as they prioritize strategies tailored to specific markets.

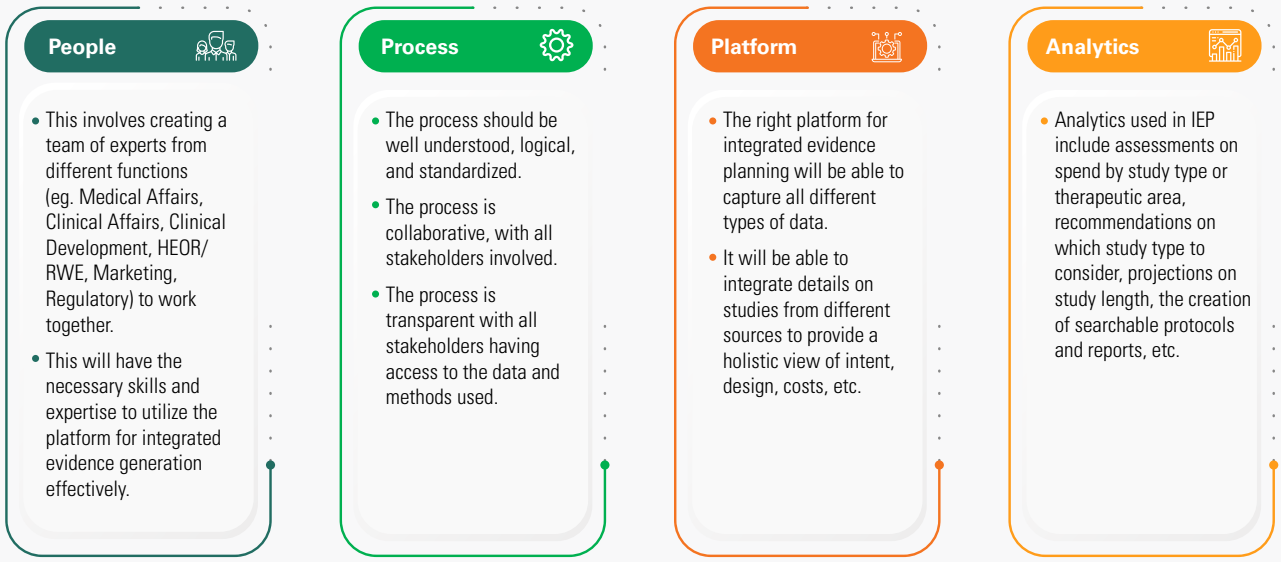
A broader IEP approach requires additional time and involvement from multiple evidence-generating functions such as clinical development, medical affairs, epidemiology, health economics and outcomes research (HEOR), and active participation from commercial, market access, regulatory affairs, etc.[9]

New types of barriers have also been emerging, making the implementation of IEP even more challenging. Data complexity and integration challenges arise from the increasing volume and diversity of available RWD, such as social media, biomarkers, and genomic data. Harmonizing disparate sources while ensuring data quality and privacy is crucial. Regulatory acceptance of RWD varies, and companies must navigate shifting expectations. The speed with which evidence is generated should be even faster for companies facing formidable market competition. Although necessary, simply generating evidence is not sufficient. Generating evidence and counter-evidence and uncovering hidden evidence about competitors with greater velocity is increasingly important.

The Four Pillars of Integrated Evidence Planning

To effectively implement IEPs, a comprehensive, multifaceted approach should be adopted, which involves engaging skilled individuals, optimizing processes, leveraging platforms, and industrializing analytics (Figure 3).

Figure 3: IEP consists of harmonizing the four pillars: people, process, platform, and analytics



Source: Axtria Inc.

People – Combining Expertise from Different Functions

The success of IEP resides in effective cross-functional collaboration. To ensure an effective and cohesive evidence-planning process throughout the product life cycle, pharmaceutical companies should prioritize cross-functional collaboration from an early stage. Moreover, biopharma companies should invest substantially in cultivating skills for key roles to enable superior cross-functional engagement, fostering a culture of collaboration and innovation.

The cross-functional team should have representation from different line functions, like R&D, clinical development, medical affairs, RWE/HEOR, marketing, and regulatory, to work together, backed by a clear mission and vision.[10] The team should include members from across global, regional, and country affiliates who can work collaboratively and effectively, gathering relevant evidence, including data acquisition, analysis, and dissemination to the stakeholders. The cross-functional team should have clear roles and responsibilities and follow specified workflows while performing all tasks. The team should have access to training and development opportunities to stay updated on the latest advances in their respective fields.

To enable this evolution, some companies have formed an IEP Center of Excellence that coordinates and is accountable for training teams on IEP principles, individual roles, and accountabilities, facilitating workshops, and ensuring a robust discussion of customer needs and evidence types.

Another approach is to *utilize external partners* (click the link to view the page) to augment the capabilities of the in-house teams. This approach offers several advantages, like optimizing cost and efficiency, innovation, scalability, and blending functional expertise with robust strategic and analytical skills.

Process – Standardized and Collaborative Process

Integrated evidence planning can be effectively enabled through a standardized process emphasizing consistency, clarity, and flexibility. Consistency ensures that all stakeholders are aligned and follow the same protocols, which helps maintain the collected data's integrity and reliability. Ensuring that the process is well understood involves comprehensive training and clear documentation so everyone involved is aware of their roles and responsibilities. Flexibility is crucial to accommodating the various needs of drug development at different stages, from early research to post-market surveillance.

The collaborative process for IEPs should be transparent and inclusive of all relevant stakeholders, providing them access to all data and methods used while maintaining data-sharing and privacy guidelines. It should capture and integrate different perspectives and feedback from stakeholders and, in a timely and appropriate manner, be able to address any question that might arise. It should have clear timelines and milestones that are relevant and actionable to all stakeholders.

This collaborative process should have precise mechanisms for disseminating evidence, including peer-reviewed publications, conference presentations, and stakeholder engagement. It should also have specific mechanisms for quality assurance and control. The standardized process can be ensured by conducting workshops and using common frameworks and templates.

Collaborative Workshops: Conduct cross-functional workshops where teams collectively define evidence requirements, endpoints, and study concepts, thus fostering alignment and shared understanding.

Common Frameworks: Use common frameworks and templates to structure evidence plans, ensure consistency, and facilitate communication across functions.

Platform – Presenting a Unified View of the Data

Integrated evidence planning is about collaboration, adaptability, and optimizing evidence generation. The platforms are typically tailored to organizations' needs and context. While there isn't a specific platform dedicated solely to IEP, several tools and practices facilitate the planning aspect. Data analytics tools can be used to assess existing evidence, identify gaps, and prioritize evidence generation. These tools help optimize resource allocation. Using a singular, interactive platform that shares the IEP and supporting studies can significantly enhance the planning aspect. This approach fosters transparency for the team

and leadership, ensuring everyone has access to the same information. For example, such a platform can provide comprehensive details about each study, including costs, resources, timelines, and necessary documents, making it easier for team members to stay informed and aligned. Additionally, the interactive nature of the platform facilitates seamless communication, allowing team members to collaborate more effectively and address any issues promptly.

Advanced Analytics

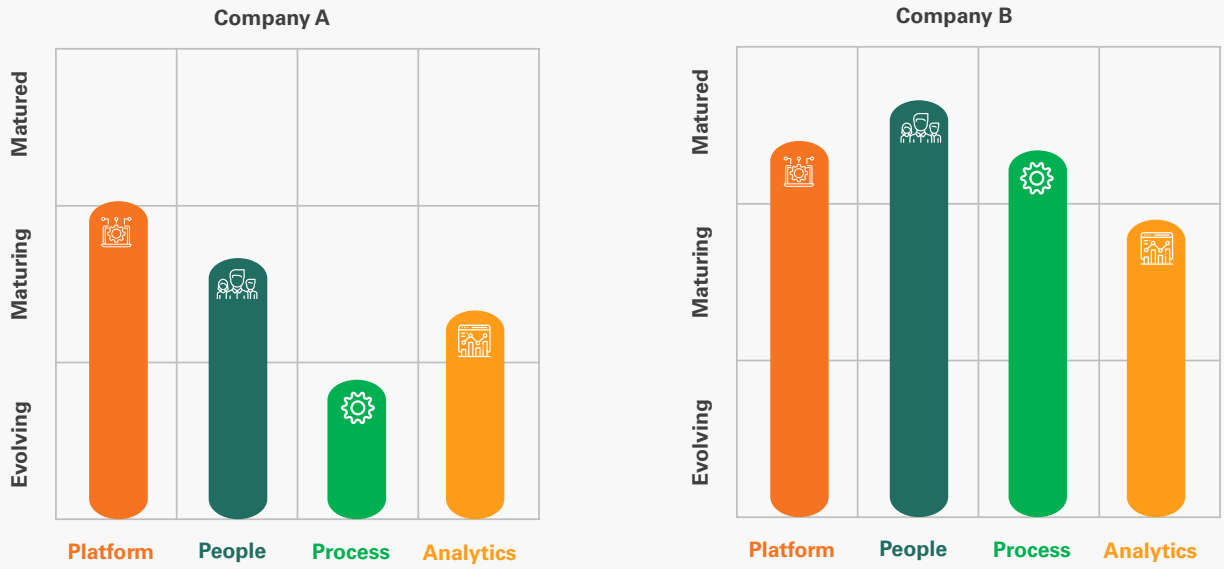
During IEP, companies should explore and consolidate all the available advanced analytic evidence from various sources, like clinical trials, real-world evidence, and literature, to identify potential methods to fill more robust evidence gaps. By comprehensively accessing the analytical toolbox, companies can estimate study costs, timelines, and resource allocation in advance, ensuring efficient resource utilization and the identification of talents needed.

Analytics can help track and analyze spending across different study types, such as clinical trials, observational studies, and external control arm studies. This helps identify cost drivers and optimize budget allocation. By analyzing spend across various therapeutic areas like oncology, cardiology, and neurology, companies can identify which ones consume the most resources and adjust their strategies accordingly. Analyzing historical data during the IEP stage can provide insights into estimates for study timelines, including patient recruitment, data collection, and analysis phases. Predictive models can forecast potential delays and suggest mitigation strategies, helping improve project management. Advanced analytics can enable the creation of a centralized database with advanced search capabilities and allow easy access to study protocols and reports, ensuring that all stakeholders can quickly find relevant information. Techniques like NLP can be used to enhance search functionalities, making it easier to find specific details within large IEP documents.

The Evolution of IEPs

When building their IEP capabilities, companies aspire to see their impact in the next few years. The following illustrative example (Figure 4) depicts the evolution and differences in IEPs with regard to platform, people, process, and analytics maturity. The figures below show that the relative IEP maturity levels for company A vs. company B may differ across platform, people, process, and analytics.

Figure 4: IEP maturity for company A vs. company B



Source: Axtria Inc.

Companies investing in their IEG capabilities should regularly assess their progress and set future goals, such as where they want to be in one year or five years. Over the next five years, spending on data and analytics platforms, accessing RWD, building internal study teams, and partnering with external experts is expected to grow significantly. As these investments continue, it is crucial for organizations to establish both qualitative and quantitative methods for measuring return on investment, which can be done through an IEP platform. The time it takes to see value will depend on factors like organizational maturity, culture, investment size, and focus.[11]

Current, Emerging, and Innovative Trends in IEP

Present State of IEP

Progress in IEP varies across the industry, so some companies have more advanced capabilities than others. Mature companies are already seeing benefits from IEPs.

Traditionally, planning has been fragmented, with multiple departments working in isolation, leading to inefficiencies and misaligned strategies. However, the industry is now moving toward a more cohesive approach, where planning is centralized and integrated across all stages of drug development. This shift is facilitated by digital platforms that provide a unified space for all planning activities. These platforms enable real-time access to critical information such as study costs, resource allocation, timelines, and documentation, ensuring that all stakeholders are on the same page. By fostering better communication and collaboration, these tools help streamline the planning process, making it more efficient and adaptable to the dynamic needs of drug development.

Current Trends in Integrated Evidence Planning

Integrated evidence planning is continually evolving, driven by technological advancements, advanced analytical capabilities, and a constantly changing regulatory landscape like the implementation of the IRA in the US. Several key innovative trends are shaping the field. First, the utilization of RWD/RWE is gaining prominence, allowing for the generation of evidence in real-world settings beyond traditional clinical trials.[12] Second, the adoption of advanced analytics, including machine learning (ML) and natural language processing (NLP), enables the extraction of insights from large, complex datasets, facilitating more precise evidence generation. Third, there is a growing emphasis on patient-centric approaches that involve collecting patient-reported outcomes (PROs) and patient-generated health data to capture the patient's experience and preferences. Fourth, integrating different data sources, such as EHRs, wearable devices, and social media, enables a comprehensive and holistic view of patient health and treatment outcomes.[13] Lastly, collaborative partnerships between stakeholders, including academia, healthcare providers, and technology companies, are fostering innovation and knowledge sharing, leading to more effective and efficient integrated evidence-generation strategies. These trends collectively drive the transformation of IEP, paving the way for more personalized, data-driven, and patient-centered healthcare decision-making.

Innovative Trends in Evidence Generation

As the evidence-generation process evolves, incorporating the patient's voice has become crucial. Recognizing the significance of patients' perspectives, including their experiences, journeys, the impact of their illness, and unmet needs, is valuable not only for patients themselves but also essential for biopharmaceutical companies to improve their communication with clinicians and payers.[14] By involving patients from the outset, their valuable perspectives can be integrated into the entire IEP process, ensuring that their needs and preferences shape the development of innovative products. This proactive approach ultimately benefits both patients and the overall success of product development, translating into better patient outcomes.

The value of incorporating patient-reported data into research investigations can be expanded by integrating information from claims and electronic medical record systems, leading to a more comprehensive understanding. While social media listening represents one method for capturing the patient's perspective and validating PROs, it is essential to explore additional avenues.

Combining rapid cycle analytics with generative AI to generate on-demand insights could also become a potential trend in the future. Pharmaceutical companies have already begun their explorations into generative AI. However, technology alone does not ensure success. To make full use of generative AI, companies must possess the right data and a deep understanding of how to utilize it effectively. In the context of IEP, generative AI has potential applications in data harmonization and downstream analytics. For example, AI and ML algorithms can facilitate data integration from diverse RWD sources, including electronic health records, claims databases, wearable devices, and patient-generated data. This integrated dataset can then be preprocessed using advanced analytics techniques to ensure data quality, address missing values, and normalize data formats. The resulting harmonized dataset is a robust foundation for subsequent analyses that can help improve decision-making. Additionally, in the context of evidence synthesis activities for IEP, AI/ML/NLP can be deployed to fast-track literature screening, data extraction, and medical writing processes in literature reviews, value dossiers, and such.[15]

Digital twins (DTs), virtual representations of objects or systems, are transforming clinical trials by leveraging RWD and AI/ML techniques.[16] Using DTs can optimize trial design, reduce costs, and minimize ethical concerns. Extending the use of simulation and AI/ML to generate DTs is an innovative approach that revolutionizes drug discovery and development and can potentially become an innovative trend in the context of IEP.

Expert Opinion: Putting IEP into Practice

An integral aspect of the spread and implementation of IEP is the introduction of specialized software to help keep track of and organize IEPs. However, barriers such as organizational inertia and gathering a sufficient amount and variety of data have prevented IEP from reaching its full potential at some companies.

The company's size also plays a role in the introduction and implementation of IEP, as smaller companies prioritize clinical development and often do not have the human capital to designate for IEP purposes. This aspect is one of several that can indicate "organizational readiness," metrics companies can use to make a rough determination of whether they are ready to start implementing IEP. One aspect mentioned previously is the need for leaders who are willing to gain stakeholder buy-in across various functions. Other measures of organizational readiness include finding the right value message and optimizing human capital and resource allocation to create a strong team.

The current focus in developing agile, adaptable, and effective IEPs is technology – technologies that document and store the IEPs themselves and tools, many of which are homegrown, that can offer deeper connectivity with other systems in an organization. Many companies have lost track of the work that different teams within the company have already done, which can lead them to build up studies from scratch, artificially increasing their workload. Aligning a company's various teams and functions can help alleviate this.

There are several ways technology and new trends, such as generative AI, can help improve the current state of IEPs and address or alleviate the challenges associated with adopting them. For example, AI can continually gather and monitor new insights, alerting relevant stakeholders when something significant enough for a shift or refresh in the IEP arises. These technologies will also be helpful in summarizing IEP insights so key stakeholders can discuss them later.

As patients begin to make even more decisions than they have in the past, it will become increasingly important for companies to think beyond their specific disease process and focus on the whole patient. Generative AI is one tool that can assist in looking at the entire patient, as it may one day be able to quickly query data and format it into actual reports and deliverables, which can be close to field-ready without much human intervention, allowing companies to be faster at acquiring data and insights. Soon, generative AI may even develop to the point where stakeholders can obtain data conversationally, one possibility being AI chatbots, which can obtain a dataset or create a graph based on a simple question. GenAI has evolved into a versatile tool that augments human intelligence. It can empower individuals and organizations to enhance their decision-making, creativity, efficiency, and accessibility. While adding AI offers significant benefits, AIs are not infallible. Their effectiveness depends on data quality, training, and the specific task they are designed for. Human oversight remains crucial.

Conclusion

Integrated evidence planning has the potential to revolutionize drug development, optimize decision-making, accelerate patient access to therapies, and improve patient outcomes. In the future, IEP will likely see increased technology adoption and the use of patient-reported data combined with advanced analytics, including AI/ML, NLP, and GenAI.

After the product launch, there are obligations and opportunities to uncover hidden evidence through real-world practices and outcomes or generate more evidence through Phase IV trials, which are often mandated by regulatory bodies. Evidence needs may change as the market evolves with competition, when patents expire, and as we gain improved disease understanding. Data will also evolve, making it important for companies to periodically revisit IEP, especially when external market events impact decision-making frameworks. In that context, an IEP must be a living, iterative document.

Integrating different analytical approaches for a well-organized IEP will also be important. Analytical approaches vary from fundamental descriptive analysis to predictive machine learning and counterfactual causal inference analysis. Combining rapid-cycle analytics with generative AI to generate on-demand insights could also become a potential new trend, and a comprehensive understanding of such an integrated analytical approach will play a pivotal role in formulating IEP. The constantly changing regulatory landscape will likely change the dynamics of IEP, and the concept of "whole patient health" will play a pivotal role in formulating IEG plans, making the planning aspect of IEP even more critical. Just as causal inference methodology is gaining traction from regulatory bodies worldwide and innovative approaches like DT will likely play a crucial role in expediting the overall drug development process, so will integrated evidence planning.

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