Streamlining success:

How integrated evidence planning transforms asset development

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A CLEARER PATH TO MARKET APPROVAL, ACCESS, AND UPTAKE

For your product to succeed, its development must be backed by quality evidence: data that demonstrates its value and informs cross-functional decision-making to optimize opportunities for regulatory and reimbursement approval as well as market acceptance and commercial success in a competitive landscape.

Evidentiary demands are complex and vary by stakeholder. Beyond satisfying the data needs of regulatory authorities, payers, and internal decision-makers, you must also build trust for your product among healthcare professionals and patients and earn the confidence of potential investors. Internal and external stakeholders can have differing perspectives and competing preferences for evidence — all of which must be addressed in a timely and cost-effective way.

The key to delivering a compelling evidence package lies in the integrated evidence plan (IEP). This strategic roadmap outlines the data required to differentiate your product clinically and commercially, and to inform key development decisions such as defining the target patient population(s), specifying the regulatory strategy for marketing authorization, and go/no-go determinations following study results. The IEP details specific tactics for generating critical data throughout the asset lifecycle. By creating an IEP, you align your cross-functional team with shared goals. You also aim to de-risk your clinical development program and minimize the need for reactive data generation — an undertaking that can ultimately lengthen an asset's time to market.

The IEP as critical component of overall asset strategy and delivery

The IEP is a living resource, updated at key milestones as data is generated. It informs the clinical development and evidence generation plans and facilitates adjustments to the asset strategy and lifecycle plan based on emerging information.

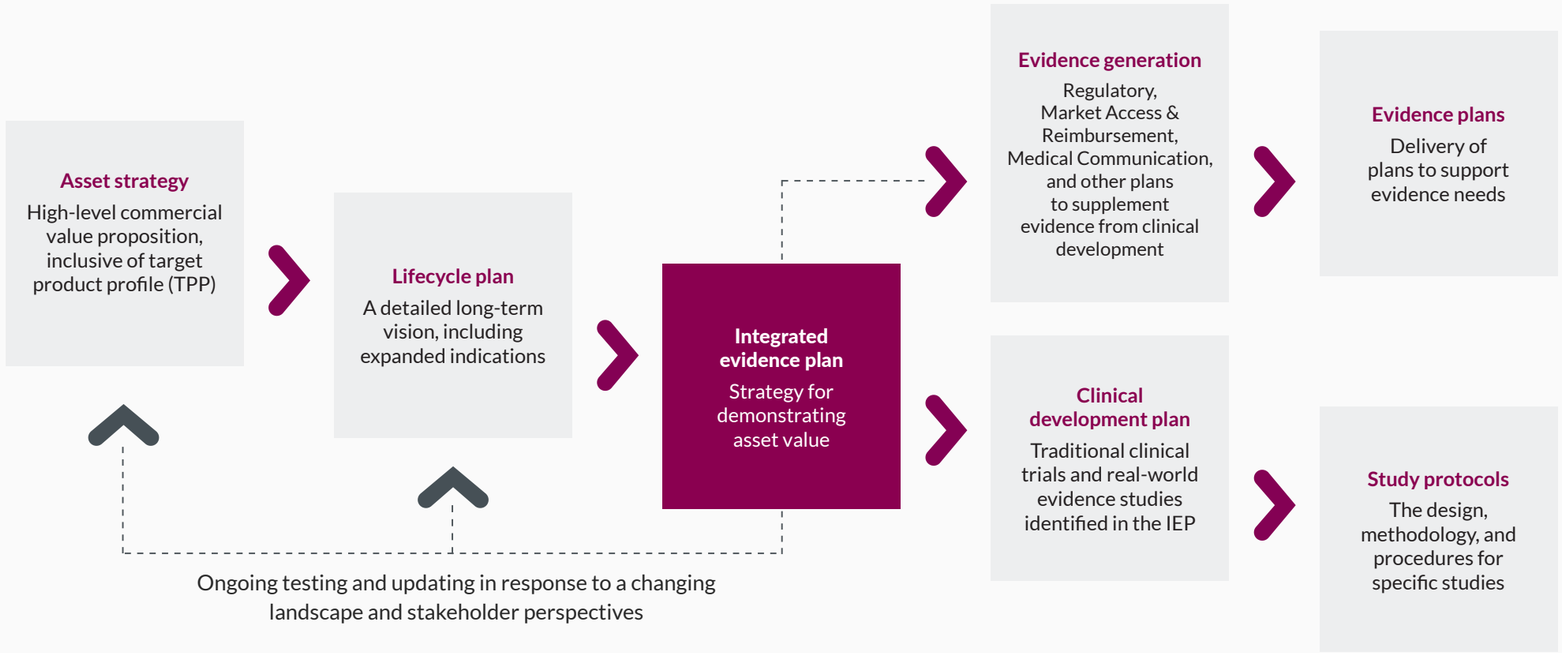

Figure 1: Integrated evidence planning as part of overall asset strategy and evidence delivery.

STREAMLINING YOUR APPROACH TO EVIDENCE GENERATION

Traditionally, life sciences companies progress an asset through the development and commercialization lifecycle with internal handoffs from one business function to another, each with its own plan for meeting key milestones specific to that functional area. This approach does not allow for a proactive and structured approach to holistic gap analysis, study prioritization, evidence collection, and risk management. Efforts are not underpinned by a comprehensive evidence generation strategy, which results in operational and cost inefficiencies, potential conflicting priorities, and evidence overlaps and gaps throughout the product lifecycle.

By adopting a unified approach to planning and evidence generation, companies can significantly eliminate evidence gaps and reduce redundancies by determining early on and through ongoing assessment, the types of data that will be required to:

- Meet **regulatory requirements** for approval
- Maximize the likelihood of **optimal reimbursement**
- Demonstrate to healthcare professionals how the product is **safe and effective** for its intended use; and, as applicable, how the product **addresses unmet needs and provides benefit over alternative therapies**
- Guide and inform **treatment decisions**
- Inform opportunities and decisions about **future expanded use**
- Build **investor confidence**

An IEP helps maximize resources by ensuring that every data source and data point serves a specific strategic purpose. It also brings clarity to the development process by ensuring whole-team consensus on product goals, strategies, and tactics.

Drug development demands significant investment — about $1.1 billion per approved product, according to a study in *JAMA*.[1] An IEP is one way to optimize that investment. It preempts evidence gaps and mitigates the need to conduct additional, costly studies, during which the market can only become more crowded and competitive. For companies that pursue outside funding or follow an exit strategy, an IEP also signals commitment to de-risking the development process by identifying and closing high value evidence gaps, making the program more attractive to investors.

PERSUASIVE EVIDENCE FOR EVERY STAKEHOLDER

When developing a product, a company might focus initially on generating data to meet regulatory requirements. However regulatory approval alone won't get a medical product to market. For example, a study found that among 105 FDA-approved drugs evaluated by health technology assessment (HTA) bodies in Australia, Canada, and the U.K., approximately 40 percent were not recommended for reimbursement.[2] Reasons included uncertain clinical benefit, small comparative clinical benefit, comparative safety concerns, and lack of cost-effectiveness at the proposed price — evidence gaps that might have been addressed through integrated evidence planning.

1. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA*, 2020.
2. Assessment of FDA-approved drugs not recommended for use or reimbursement in other countries, 2017-2020. *JAMA Internal Medicine*, 2023.

THE MARKET VIEW

In a recent Parexel survey of 150 medical affairs leaders from pharmaceutical and biotechnology companies in the U.S. and Europe, just under half (49 percent) of all respondents said they use IEPs in their development programs. Of companies not currently using IEPs, about three-quarters said they plan to start using them.[3] "We are now going over the last … two to three years into an integrated evidence plan because we have seen quite a lot of redundancies and overlaps," said a vice president at a large European pharmaceutical company.

When asked about their primary objective for integrated evidence planning, the leaders we spoke with were largely focused on commercial purposes.[4]

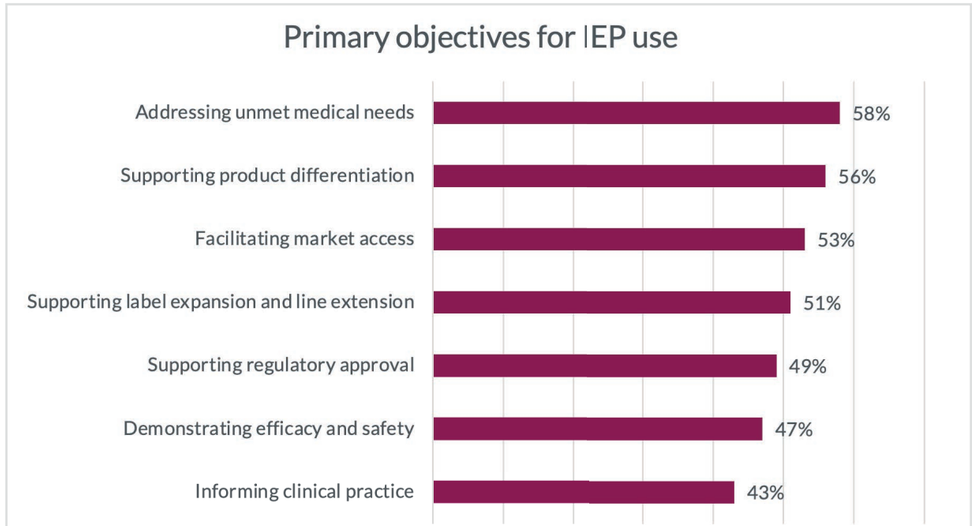

Figure 2: Medical affairs leaders report their primary objectives for using integrated evidence planning.

Our research also shows that while many companies recognize the value of integrated evidence planning, the extent to which it is implemented varies. Commonly reported challenges included internal organizational silos, resource constraints, and balancing short-term needs with long-term strategic goals.[5]

Through this playbook, we discuss three key practices for successful IEP implementation and delivery and three actions to maximize IEP value. When done effectively, integrated evidence planning will:

- Enable teams to align on long-term goals that make evidence generation more effective in the short term and beyond
- Reduce silos and improve efficiencies through collaboration and clearer communication
- Alleviate constraints on both resources and budgets

3. Proprietary internal data, 2024.
4. Ibid
5. Ibid

THREE KEY PRACTICES FOR SUCCESSFUL IEP IMPLEMENTATION AND DELIVERY

Practice 1: Work collaboratively

The process of creating an IEP begins with assembling a cross-functional team that represents key internal groups, each of which is accountable to external stakeholders: regulators, payers, healthcare professionals, and patients, as well as the care partners and advocacy groups that support them.

INTERNAL GROUPS *	EVIDENCE FOCUS
Clinical development	The design of a clinical trial program, including an approvable, commercially viable protocol, based on factors including historical and real world evidence, statistical considerations, regulatory requirements, and unmet needs.
Commercial	Understanding, and influence of potential market priorities to drive commercial value.
Market access and HEOR	Demonstration of a product's economic value and added benefit over the current standard of care to ensure that the appropriate patient population has access to the product through revenue-optimized reimbursement or payer coverage.
Medical affairs	Differentiation of the product and demonstration of real-world clinical benefits, improved outcomes, public health impact, and impact on quality of life.
Patient advocacy	Provision of information to healthcare professionals and the patient community about a product's appropriate place in treatment to inform treatment guidelines and individual treatment decisions.
Postmarket surveillance	Evaluation of expanded and off-label uses of product, and associated safety/effectiveness to inform opportunities for new indications for use.
Quality/CMC	Understanding and delivery of the dosage form and packaging that is most convenient to target patients and healthcare professionals, and is adaptable for new populations. Also, reduction of risk in medication errors.
Real-world evidence (RWE)	Collection and analysis of data from real-world settings to support internal groups in their evidence-generation requirements.
Regulatory affairs	Evidence required to support safety, efficacy and positive risk/benefit and compliance with regulatory guidelines, as well as regulatory strategies to streamline product development.
Common goal: Delivery of a drug, with adequete user information, to the appropriate patient population in a timely, revenue-optimal way.	

Figure 3: Key internal groups within life sciences companies and their primary evidentiary requirements for external stakeholders.
*Internal structures vary significantly among companies.

FROM OUR RESEARCH

A director at a European biopharmaceutical company told us that lack of strategy has hampered their organization's efforts to plan for evidence generation.

> Where it hasn't worked is where there's been a general idea to say, let's collect the evidence, and we're not quite sure what we'll use it for yet, but it seems like a good idea that we collect that evidence."

SOURCE: Internal data, 2024.

Specific functions may prioritize a particular milestone or external stakeholder — for example, Regulatory Affairs may focus on plans that meet regulatory requirements. By considering the full product lifecycle very early in their evidence planning, companies can align functions to collectively meet the needs of all stakeholders, from earning regulatory approval to supporting optimal commercial performance and more.

At the early planning stage, we recommend preparing for ongoing Target Product Profile (TPP) testing as part of the evidence strategy. Validating the TPP with internal and external stakeholders is crucial as it provides early insights into product requirements, target population, value proposition, and evidence needs, ultimately addressing unmet market demands.

This early alignment on the TPP enables a company to focus on critical evidence and activities for market access and uptake and promote cross-functional collaboration to achieve aligned and holistic goals.

Guided by the TPP focus, the cross-functional group should identify the evidence each function needs to substantiate the asset strategy and the product's value proposition. Input should be informed by a landscape analysis, among other considerations such as mechanisms of action, indications, unmet treatment needs, treatment effects — as well as potential risks identified from gap analysis. From there, the group will decide by consensus what evidence must be generated and through which tactics, ensuring that every tactic contributes to a stated goal.

Decision-making may require trade-offs. For example, comparative patient outcome data could have limited impact on regulatory decisions but may be critical to payers, and is preferred by HTA bodies to model cost effectiveness. To manage these varying requirements, teams should consider incorporating evidence sources other than clinical trials, which may also optimize budgets and timelines. While clinical trials will be central to any product development plan, sources and methods like real-world data (RWD), data modeling, and data simulation also offer value by informing trial design and maximizing data interpretation.

The need for comprehensive data must be balanced against timelines and budgets, making it unlikely that any function will be able to collect every proposed data point. Teams should pursue the evidence that will best support long-term product goals, prioritizing that which will satisfy the needs of multiple stakeholders.

Integrated evidence planning requires multidisciplinary inputs, and the outputs guide strategic plans

Figure 4: The internal groups that contribute to IEP development and the outputs that inform ongoing strategy and tactical evidence delivery.

STRUCTURING AND OVERSEEING YOUR TEAM:

An IEP steering team should include a representative from each function in the organization, with an overall project lead responsible for keeping participants engaged and accountable — potentially a global medical affairs representative. The organization should also consider governance for the IEP team. For example, if the team reaches an impasse when determining evidence priorities, who in the organization will make the final call? And who will champion the IEP process and is influential enough to ensure its adoption. In many cases, the therapeutic or program lead can provide support in this area.

This model is adaptable to various company sizes. In larger organizations, it can streamline complex, multi-level decision-making processes. Smaller companies can adopt a simplified approach, ensuring adequate coverage of all functions, even if individuals represent multiple areas. The key is to maintain cross-functional input while tailoring the structure to the organization's scale and resources.

CASE STUDY

Differentiating a new drug in a competitive market

Focus on practice 1: Work collaboratively

While developing a medicinal therapy to treat a chronic autoimmune disease, a major pharmaceutical company asked Parexel how best to demonstrate the product's comparative value in an increasingly crowded market.

Our first task in establishing a strategy was to help the company's product team identify and agree on the most pressing challenges they faced. Those included:

- **Patient recruitment:** Given the limited patient pool due to specific eligibility criteria, researchers knew they would struggle to reach adequate sample sizes for clinical trials.
- **Comparisons to a wide range of existing treatments:** Many patients in the target population were using drugs that regulated the immune system or reduced inflammation but that weren't specific to their condition — and were often prescribed off-label. Because the treatment landscape was so varied, the product team wasn't sure which comparators might be most meaningful to patient groups, payers, and HTA bodies.
- **A crowded market:** The company's drug would be one of many options available.

Once we had reached consensus on these challenges, we identified key evidence needs and developed a plan for generating data that would address the needs and bridge any gaps, thereby making a strong case for reimbursement. This plan included patient education and outreach tactics to bolster recruitment. We also advised on patient subgroup selection to best position the product among the treatment options, to demonstrate the therapy's economic value. Finally, we recommended treatment comparators for use in the clinical studies that would be strongly relevant to the product's intended position in the treatment paradigm.

Equipped with this plan, which became a keystone for decision making, the company's access team ensured that its evidence requirements were represented within the broader development program and that data from clinical studies and real-world sources would support favorable reimbursement decisions.

Although the development program is still in progress, our customer has reported that the collaborative integrated evidence approach has improved efficiency and minimized the requirement for reactive evidence generation. Ultimately, they are on track to deliver a strong value story to support positive reimbursement decisions.

Practice 2: Begin early

Our market research found that only about half of organizations surveyed launch IEPs during preclinical or phase 1 development and a quarter of respondents don't begin creating IEPs until phase 3 or commercialization.[6] Based on our experience, we recommend planning for evidence as early as the preclinical phase, and as soon as data allow for a comprehensive viability assessment.

By identifying the most meaningful evidence prior to first-in-human studies, an IEP helps ensure that every piece of data is collected for a specific and intentional purpose, and meaningfully contributes to the larger goal of demonstrating product value. Early considerations about the IEP are important for any organization, even if you anticipate selling your asset before later-phase studies conducted, or commercialization. A solid data story that demonstrates a product's potential will only increase an asset's market value, and enhance organizational reputation and investor confidence.

By focusing on value drivers from the outset, IEPs ensure that evidence generation directly contributes to product success and patient outcomes. In terms of quantifying the benefit of such value-based decision-making, Olson and Capkun[7] describe the use of expected net present value (eNPV) and return on investment (ROI) calculations to allow for a more objective assessment of the value of evidence generation activities.

FROM OUR RESEARCH

> "It's new standard practice to develop [the IEP] alongside the clinical development plan. We try to do this as early as possible. So once we know that … we get good [phase 1 or first-in-human] data enough to justify going onto the next phases, it's where we go with the integrated evidence plan. It does cover the whole spectrum, essentially."
>
> — An associate director at a European biopharmaceutical company

SOURCE: Internal data, 2024.

6. Proprietary internal data, 2024.
7. Olson, M, Capkun, G. *The value of evidence and its role in driving product strategy.* Journal of Comparative Effectiveness Research. 2024 Jul 1;13(8):e240074. doi: 10.57264/cer-2024-0074

Practice 3: Check in regularly

Integrated evidence planning is a proactive approach that addresses a product's full lifecycle. The process, by design, is iterative — the initial value proposition will require reassessment as development progresses.

To ensure that the IEP continues to best serve the product, its steering team should regularly revisit goals and revise strategies and tactics as needed. Newly acquired data could alter plans for subsequent evidence generation, necessitating adjustments to the IEP. These adjustments should be tested among both internal and external stakeholders. Teams should also consider how changes within the landscape and development program might impact an IEP. For example, new competitors, new treatment guidelines, emerging safety signals, or a reassessment of product indication could all impact evidence requirements and planning. And while an IEP is a global strategy, teams should consult with their local affiliates as individual markets may require adaptations to the plan.

Based on our experience, teams find it helpful to link regular IEP reviews to major project milestones: prior to first-in-human studies; at the conclusion of phases 1, 2, and 3; prior to commercialization, the conclusion of post-marketing studies, and ongoing lifecycle management checkpoints.

As IEP is both a living resource and a single source of reference, so it needs to be visible and accessible across the organization. Approaches to data management will vary among companies, though life sciences companies are increasingly adopting technology-driven evidence platforms that allow them to more efficiently assess — and capitalize on — large volumes of dynamic data. When choosing or creating a digital repository for both the IEP and associated data, we recommend the use of tools and methods that will give stakeholders timely, trackable access to evidence and insights.

FROM OUR RESEARCH

> "On a yearly basis, we check the progress ... It is all, in a sense, documented and within an integrated evidence-generating plan that is a living document."
>
> — A vice president at a North American pharmaceutical company

SOURCE: Internal data, 2024.

MAXIMIZE IEP VALUE WITH THREE ACTIONS

Action 1: Harness the power of Real World Research

As the industry standard, traditional clinical trials are the foundation of an evidence plan, although there are exceptions – cases of accelerated approval pathways or product development for rare diseases, for example. Several respondents to Parexel's market research confirmed their growing focus on integrating RWE into broader evidence generation strategies — a trend driven by the need for more comprehensive data and the desire to optimize resource allocation. They also report that they are more frequently generating RWD from diverse sources, including claims databases, electronic medical records, and patient registries.[7]

With the increasing availability of high-quality RWD and RWE studies, there is growing acceptance by regulatory bodies of the use of these to complement traditional clinical trials and as support for product efficacy. We are seeing an increasing number of drug approvals with the inclusion of RWE approaches and designs in regulatory application for new indications and label expansions across multiple therapeutic areas.[8,9] At the same time, there are an increasing number and type of new guidances from regulatory agencies related to the collection, analysis and incorporation of RWD/E in drug development programs.[10]

7. Proprietary internal data, 2024.
8. Alipour-Haris G, Liu X, Acha, V, Winterstein A, Burcu M. Real-world evidence to support regulatory submissions: A landscape review and assessment of use cases. *Clinical and Translational Science*. 2024 Aug 2;17(8):e13903. doi: 10.1111/cts.13903
9. Purpura C, Garry E, Honig N, Case A, Rassen J. The Role of Real-World Evidence in FDA-Approved New Drug and Biologics License Applications. *Clinical Pharmacology & Therapeutics*. 2021 Nov 22;111(1):135–144. doi: 10.1002/cpt.2474
10. Considerations for the Use of Real-World Data and Real-World Evidence to support Regulatory Decision-Making for Drug and Biological Products. U.S Food & Drug Administration, 2023.

RWE provides value throughout the product lifecycle

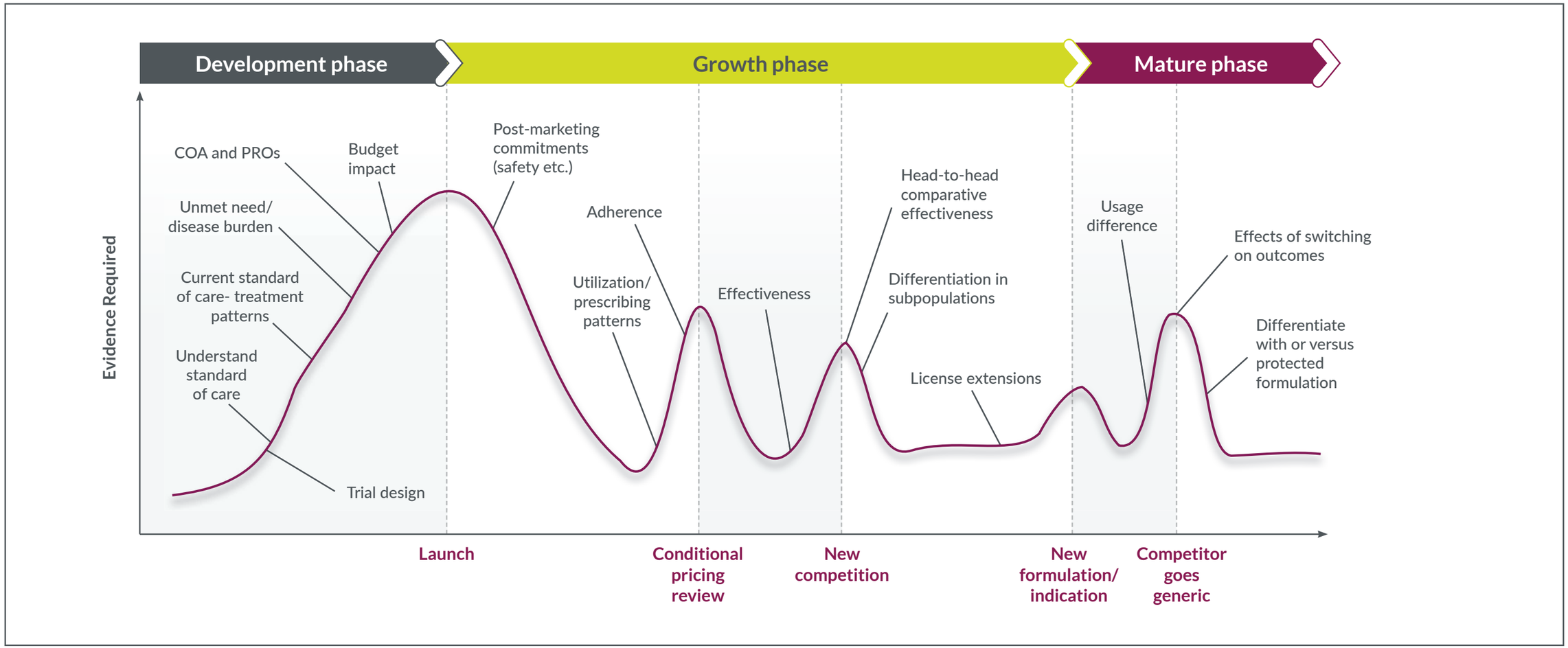

Figure 5: RWE opportunities from development through to mature phases.

An IEP should include a strategy for developing and using RWE throughout the product lifecycle, which will require stage-specific approaches informed by robust scientific leadership for accurate methods, protocol, and study design.

Development phase

RWD modeling and simulation may be initiated at the preclinical stage to help companies better understand the clinical need and make choices about necessary and relevant investments into the development program. RWD is also useful for understanding current clinical practice and effectiveness of standard of care (including off-label uses of available therapies). RWD can facilitate robust clinical trial design and planning (through data on patient characteristics, patient preferences about dosing regimens, clinician- and patient-preferred endpoints, and other factors).

Employing RWE to meet regulatory standards involves many complexities, including identifying data sources, linking disparate data sources through a common data model, and establishing standard definitions of populations and outcomes consistent with those studied in clinical trials. These considerations should be addressed early as part of a comprehensive IEP strategy.

Development and growth phases

An experienced epidemiology team should deliver the methodological backbone for RWE studies, ensuring that they are scientifically rigorous, clinically relevant, and capable of generating valid and reliable evidence to inform health care decision-making. The principles and methods of epidemiology are central to high-quality RWD research that can complement and potentially replace RCTs and contribute to a more comprehensive understanding of health interventions in real-world settings.

Growth phase

RWD can be used during reimbursement discussions, when modeling may help address clinical data gaps — comparator data to demonstrate superiority to an on-the-market product, for instance. As more medicines gain market access, patients and healthcare professionals need to know how therapies are being used and responded to in real-world environments. We recommend using patient-reported outcomes and clinical outcome assessments to better understand quality-of-life impacts and other measures that are important to patients.

Mature phase

As companies seek to minimize revenue decline at time of loss of exclusivity and develop barriers against generic erosion, they can use RWE to help differentiate a product, at this point and beyond. For example, new data on patient preferences, outcomes, and QoL can inform strategies for effective patient education and communication with healthcare professionals. Longitudinal data can be used to construct head-to-head comparator studies, as well as generating RWE for informed decisions about potential line extensions.

Action 2: Strategize communication with all stakeholders

Every IEP must address the needs of regulatory and reimbursement decision-makers. Companies also should not overlook the needs of healthcare professionals, hospital systems, patients, patient care partners, and patient advocacy groups — all of whom want evidence that demonstrates not only the safety and efficacy of a therapy but how best to use the therapy and how that therapy differs from other options available on the market.

As you are planning for evidence generation, consider how to best communicate your strategy and emerging data to all stakeholders. While avenues for sharing regulatory and reimbursement evidence packages are part of an established process, methods of communication with patients and healthcare professionals are varied and must be tailored according to the condition, the characteristics of the therapy, the geographic region, and each stakeholder's preferred communication formats and channels. A strategic communication plan can contribute to the success of an IEP by ensuring that valuable scientific data is conveyed effectively throughout the product lifecycle. This includes:

- Customizing content for multiple stakeholders, including healthcare professionals , patients, payers, and regulators
- Developing consistent core content and key messaging, maintaining coherence across various communication channels
- Creating strategies to disseminate evidence, including presentations at scientific conferences and publications in medical journals
- Designing patient education materials and plain-language summaries of research results that demonstrate the value of the treatment to the people who will use it

A robust medical communications strategy ensures that the wealth of data and insights generated through research activities is effectively translated into clear, compelling, and actionable information. This approach supports informed decision-making, enhances stakeholder engagement, and ultimately contributes to the overall success of the product in addressing unmet medical needs.

Multiple models of IEP engagement offer flexibility

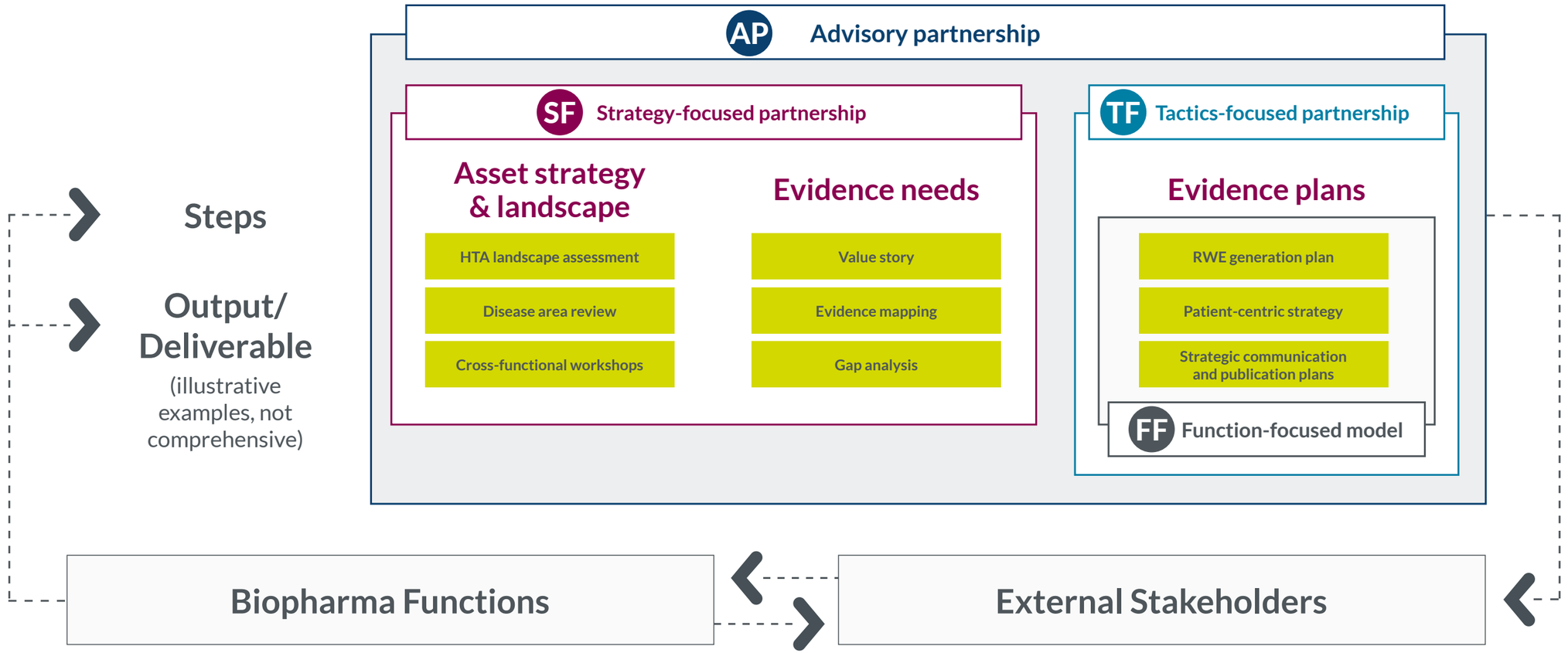

Figure 6: Four different models for engagement and delivery, mapped to the IEP process.

Action 3: Engage a partner

When asked about working with an external partner for IEP development, a senior digital health lead we spoke with said, "Absolutely, external consultants and vendors help support [IEP] development [and] execution and stress test the IEP. There's value because you [have to] get over that insular approach. You do need that diversity of thought."[11] Outside perspective is one of the advantages a partner can bring to the IEP process — an organization-wide undertaking that involves competing priorities and multifaceted requirements. Given that complexity, it can be helpful to engage a partner to facilitate the IEP process in an inclusive, efficient way.

Four partnership models to meet diverse needs

Parexel's teams, by design, align to internal functions within life sciences organizations. Our multiple models of IEP partnership provide flexibility to fit your team, product, and needs. Our models include:

SF **The strategy-focused partnership:** In this model, we work with a company as early as preclinical stages, mapping the landscape and developing an asset strategy by leading cross-functional workshops and disease-area reviews. Based on that output, we help determine evidence needs through value-proposition development and gap analysis. This informs the development of an evidence plan that includes specific tactics for evidence generation. Strategy-focused partnerships can extend to include execution, with Parexel helping to generate data and deliver the evidence and develop the communication strategy. This style of engagement is well suited to smaller organizations that need to supplement internal resources throughout the process.

TF **The tactics-focused partnership:** If your organization has already established its evidence needs, we deliver tactical evidence plans with recommendations for specific research activities and data sources to support your evidence-generation strategy. We can design and execute tactics for every function to help secure regulatory approval, favorable reimbursement decisions, and acceptance from healthcare professionals, patients, and patient advocacy groups.

FF **The function-focused model:** This model is best for organizations that have established their evidence needs and are developing generation tactics but would like technical and operational support designing and delivering an evidence-generation program to address a specific requirement. These requirements could be related to regulatory approval or market access challenges or guidance on communication strategy or evidence dissemination to educate and inform healthcare professionals and the patient community.

AP **The advisory partnership:** For organizations that have developed a full IEP but would like to validate their approach, we can evaluate your plan and make recommendations for addressing possible weaknesses or oversights. Because our internal functions align with internal functions within life sciences companies, we can support every internal stakeholder with equivalent expertise. We can also evaluate and advise on specific aspects of your plan, such as RWE generation, patient-first approaches to research or evidence dissemination.

Within all partnership models, Parexel can help companies optimize their approach to data management — an essential consideration for any evidence-generation effort, which requires the collection and analysis of massive amounts of data. To accommodate expanding data sources and evolving stakeholder needs, Parexel takes an adaptive, modular approach to data management and analytics. In general, an initial platform would include modules that provide ongoing clinical trial data that can be contextualized with additional data and, in the future, could be linked to RWD sources for enhanced insights. As a product matures commercially, we can build additional modules for enterprise data, licensed data sources, and dynamic commercial and regulatory intelligence data. Every solution uses a strong data governance model that is tied directly to the IEP so that evidence and insights are delivered to stakeholders in a timely, actionable way.

11. Proprietary internal data, 2024.

FROM OUR RESEARCH

When asked how an external partner could help better integrate their evidence planning, a director at a European biopharmaceutical company said that a CRO can serve as a neutral party to facilitate collaboration.

> Within my organization, you would need to be talking to medical and HEOR at the same time," the director told us, adding that "encourag[ing] a conversation between the two functions would be a huge value-add."

SOURCE: Internal data, 2024.

CASE STUDY

Using RWE to accelerate development and reimbursement timelines

Focus on action 3: Engage a partner on a tactics-focused partnership

Working with a small biotech company on a gene therapy product for cardiovascular disease, Parexel proposed an approach to evidence planning that would take fuller advantage of RWD and other non-RCT data sources. This included:

- **Identifying research gaps** in the product's development lifecycle, including opportunities for using natural history data to create external control arms.
- **Developing a comprehensive plan** detailing the use RWE to support the needs of payers, healthcare professionals, patients, and governmental policymakers. This would include evidence regarding comparative value, product differentiation, and QoL outcomes.
- **Helping internal stakeholders reach consensus** on RWD and RWE strategy and tactics.

As part of this engagement, we presented strategies to reduce development and reimbursement timelines throughout the product's full development lifecycle. This planning provided the client a clear path to achieving clinical and commercial potential, allowing for efficient use of resources and creating a robust rationale for investment.

Because our functions match those of most life sciences companies, Parexel can complement internal expertise and offer broad multidisciplinary support — particularly helpful for biotech companies with relatively small product teams. In this case, we offered combined expertise in RWE, market access, and regulatory consulting — an approach that results in holistic evidence planning to address the needs of multiple stakeholders.

CASE STUDY

Advancing real-world understanding of the management of a rare cancer

Focus on action 3: Engage a partner on a strategy-focused partnership to harness the power of Real World Research and strategize communication with all stakeholders

A developer of a therapeutic to treat a rare cancer needed to better understand how that cancer is managed in real-world clinical environments. To assist in that work, Parexel is helping a multi-functional team build consensus about the optimal approach to generating evidence. This includes coordinating efforts to identify evidence gaps and prioritize how they will be filled via development of an IEP. As part of this work, we are helping the developer better understand the treatment and reimbursement landscape. Our key objectives include:

- Building an evidence base that supports expanded treatment use and demonstrates value to prescribers and patients.
- Filling gaps by leveraging RWD to generate RWE.
- Creating a plan to effectively communicate findings to target audiences.

To address these objectives, Parexel is working with the company to develop a strategic plan mapping future studies and activities to drive evidence generation. We are also recommending solutions and tools based on best practices in data collection and RWE study design. Additionally, we will:

- Help the team explore and understand potential critical barriers to effective data collection and reliability from the perspectives of study centers, healthcare professionals, patients and data scientists.
- Provide recommendations to support communication and outreach strategies for sites, healthcare professionals, and patients.
- Develop a managed access program and a plan for post-authorization studies.
- Implement a strategic communication and publication plan to increase awareness, engagement, and data dissemination among healthcare professionals and the patient community.

Integrated evidence planning can lead to better commercial outcomes. In a complex environment that demands flexibility, an IEP keeps teams both nimble and focused. It's important to acknowledge that achieving organization-wide collaboration will take time. It will also require an investment — one that will pay off for your organization and the patients you serve.

While implementing an integrated approach is a significant shift, it's not a step you have to take alone. Connect with the team at Parexel to learn how we can support you in developing, executing, and validating IEPs.

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Could a partnership like that put your product ahead?
We're always available for a conversation.

With Heart™

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