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WHITE PAPER

Evidence Generation in a Post-IRA World

Maximilian Hunt • Nandini Hadker

April 2024

Executive Summary

Since the passage of the Inflation Reduction Act (IRA) in 2022, the pharmaceutical industry has significantly altered how they approach and plan for evidence generation activities to best support product launches and pricing and access negotiations. Leading life science companies are taking proactive steps to adjust how and when they develop evidence and how they deploy it to better support their innovative medicines at launch and beyond.

Key Shifts that Trinity Life Sciences Sees Emerging

Increased Investment in Real-World Evidence Generation

Given the focus of the Centers for Medicare & Medicaid Services (CMS) on understanding unmet needs in their maximum fair price (MFP) calculations, companies are proactively investing more in real-world evidence (RWE) studies pre-launch to demonstrate the need for their therapies, including real-world studies with patients to demonstrate burden of disease and unmet needs, RWE/Claims analyses, comparative effectiveness studies, economic modeling analyses and more. The main focus of these studies is to develop holistic evidence packages supporting value narratives beyond traditional randomized controlled trial (RCT) endpoints.

Strategic Pricing and Market Access Planning

Manufacturers are developing comprehensive workplans for key activities across the negotiation process that clearly outline tasks and responsibilities for each cross-functional team. In addition, given potential limits on price increases downstream, there is increased emphasis on strategically pricing products at launch to reflect their holistic value and triangulate with economic value across the product lifecycle.

Early Engagement with Payers and Regulators

Convincing physicians and key opinion leaders (KOLs) is a necessary but not sufficient condition to drive successful launches. More and more, companies are engaging with payers and regulatory agencies – and doing so earlier in the drug development process. The downside risk of not focusing on the needs, expectations and requirements of these stakeholders is too high for even the biggest players in the industry. De-risking clinical trial designs and including endpoints that matter to payers and regulatory agencies is key to saving clinical development dollars and streamlining the regulatory approval process.

Emphasizing Patient-Centricity

Industry is adopting a more patient-centric approach to drug development, marketing and education. The "Voice of the Patient" has never been more important and patient advocacy groups are a force to reckon with. Industry is harnessing the authenticity that only patients and caregivers can provide to create educational materials, online resources and patient support programs that empower both physicians and patients with key information about disease states and treatment options.

Trinity's Take

To be clear, the shifts we are seeing were already underway. The passage of the IRA was an accelerant, and pharma executives are now more aware than ever before that their non-action will have significant consequences. The industry is therefore wasting no time adapting. The bill introduced additional pressures and uncertainty into the pricing and market access landscape, putting additional strains on the biopharma industry.

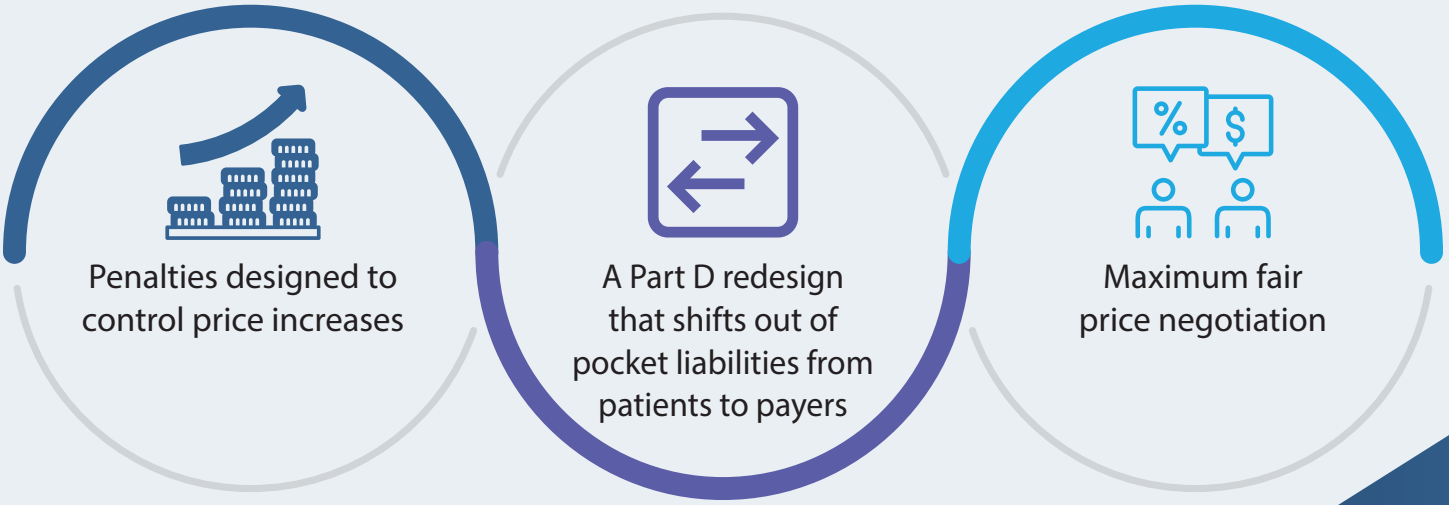
By design, the IRA does not specifically govern prices at launch or fundamentally shift the economic model from its current system of rebating. However, the IRA could "deflate" the rebate bubble on the Part D side once drugs enter MFP. Companies are now faced with implicit caps on price increases and direct negotiation cliffs after fixed times post-approval, both of which are likely to drive increased pressure on launch pricing.

Companies, especially those we at Trinity would peg as setting up to be "winners," are gearing up for this new reality as fast as they can – preparing for earlier and more strategic engagement with stakeholders and shifting their paradigms around what types of evidence and tactics will be needed and when. Given that the opportunity to capture value may be limited, what approach should companies take designing and executing evidence generation to be maximally impactful and fit-for-purpose? How should they critically assess likely winners versus losers to de-risk assets early enough so that capital can be (re)allocated earlier and more efficiently in the clinical development process? With less room to maneuver and adjust later in the product's lifecycle, the pressure to get it right at the get go has never been higher.

The full impact of the IRA won't be known for several years, but there is no question that the IRA places serious constraints on industry's ability to fully capture revenue potential across a product's lifecycle. Innovative companies, planning ahead and setting up for success, have already started taking steps to address these constraints, asking tough questions upfront and taking proactive steps to shift to this new normal.

The IRA's three base initiatives – penalties designed to control price increases, a Part D redesign that shifts out of pocket liabilities from patients to payers and maximum fair price negotiation – all affect life science companies' research and development, launch planning and market access strategies in significant ways.

Three Core Initiatives of the Inflation Reduction Act



Introduction

In August 2022, the Inflation Reduction Act was signed into law. The broad omnibus bill made changes to many social programs, including the CMS and these changes were predicted to significantly impact the biopharma landscape, particularly for developers of innovative medicines.

The ostensible goal of the IRA was to reduce the federal budget deficit by $288 billion from 2022 to 2031, with an estimated $102 billion in Medicare savings as a result of the new drug price negotiation policy.

The IRA proposed to achieve this expenditure reduction through three broad measures:

01 Requiring manufacturers to pay rebates to CMS if prices of therapies exceed current levels of inflation

02 Creating an annual cap on out-of-pocket (OOP) spending of $2,000 for Medicare Part D beneficiaries, with health plans covering most of the capped costs

03 Allowing Medicare to negotiate prices directly with manufacturers and establish a maximum fair price for a group of selected therapies that met set criteria.[1] Starting in 2026, these selected therapies will be subject to price negotiation with the Secretary of Health and Human Services and the list will expand to 60 Part B and Part D drugs by 2029

As the single largest payer in the U.S. healthcare market, changes to CMS price and negotiating approaches are expected to have significant spillover effects both among U.S. private payers and among ex-U.S. payers.

Below, we dive into some of the most industry-impacting topics in more detail.

[1]Therapies must be on the market for at least nine years for NDA and thirteen years for BLA, have no approved generic or biosimilar competitors and must be identified as significant drivers of Medicare spending.

Additional Trinity IRA Intelligence

Blog | Inflation Reduction Act of 2022: No Room for Negotiation
Read Now >

Blog | The Implementation Game: The Inflation Reduction Act Medicare Drug Price Negotiation Program Guidance
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On-demand Webinar | IRA Medicare Inflation Penalties: Implications for Manufacturer Pricing and Contract Strategy Decision Making
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White Paper | Picking Winners: Portfolio Management for a New Era
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Medicare Direct Negotiation and Maximum Fair Pricing

One of the key features of the IRA granted CMS the ability to negotiate prices with manufacturers for a set of selected medicines – the first time that CMS has been given the power to negotiate with industry. However, one important feature of the IRA is that instead of negotiating prices at initial launch, the IRA mandates minimum discounts for products later in their lifecycle, a significant departure from the more common upfront price negotiation typical in European markets. The scope of negotiated discounts will be gradually expanded between 2023 and 2029, with the objective of covering 60 eligible Part B and Part D drugs by 2029.

Maximum discounts are not quantitatively defined in the legislation, but steep minimum discounts leave manufacturers with little room for true negotiation. When setting the discount level above the minimum, the law instructs the Secretary to consider manufacturer-specific data, including research and development costs, unit costs, prior federal financial support for the discovery and development of the drug, pending and approved patent applications and market, sales and volume data for the drug in the United States. This broad imperative seems to leave much of the interpretation of the rule to the incumbent Secretary and will thus likely be one of the most challenging components of the legislation to put into practice. Every Secretary could also interpret it in their own way, leading to a lack of consistency in philosophy and approach. CMS could decide to accept some or all the manufacturer's data or completely reject it. There doesn't appear to be any guarantee that submissions will be considered properly and/or consistently across products, therapy areas and/or manufacturers. The goal – seeking to reduce Medicare expenditure – is crystal clear, but the potential implementation is not.

Implementation and Process

The IRA defines nine areas that will guide the Secretary in initial determinations and subsequent negotiations. These nine focus areas include three that especially pertain to evidence generation: **demonstrated unmet need** within the therapeutic area, **identified therapeutic alternatives** and data demonstrating **comparative effectiveness** for the product.

Manufacturers of a selected therapy must submit all required data related to these nine negotiation levers. After submitting the data, manufacturers will have the opportunity to provide additional context on their data submission and share new data during a live session with CMS.

Nine Negotiation Levers Defined in the IRA

Following a manufacturer's submission, the Secretary must share an initial maximum fair price of the drug with written justification and within one month, the manufacturer must either accept this maximum fair price or share a counteroffer. As part of this process, CMS will host a listening session that will allow for key patient-focused voices to be heard, including patients themselves, beneficiaries, caregivers and consumer and patient organizations. This critical element introduces patient-focused feedback on the therapeutic alternatives and other information regarding selected drugs and centers patients in the process. Any counteroffer must include an alternative proposed MFP, justification and a response to CMS's initial offer. Should CMS reject the counteroffer, up to three meetings will take place to discuss the negotiation levers. If CMS and the manufacturer fail to reach an agreement, a severe excise tax is likely to be levied.[2]

[2]See further details: H.R.485 - Protecting Health Care for All Patients Act of 2023

How Will Industry Respond?

Manufacturers are not entering this brave new world totally unarmed. The most prepared and forward-looking companies will respond with early, deliberate and pragmatic evidence generation, that speaks to multiple key stakeholders, with an eye to communicating the holistic value story for their therapy at launch. Given that the IRA impacts are back loaded, industry efforts will need to be front-loaded, collaborative across functional groups and strategically positioned to resonate with a diversity of stakeholders – from physicians/KOLs to regulators to payers to patients, caregivers and patient advocacy groups.

> *We need to be strong coming out the gate, because there isn't much room or time to course correct. In the past, first to market, first FDA-approved therapies, that too in rare disease areas, had it somewhat easier but with the high degree to scrutiny now and the tightening environment down the road means we can't afford to not get it right.*
>
> *— Biotech Executive*

Given the uncertainties and perceived threats to long-term revenue potential, combined with constraints around future price increases and capped out-of-pocket spend in Medicare, Trinity anticipates that innovators may seek higher prices for their therapies at launch, as price-setting freedoms at launch are not affected by the new legislation. This approach would offset potential reductions in future revenues once discounting takes effect and caps constraint profits.

As part of the negotiation process by which CMS will set MFP levels, a number of inputs, such as current unmet needs, comparative effectiveness and evolving therapeutic landscapes will be considered. As industry stalwarts know, the nine focus areas listed above, especially those highlighted, are great opportunities for manufacturers to shine and show value by producing rich and impactful real-world evidence to complement traditional RCT data. Trinity anticipates that the most prepared and forward-looking manufacturers will come to the table armed with compelling evidence to communicate the holistic value of their therapies.

> *We have very compelling evidence for [our asset] in Phase 2 and Phase 3 studies but we know we will still need a robust real-world burden of illness study demonstrating unmet needs and to communicate exactly why our new therapy is needed in this market. Real-world studies are needed to enhance our evidence package and (an) advocacy group is partnering with us to recruit patients for the study.*
>
> *— Big Pharma Executive*

Levers and Opportunities for Excellence in Evidence Generation

Trinity has identified key opportunities for life science innovators to generate and communicate the value of their products, support equitable MFP determination and provide appropriate, optimal patient access to medicines. In 2023, Trinity surveyed several large-, mid- and small-cap pharmaceutical companies to understand how they are preparing for anticipated impacts of the IRA – and MFP negotiations in particular. Based on these discussions and Trinity thought leadership, four areas of focus were highlighted.

Our Focus Areas to Help Companies Prepare for Impacts of the IRA

1. **Plan early and collaboratively**
2. **Focus on unmet needs**
3. **Plan for pricing scenarios and set expectations**
4. **Develop compelling value arguments**

1

Companies are preparing integrated evidence generation plans early and well before anticipated negotiations. It is essential to build comprehensive work plans that identify and pre-emptively address key activities across the negotiation process, with clearly outlined responsibilities for each functional team. Truly integrated plans include pricing and contracting, medical affairs, commercial, regulatory, market access, RWE and health economics and outcomes research (HEOR) functional partners. Early internal alignment on the preparation path will be essential. There will be a high cost to pay for cross-functional teams that compete rather than collaborate. Cooperation and teamwork will win over territoriality and dysfunction.

2

CMS guidance around focusing on the area of unmet needs indicates an openness to considering the holistic unmet medical needs in a therapeutic area, how a therapy addresses need in defined populations or how a therapy impacts longer-term needs for society. The importance of demonstrating unmet need represents a significant opportunity for the collection of RWE using both primary and secondary research methodologies.

An essential consideration is health equity, as CMS considers health disparities among underserved populations as its own unmet societal need. Capturing additional evidence around patient and caregiver experience with the current care paradigm, unmet needs and impacts on productivity, independence and quality of life in underserved populations and the potential benefit of new therapies in these populations can be highlighted. Expanded and deeper comparative effectiveness research is another avenue. Although CMS has not yet determined the comparative effectiveness methodology to be used in negotiations, the U.S. Congress reaffirmed that quality adjusted life years (QALYs) may not be used in the negotiation process, opening the door for additional, potentially novel measures of benefit.[2]

3

It is critical to establish clear expectations and plan for pricing scenarios that may arise. Success is tied to setting internal expectations regarding the likelihood of pricing scenarios, potential landing points and financial implications for each outcome. Establishing the Economically Justifiable Price (EJP) for your asset prior to launch is no longer an academic exercise. Companies also need to consider the potential for an ICER review. Hence, it is critical to be prepared at launch, even if you plan to price comfortably above the EJP. Given that there may be less pricing flexibility downstream, upfront preparation will be crucial. Robust health-economic modeling and early scenario planning across the whole lifecycle will be key if biopharma wants to fully capture the lifetime value associated with innovative therapies.

4

Access negotiations must focus on establishing holistic product value. Teams must develop compelling value arguments that are consistent with the negotiation strategy to guide the development of counter-arguments to CMS that go beyond traditional objection handlers. The key to successful negotiations is ensuring that the team has compelling and convincing value arguments that can be articulated clearly to directly address specific issues. Investment will be needed in early mock negotiations, cross-functional workshops and strategic advisory boards to de-risk value propositions, evidence generation plans, value messages and the downstream activities leveraging these efforts. This planning will be needed not just for traditional KOL, physician and payer stakeholders, but also for patients, caregivers and patient advocacy groups.

Generating the Necessary Evidence

The aforementioned strategies afford several opportunities for life science companies to develop and disseminate compelling evidence to support better value-based pricing and access decisions and potential later negotiations with CMS. Some of the approaches - for example, health economic models of budget impact or cost-effectiveness – will continue to be important, but they may become table-stakes and not differentiating. Payers may not always 'trust' them. There are also novel approaches that leading-edge companies are already implementing. With the growth of advanced analytics, Trinity sees the pace of this innovation in evidence strategy, evidence generation and evidence communicating accelerating.

Four key opportunities rise to the top for investments in evidence generation that can help prepare manufacturers for the impact of the IRA: enhanced unmet medical needs studies both pre-and post-launch; expanded investment in comparative effectiveness research (CER); expanded RWE generation studies; and deployment of advanced analytics and machine learning.

Four Key Opportunities for Investments in Evidence Generation

Demonstration of Unmet Needs

One of the nine pillars that CMS will rely on to support its negotiating position is the current and projected unmet needs in a specific therapeutic area. It is essential that manufacturers come armed with the data to fully describe the unmet needs and how their therapies address these needs. There is also an increased focus on health equity, amplifying the need for evidence in defined sub-populations, especially in traditionally underserved populations. Ensuring sufficient representation of such populations in any analysis of unmet need is a significant challenge.

Unmet needs analyses are typically conducted early in product development to support stakeholder education and support value communication materials, such as value dossiers. The IRA negotiating framework will also require this information several years after launch. Thus, the new paradigm requires that companies start early in the product development phase to identify and quantify unmet medical needs and then continue to monitor developments during the product lifecycle. Ongoing research is critical and success requires that teams align research efforts with both regulatory milestones and product lifecycle timelines to ensure that evidence for negotiation is ready in advance to allow for proper argument preparation and team training.

Finally, as unmet need is a critical component in the negotiation process, there are increasing efforts to broaden the definitions of stakeholder needs. The core needs remain clinical outcomes, but increasingly, other facets such as bringing in measures of caregiver burden and societal costs, are gaining traction. These measures historically have been marginalized or excluded from traditional cost-effectivenevss analysis, partially due to the compartmentalization of private payer spending (e.g., examining economic burdens for medical versus pharmaceutical spending). CMS, unlike private payers, is accountable for broader societal stakeholder needs.

A greater emphasis on capturing the patient voice in evidence generation efforts goes hand in glove with the enhanced focus on unmet needs. While CMS intends to consider patient input during negotiation, there is currently a lack of systematic methods to capture this perspective. Manufacturers will need to develop strategies to incorporate patient perspectives into their evidence generation plans to demonstrate the value of their products effectively.

Ultimate accountability for negotiations rests with the Secretary of Health and Human Services and the ostensible purpose of the IRA is to reduce overall spending. Thus, it is anticipated that a more holistic view of unmet needs will mark a significant change, offering an opportunity for the life science industry to expand the conventional parameters of unmet needs.

Comparative Effectiveness Research (CER)

Currently, comparative effectiveness research often has been relegated to a basic box-ticking exercise. HEOR teams typically conduct utilization and uptake studies to identify channeling effects, followed by traditional retrospective claims analyses comparing outcomes and healthcare resource utilization studies using propensity score matching or regression models to help field teams defend or expand formulary positions. The IRA mandates comparisons among approved products, as well as anticipated newcomers, with broader measures of clinical, economic and humanistic value.

As a result, Trinity recommends that industry leaders approach CER with expanded and deeper research approaches. Going forward, it is imperative that such analyses consider the holistic value of therapies beyond traditional metrics. In particular, since QALYs are explicitly excluded, other measures must be included. Novel measures of benefit must align with the negotiated pricing framework and address the specific therapeutic and patient needs outlined by Medicare. Given the broader stakeholder scope, such measures should consider societal outcomes, especially in context of traditionally undeserved communities.

In addition to what is measured, the paradigm for CER is also shifting. The most significant shift is that CER should be part of an integrated evidence plan and planning should be initiated during the clinical development phase in order to support longitudinal and consistent evidence on therapy outcomes and benefits that can be tied to the clinical program and then extended into the real world. The advent of advanced analytical approaches and the ability to tokenize and link diverse data sets, including extending clinical trial data to claims and electronic health record (EHR) data, significantly empowers the ability to gather long-term data to address questions of durability. Leading companies also must continuously evaluate and refine CER methodologies to address the evolving regulatory landscape and changing economic needs.

Real-World Evidence

A cornerstone of planned activities to address the IRA is significant additional investment in the collection of real-world data, especially after product launch to support evidence generation efforts. Though RWE activity has long been a significant portion of HEOR activities, its role is expected to grow significantly in scope and relevance as the negotiation timelines specified by the IRA are several years post-launch. Comparative effectiveness research will largely be built on top of real-world studies and real-world data sets as described above.

Traditionally, retrospective analyses, especially claims-based studies have been the backbone of RWE work and according to 2023 Trinity research, these studies remain the largest single source of real-world evidence. However, there is a growing appetite for prospective real-world studies that are tailored to the specific, identified drivers of unmet needs. Updated health economic models, primarily budget impact models that capture real-world holistic costs and observed cost offsets are the leading type of studies that companies plan to develop to demonstrate the long-term economic value and mitigate arguments for price reductions.

The key to optimal deployment of RWE is to align RWE generation activities with evidentiary needs throughout the life cycle. Anticipating IRA-driven changes, companies are investing in evidence generation plans that begin prior to product launch to establish baseline data and capture real-world treatment patterns. These plans have solid pre- and post-launch data that minimize evidence gaps and deliver appropriate data as required over time. They also ensure a steady stream of evidence that can be communicated through scientific publications and outreach to patient advocacy and thought leader stakeholders.

Increasingly, RWE and economic endpoints relevant to payers are also being incorporated into pivotal trials as early as Phase 2. The advent of linked data sets is being exploited by leading companies to demonstrate the long-term effectiveness, safety and economic value of products. This approach addresses two of the key objections often heard about evidence derived from contemporary RWE studies and clinical trials: the patients and data in the clinical studies do not reflect reality and results are short-term/do not represent the durability of benefits.

The IRA is forcing companies to continuously update RWE datasets and analyses to reflect changes in clinical practice and patient outcomes and capture the long-term effectiveness, safety and economic value of therapies as treatment settings evolve.

The Role of Advanced Analytics

Over the past decade, there have been significant advances in analytical techniques that have accompanied the proliferation of broader, deeper, more diverse data sets. Advanced analytics, including machine learning, are seen by most of the companies Trinity surveyed as a powerful tool to address the IRA, as well as a growing best practice for value demonstration more generally.

Predictive modeling is being deployed as a tool to enhance CER. Machine learning techniques can be used to develop learning models for comparative effectiveness research, allowing researchers to identify factors that influence treatment outcomes and healthcare costs. These models are already helping to identify high-value interventions, optimize treatment pathways and inform decision-making regarding the adoption and reimbursement of therapies. This is especially helpful in preparing for negotiations by modelling anticipated impacts of new competitors and perturbations due to patent loss.

Machine learning algorithms are also being deployed on large datasets of real-world patient data to identify real-world treatment patterns, patient outcome and adverse events associated with comparator therapies. These tools extend the ability of HEOR researchers and medical affairs professionals to glean insights into the real-world effectiveness, safety and utilization of drugs. When executed early, machine learning not only provides evidence to assist in the negotiations by identifying value, but also when it is deployed early in the process, it can help access teams make decisions around negotiation tactics and the necessary evidence generation strategies that should be implemented.

One of the key levers in the negotiation process is the evolution of market factors. Advanced data mining algorithms are being deployed on large datasets of market and sales data, including pricing trends, competitor strategies and payer preferences. These powerful tools assist in identifying opportunities and risks in the therapeutic market and can help companies anticipate market dynamics, identify pricing strategies and optimize resource allocation for evidence generation activities well in advance of the negotiations. They can also guide rapid reactions to changes as they happen.

Advanced analytics and artificial intelligence are already being used to analyze historical trial data and outcomes to optimize clinical trial designs. Machine learning is increasingly being used on historical trial datasets and new RWE to identify patient subpopulations and assist in patient enrolment. A 2018 Tufts University study found that fully 80% of Phase 2 and Phase 3 trials fail to meet their enrolment timelines[3,4] leading to significant time and cost over-runs. Analytics are already helping researchers design more efficient and cost-effective trials, reduce patient recruitment timelines and maximize the likelihood of trial success.

Finally, "personalized medicine" and improving outcomes in historically marginalized populations is an explicitly stated goal of CMS in improving health equity whilst delivering more efficient care. Machine learning algorithms applied to rich genetic, genomic and biomarker data are proving successful at identifying patient subgroups that are most likely to benefit from specific therapies and help enrich clinical trials. In turn, this work is enabling pharmaceutical companies to develop more targeted therapies, tailor treatment strategies to individual patients and demonstrate the value of personalized medicine approaches.

Partnered with improved data sets, advanced analytics, including machine learning, are already contributing to evidence generation and negotiation strategies within the pharmaceutical industry. By leveraging data-driven insights and predictive modeling techniques, pharmaceutical companies can optimize decision-making, enhance the value proposition of their products and navigate complex regulatory and market dynamics more effectively.

In a 2023 study, fully 30% of companies surveyed by Trinity were already using machine learning and advanced analytics across HEOR and market access activities. All of the surveyed companies indicated a desire or plan to integrate advanced analytics and among those that had not yet done so, the most cited obstacle was a lack of internal expertise. There is a significant need for companies to upskill their teams to fully benefit from the advances available.

[3] Journal of Medical Internet Research, 2020, 22(11): e22179

[4] University of Mississippi Medical Center, Office of Clinical Trials

Evidence Strategy: Bringing It All Together

Wrapped around these tactics, winning companies must implement strategic approaches to ensure that evidence generation activities are aligned to stakeholder needs - both internal and external, address the holistic questions that CMS are asking and are communicated strategically and in a timely way that aligns to specific needs. These strategic approaches include early and thorough cross-stakeholder engagement and training and coordinated development of specific value arguments that the generated evidence is designed to support. These activities necessitate senior and seasoned talent across the entire continuum of evidence planning, from execution to scientific dissemination and spans multiple functional groups across Clinical Development, Regulatory, Medical Affairs, HEOR, RWE, Insights/ Market Research, Market Access and Commercial, which will have to learn to come together and collaborate from early planning to execution. As 2023 has demonstrated, companies must do all this in a challenging macroeconomic climate.

It is precisely because the task of launching a product is so complex and prone to risk that companies must prepare now by making investments. To maximize the likelihood of success, companies who want to be "winners" - who want to succeed given these market and policy challenges, must get the right talent in the door early, plan and collaborate across functional groups and develop integrated evidence and negotiation plans early in the product lifecycle. It will be critical to bring all relevant functions together – involving cross-functional teams from Pricing, Medical Affairs, Commercial, Regulatory, Clinical Development, Market Access, RWE and HEOR. The required expertise is diverse and cross-functional and it is imperative that all stakeholders weigh in to design the best evidence strategy. Teams must establish clear expectations for scenarios, align on the potential negotiation outcomes and financial implications and align internal stakeholders and functional teams with strategic objectives.

Using the aligned evidence, the next step is for teams to translate the evidence into compelling value arguments that align with the negotiation strategy, emphasizing the holistic value proposition of therapies and addressing CMS requirements. The objective must be to prioritize value messages and supporting evidence that not only speak to the science and novel mechanisms of action in today's market but fully appreciates and addresses the specific needs of diverse stakeholder types, incorporating evolving market knowledge and competitive pricing insights into value propositions.

With the strategy aligned and evidence in hand, teams must seek early internal and external stakeholder engagement, providing training and workshops to prepare teams for negotiation challenges and objections. The issues and elements are complex and the negotiation teams must be fluent with all elements of the strategy. Cross-functional collaboration and fluency with evidence generation and dissemination strategies will empower negotiation teams to make informed decisions and respond effectively to stakeholder needs.

Conclusion

The IRA undeniably places significant constraints and restraints on industry. However, by implementing evidence-generating activities and focusing on strategic areas outlined in the IRA framework early, pharmaceutical companies can enhance their negotiation readiness, demonstrate the value of their products and support equitable access to medicines for patients within Medicare programs.

In summary, the IRA has and will continue to have a major impact on the biopharma industry. While companies are pivoting and adapting to the new reality as best they can, will there be a point where the discounts are so steep and expansive that the incentives to develop innovative medicines for the Medicare population are materially damaged? Time will tell, but it would be unwise to kill the goose that lays the golden egg.

Manufacturers need to continue to bring strong evidence to optimize outcomes within the framework of government regulation, but they may also need to make a stronger, more direct appeal to the public about the value of biomedical innovation to shape the conversation around government regulation and the perils of price controls in innovative marketplaces. Sometimes, it is not enough to play by the rules; industry may also need to stand together to forge a new path forward that regains the trust of the public.

In the midst of these policy and regulatory changes, it is critical that the industry does not lose sight of its core purpose and obligation – to meet the needs of patients, perhaps at the time when they are most vulnerable. For this reason, biomedical discovery and innovation must continue to march forward no matter what headwinds arise.

To learn more about Trinity's Evidence, Value, Access and Pricing team, please visit trinitylifesciences.com/services/evidence-access-pricing.

Authors

Maximilian Hunt | Partner, Value Access Pricing

Max is a Partner in Trinity's Value, Access and Pricing practice. His experience as a global life sciences strategy consultant spans all stages of product development and a wide range of therapeutic areas, including oncology, inflammatory conditions, rare diseases and cell and gene therapies.

Prior to joining Trinity, Max's engagement work at CBPartners targeted a variety of commercial business issues related to pricing, access and value with a focus in the U.S., Europe, Japan and other global markets. Max is devoted to delivering innovative and impactful commercial strategy recommendations to biopharmaceutical manufacturers working to navigate the evolving global payer marketplace.

Max previously worked in the strategy consulting division of Leerink Partners and holds a BS in Biomedical Engineering from Johns Hopkins University.

Nandini Hadker | Partner, Evidence Strategy

An economist by training, Nandini is a Partner at Trinity Life Sciences with over two decades of experience in custom research and strategy consulting. She is seasoned at helping clients identify what evidence will be crucial in driving their product's success, generating that evidence using publication-grade research and pulling the insights through scientific dissemination. She has helped to develop dozens of holistic Value Propositions and effective Evidence Generation Roadmaps. Employing the right methodologies – RWE/ Claims, Primary Research, Literature Synthesis, HECON modeling, etc. depending on the client needs, she has also conducted dozens of evidence generation studies that help clients prove their differential value in the marketplace, address unmet needs in an underserved market and demonstrate value across efficacy, safety and humanistic dimensions. She is widely published in several highly rated journals as well as in industry forums.

Prior to joining Trinity, Nandini worked at United Biosource Corporation (now Evidera), as a Managing Director, developing and leading the Commercial Strategy and Reimbursement practice. Prior to that, Nandini was an Executive Director and Principal at Abt BioPharma Solutions.

Nandini has a Master's degree in Economics from Boston University. Her research has been widely published in peer-reviewed pharmacoeconomic journals. She has been a speaker at PMRG and the lead feature in Boston Herald's 2010 special edition on "Women Leaders under 40".

Acknowledgements:

Trinity Life Sciences would like to thank David Budd, PhD and Jeff Skaar, PhD for their contributions to this article.

About Trinity

Trinity Life Sciences is a trusted strategic commercialization partner, providing evidence-based solutions for the life sciences industry. With over 25 years of experience, Trinity is committed to revolutionizing the commercial model by providing exceptional levels of service, powerful tools and data-driven insights. Trinity's range of products and solutions includes industry-leading benchmarking solutions, powered by TGaS Advisors. To learn more about how Trinity is elevating life sciences and driving evidence to action, visit trinitylifesciences.com.

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