



Practice Area
Life Science Advisory



Inflation Reduction Act

**The Catalyst to Accelerate
Digital Transformation**

September 2023

Life Science companies are preparing for a significant transformation driven by the Inflation Reduction Act (IRA), mainly due to Medicare Drug Price Negotiation regulations.

Discover how embracing digital strategies is not merely a choice – it's a necessity. Learn how an enterprise digital mindset can empower your organization to resolve operational challenges and regulatory complexities presented by the Negotiation Program.



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The Inflation Reduction Act of 2022

The Inflation Reduction Act (IRA) of 2022 has far-reaching implications for pharmaceutical manufacturers and the US healthcare ecosystem. As a pharmaceutical or biotech executive, it is essential to understand these legislative changes, particularly regarding drug price setting, exemption policies, and regulatory enforcement. The Medicare Drug Price Negotiation Program is just one of many healthcare provisions in the IRA legislation, which presents new challenges on top of ongoing advancement and disruption of industry business models. In this article, we delve into the vast implications of the Negotiation Program. We aim to provide insights into some of the ways organizations can navigate these complex regulations and promote compliance by adopting enterprise digital capabilities.

Medicare Participant Benefits

The IRA will empower Medicare to negotiate high-cost single-source drug prices, thus broadening access to innovative and life-saving treatments at lower costs, specifically for Medicare beneficiaries. Another important change includes making healthcare accessible and affordable by requiring manufacturers of select single-source drugs to issue rebates to Health and Human Services (HHS) on any medication that increases their annual price more than the Consumer Price Index for All Urban Consumers (CPI-U). The benefits realized by an individual will depend on the implementation and realization of the legislation, particularly given the industry's harsh response.

Medicare Drug Price Negotiation Program

Under the Medicare Drug Price Negotiation Program, single-source brand-name biologics and drugs with the highest aggregated cost to Medicare over the prior 12 months will undergo price negotiations with the Centers for Medicare & Medicaid Services (CMS). The Negotiation Program has significant implications for all sizes and maturities of pharmaceutical and biotech companies. It will specifically impact pricing strategies and pipeline investment decisions due to price caps by CMS. As more drugs are subject to price negotiation and more interdependent portfolio planning demands, organizations must prepare to adapt their business strategies with an understanding of the regulatory landscape, the effects of negotiated drug prices, and, most importantly, the cross-functional impact of new organizational risks. We anticipate that biopharma companies will

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accelerate their transition to embrace a holistic set of enterprise-wide digital capabilities to offset the IRA's operational complexity.

The Catalyst for Digital Solutions

The IRA creates a burning platform to achieve digital maturity. Organizations need to begin preparing for the inevitable headwinds, which may include increased operational complexities, downward price pressure, compressed margins, and reduced profitability. To offset these headwinds, organizations will need to place an increased urgency on embracing innovation and digital solutions to reduce the drug development timeline, particularly given the new regulatory duration between FDA approval and drug eligibility for Medicare price negotiation – 13 years for biologics and 9 years for small molecules.

Digital solution programs in Life Science (LS) organizations are witnessing noteworthy macro trends that accelerate the approval timeline while optimizing the delivery of therapeutic value. These trends include:

- **Global Digital Transformation Spending:** The estimated spend on digital transformation efforts globally will likely exceed \$3.4 trillion by 2026¹. This indicates a significant investment in leveraging digital technologies to drive innovation and operational improvements within the industry.
- **Emphasis on Digitization:** Around 62% of executives have initiatives in place to make their businesses more digital². This demonstrates a recognition of the value and benefits that digital transformation can bring, leading to a concerted effort to adopt digital strategies and technologies.
- **Success of Digital-First Companies:** Companies that prioritize digital capabilities are 3X more likely to exceed their business goals³. This highlights the competitive advantage and

¹ IDC.com IDC press release. IDC. (n.d.). <https://www.idc.com/getdoc.jsp?containerId=prUS49797222>

² Gartner Survey reveals that CEO priorities are shifting to embrace digital business. Gartner. (n.d.). <https://www.gartner.com/en/newsroom/press-releases/2018-05-01-gartner-survey-reveals-that-ceo-priorities-are-shifting-to-embrace-digital-business>

³ Experience index 2020 digital trends - adobe experience cloud. (n.d.). <https://business.adobe.com/content/dam/dx/us/en/resources/reports/digital-trends-2020/digital-trends-2020-full-report.pdf>

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superior performance that can be achieved by organizations that embrace digital-first approaches and leverage digital technologies effectively.

These macro trends underscore the growing importance of digital transformation in Life Science organizations. How will your organization prepare for the headwinds introduced by the Inflation Reduction Act and the broad implications on the drug development lifecycle?

Defining A Digitally Mature Organization

A digitally mature organization integrates advanced technologies, data-driven decision-making, and a culture of innovation. Additionally, it leverages digital tools and platforms to streamline operations and enhance customer experience, enabling competitive advantages.

At the core of a digitally mature organization is utilizing advanced technologies such as artificial intelligence (AI), machine learning (ML), natural language processing (NLP), robotic process automation (RPA), data analytics, and cloud computing capabilities to deliver business value. These technologies enable the organization to collect and analyze data in real-time and provide valuable, actionable insights for strategic decision-making. By harnessing the power of these digital capabilities, an organization can automate repetitive tasks, optimize processes, improve patient experience, and identify trends and patterns that can accelerate the delivery of therapeutic value.

In today's rapidly evolving landscape, transitioning to a digitally mature organization can realize transformational outcomes. Robust digital enterprise solutions enable strategic decision-making by gaining valuable insights into pricing strategies and identifying cost-saving opportunities.

Common Digital Challenges

We have identified a few common challenges LS organizations often face when considering digital capabilities. Challenges may include a lack of organizational digital expertise, limited capacity to assess options in line with current and evolving needs, making decisions based on anecdotal assessments, or following "hot trends" without a comprehensive understanding of business needs. To keep pace with competition and industry trends, departmental decisions are made to demonstrate activity but often lack a true north star in achieving a holistic digital end-state. Resource limitations may lead to decisions based on prior experience rather than adopting fit-for-

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purpose solutions. Inadequate integration may occur due to fragmented system purchases or unfinished integration programs across departments.

To effectively address the challenges, companies should prioritize the involvement of specialists to provide crucial support and industry expertise. Beginning the digital journey with the guidance of digital experts allows organizations to overcome internal limitations, make informed decisions aligned with strategic goals, and stay ahead of market competitors and industry trends. With the assistance of a specialist, companies can optimize resources, ensure seamless integration, address cost concerns related to targeting and engagement, and improve data collection for better real-world insights.

Unlocking the Power of Digital

Digital investment can deliver vast benefits across a Life Sciences organization. Some firms struggle to translate broad capabilities into tangible solutions to address and resolve their specific challenges. In Clinical Operations, digital investment can lead to improved patient enrollment and more effective execution of clinical trials through accurate patient and site selection, potentially reducing trial durations. Additionally, decentralized clinical trial execution can reduce complexity, cost, and patient burden. In R&D, cohesive data capture and insights enable informed strategic therapeutic investments. In Clinical Development, digital solutions can increase the probability of therapeutic and regulatory success. In Medical Affairs, digital investment can enhance the patient and Healthcare Professional (HCP) experience, accelerate the development of scientific content, and adapt to evolving consumer preferences. It also enables high-quality Real-World Data (RWD) collection and the generation of Real-World Evidence (RWE) while streamlining personalized and connected experiences for patients and HCPs. Finally, in Drug Safety, digital tools can reduce the operational burden associated with the collection of adverse events by automating all aspects of adverse event intake and assessment.

Conclusion

In the face of the Negotiation Program and its anticipated impacts on pharmaceutical and biotech executives, embracing digital strategies is essential. The journey toward achieving digital maturity holds immense potential for organizations facing the broad operational and compliance implications of the Negotiation Program. Adopting a digital enterprise mindset is crucial for

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effectively navigating the complex regulatory landscape and unlocking long-term success to achieve sustainable growth alongside accelerated drug development. Acquis has a unique blend of medical subject matter expertise, business acumen, and innovative digital transformation experience. We enable a cohesive strategy by reducing the organizational burden and creating a seamless intersection of holistic digital solutions and therapeutic goals to achieve desired outcomes. As the IRA unfolds, the time is *now*, to leverage the opportunity presented by the IRA to embrace digital solutions, as it provides a model catalyst to accelerate the competitive advantages necessary to thrive in an ever-evolving market.

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As an accomplished Engagement Manager in Acquis Consulting's Life Sciences practice, Kristian excels in generating business value by skillfully transforming organizational challenges into strategic victories. Serving as a strategic client advisor, Kristian possesses exceptional cross-industry program management expertise encompassing life sciences, technology, and finance. His diverse background empowers the seamless integration of innovative solutions and the realization of critical client priorities.

As a true catalyst for fostering relationships, Kristian bridges connections within global matrixed organizations to facilitate and realize strategic priorities. His areas of expertise include program and portfolio management, brand strategy, regulatory compliance, system integration, clinical informatics, and the successful launch of commercial products.

Kristian's academic background, including a Master of Management in Clinical Informatics from the Duke School of Medicine and a Bachelor of Science in Biology from Georgetown University, informs his multifaceted perspective. His certifications as a Certified Scrum Master and Six Sigma practitioner underscore his commitment to continuous improvement and innovative methodologies.



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As a Principal and Life Sciences Digital Lead at Acquis Consulting, Rishi is an accomplished transformational leader with 20+ years of cross-functional business and technology expertise. He has led large-scale, global, digital initiatives with a keen understanding of organizational challenges, from the perspective of both the business and end-to-end applications. He brings extensive project management experience and process improvement, by increasing efficiency and maximizing ROI for his clients.

He has deep expertise in developing enterprise-wide Digital Transformation strategies and associated implementation roadmaps. He has led digital programs from ideation to launch, including evaluation, development, and implementation of digital capabilities across R&D functional areas.

With certifications in Big Data & Artificial Intelligence from Rutgers and MIT, an executive MBA from Rutgers, and a Bachelors in Mechanical Engineering (B.Eng), Rishi successfully guides his clients in developing and executing the right Digital initiatives, tailored to their specific long-term strategic business goals.