

# THE EVOLUTION OF VALUE-BASED AGREEMENTS IN US HEALTHCARE: BARRIERS, OPPORTUNITIES, AND FUTURE PROSPECTS

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## INTRODUCTION

- ▶ The U.S healthcare system is experiencing a shift in how pharmaceutical innovations are paid for by the healthcare system.
- ▶ Traditional fee-for-service models are increasingly being challenged by more dynamic, value-based agreements (VBAs) that align reimbursement and price with the value of a medicine as measured by agreed parameters that reflect the clinical or economic benefits provided by the therapy.
- ▶ VBAs are gaining attention globally as a potential solution to improve access to innovative yet costly therapies.
- ▶ However, VBA use in the U.S has been limited by several challenges that have left some manufacturers debating their level of engagement and investment in these deals.

## OBJECTIVE

- ▶ This poster examines the evolving VBA landscape in the U.S, focusing on current implementation, barriers, and future potential.

## RESULTS

- ▶ A targeted literature review revealed growing interest in the use of VBAs amongst both payers and industry.<sup>1</sup>
  - ▶ One study reported nearly one-third of respondents (industry: 34%, payers: 27%) successfully implemented a VBA between 2020-2023.<sup>2</sup>
- ▶ VBA use varies by therapeutic area. In oncology, the use of VBAs for medical benefit products was predicted to rise from 49% to 67% by the end of 2023.<sup>1</sup>
  - ▶ Results from Cogentia’s survey indicated oncology products and gene therapies were viewed as having the most potential for VBA use in the U.S.

Table 1: Type of VBAs

Types of VBA	Examples	Description	Strengths	Weaknesses
Finance-based agreements <i>Links payment to utilisation or clinical data to reflect a therapy’s value</i>	Discount & rebates	Often confidential. Reduce list price to an acceptable value.	Simple & fastest route to market.	Blunt and relatively inflexible instrument
	Instalment or annuity payments	Costs spread over time or multiple financial years.	Reduces risk with upfront payment.	Legislative barriers can prevent staggered payments due to reporting & accounting rules.
Outcomes-based agreement <i>Links payment to real-world outcomes of the therapy</i>	‘Netflix’ Subscription model	Lump-sum payment to manufacturers for unlimited access to therapy for determined period.	Predictable manufacturer revenues & payer budget impact	Could require the payer to take more risk upfront should demand be lower than expected.
	Population-level coverage-with-evidence (CED)	Addresses clinical & financial uncertainty through real-world-evidence.	Manages uncertainty via real-world-evidence.	Risk of overpaying upfront based on worse than expected value. Increased HTA workload.
	Outcomes-based rebate agreement.	Upfront payment followed by manufacturer giving discounts (or rebates) if product does not meet expectations.	Shares risk of treatment failure with manufacturer.	High administrative burden on both healthcare professionals and patients to report and track outcomes. Requires advanced data infrastructure.
	Outcomes-based payment by result.	Manufacturer receives payment upon patient demonstration of agreed outcome within the defined period.		

- ▶ **Case study 1: Repatha.** PCSK9 inhibitor to lower LDL-C in patients with hyperlipidemia, homozygous familial hypercholesterolemia and to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease. If Repatha lowered LDL-C to a similar extent in the real-world as in the clinical trial, then the negotiated price discount would remain, if not then further discounts would ensue.<sup>3</sup>
- ▶ **Case study 2: Rebif.** Indicated for relapsing remitting multiple sclerosis. The manufacturer tracked hospitalisations and emergency room visits. Rebif discounts were linked to adherence and event rates.<sup>3</sup>

## DISCUSSION

- ▶ Whilst VBAs have been gaining attention in the U.S as a potential solution to improve access to innovative therapies, their uptake has historically been limited by challenges such as administration burden and outcomes tracking.<sup>3</sup>
- ▶ Survey results indicated a positive outlook for the future of VBAs in the U.S, with the majority of U.S industry participants stating they would consider implementing a VBA in the future.
- ▶ Oncology and gene therapies were reported here as the most appropriate fit for VBA use; likely due to the high-cost nature of these therapies necessitating the need for innovative contracts.
- ▶ For manufacturers, VBAs typically require significant investment in infrastructure for tracking patient outcomes across many contracts and states and managing rebate calculations.

## REFERENCES

1) Roulston H. Key Trends in Medical Benefit Contracting and Value-Based Agreements. Drug Channels; 2023 Apr 17. Available from: <https://www.drugchannels.net/2023/04/key-trends-in-medical-benefit.html> 2) Barlow JF, Ford MA, Licking EF. Major Trends in Innovative Contracting: A Survey of Payers and Industry. J Managed Care Med. 2023;26(1):3-11. Available from: [https://namco.org/InnovContract\\_Monograph\\_Jan2023.pdf](https://namco.org/InnovContract_Monograph_Jan2023.pdf) 3) Huron Consulting Group. Value-Based Contracting In The U.S. Huron Consulting Group. Available from: <https://www.huronconsultinggroup.com/insights/value-based-contracting-in-us>

## METHODS

- ▶ A targeted literature review assessed the current and historical VBA landscape including factors influencing uptake and interest in VBAs in the U.S.
- ▶ Different types of VBAs were compared and contrasted, highlighting their strengths and weaknesses.
- ▶ Case studies provided examples of how VBAs have been applied in real-life practice in the U.S.
- ▶ A survey of U.S market access industry experts (n=9) was conducted to gauge insights into current and future use of VBAs, including perceived opportunities and barriers.



Figure 1. Participant’s likelihood of implementing VBAs in the U.S in the next 5 years

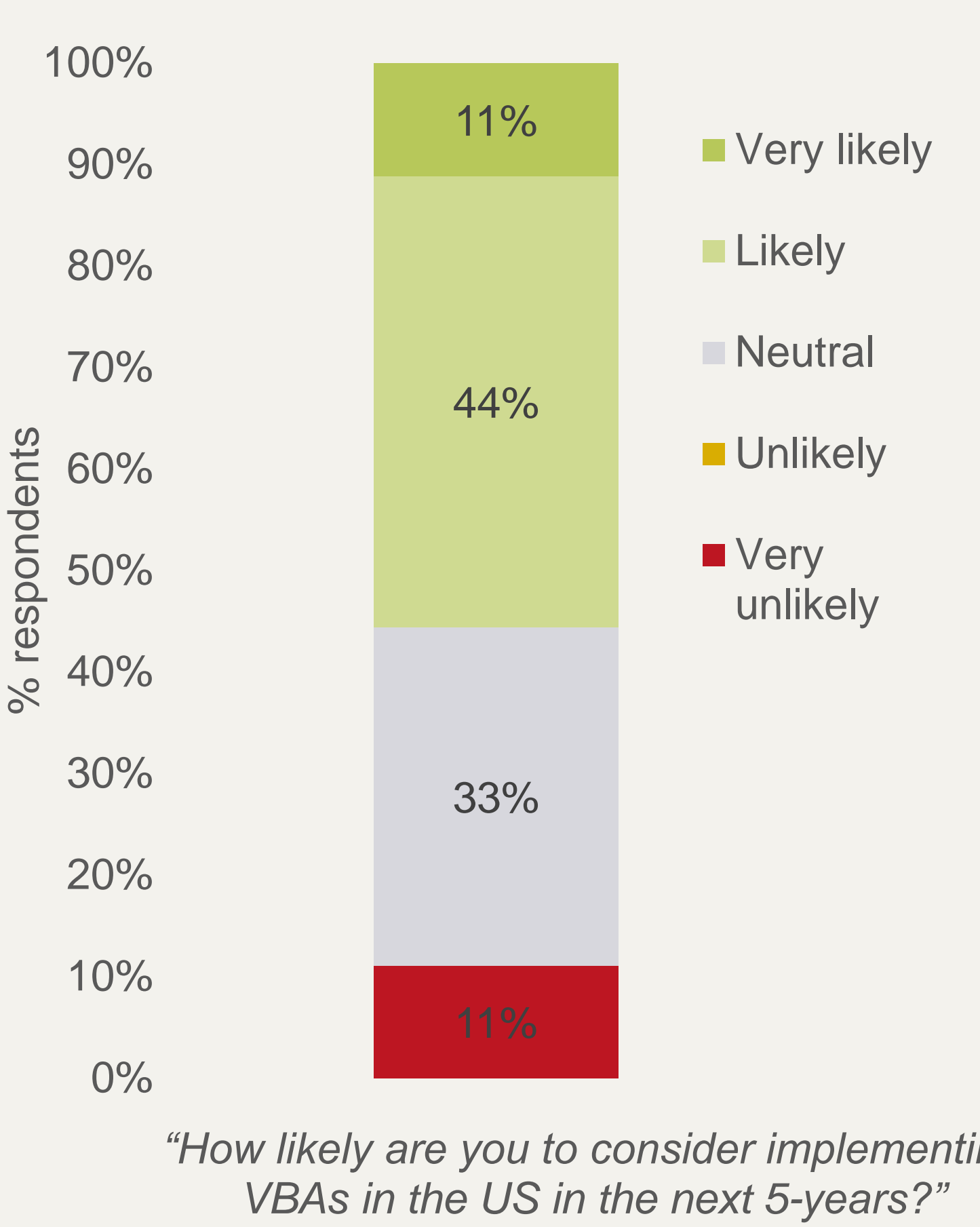
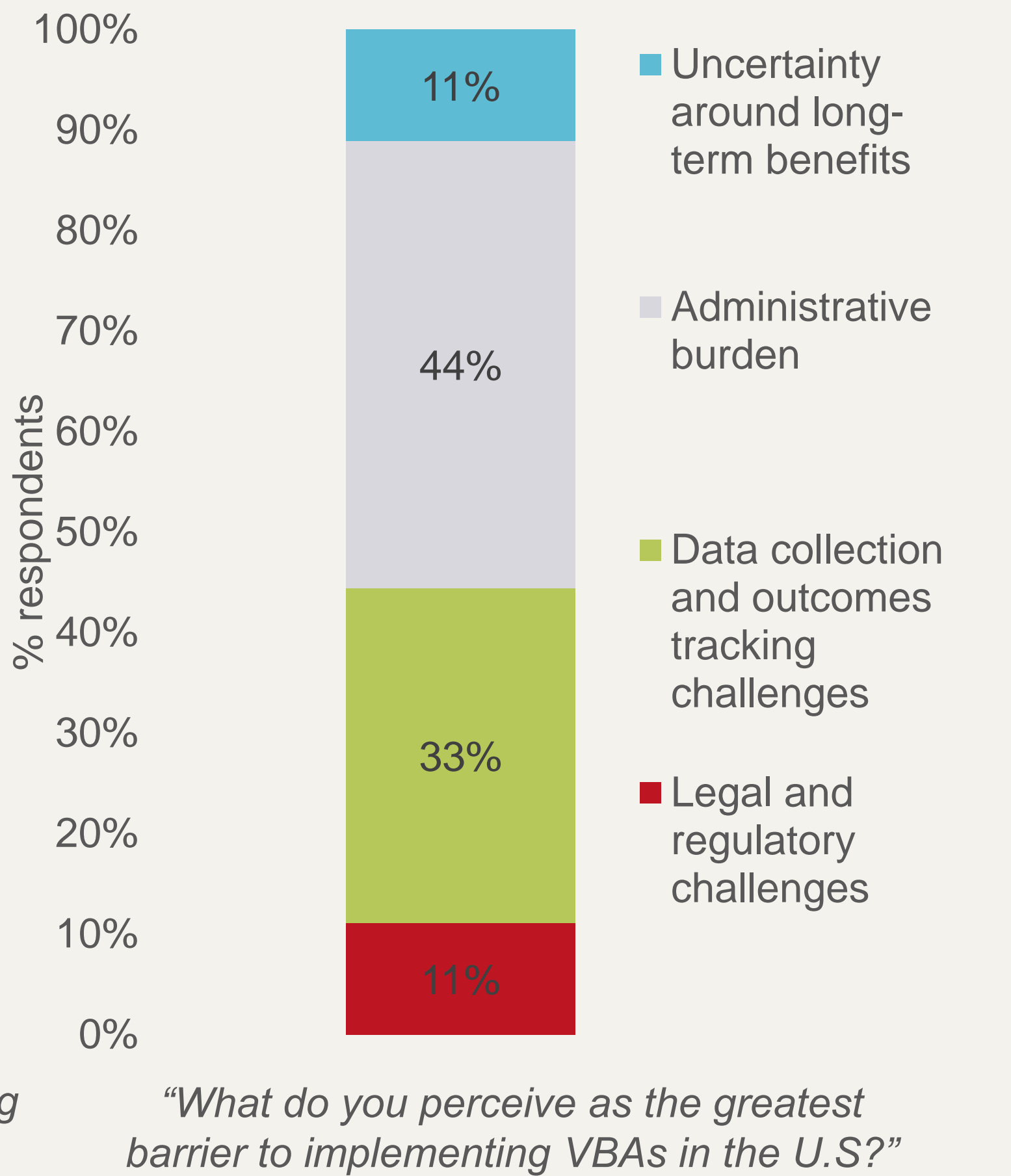


Figure 2. Barriers to VBA implementation in the U.S



- ▶ Cogentia’s survey results show the majority (55%) of U.S industry participants expect to consider the implementation of VBAs in their work in the next 5 years (Fig.1).
- ▶ Survey results also indicate that the majority of participants (77%) view administrative burden and data collection and outcome tracking challenges as the greatest barriers to VBA implementation in the U.S (Fig.2).
- ▶ These challenges are supported by literature which details how under the Centers for Medicare & Medicaid services (CMS) revised rule, manufacturers must offer the same VBAs to state Medicaid programs as they do to commercial payers. In practice, this means manufacturers must manage complex tracking, reporting, and reconciliation for multiple pricing scenarios to report the “best prices” from VBA agreements to Medicaid.<sup>3</sup>

## CONCLUSIONS

- ▶ The trend toward VBAs is driven by the need for more dynamic payment models that align reimbursement with real-world outcomes, particularly for high-cost therapies or therapies with uncertainties over the long-term duration of effect. As healthcare stakeholders increasingly seek to demonstrate the value of pharmaceutical innovations, VBAs offer a mechanism to share risk and ensure payment reflects the actual clinical and economic benefits of a treatment.
- ▶ However, the widespread adoption of VBAs hinges on overcoming existing barriers including administrative complexity, outcomes tracking and regulatory hurdles, such as the need to extend the same VBA terms to Medicaid as to commercial payers.
- ▶ Successfully addressing these issues will require continued investment in robust data infrastructure, streamlined contracting processes, greater regulatory flexibility and long-term collaboration with payers and policymakers.
- ▶ Given the growing interest from both payers and manufacturers, and the potential for VBAs to support value demonstration, it is likely such agreements will continue to evolve and become more prevalent in the U.S. healthcare landscape, although their use is unlikely to be suitable for all therapeutics.