Value-Based Contracting in Pharma: A Guide to How It Works

By Adrien Laurent, CEO at IntuitionLabs • 1/10/2026 • 50 min read

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Executive Summary

Value-based contracting (VBC) in pharmaceuticals – also known as outcomes-based or risk-sharing agreements – ties drug payment to real-world clinical or cost outcomes rather than simply sales volume. These agreements aim to align incentives among manufacturers, payers, providers, and patients to improve care value under budget constraints. The literature and industry reports are unanimous that interest in VBC is high: over 70% of health systems now view VBC with drug makers as a priority, and many expect rapid growth in new agreements ([1] www.techtarget.com) ([2] pmc.ncbi.nlm.nih.gov). Pharma companies see these deals as a way to gain market access and demonstrate product value, while payers hope to mitigate uncertainty and control costs ([3] pmc.ncbi.nlm.nih.gov) ([4] pmc.ncbi.nlm.nih.gov). Yet, actual uptake remains limited due to practical hurdles. Studies and expert panels consistently highlight **data gaps and analytical burdens** as top obstacles – for example, 64% of payers identify "insufficient data infrastructure" as a deal-killer ([5] www.hmpgloballearningnetwork.com) – and note that negotiation complexity and misaligned metrics often derail agreements ([6] www.hmpgloballearningnetwork.com) ([7] www.hmpgloballearningnetwork.com). In practice, many planned VBCs fall apart when parties cannot agree on measurable outcomes, or when collecting outcome data proves infeasible. Patients and clinicians also face risks if rigid outcome targets damage care continuity. Socialized health systems in Europe and some U.S. innovators (like UPMC's contracts on diabetes and opioid treatments) have shown proof-of-concept, but comprehensive evaluations of long-term impact are scarce.

This report provides an in-depth analysis of VBC in pharma, covering:

- **Definitions and Rationale:** Clarifying what constitutes a VBC, why stakeholders pursue them, and how they differ by type (e.g. outcomes-based vs indication-based). We document global trends (e.g. Europe's early adoption of pay-for-performance, the PhRMA taxonomy) and the business motivations (cost control, access expansion, evidence sharing).
- **Data and Measurement Requirements:** Detailing *what to measure* – e.g. survival rates, biomarker targets (HbA1c, LDL), hospitalization rates, patient-reported outcomes (PROs), adherence, and total cost of care – and *how* to capture these metrics. We discuss the need for integrated claims/EHR registries, patient registries, and analytics platforms. Examples include multi-year registries in Catalonia and NHS data-mining tools in Wales ([8] pmc.ncbi.nlm.nih.gov) ([9] pmc.ncbi.nlm.nih.gov). We outline common quantitative hurdles: defining clear inclusion criteria, ensuring sufficient sample sizes, and controlling for confounders in real worlds.
- **Contract Operationalization:** Explaining the logistic process of designing and running VBCs. This involves product selection, stakeholder alignment, data sharing agreements, and litigation-proof payment structures. We report expert-recommended best practices – for instance, a Deloitte panel advised pharma to first analyze internal outcomes data before drafting any contract ([10] www.hmpgloballearningnetwork.com) ([11] www.hmpgloballearningnetwork.com) – and we cover legal/regulatory considerations (e.g. FDA guidance on off-label communications, CMS "best price" rules, EU privacy laws affecting data access).
- **Common Failure Modes:** An evidence-based review of why VBCs break down. Drawing from payer surveys and systematic reviews, we identify frequent pitfalls: *data issues* (missing or unlinked EHR/claims data causes 64% of planned deals to collapse ([5] www.hmpgloballearningnetwork.com)); *metric mismatch* (84% of negotiations stall because parties cannot agree on a valid, measurable outcome ([7] www.hmpgloballearningnetwork.com)); *operational complexity* (80% of payers say proposed agreements are too burdensome relative to their benefit ([6] www.hmpgloballearningnetwork.com)); and *financial/regulatory disincentives* (concerns over price-reporting and legal risk ([12] www.techtarget.com)). We cite real-world examples (see Table 2) such as the U.S. CAR-T therapy Kymriah, where CMS abandoned an outcomes pilot amid implementation confusion ([13] www.pharmaceutical-technology.com) ([14] www.pharmaceutical-technology.com), and a diabetes study showing that targeting HbA1c alone yielded no net value because patients could reach the goal with cheaper generics ([15] www.sciencedirect.com).
- **Case Studies and Evidence:** We present detailed cases from U.S. health plans (e.g. UPMC's Jardiance and Vivitrol contracts ([16] www.managedhealthcareexecutive.com) ([17] www.managedhealthcareexecutive.com)), European pilots (Italy/Spain diabetes and cancer contracts ([18] pmc.ncbi.nlm.nih.gov) ([8] pmc.ncbi.nlm.nih.gov)), and manufacturer-led initiatives (Amgen's PCSK9 inhibitor deals ([19] www.mckinsey.com), Bluebird's sickle-cell gene therapy deals ([20] investor.bluebirdbio.com)). For each, we cover measured outcomes, data systems used, and reported results (if available). Where possible, we quantify outcomes (e.g. % of patients reaching target) and financial impacts (rebates, cost savings) to date.
- **Future Directions:** Based on current trajectories, we analyze how VBC may evolve. We consider technological enablers (AI-driven RWE analytics, FHIR data standards), policy trends (broader MVC-safe harbor provisions, Medicare demonstration projects), and shifting norms (more patient-centered outcomes).Finally, we discuss implications for stakeholders: how VBC can affect pharma R&D strategy (spotlighting drugs with quantifiable benefit), payer budgeting, and patient access, as well as whether VBCs are likely to remain niche experiments or become mainstream.

All analyses are grounded in up-to-date literature and real-world data. Claims are backed by extensive citations across journals, industry reports, and expert commentaries. The following sections unpack these topics in depth, offering a comprehensive view of the current state and challenges of value-based contracting in pharma.

Introduction and Background

The cost-value challenge in modern pharmacotherapy. Across the developed world, healthcare systems face unsustainable pressure from both rising expenditures and a pipeline of highly effective yet extremely expensive therapies. National health expenditures in the U.S. and Europe are accelerating, with prescription drug costs being a large and growing component ([21] www.techtarget.com) ([22] pmc.ncbi.nlm.nih.gov). In this environment, payers (insurers, government programs, integrated health systems) seek ways to ensure that they pay for drugs to the extent that the patient actually benefits. Conversely, manufacturers struggle to justify high launch prices without clear evidence that real patients (especially the insured population) will see commensurate improvements in outcomes.

Value-based contracting (VBC) in pharmaceuticals has gained prominence as one response to this dilemma. Unlike the traditional "per-pill" or fixed-reimbursement models, a VBC ties the price or continued coverage of a drug to some measure of its real-world effectiveness or cost impact. In general, a VBC aims to **share financial risk** between the manufacturer and payer: if the drug fails to deliver agreed-upon results, the manufacturer pays/(rebates) back part or all of the cost, but if outcomes are attained or exceeded, the manufacturer receives full (or even premium) payment. In effect, it aligns drug revenue with patient benefit. As one review puts it, value-based purchasing "links reimbursement and price to the real-world usage and impact of a medicine, thereby enabling patient access while reducing clinical or financial uncertainty for the payer" ([23] pmc.ncbi.nlm.nih.gov). Such arrangements promise both improved care (since only effective treatments retain funding) and cost control (since payers can limit their upside risk). Researchers note that these agreements shift focus "from a volume to a value focus" in healthcare ([24] pmc.ncbi.nlm.nih.gov).

Stakeholder motivations. Both payers and manufacturers have pressing reasons to consider VBCs. Payers find them attractive because they can reduce exposure to the risk of new expensive therapies. As one industry survey explains, under a VBC "payment is greater for a drug when it works and less when it does not" ([25] www.hmpgloballearningnetwork.com). In other words, payers pay more when patients do well, but they are protected if therapies disappoint. From the payer perspective, any solution that can "achieve the goals of sharing risks with manufacturers and alleviating the uncertainty regarding the value of costly new therapies" is desirable ([25] www.hmpgloballearningnetwork.com). At the same time, manufacturers can benefit by gaining faster or broader market access. A guaranteed rebate or refund may make it politically or financially feasible for payers to cover an innovative drug, and the manufacturer can tout the VBC as proof of its product's benefit. In short, many view VBCs as a way for companies to "reinforce a product's value proposition" in a credible way ([25] www.hmpgloballearningnetwork.com). Moreover, prominent voices argue that the traditional discount and rebate model ("per-unit, volume-based pricing") has broken down, and that innovative, value-centered approaches are needed ([26] www.hmpgloballearningnetwork.com).

Pharma industry documents and surveys suggest growing interest. For example, a 2019 *TechTarget* survey of over 200 healthcare executives found that **73% of health systems identified VBC with drug makers as a priority**, and 81% wanted more suppliers offering such options ([1] www.techtarget.com). Similarly, PwC's Health Research Institute reported that among pharma executives, only ~25% had tried a VBC, but 80% of those who did called them successful ([27] www.techtarget.com). These data imply both demand and a perception of upside potential. The *New England Journal–Va lue in Health* commented that outcome-based pricing is "one of the solutions" to the cost problem ([21] www.techtarget.com), echoing a broad consensus that we need novel payment models.

Early adoption and evolution. Value-based drug contracts have a history dating back to the late 1990s–2000s, especially in Europe. Countries like Italy, the U.K., and Spain started experimenting with outcome guarantees and "managed entry agreements" for expensive therapies (oncology, rare diseases) ([28] pmc.ncbi.nlm.nih.gov) ([29] www.mckinsey.com). For example, Italy requires outcomes-based deals for certain oncology and rare drugs, making it a leader with roughly 35% of disclosed innovative contracts world-wide ([29] www.mckinsey.com). In the U.S., activity was initially modest but started to pick up in the mid-2010s (the first CAR-T contracts and PCSK9 inhibitor deals under Cigna/Novartis around 2017). A JMCP survey found that by 2015 most U.S. payers and EU-5 payers expected **2–3 times more outcomes-based contracts in the next five years than had existed in the prior five years** ([2] pmc.ncbi.nlm.nih.gov), reflecting rapid growth expectations. But despite enthusiasm, many deals remain confidential or pilot-stage, and broad adoption has lagged.

By 2025, the landscape is mixed. Some big healthcare organizations have launched ambitious programs. For instance, UPMC's Center for Value-Based Pharmacy has executed contract pilots on type-2 diabetes (Jardiance) and opioid addiction (Vivitrol)

([16] www.managedhealthcareexecutive.com). Bluebird Bio publicly signed value-based agreements for its sickle-cell gene therapy **LYFGENIA™** with multiple payers (including Medicaid and national insurers) ([20] investor.bluebirdbio.com). Nonetheless, many industry leaders caution that most pharmaceutical segments are still at an "inflection point": while value contracting is a growing trend, substantial operational and legal challenges remain before it becomes routine ([30] www.techtarget.com) ([4] pmc.ncbi.nlm.nih.gov).

Defining value-based contracts. There is no single definition, but most frameworks separate VBCs into main categories. PhRMA, the U.S. drug manufacturers' association, describes **"performance-based"** deals (linking payment to clinical outcomes or conditional therapy continuation) versus **"differential pricing"** deals (like indication-based pricing, REGO pricing, or cost caps) ([31] www.techtarget.com). In industry practice and literature, common types include:

- **Outcomes-based agreements (OBAs)** – Payment/rebate is tied to patient outcomes (e.g. a biomarker threshold, event rate, or patient-reported outcome). If agreed targets (say, blood sugar control, progression-free survival) aren't met, the manufacturer gives rebates or refunds. For example, an OBA might refund treatment costs for patients who fail to respond by a certain time. Novartis's CAR-T therapy *Kymriah* in the U.S. has such a clause: if a patient does not respond in 30 days, the treatment is offered at no charge ([32] www.pharmaceutical-technology.com). AstraZeneca also struck an OBA for Brilinta (ticagrelor) where payment was tied to reduced 30-day readmission rates ([33] www.mckinsey.com).
- **Indication- or population-based pricing** – Different prices for different indications or patient subgroups based on expected value. For example, an oncology drug might cost more in patients with very severe disease than in milder cases. These are often unilateral manufacturer offerings or negotiated separately from outcomes. (McKinsey groups this as "segmentation" deals ([34] www.mckinsey.com).) A classic illustration is Novartis's arrangement for Lucentis (an eye drug) with the UK NHS: NICE recommended 14 injections; Novartis agreed to cover the cost of any injections beyond 14, effectively placing a cap on patient spending ([35] www.mckinsey.com).
- **Financial-based contracts / budget caps** – Manufacturer helps cover costs if overall spending exceeds a threshold. Examples include global or per-patient spending caps (also known as "subscription" models). Again, the Lucentis UK example fits here: the manufacturer assumes costs beyond the budget cap of 14 doses ([35] www.mckinsey.com). Another example not detailed here was Australia's "Netflix model" deals for hepatitis C cure drugs, where the government paid a lump sum for unlimited treatment.
- **Money-back guarantees** – A form of OBA where the manufacturer refunds the full drug cost (or large share) for patients who do not benefit. This effectively makes payment conditional on outcome. As noted above, Bluebird Bio's program for gene therapies (alglucosidase alfa, Lovo-cel) includes strong money-back terms for treatment failures ([20] investor.bluebirdbio.com).
- **Coverage with Evidence Generation** – Interim coverage provided while additional data is collected. This is more common in regulatory/payer frameworks (like the UK's Cancer Drugs Fund or Medicare's CED for new devices). In the U.S., the "CMMI CAR-T demonstration" (Medicare's new pilot for cell/gene therapies) is an example of using a research framework to enable access pending outcomes data.

In practice, many agreements combine elements. For instance, a VBC might set an outcome goal and also cap total spending. The structure can be complex, with different rebates for different outcome levels. Furthermore, the term "value-based" is sometimes used loosely to include any risk-sharing or performance incentive, blurring lines. For clarity, we will use "value-based contract" (VBC) broadly to refer to any arrangement where reimbursement depends on real-world performance or stratified pricing rather than flat wholesale price.

Scope and perspectives. This report focuses on pharmaceutical products (drugs and biologics). We include both payer-provider mandates (e.g. mandated by law or regulation) and voluntary negotiations between manufacturers and payers. We examine the U.S. system in detail, as well as lessons from Europe (especially Italy, UK, Spain) and select other markets (Canada, Australia) where VBC has been piloted. We highlight viewpoints of multiple stakeholders: payers, providers, manufacturers, plus the regulatory context. We also consider patient and provider perspectives implicitly through outcome choices and practical implementation issues.

Before diving deeper, we note the state of evidence: detailed outcome data on VBCs is limited by confidentiality. Many reports are qualitative or retrospective. Thus, we rely on published analyses, expert panels, surveys of key decision-makers, and available case descriptions. Whenever possible, we cite peer-reviewed studies or official sources. We organize content thematically but also reference real-world examples (see summary tables below) to ground our analysis.

Models of Value-Based Pharmaceutical Contracts

Pharmaceutical value-based contracts come in various forms. Below we outline the main models and give examples of how they work in practice.

Contract Type	Description	Examples
Outcomes-Based / Pay-for-Performance	Reimbursement (or rebates) tied to patient outcomes or clinical endpoints. Manufacturer refunds or discounts if agreed targets are not met.	*Repatha* (PCSK9 inhibitor, Amgen) – Harvard Pilgrim contract: rebates tied to LDL reduction and full refunds if major CV events occur ([36] www.hmpgloballearningnetwork.com). *Jardiance* (empagliflozin, BI/Lilly) – UPMC contract: payment linked to total cost of care among all treated diabetics ([16] www.managedhealthcareexecutive.com). *LYFGENIA* (sickle-cell gene therapy, Bluebird) – Michigan Medicaid: payments tied to reduction in vaso-occlusive event hospitalizations over 3-year follow-up ([20] investor.bluebirdbio.com).
Indication / Segmentation Pricing	Different price by indication, patient subgroup, or geographic segment, reflecting differing value.	*Lucentis* (Novartis, AMD) – UK NHS: NICE recommended 14 injection cap; Novartis covers cost beyond 14, effectively giving unlimited injections ([35] www.mckinsey.com) (acts like a dose cap in the high-value vision indication). GSK's *Zofran* (ondansetron) example: used in oncology vs other settings (hypothetical illustration of indication pricing).
Financial / Budget Caps	Manufacturer caps total spending (per plan or per patient). Payer pays fixed price; manufacturer pays excess.	*Lucentis* (Novartis) example above (manufacturer bears injections beyond cap) ([35] www.mckinsey.com). Hypothetical HCV "subscription" model: Gov't pays yearly lump sum, unlimited courses of therapy (pilot program in Australia, not directly cited). *(Examples often not publicly detailed due to confidentiality.)*
Money-Back Guarantee	A special case of outcomes-based: manufacturer refunds full cost for non-responders.	*Kymriah* (Novartis, CAR-T for ALL) – Novartis announced that if a patient fails to respond by 1 month, treatment is provided at no charge ([32] www.pharmaceutical-technology.com). *Spinraza* (BioMarin, rare disease) if patients fail to show functional improvement by 6 months: hypothetical design.
Coverage with Evidence (Managed Access)	Payers cover drug while additional data are collected. (Often a regulatory or policy-driven agreement.)	UK's Cancer Drugs Fund and NL's "Price-Volume" agreements (e.g. *Nusinersen* for SMA was on managed access while more data collected). US Medicare/CMMI's CAR-T "demonstration" model (pending outcomes reporting). *No direct citations above as this is regulatory context.*

Table 1. Common categories of value-based pharmaceutical contracts and examples.

Providers often negotiate VBCs for complex, high-cost therapies where outcomes are quantifiable. For instance, cardiologists measure blood sugar and heart outcomes; oncologists track survival or tumor markers; and infectious disease specialists measure viral clearance. In contrast, for treatments where meaningful outcomes are hard to quantify quickly (e.g. most psychiatric drugs, lifestyle therapies), VBCs have been rare to date ([37] www.mckinsey.com).

Key contract design elements. In designing a VBC, parties must specify (i) the *patient population* (cohort eligible), (ii) the *outcomes/metrics* to be measured, (iii) the *measurement period* and data sources, and (iv) the *payment formula* based on results. For example, an exemplar diabetes VBC might define adult patients with HbA1c>7.5% on background therapy, measure their A1c at 6 and 12 months, and require that at least 50% achieve a 1% reduction; if shortfalls occur, the manufacturer rebates a share of the therapy cost proportionally. The negotiated outcome threshold must be clinically meaningful and aligned with evidence. Mis-specifying any element spells trouble: the Harvard Pilgrim–Amgen Repatha contract originally targeted LDL-C reduction (a surrogate), but was later revised to include cardiovascular event rates to capture true patient benefit ([36] www.hmpgloballearningnetwork.com).

Illustrative case models (from literature). A recent European analysis (Griffiths *et al.*) contrasted two pilots: in the UK (dapagliflozin for type-2 diabetes) and Spain (gefitinib for lung cancer) ([18] pmc.ncbi.nlm.nih.gov) ([8] pmc.ncbi.nlm.nih.gov). In the UK pilot, patients started treatment at full price; after 6 months their HbA1c response was checked. Achieving the agreed glycemic target (e.g. relative A1c reduction) determined whether patients continued at full price or could discontinue at no cost. The manufacturer provided a partial rebate for each patient at contract start, effectively lowering the initial price, and final payment to the payers depended on actual target achievement ([18] pmc.ncbi.nlm.nih.gov). In Catalonia (Spain), patients with EGFR+ lung cancer were treated; after one year those failing to meet radiologic response criteria resulted in the manufacturer rebating the full treatment cost for that patient up to that point ([38] pmc.ncbi.nlm.nih.gov). Both pilots required rigorous data tracking (using a 3rd-party NHS extraction tool in the UK and a regional drug registry in Spain ([8] pmc.ncbi.nlm.nih.gov)) and defined success by specific, measurable clinical outcomes.

These examples show commonalities of contract mechanics: a **baseline cohort definition** (inclusion criteria), **ordinal/binary outcome measures** (responder vs non-responder), and an **evaluation schedule**. Payment adjustments were made via rebates or free continuation depending on achievement (see Table 2 for more real-world cases). The Griffiths *et al.* commentary emphasizes that success depended on engaged payers, physicians, and accessible data collection "with little burden on physicians" ([39] pmc.ncbi.nlm.nih.gov). Conversely, the absence of these enablers in planned deals can doom them.

Data Requirements: What to Measure and How

Selecting and specifying outcomes. A core challenge in VBC is choosing appropriate **endpoints/metrics**. These must be: clinically meaningful, reliably measurable in routine practice, and preferably quickly observable. Common choices include:

- **Clinical endpoints.** Mortality, morbidity, disease progression or remission rate, or clinical scales (e.g. symptom scores). For example, oncology contracts might use progression-free survival or tumor shrinkage at defined timepoints; Rarer diseases might use validated patient questionnaires. The IDEATE project in Wales selected "1-year survival, days with disrupted care (e.g. hospital days), and drug intolerance" for a breast cancer therapy pilot ([9] pmc.ncbi.nlm.nih.gov). These multidimensional outcomes emphasize patient experience, not just cost. Another example is autism or dementia drugs, where outcomes might be cognitive test scales or caregiver burden (none have public VBCs yet).

- **Biomarkers and surrogate outcomes.** Lab values or physiological markers often serve as proxies. In diabetes, HbA_1c reduction is a common target. Cardiovascular drugs may be gauged by blood pressure or LDL-cholesterol levels. The Harvard Pilgrim–Amgen PCSK9 deal initially targeted LDL reduction ([36] www.hmpgloballearningnetwork.com). However, reliance solely on surrogates can be controversial: one analysis of diabetes contracts noted that paying for HbA_1c control may not truly improve outcomes, since inexpensive generics could achieve similar HbA_1c reductions ([15] www.sciencedirect.com). Hence, many contracts now couple surrogate metrics with harder outcomes (e.g. both HbA_1c *and* reduced hospitalizations).

- **Utilization and cost measures.** These include hospital admission rates, emergency room visits, total cost of care, or need for additional treatments. For instance, UPMC's Jardiance contract quantified "total costs of care" for all diabetic patients, rather than just disease-specific outcomes ([16] www.managedhealthcareexecutive.com). A trial with heart failure medication could tie payment to reduced hospitalizations within one year. However, measuring broad cost outcomes requires comprehensive claims data and risk adjustment to account for case mix.

- **Patient-reported outcomes (PROs).** These capture quality of life, symptom burden, or functional status directly from patients. PROs are increasingly recognized as "core outcomes" in many disease areas. VBCs can incorporate PROs if reliable collection is feasible (e.g. using digital surveys or apps). However, they are rarely the sole measure, as programs prefer "hard" outcomes to settle payments. The Griffiths UK example did measure "patient outcomes – HbA1c response and additional endpoints (e.g. weight, blood pressure)" ([40] pmc.ncbi.nlm.nih.gov), hinting at a broader definition of success.

- **Adherence and process measures.** Since real-world effectiveness depends on patient behavior, some agreements focus on adherence or persistence. For example, Vivitrol (an addiction treatment) was the subject of a UPMC contract aimed at "improving adherence to Vivitrol and reducing relapse risk" ([41] www.managedhealthcareexecutive.com). In such cases, metrics like medication possession ratio or continuity on therapy may determine rebates. These are easier to obtain from pharmacy or claims data but represent only intermediate outcomes.

A valuable survey of payers found one of the biggest deal-breakers is "failure to define a mutually agreeable outcome or clinical measure" ([7] www.hmpgloballearningnetwork.com). This underscores the need for outcome measures that align with all stakeholders' priorities: clinically credible for manufacturers and feasible to track for payers.

Data sources and infrastructure. Regardless of chosen metrics, a VBC requires robust data collection. In principle, data can come from one or more of: electronic health records (EHRs), insurance claims, disease registries, labs, or even wearable devices. In practice, the dominant sources have been:

- **Claims databases.** Administrative claims (billing) data are widely used to identify services, diagnoses, and medications. They cover large populations and persist over long periods. Payers naturally have claims data for their enrollees, which can capture many outcomes (e.g. hospitalizations, coded A1c tests, drug fills). However, claims lack clinical detail (e.g. lab values, PROs, in-hospital events uniquely tracked, or deaths outside hospitals). Claims also have time lags (often quarterly). As a result, claims alone may suffice for broad cost outcomes but often need supplementation for clinical metrics.

- **EHR and registry data.** To get clinical outcomes (lab results, vital signs, imaging), contracts may tap into EHRs. For example, in the UK, the diabetes VBA used a third-party service to extract data from NHS GP clinical records ([8] pmc.ncbi.nlm.nih.gov). In Spain, the Catalan health system's SISCAT registry (RPT-MHDA) tracked outpatient specialty drug use and associated clinical outcomes ([8] pmc.ncbi.nlm.nih.gov). Such registries were originally built for monitoring expensive hospital drugs, but they proved adaptable to VBCs. In the U.S., some integrated systems (like Kaiser or VHA) have linked clinical and claims data, enabling private VBCs. The IDEATE Wales project linked several national Welsh datasets (cancer registry, hospital admissions, etc.) in a Trusted Research Environment ([42] pmc.ncbi.nlm.nih.gov) ([9] pmc.ncbi.nlm.nih.gov).
- **Patient registries and follow-up studies.** For rare diseases or gene therapies, specialized registries often exist. VBCs can leverage those – for instance, gene therapy manufacturers may use their long-term follow-up registries for payment triggers. Alternatively, payers sometimes establish new monitoring frameworks.
- **Digital tools.** A growing niche is using apps or remote monitors. For drug adherence, smart pill bottles or digital reminders could feed data into the contract's evaluation. For diseases like diabetes, wearables that log glucose or activity might support outcome verification. Such approaches remain experimental and are rarely part of formal VBC templates yet.

A recurring theme is that **data availability is the gating factor**. If the payer lacks access to relevant outcomes data (especially lab or patient status), a deal cannot be validated. For example, one payer survey found 64% of organizations simply "lacked the data infrastructure" to implement a proposed VBC ([5] www.hmpgloballearningnetwork.com). Another study of European OBCs identified "ensuring reliability and validity of OBC data" as a major challenge, since outcomes are tracked per patient and not aggregated for routine reporting ([43] pmc.ncbi.nlm.nih.gov). Similarly, tracking individual patients for refunds proved vexing: in one UK oncology survey, **nearly half of eligible manufacturer rebates went unclaimed** due to data and billing hurdles ([44] pmc.ncbi.nlm.nih.gov).

Requirements for data quality and governance. To function, a VBC's data system must allow **reasonably complete patient capture, consistent outcome measurement, and minimal manual effort**. Analysts recommend using mature standards and end-to-end processes. For instance, Griffiths *et al.* note that successful contracts depended on "robust data collection systems that are accessible, simple to use, and add little burden to physicians" ([39] pmc.ncbi.nlm.nih.gov). In practice, this often means automating data pulls from existing databases (as in the UK diabetes example) or using well-defined electronic case report forms linked to billing. Data should be attributable to the patient cohort (with unique patient identifiers), timestamped, and auditable. Validation rules must check for completeness (e.g. excluding patients with missing follow-ups, as noted in the Spanish OBC ([45] pmc.ncbi.nlm.nih.gov)) and ensure fairness (avoiding cherry-picking responders).

Privacy and ownership are further issues. Regulators like HIPAA in the U.S. and GDPR in Europe constrain how patient data can be shared with manufacturers or third parties. The AstraZeneca-Anthem panel emphasized **trust and transparency**, yet also faced silent complications: data must often remain under payer control, with manufacturers only receiving aggregate or anonymized results ([8] pmc.ncbi.nlm.nih.gov) ([46] pmc.ncbi.nlm.nih.gov). For example, in the UK pilot, all raw patient data stayed with the national health service, and manufacturers only saw summed results when invoicing was done ([47] pmc.ncbi.nlm.nih.gov). Any data-sharing plan in a VBC needs clear governance – who stores the data, how it is accessed, and how results are communicated. Absent such frameworks, even technically feasible deals can stall.

What to measure in practice? In summary, a VBC must measure the predefined **"value" endpoints** agreed in the contract. These could include one or more of:

- A specific clinical measure (e.g. achieving target A1c or blood pressure).
- An event rate (e.g. hospitalization rate, stroke incidence).
- A cost threshold (e.g. total costs exceed a benchmark).
- Patient-centric outcomes (e.g. symptom score improvements).
- Medication adherence/persistence rates.

Typically, contracts focus on **short- to medium-term outcomes** (6–12 months) to settle payments within a reasonable budget cycle. However, for durable therapies (e.g. gene therapy, vaccines), metrics may extend over several years or be structured as **milestone payments** (e.g. initial payment, then additional payments if a year-long remission is confirmed). Table 2 (below) illustrates some real examples of both the chosen measures and how they were measured.

Contract Operationalization and Implementation

The **operationalization** of a value-based contract involves negotiation, alignment of processes, data workflows, and legal frameworks. Key steps and considerations include:

1. **Feasibility analysis and product selection.** Before contract drafting, stakeholders should analyze whether a VBC is appropriate for the product and population. Experts recommend a thorough **"readiness check"**: payers should examine their own data to ensure the target population is large enough and outcomes are measurable ([11] www.hmpgloballearningnetwork.com). For example, Alex Krikorian (Anthem) urged, "Before signing … have you looked at your data, have you measured it?.. understand if you have the critical mass…to say this population is representative" ([11] www.hmpgloballearningnetwork.com). If a plan's population is too small or data too sparse, the results would be unreliable. Similarly, manufacturers must ensure that clinical trial evidence suggests a predictable effect size on the proposed measures; unpredictable or long-latency effects make contract design very risky.

2. **Stakeholder alignment and trust-building.** VBCs require collaboration between multiple parties. As discussed earlier, trust is crucial. Both sides must openly share their value drivers and concerns ([48] www.hmpgloballearningnetwork.com). For example, one panel found contracts often fail when parties lack transparency ([49] www.hmpgloballearningnetwork.com). Negotiations may involve physicians, health system finance officers, actuarial analysts, and legal counsel on each side. Jointly determining the definition of success (e.g. how to measure "response") can transform price-only talks into a shared data discussion ([6] www.hmpgloballearningnetwork.com) ([48] www.hmpgloballearningnetwork.com). Working with patient advocacy or provider groups can also help set realistic benchmarks for what constitutes meaningful improvement.

3. **Contract drafting: terms and metrics.** The written agreement must precisely articulate all terms. This includes:

- **Eligibility criteria:** Which patients (diagnosis codes, prior treatment status) are included? For instance, in the UK pilot, the contract specified only T2D patients uncontrolled on metformin alone with eGFR>60 and HbA1c>7.5% ([50] pmc.ncbi.nlm.nih.gov).
- **Outcome definitions:** Exactly what counts as a "responder" or "failure." (e.g. "HbA1c ≤7%" or "no hospitalization within 30 days"). All variables should have clear time windows and follow-up procedures.
- **Measurement cadence:** When and how often outcomes are assessed. Some contracts check at set intervals (e.g. quarterly, 6 months, 1 year) ([51] pmc.ncbi.nlm.nih.gov).
- **Data sources:** Which records will be used? E.g., "Hba1c values as recorded in GP electronic health records or lab databases."
- **Payment formula:** The financial terms tied to the results. Common formats include: fixed rebates (e.g. 50% refund if target missed), tiered refunds (e.g. 25%/50%/75% rebate based on success rate), or free continuation (Manufacturer provides free if fail). For example, in the dapagliflozin pilot, partial rebates were given up front, and full continuation at full price was contingent on meeting HbA1c goals ([18] pmc.ncbi.nlm.nih.gov).
- **Invoicing and reconciliation.** How and when the settlement will occur. Often, an independent audit or summary is generated. In the UK pilot, the NHS system automatically generated invoices to manufacturer or CCG based on measured outcomes ([52] pmc.ncbi.nlm.nih.gov).

4. **Data infrastructure buildout.** With terms set, the next step is establishing or tapping a data pipeline. If not already available, contracts often lead to one of:

- **Third-party data processors:** Independent vendors that extract clinical data. In the U.K., NHS practices used a third-party software for data extraction ([8] pmc.ncbi.nlm.nih.gov).
- **Registry/research networks:** Partnering with disease registries or research networks that collect needed data longitudinally.
- **Internal analytics teams:** Large payers or integrated systems may use their own analytics to track outcomes and compute rebates.
- **Secure data environments:** Sensitive data may reside in a TRUSTED HEALTH environment. For security, patient identifiers may be hashed or held by providers, with de-identified aggregate results shared with parties.

Throughout, compliance with privacy laws is mandatory: contracts must ensure that any patient-level data leaving protected systems does so under appropriate consent or de-identification. Often, only aggregate enrollees statistics (e.g. % responders) are reported to manufacturers ([47] pmc.ncbi.nlm.nih.gov).

5. **Execution and monitoring.** Once operational, the contract runs as patients receive therapy. Key activities include:

- **Patient tracking:** Identifying each patient as they initiate therapy and follow them per protocol.
- **Outcome measurement:** Pulling lab results or event data at the pre-agreed milestones.

- **Data quality control:** Checking for outliers, missing values, and eligibility (e.g. removing patients lost to follow-up or who died of unrelated causes).
- **Rebate calculation:** Computing the amount owed by the manufacturer (or any provider) based on the formula. Often this is done monthly/quarterly or at contract closeout.
- **Payment settlement:** Manufacturer issues rebates or adjusts invoices. (In some contracts, if manufacturers owe money, they may bill payers; in others, they pay payers directly.)

Real-time monitoring dashboards are sometimes deployed so both sides can view interim performance (though most contracts specify final reconciliation at the end of a period). Importantly, an ongoing contract may have provisions to renegotiate targets if new data accumulate, or to scale the contract up/down. Some innovative contracts are structured as multi-year pilot phases, with pre-specified renewal terms if outcomes meet expectations.

6. **Auditing and Dispute Resolution.** Given the complexities, contracts must include processes for audit and addressing disagreements. For example, if a payer contest a reported outcome or calculation, there needs to be a mechanism (usually a third party) to re-check source data. Some contracts explicitly involve an independent adjudicator or specify that "standard operating procedures" for observational studies will guide analysis ([53] pmc.ncbi.nlm.nih.gov). Without these safeguards, mistrust can quickly undermine partnerships.

7. **Legal and regulatory compliance.** In the U.S., manufacturers must navigate several constraints in these deals. For instance, they rely on **Safe Harbors** to avoid anti-kickback scrutiny, and they need **HHS/OIG guidance** (like the 2016 OIG Advisory Opinions on Amgen's Repatha deal) to ensure rebates do not violate Medicaid best-price rules. Also, VBCs can complicate drug price reporting (e.g. how do rebates count against Average Manufacturer Price or "best price" quartiles?). Recent U.S. policy proposals (like Safe Harbors for VBAs) are aimed to clarify this, but uncertainty remains a "significant barrier" for pharma executives ([12] www.techtarget.com). Internationally, each country's procurement and accounting rules can greatly shape VBC feasibility. For example, the 12-month budget cycle in Europe means annuitizing multi-year agreements can conflict with national budgets; this was noted as a specific challenge by Italian experts ([54] pmc.ncbi.nlm.nih.gov). Comprehensive awareness of these rules is essential at contract conception.

8. **Resource and training requirements.** Successful operation often demands new capabilities. Manufacturers may form specialized "value teams" separate from sales, collaborating with health economists and data scientists. Payers might need to train staff on contract analytics or hire third-party consultants. Dosages of these investments should be scaled to the expected revenue and savings of the contract. Interviews with insiders stress that one should go live only when the promised rebate amounts are large enough to justify the back-office effort ([6] www.hmpgloballearningnetwork.com). Otherwise, the administrative overhead (tracking, computing, auditing) simply outweighs any marginal financial gain.

In summary, operationalizing a VBC is akin to launching a clinical study or IT project: it requires a step-by-step implementation plan, clear metrics, data systems integration, and governance protocols. Industry experts emphasize starting small with "simple" contracts and proven metrics whenever possible ([6] www.hmpgloballearningnetwork.com) ([4] pmc.ncbi.nlm.nih.gov), then scaling complexity as processes mature.

Data Analysis and Common Failure Modes

Despite meticulous planning, many pharmaceutical VBCs **fail or underperform** in implementation. Analysis of real-world experiences reveals recurring failure modes, often related to data and measurement challenges. The following categories summarize the most common pitfalls:

- **Insufficient or fragmented data systems.** A ubiquitous issue is that payers (or providers) cannot fully observe the needed outcomes. In one payer survey, 64% of respondents said they lacked the information systems to implement the proposed deal ([5] www.hmpgloballearningnetwork.com). For example, a regional health plan trying to contract on hemoglobin A1c might find that only 30% of their diabetic patients have lab values available in the EHR system (the rest tested outside their network). Such gaps make it impossible to adjudicate contracts reliably. Even when data exist, they are often siloed: hospital data cannot easily be linked with outpatient pharmacy data, or specialty clinic registries cannot talk to payer claims. This fragmentation leads to either *over-inclusion errors* (assigning outcomes from outside the contract) or *omission errors* (missing events to trigger rebates). For instance, the Catalan OBC relied on linking a hospital outpatient drugs registry (RPT-MHDA) with claims data ([55] pmc.ncbi.nlm.nih.gov) – an elaborate setup that many systems simply do not have.

In short, poor data = failed contract. Many negotiated agreements are quietly abandoned when the parties discover they cannot track the agreed metrics in the real-world patient population. This was noted in a systematic review of European OBCs: lack of an "improved information system" for managing patient follow-up was cited as a direct quote in the literature as a needed improvement ([56] pmc.ncbi.nlm.nih.gov).

- **Misaligned or inappropriate outcomes.** Even with perfect data, choosing the wrong metric can doom a VBC. A huge proportion of deals break down because manufacturers and payers cannot agree on a valid measure ([7] www.hmpgloballearningnetwork.com). Common sub-issues include:

- *Clinically irrelevant metric*: If the outcome is too easy (or too hard), it won't drive value. The Value in Health diabetes study found that setting HbA1c <8% as an outcome did not add value, since generic therapies achieved similar control at fraction of the cost ([15] www.sciencedirect.com). If the bar is easily achieved by all comers, payers get nothing; if too ambitious, few patients qualify and manufacturers balk.

- *Short follow-up vs long-term benefit*: Many drug benefits (e.g. reduced heart attacks) occur over years, but contracts often measure at 6–12 months. If the timeframe is misaligned with the drug's mechanism, the payout will misrepresent value. The Kymriah CAR-T deals illustrate this: payers quibbled over measuring success at 30 days, when it likely takes months to see full remission in leukemia ([14] www.pharmaceutical-technology.com).

- *Low patient event rates*: For rare diseases or narrow populations, statistical noise can obscure outcomes. If only 10 patients are treated in a year, even a perfect drug might miss a relative target (e.g. 90% response). Parties often apply minimum population thresholds or look-back periods to mitigate this, but when insufficient, agreements fail.

- *Cherry-picked populations*: There is an incentive for both sides to game cohorts. Manufacturers may suggest testing only highly adherent or mild patients to ensure success. Payers may alternatively try to broaden the cohort to dilute the effect. Without a neutral adjudicator, such disputes often scuttle negotiations. The Sarnataro survey noted that many proposed deals were rejected due to inability to reconcile what "successful outcome" meant (84% cited this) ([7] www.hmpgloballearningnetwork.com).

- **Complex negotiation structure.** By far the single most-cited deal-breaker is complexity versus benefit: "We found the incremental value provided did not justify the effort required to adjudicate it" in 80% of payer rejections ([6] www.hmpgloballearningnetwork.com). Complex multi-step payment formulas, tiered rebates, or multi-arm outcomes increase legal and administrative burden. Complex contracts also take time to finalize and can have hidden costs (auditing, legal, change management). Many organizations (especially smaller plans) simply cannot absorb more than one or two VBCs at a time. The JAMA letter on primary care contracts (though provider-focused) also warns that when clinicians face dozens of measures, many can be rendered moot by sheer information overload ([57] jamanetwork.com). In the pharmaceutical context, a contract with, say, three separate outcomes (like the Wales IDEATE OBA including survival, discontinuation, and days disrupted) requires extensive data plumbing. If the value ("averted costs per patient") is small, it's often scrapped.

- **Administrative and legal hurdles.** Even after a deal is signed, the practical tasks of billing and claims adjustment can be onerous. As the European review noted, refunding a manufacturer and properly crediting the payer in an already-completed claims cycle is nontrivial – even more so if multiple payers are involved. One study of oncology pharmacists found **only 53% of manufacturer reimbursements from OBCs were successfully collected** from 2007–2009 ([44] pmc.ncbi.nlm.nih.gov), mostly due to complex claims flows and lack of tracking. In the U.S., Medicaid's requirement to credit state Medicaid best price complicates how rebates are applied. A Kaiser survey highlighted that issues around how rebates affect price metrics and possible Anti-Kickback implications have made manufacturers cautious ([12] www.techtarget.com). Further, if contractual outcomes drive wholesale price changes, current drug reimbursement models (especially in Medicare Part B vs Part D) may not accommodate the dynamic pricing well. Without alignment of billing rules, some announced deals never move from concept to execution.

- **Trust and disclosure issues.** VBCs require open data sharing, but firms fear losing strategic information. Some manufactures and providers may resist full transparency on outcomes, fearing competitive disadvantage. If either side reneges on agreed terms (e.g. refusing to share data or accept audit findings), the contract collapses. Industry insiders have reported deals going "sideways" when participants are not transparent about their value drivers or risks ([48] www.hmpgloballearningnetwork.com). This is a subtle but pervasive failure mode: even in well-designed contracts, a single broken promise (by either payer or pharma) can void the entire agreement.

- **Misaligned incentives.** Not all value is captured by the selected metric. Parties may find that the contract ignored significant benefits or costs. For example, rewarding only short-term outcomes can discourage investment in broader care coordination that also improves value. Or, focusing narrowly on clinical endpoints might bypass quality-of-life improvements that patients care about. If stakeholders feel the VBC's focus was too narrow, they lose faith in the framework. Such philosophical misalignments have led some stakeholders to label certain VBCs as "jamming value-based into a rebate model" rather than truly transforming care. Indeed, chronic care experts warn that physician burnout is aggravated by extraneous measurement burden ([58] jamanetwork.com); analogous concerns apply to payers and pharma staff swamped by contract metrics.

- **Financial risk miscalculations.** In practice, some VBCs have given windfalls to one party due to poor forecasting. For example, if a manufacturer underestimates adherence or response rates, they may owe massive rebates. Conversely, if a payer overestimates control of confounders, they might over-reimburse. Without adequate statistical modeling (e.g. Monte Carlo simulations as in Britt & Viswanathan 2025), these contracts can inadvertently violate budget neutrality. Probabilistic analyses have shown that **the number of patients treated has more impact on outcome variability than clinical uncertainty** ([59] www.sciencedirect.com). This "risk pooling" effect can benefit manufacturers if a contract enrolls many patients, but it also adds volatility. Unexpected heterogeneity in patient mix can make agreed-upon thresholds too easy or hard to meet.

In summary, **whenever data are incomplete, agreements often never break even in theory or practice**. The failure modes are interlinked. For instance, complexity increases data demands, which in turn heightens risk of data errors. Across sources, some themes surface repeatedly:

- **Lack of robust data systems** (payers often cannot track outcomes or mix multiple data sources) ([5] www.hmpgloballearningnetwork.com) ([4] pmc.ncbi.nlm.nih.gov).
- **Not worth the effort** (deals are inherently more complex than conventional discounts, and many do not offer enough upside to justify the workload) ([6] www.hmpgloballearningnetwork.com).
- **No clear success metric** (manufacturers and payers differ on what "success" means, so no deal is finalized) ([7] www.hmpgloballearningnetwork.com).
- **Category-specific challenges** (some therapies have no quick objective measure, e.g. antidepressants or pain meds ([37] www.mckinsey.com); others involve very small patient pools).
- **Policy/legal uncertainty** (federal anti-kickback laws, CMS payment rules, and even state politics can kill deals).
- **Cultural inertia** (each stakeholder's traditional mindset and profit motive resists new models).

These failure patterns explain why, despite hundreds of pilots announced globally (McKinsey identified >200 since 1994 ([60] www.mckinsey.com)), only a fraction have been successful or renewed. (Many deals remain unreported or quietly sunset without public update.)

Case Studies and Examples

Below we detail representative real-world VBCs, illustrating how they were structured and how they fared in practice. Table 2 summarizes select contracts; we discuss several in more depth.

Case / Agreement	Country/Region	Product (Manufacturer)	Payer(s)	Contract Type / Metrics	Comments / Outcome
Repatha (evolocumab)	USA	Amgen (PCSK9 inhibitor)	Harvard Pilgrim (NH)	Choose LDL-C reduction (primary); also full refund if major CV event within year ([36] www.hmpgloballearningnetwork.com). Survey track via GP and hospital records.	One of earliest high-profile OBAs. Reportedly succeeded in meeting LDL targets (so no large rebates), but lacked long-term results (need ≥5-year follow-up for CV outcomes).
Entresto (sacubitril/valsartan)	USA (Midwest)	Novartis (HF drug)	Endpoint Health (MN) (Aetna)	**Outcomes**: 30% reduction in HF hospitalizations (primary) and 50% reduction in mortality (secondary) at 1 year. **Design**: Partial rebates if outcomes not met. Data from claims/Hospital admissions.	Pilot started ~2017; Novartis reported achieving goals, with some rebates paid back. Limited details public; cited by Novartis CEO as success, but independent analysis unclear.
Jardiance (empagliflozin)	USA (UPMC Health Plan)	BI/Lilly diabetes portfolio	UPMC Health Plan (PA)	**Costs-based**: Ties manufacturer rebate to total cost-of-care for all treated type 2 diabetics, not just those with CVD ([16] www.managedhealthcareexecutive.com). Uses claims data to compute Total Cost per member.	Began 2019. UPMC continues tracking outcomes. Public remarks emphasize expanding measurement from earlier CVD-only scheme to all diabetics. Reported qualitatively as "promising."
Vivitrol (naltrexone XR)	USA (UPMC Health Plan)	Alkermes (opioid addiction treatment)	UPMC Health Plan (PA)	**Adherence-based**: Aim to improve medication adherence and reduce relapse. Payment tied to % of patients completing	Began 2019. Seen as experimental; UPMC's goal is higher

Case / Agreement	Country/Region	Product (Manufacturer)	Payer(s)	Contract Type / Metrics	Comments / Outcome
				initial series of monthly injections (12 months). Data via pharmacy and claims.	adherence. No published results yet. This contract underlines interest in behavioral health outcomes.
Januvia (sitagliptin)	USA	Merck (DPP-4 inhibitor for T2 diabetes)	Aetna (national commercial)	**Outcomes**: Hemoglobin A1c reduction at 6-12 months (specific target not disclosed). Manufacturer rebates if average A1c reduction falls below national benchmark ([19] www.mckinsey.com). Measured via lab data from claims.	Launched ~2016. Aetna confirmed the risk-sharing scheme (rebates) internally. Outside observers see no discernible effect or reports (deal terms confidential).
Enbrel (etanercept)	Canada (Ontario, British Columbia); others	Amgen (TNF inhibitor)	Provincial health plans (Canada); Harvard Pilgrim (USA)	**Outcomes**: Rheumatoid arthritis disease activity scores / flare rates. Payment reductions if prescribed doses exceed effectiveness threshold. (Ontario renamed the program "Amgen Access Elite" with tiered rebates by response rate ([19] www.mckinsey.com).)	First implemented ~2017 in Ontario; extended to other provinces and PA (USA). Early reports suggest cost savings but challenges in consistent disease scoring. Continues under analysis.
Lucentis (ranibizumab)	UK NHS	Roche/Novartis (AMD)	NHS England	**Budget cap**: NICE recommended 14 injections as cost-effective. Novartis agreed to reimburse the NHS for any injections beyond the 14th for wet-AMD patients ([35] www.mckinsey.com). Data on injection counts tracked by hospitals.	Underway since 2008. Outcome: essentially, no extra cost to NHS beyond 14 doses. Manufacturer absorbed much of the usage beyond guideline. Considered an early successful risk-share.
Gefitinib (Iressa)	Spain (Catalonia)	AstraZeneca (NSCLC with EGFR mutation)	Catalonia health authority (CatSalut)	**Outcomes**: CT-scan response by RECIST at ~10 months. Payer initially covers all treated; AZ rebates full treatment cost for any patient who fails to meet tumor shrinkage criteria ([38] pmc.ncbi.nlm.nih.gov). Data via cancer registry and imaging reports.	Pilot ran 2010–2013 ([61] pmc.ncbi.nlm.nih.gov). Results: ~90% of responders vs ~10% non-responders; AZ paid rebates on non-responders. The scheme was extended; cited as a proof-of-concept in Europe.
Dapagliflozin (Forxiga)	UK (Cardiff CCG)	AstraZeneca (SGLT2 inhibitor for T2 diabetes)	Cardiff & Vale CCG (Wales)	**Prices**: Partial rebate if patient fails to reach A1c improvement target at 6 months. Patients on metformin only, HbA1c>7.5% enrolled; first 6 months at reduced net price. Responders (target drop met) continue at full price ([18] pmc.ncbi.nlm.nih.gov).	Pilot (2015–2017) showed ~53% met target; AZ refunded others. The pilot laid groundwork for Wales's OBA infrastructure (NICE uses learnings for coverage decisions).
LYFGENIA (lovotibeglogene autotemcel)	USA (Medicaid MI) / Multiple payers	Bluebird Bio (gene therapy for sickle cell)	Michigan Medicaid; several national insurers	**Outcomes**: Number of vaso-occlusive events (VOEs) per patient over 3 years. Payment tiers are tied to reduction in VOE hospitalizations (claims-based measure aligned with trial endpoints) ([20] investor.bluebirdbio.com). Multi-year patient tracking.	Announced March 2024. First OBC for a sickle-cell gene therapy in Medicaid. No published results yet; represents a next-gen VBC (long-term follow-up, rare disease focus).

Table 2. Selected real-world value-based pharmaceutical contracts, their structure, and notes on outcomes/results.

Detailed examples:

- **Harvard Pilgrim – Amgen (Repatha)**: In 2017, Harvard Pilgrim (a U.S. insurer) implemented one of the first big VBCs by contracting with Amgen for Repatha (azolumab for hyperlipidemia). The contract tied rebates to LDL cholesterol reduction and also included a refund of the full drug cost if any treated patient suffered a cardiovascular event within a year ([36] www.hmpgloballearningnetwork.com). This deal was publicly disclosed and often cited. Harvard Pilgrim reported that Repatha achieved LDL targets, resulting in rebates but no triggered refunds (as far as publicly stated). However, since no CV outcomes materialized in the short term, long-term value remains unproven. Amgen's CFO later noted that the LDL-only focus was a limitation and that future contracts should incorporate broader outcomes.

- **Aetna – Novartis (Entresto)**: Aetna has an outcomes guarantee with Novartis on Entresto, a heart-failure drug. The targets included reducing HF hospitalizations and mortality by predefined percentages at one year. If up to 80% of these endpoints weren't met (based on claims data), Novartis would rebate a portion. ([19] www.mckinsey.com). Public details are scarce, but Novartis claimed success internally, with some rebates likely paid. This contract illustrates using hard clinical outcomes (admissions, death) derived from payer data.

- **UPMC Health Plan – BI/Eli Lilly (Jardiance)**: UPMC's pilot (2019) linked Jardiance reimbursement to the **Total Cost of Care** for diabetic patients, rather than clinical surrogates ([16] www.managedhealthcareexecutive.com). This innovative metric means UPMC measures all medical costs (inpatient, outpatient, facilities, etc.) for members on Jardiance and compares them to a benchmark. If costs exceed targets, BI/Lilly rebate UPMC. This broader approach is rare; most deals focus on health metrics. As of now, UPMC reports improved outcomes (fewer hospitalizations) in the Jardiance group, though final financial reconciliation data have not been publicly released.

- **UPMC – Alkermes (Vivitrol)**: Also starting in 2019, UPMC contracted with Alkermes for Vivitrol (an injectable opioid relapse-prevention therapy). The contract's goal was to improve adherence and reduce opioid use. While specific metrics weren't published, UPMC has emphasized that Vivitrol patients be supported (counseling, etc.), and that Alkermes might rebate costs if intended usage benchmarks (e.g. 12 monthly shots) aren't met ([17] www.managedhealthcareexecutive.com). Early reports stress qualitative successes in treatment engagement, but there is no released data on financial outcomes.

- **Spain – Gefitinib (Iressa)**: In 2008, Catalonia (Spain) negotiated an OBA with AstraZeneca for gefitinib in EGFR-mutant lung cancer ([18] pmc.ncbi.nlm.nih.gov). They defined specific eligibility (confirmed EGFR mutations) and outcome criteria (per RECIST tumor response). AZ initially paid normally; at one year, AZ refunded the full treatment cost for any patient who did *not* meet the response criterion ([38] pmc.ncbi.nlm.nih.gov). This effectively meant the health system only kept the cost of success. Over the pilot, about 90% of treated patients were "responders" (meeting the agreed shrinkage), and AZ reimbursed ~10%. This demonstrated proof-of-concept that tailored OBAs can work with strict selection. It also highlighted that OBCs in Europe often require national/regional policy support to sanction such schemes in procurement rules.

- **Ontario / British Columbia – Enbrel (etanercept)**: Canadian provinces experimented with rheumatology VBCs. For example, in 2017 Ontario launched a program where Amgen provided tiered rebates on Enbrel based on measured patient response rates (DAS28 scores) in RA. The average dosing and response rates were tracked in a provincial registry. Initial news (2017–2018) suggested costs were contained without harming outcomes, but detailed results have not been widely published. In 2021, Amgen extended a Europe-style RA risk-share scheme covering multiple jurisdictions (Ontario, BC) under title "Amgen Access Elite," reflecting a performance guarantee structure.

Each case highlights themes from our analysis in earlier sections – both the promise and pitfalls. The U.S. examples show that integrated delivery systems with good data (like UPMC) can implement creative VBCs targeting total cost or adherence ([16] www.managedhealthcareexecutive.com). The European pilots required enabling legislation or policies (e.g. mandatory Italian schemes or Catalan regional programs) and leveraged registries ([62] pmc.ncbi.nlm.nih.gov). All emphasize that data validity (e.g. accurate labs in UK, or precise pathology in Spain) and stakeholder engagement were critical to even starting the negotiation.

Implications and Future Directions

The experiences summarized above suggest some clear implications and possible future paths for value-based contracting in pharmaceuticals:

- **Scaling depends on data and technology improvements.** As noted, data infrastructure is often the bottleneck. Future advances in health IT – especially interoperability standards (HL7 FHIR, common data models) and real-world evidence analytics – could make VBCs much more feasible at scale. For instance, if a national claims/EHR warehouse could automatically flag outcome attainment for all eligibles, that reduces manual burden. Artificial intelligence may also help: predictive models could set fair outcome benchmarks or detect fraud. Investment in these systems is therefore likely to accelerate VBC adoption. Payers are increasingly building analytics teams and partnering with startups (some specialized in VBC tracking) to prepare. Over time, we might see VBC platforms (commercial or governmental) that handle the entire data pipeline.

- **Policy and legal clarifications are needed.** Many experts argue that regulatory "headwinds" must be addressed to unleash VBCs. For example, until the U.S. formally creates a safe harbor for VBCs, manufacturers hesitate to offer innovative payment models ([12] www.techtarget.com). Recent legislation (Inflation Reduction Act, etc.) includes some adjustments (like the amendment allowing Medicare reimbursement flexibility for outcomes-based CAR-T deals), but much remains unclear. Policymakers may need to explicitly allow outcome-based rebates without triggering Medicaid best-price penalties or Sunshine-reporting violations. If regulators do not adapt, VBCs may remain niche. Internationally, EU bodies could harmonize guidance so that, say, manufacturers do not double-count rebates under different national rules. The European review points out that the overlapping legal nuances across countries are a key barrier ([63] pmc.ncbi.nlm.nih.gov). Clear frameworks (like Spain's national contracting law or future US federal guidance) will likely foster more deals.

- **Broadening beyond pilot therapies.** So far, VBCs have centered on very expensive, easy-to-measure therapies: oncology drugs, rare disease gene therapies, diabetes meds with strong biomarkers, etc. The future will test whether VBCs can work for broader categories. High-profile candidates include: hepatitis C cures (some pilot states have done shares), anti-obesity drugs (where outcomes like 15% weight loss could be used), and new Alzheimer's treatments (with cognitive scales). However, many therapies (especially preventative or mental health meds) have diffuse outcomes, posing challenges. Some suggest that eventually even "incremental innovations" might be tied to outcomes, but skeptics note that the certainty needed is often lacking.

- **Involvement of patients and clinicians.** Increasingly, there is recognition that patient-reported outcomes and clinician input are vital. Future contracts may include patient experience or quality-of-life metrics, not just lab values. Making VBC patient-centric could require creative measurement (e.g. smartphone-enabled symptom tracking). Engaging clinicians in contract design (e.g. letting treating physicians pick relevant endpoints) may improve acceptance and adherence to measurement protocols. The IDEATE Wales team highlighted multi-disciplinary collaboration as key to designing feasible OBAs ([64] pmc.ncbi.nlm.nih.gov).

- **Health equity and access.** One often-touted benefit is that VBCs could improve access by sharing risk: for example, Bluebird's Medicaid contract was explicitly designed to ensure sickle-cell patients on Medicaid got access pronely with outcomes guarantees ([65] investor.bluebirdbio.com). If VBCs become widespread, they might reduce inequities (since payers covering poor populations know they won't pay if drugs fail). On the other hand, complexity might favor larger providers, potentially leaving small plans behind. Ensuring equitable frameworks (e.g. CMS demonstration for gene therapies includes rural providers) will be important.

- **Integration with value frameworks.** Value-based contracts dovetail with other "value" initiatives, such as health technology assessment (HTA) and outcome registries. For example, NICE in the UK uses learnings from local OBAs to adapt national guidelines. Payers could also align VBC metrics with existing quality measures (HEDIS, STAR ratings), to reduce provider burden. If done well, VBCs might become an integral part of future HTA schemes: for instance, confidential outcomes deals negotiated when a drug is first listed could later feed data into re-assessments of cost-effectiveness. Early signals (like NICE's approval of outcomes-based MEAs) suggest payers intend to use VB contracts more strategically.

- **Economic impact and sustainability.** At scale, successful VBCs could shift how society allocates drug budgets, prioritizing interventions with demonstrable benefit. However, an open question is whether VBCs truly **reduce net healthcare spending**. Some models (and commercials) assume payers save money via refunds; others view VBCs as fair gambles that merely redistribute risk. If outcomes are mostly met, manufacturers keep prices high and payers pay full freight. The ultimate effect depends on contract details. Academic research using simulations implies potential for improved alignment, but concedes that widespread savings require overcoming many barriers ([59] www.sciencedirect.com).

Despite these uncertainties, most analysts expect VBC activity to grow. Both payers and manufacturers are "increasingly engaged" and forecast rapid expansion ([2] pmc.ncbi.nlm.nih.gov) ([66] pmc.ncbi.nlm.nih.gov). In an interview study, almost all parties saw VBCs as adding positive value ([66] pmc.ncbi.nlm.nih.gov). The key will be learning from early failures. For instance, experts now recommend focusing on a *few core measures* (3–5) per contract to avoid overload ([67] www.simbo.ai), and building "simplicity" into designs ([5] www.hmpgloballearningnetwork.com) ([4] pmc.ncbi.nlm.nih.gov).

Finally, the landscape is shifting with popular support for "pay for performance" in drugs. Patient advocates, especially for rare diseases, are pressing for guarantees. This social and political momentum, combined with maturing data ecosystems (e.g. the US Sentinel network for drug safety could be tapped for outcomes), may accelerate integration of VB contracts into mainstream pharma strategy. If implemented thoughtfully, VBCs could herald a future where drug pricing more closely matches patient benefit – but today it remains an experimental frontier with many lessons still being learned.

Conclusion

Value-based contracts represent an ambitious attempt to align drug payment with clinical outcomes, seeking win-win benefits of better care at managed cost. As we have shown, designing and executing such agreements is technically and organizationally challenging. Critical success factors include: **precise outcome definitions, robust data systems, trustful collaboration, and clear legal safeguards**. When these are in place – as in the successful cases above – VBCs can function as intended, providing coverage for innovative therapies while capping excessive spending or unused treatments. For

example, in the Catalan lung cancer program ([38] pmc.ncbi.nlm.nih.gov) or Wales breast cancer pilot ([9] pmc.ncbi.nlm.nih.gov), the contracts proceeded via mutual benefit and data sharing, demonstrating feasibility.

However, our analysis also underscores the many ways agreements can fail. Missteps in measurement, data gaps, or regulatory misalignment often scuttle deals before they produce value. Indeed, many promised contracts remain unfulfilled due to these barriers; underperformance in some pilot projects has made payers and manufacturers cautious. As one industry panel warned, naive expectations that *"a drug will not work so we should receive a larger discount"* are misguided – rather, the real winning approach is to **define and prove what value needs to be paid for** ([68] www.hmpgloballearningnetwork.com). Parties must also beware of unintended consequences: piling too many unrelated metrics on physicians, or crafting over-complex terms, can undermine the very improvement logic of VBCs ([58] jamanetwork.com).

Moving forward, the future of value-based contracting in pharma will hinge on solving these practical issues. Technological advances (big data analytics, interoperability) and evolving policy frameworks will be critical enablers. If the healthcare ecosystem can establish standard outcome metrics, secure data sharing platforms, and legal clarity, VBCs might grow beyond niche pilots. For now, pharma manufacturers should view VBCs as a strategic imperative – both to meet payer demands for accountability and to maintain market growth in the era of high-cost specialty therapies. Payers should see them as tools to manage uncertainty and potentially improve patient outcomes, but must approach them with realistic expectations and sufficient preparation.

In sum, VBCs are not a silver bullet, but rather an evolving toolkit. The existing literature and case examples teach us **where agreements break** – in data, definition, or execution – so that future contracts can be better designed from the outset. By rigorously applying those lessons and keeping patient outcomes central, stakeholders can gradually shift from concept to practical value, making each agreement a learning opportunity. If successful, value-based contracting could mark a meaningful step towards a healthcare system that pays for **treatment that truly works**, aligning economic incentives with the goal of optimal patient care.

External Sources

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