Int. j. adv. multidisc. res. stud. 2024; 4(6):3378-3395

Received: 10-11-2024
Accepted: 20-12-2024

International Journal of Advanced Multidisciplinary Research and Studies

ISSN: 2583-049X

The Impact of Biosimilars on Pharmaceutical Marketing and Commercial Strategy in Global Biologics Markets

[1] Imoiboho Williams, [2] Isaac Awulu, [3] Valentina Ochuko Obukadata
[1] Institute of Human Virology Nigeria, Abuja, Nigeria
[2] Novartis Nigeria Limited, Lagos, Nigeria
[3] University of New Haven, Connecticut, United States

Corresponding Author: **Isaac Awulu**

Abstract
Biosimilars were introduced into regulated markets as a cost containment mechanism modelled loosely on small molecule generics. This paper argues that their more consequential effect has been structural rather than fiscal: Biosimilars have dismantled the marketing logic on which the branded biologics industry was built. Drawing on market data, regulatory documents and corporate disclosures published during 2023 and 2024, and situating these against a conceptual literature on regulated market positioning, health system financing, supply chain governance and commercial data infrastructure, the study examines how biosimilar competition reallocated commercial power from prescribers to intermediaries, forced originators into portfolio substitution rather than brand defence, and produced a new channel form, the payer affiliated private label biosimilar, that has no clear precedent in pharmaceutical distribution.

Four findings are advanced. First, the decisive commercial variable in 2024 was not clinical differentiation or regulatory status but formulary architecture: The removal of Humira from a major national commercial formulary in April 2024 moved more market share in weeks than the preceding period of biosimilar promotion had moved. Second, interchangeability, long treated by manufacturers as a commercial asset worth substantial clinical investment, was empirically decoupled from market share and then regulatorily devalued by the FDA's June 2024 draft guidance. Third, originators increasingly responded to loss of exclusivity not by defending the eroding asset but by migrating demand to adjacent, patent protected molecules, a strategy visible in AbbVie's transfer of immunology revenue from Humira to Skyrizi and Rinvoq. Fourth, the pharmacy benefit and medical benefit now behave as two distinct markets requiring incompatible commercial models.

The paper further argues that the capabilities determining biosimilar commercial outcomes are increasingly infrastructural rather than promotional, residing in contracting systems, customer data architecture, analytics governance, distribution visibility and manufacturing quality assurance. It concludes that biosimilar marketing has become an exercise in channel economics and gross to net engineering rather than in demand generation, and that this shift carries consequences for market sustainability, patient access and the durability of biosimilar development pipelines.

Keywords: Biosimilars, Pharmaceutical Marketing, Commercial Strategy, Loss of Exclusivity, Pharmacy Benefit Managers, Private Label, Market Access, Interchangeability, Gross to Net, Supply Chain Governance

1. Introduction

1.1 Background

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated licensure pathway for biological products demonstrated to be highly similar to an approved reference product. Policymakers anticipated that this pathway would reproduce, in the biologics sector, the price competition that the Hatch Waxman Act of 1984 had produced for small molecule drugs. The analogy was imperfect from the outset. Generic small molecules are chemically identical to their reference products, are approved on bioequivalence data, and in most jurisdictions are automatically substitutable at the pharmacy counter under state law. Biosimilars are highly similar but not identical, are approved on a comparative analytical and clinical package, and historically required a separate regulatory designation before automatic substitution was permitted.

These differences matter commercially. The generic model works because substitution occurs downstream of the prescription and is largely invisible to the prescriber, which means generic manufacturers do not need a marketing function in any conventional sense. Biosimilar manufacturers, by contrast, entered a market in which prescribers retained meaningful control, patients had years of exposure to originator brand equity and patient support infrastructure, and payers and intermediaries had contractual reasons to prefer the incumbent. The result was a hybrid: A low margin product that nonetheless required brand style commercial investment.

The gap between what a biosimilar can theoretically deliver and what it delivers in practice is an instance of a more general phenomenon in health systems, in which scientific innovation fails to translate into improved patient outcomes where the surrounding delivery and financing infrastructure is not aligned to carry it (Ilodigwe & Adesemoye, 2019b). Biosimilars are a particularly clean example, because the science is settled and the failure, where it occurs, is entirely commercial. Comparable translation gaps have been documented between healthcare infrastructure investment and measurable population health outcomes, where the determining variable is the operating model rather than the asset itself (Ogbete & Aminu-Ibrahim, 2024).

By September 2024 the FDA had approved 61 biosimilars across 17 reference molecules, of which 41 had reached the market (Samsung Bioepis, 2024). Savings attributed to biosimilars rose by more than 30 percent to $12.4 billion in 2023, bringing cumulative savings since first entry to approximately $36 billion, across almost 2.7 billion days of patient therapy and more than 495 million incremental days of treatment that would not otherwise have been delivered (Association for Accessible Medicines, 2024). On these measures the policy is working. On other measures, particularly the sustainability of biosimilar development and the distribution of savings between patients and intermediaries, the picture is considerably less settled.

1.2 Problem statement

Most existing analysis treats biosimilars as a pricing and access question. The commercial and marketing dimension has received comparatively little systematic attention, despite the fact that biosimilar market outcomes in 2023 and 2024 were determined overwhelmingly by commercial rather than clinical or regulatory factors. The adalimumab market provides the clearest illustration. Ten biosimilar versions of Humira were available in the United States from 2023, several with list prices substantially below the reference product and one holding the first interchangeability designation, yet Humira retained roughly 97 percent of adalimumab prescriptions through March 2024 (GaBI Online, n.d.). A single formulary decision by one intermediary in April 2024 changed that position more quickly than the entire preceding period of commercial effort.

This outcome is not explicable within the traditional pharmaceutical marketing paradigm, in which share follows clinical evidence, prescriber preference and brand investment. It requires a different analytical frame, closer to the literature on differentiation and market entry in heavily regulated sectors, where permissible claims are constrained and competitive position is established through structural rather than promotional means (Sanni *et al*., 2020b; Sanni & Attah, 2023c).

1.3 Research questions

1. How has biosimilar entry altered the identity and behaviour of the decision maker in biologics markets?
2. What commercial strategies have originator companies adopted in response to biologic loss of exclusivity, and how do these differ from small molecule patent cliff strategies?
3. What marketing and go to market models have biosimilar entrants adopted, and which have proved effective?
4. How do the medical benefit and pharmacy benefit channels differ in their commercial logic, and what does this imply for strategy?
5. What commercial infrastructure, in data, systems, distribution and quality assurance, is required to compete under biosimilar economics?
6. How do United States dynamics compare with European markets operating under statutory pricing and tendering?
7. What are the implications for long term market sustainability and patient access?

1.4 Significance

The paper contributes to four literatures. For marketing scholarship, it documents a market in which classical differentiation has been regulatorily suppressed, offering a natural experiment in what remains of marketing when product attributes are held constant by law. For health policy, it identifies mechanisms by which savings are absorbed within the supply chain rather than transmitted to patients, extending work on the relationship between supply chain structure and medication affordability (Asiedu & Asiedu, 2023b). For operations and supply chain scholarship, it treats commercial performance as a function of distribution visibility, quality assurance and resilience rather than of promotion (Nnabueze *et al*., 2021; Asiedu & Asiedu, 2024b). For practitioners, it offers a typology of viable commercial archetypes in a category where conventional launch playbooks have repeatedly failed.

1.5 Scope and structure

The analysis centres on the United States market during 2024, with comparative treatment of the EU4 markets and the United Kingdom. Adalimumab is used as the principal case, with supporting evidence from infliximab and the oncology monoclonal antibodies. Section 2 reviews the relevant literature across six streams. Section 3 sets out the method. Section 4 presents findings. Section 5 discusses implications, Section 6 draws out managerial and policy recommendations, Section 7 addresses limitations and Section 8 concludes.

2. Literature Review and Conceptual Framework

2.1 The economics of biologic loss of exclusivity

The classical patent cliff literature describes a predictable sequence: Generic entry, rapid price collapse, near total volume transfer, and originator revenue decline of 80 to 90 percent within twelve to eighteen months. Biologics have not followed this curve. Erosion has been slower, price reductions have been shallower, and originators have

retained share long after exclusivity lapsed. Several explanations have been proposed, including manufacturing complexity, physician conservatism regarding immunogenicity, patient attachment to devices and support programmes, and the cost of biosimilar development, which limits the number of entrants and therefore the intensity of price competition.

The evidence assembled here suggests these explanations are secondary. The primary constraint is contractual. Where an intermediary earns revenue proportional to a product's list price, that intermediary has a direct financial interest in maintaining the highest list price product on formulary, irrespective of net cost to the plan sponsor. This mechanism, described in the literature as the rebate wall, converts an apparently competitive market into a de facto exclusive one. It is a specific instance of the incentive misalignment that arises wherever payer and provider payment mechanisms reward gross rather than net economic outcomes (Ilodigwe & Adesemoye, 2019a).

2.2 The rebate wall and misaligned intermediary incentives

Analysis of the adalimumab market found that an additional $5.7 billion in savings might have been realised over the first eleven months of 2023 had all Humira volume converted to biosimilars, but that such conversion would have reduced pharmacy benefit manager profits in the category by close to 90 percent through lower rebates, lower specialty pharmacy fees and lower reimbursement spreads (Biosimilars Review and Report, 2024). Separately, rebate arrangements were estimated to protect roughly $2 billion in profit associated with the originator, and biosimilars listed more than 80 percent below the reference product had nonetheless secured only about 2 percent share (American Journal of Managed Care, n.d.). The commercial implication is stark: For a period, the entity best positioned to drive biosimilar adoption was the entity with the strongest financial reason to prevent it.

Structurally, this is a compliance and incentive design problem rather than a failure of competition. Where contracting arrangements generate incentives that diverge from the stated policy objective, the observable outcome is systematic and predictable, and assessing that divergence is properly a compliance risk exercise (Akomolafe *et al*., 2023b).

2.3 Marketing theory under enforced parity

Pharmaceutical brands are conventionally analysed as credence goods, where the buyer cannot readily verify quality and therefore relies on brand signals, professional endorsement and accumulated trust. Biosimilar regulation deliberately suppresses the attributes on which such differentiation would normally rest. A biosimilar must demonstrate no clinically meaningful difference from its reference product, and asserting superiority is generally not permissible.

Marketing theory offers limited guidance for this condition. The nearest analogue is the literature on brand positioning in regulated professional markets, where claim latitude is externally constrained and positioning must be constructed from evidence, service and structural access rather than from asserted product advantage (Sanni *et al*., 2020b). Related work on entry barriers in regulated industrial service sectors indicates that in such environments the decisive competitive constraint is frequently institutional rather than promotional (Sanni & Attah, 2023c), and analyses of go to market design under compliance constraint reach a similar conclusion (Sanni & Atima, 2021a). The pattern parallels the adoption gap identified in other technology diffusion contexts, where objectively superior or lower cost solutions fail to displace incumbents because adoption is treated as a technical rather than a commercial problem (Ogundairo & Ayivi-Donkor, 2024a). Emerging work on autonomous purchasing agents suggests this dynamic will intensify as more purchasing decisions are mediated by systems rather than by persuadable individuals (Ogundairo & Ayivi-Donkor, 2024b).

Portfolio level framing is also relevant. Where a firm holds multiple assets addressing overlapping demand, value maximisation operates across the portfolio rather than within any single brand, which reframes the defence of an individual product as a capital allocation question (Lawal & Oduleye, 2021a, 2023a).

2.4 Channel theory and vertical integration

The emergence of payer affiliated private label biosimilars, in which a pharmacy benefit manager's subsidiary co commercialises a manufacturer's product under its own label and then preferences that label on its own formularies, represents vertical integration into the marketing function itself. Channel theory would predict that such integration reduces transaction costs and aligns incentives, but also that it concentrates bargaining power and raises barriers to entry for non partnered suppliers. Both predictions find support in the 2024 evidence.

Analogous dynamics appear in the procurement literature, where supplier relationship structures, qualification requirements and negotiation design determine which suppliers can participate at all, irrespective of their price competitiveness (Akin-Oluyomi *et al*., 2023b, 2024; Akinleye & Adeyoyin, 2022b; Ike *et al*., 2021). Negotiation optimisation models indicate that outcomes in concentrated buyer markets are driven by structural position rather than by incremental concession (Akinleye & Adeyoyin, 2022a), and multinational procurement risk frameworks identify supplier dependency of exactly the kind private label arrangements create (Bello *et al*., 2023).

2.5 Supply chain governance, resilience and access

A parallel literature treats medicine availability as a supply chain governance outcome rather than a pricing outcome. Work on pharmaceutical supply chain governance links environmental and operational risk management directly to sustained access to essential medicines (Eze *et al*., 2023). Supply chain inefficiency has been shown to translate directly into affordability loss at the patient level (Asiedu & Asiedu, 2023b), and last mile distribution research demonstrates that formulary availability and actual patient access are distinct conditions (Asiedu & Asiedu, 2022).

Resilience frameworks developed after pandemic era disruption are directly applicable to a market where price compression may thin the supplier base (Efobi *et al*., 2023; Anene & Clement, 2022; Tonoyan *et al*., 2024a). End to end visibility and traceability frameworks provide the operational instrumentation such resilience requires (Nnabueze *et al*., 2021; Okoruwa *et al*., 2024), and lean

supply chain practice offers the cost structure that low margin biosimilar operations demand (Ike *et al*., 2022; Efobi *et al*., 2022b).

2.6 Commercial data infrastructure and analytics

A biosimilar commercial organisation competing on contracts rather than promotion depends on systems more than on messages. Three infrastructural streams are relevant. The first concerns customer data and relationship management architecture. Governance frameworks for platform management in regulated healthcare environments address precisely the conditions biosimilar commercial teams operate under, in which customer records contain sensitive information and access must be controlled by role (Badmus *et al*., 2019b, 2024). Integration and data engineering design determine whether account, contract and dispensing data can be reconciled at all (Badmus *et al*., 2019a), while deployment governance determines whether commercial systems can change at the speed contracting cycles require (Badmus *et al*., 2018, 2022a).

The second concerns analytics and measurement. Marketing return on investment measurement is unusually difficult in regulated categories, where the buyer, the prescriber and the patient are distinct parties and the causal chain between activity and revenue is long (Sanni *et al*., 2020a). Attribution modelling addresses the resulting bias in multi touch journeys (Sanni *et al*., 2022b; Basnet *et al*., 2024), and funnel level instrumentation addresses revenue leakage between stages (Sanni & Wedraogo, 2024; Eyetsemitan *et al*., 2024b). Forecasting under volatility, dashboard design for executive visibility and real time performance tracking complete the measurement stack (Sanni & Atima, 2021b; Tonoyan *et al*., 2024b; Medon & Oduleye, 2024).

The third concerns the governance of analytics itself. As commercial decisions are increasingly automated, auditability and explainability become preconditions rather than refinements, particularly in healthcare applications (Sanni *et al*., 2022c). Data protection constraints shape what customer and patient data may be used and how (Aliliele *et al*., 2024b; Atakpa & Abolaji, 2022), and federated approaches offer a route to cross organisational analysis without pooling sensitive data (Sanni *et al*., 2023).

2.7 Compliance, audit and the governance of commercial practice

Because biosimilar competition is conducted through contracts, rebates and channel arrangements rather than through promotion, the governance risks migrate accordingly. Risk based auditing and compliance risk assessment frameworks provide the control environment for contracting practice (Akomolafe *et al*., 2023a; Akomolafe & Agu, 2018), and integrated governance approaches link compliance capability to financial resilience (Akomolafe & Agu, 2019c). Audit analytics applied to healthcare financial oversight offers the detection layer (Abetoh & Atakpa, 2024; Atakpa & Fobellah, 2023; Adelanwa *et al*., 2023b).

A distinct legal literature addresses the governance of algorithmic decision making, data privacy across jurisdictions and the treatment of proprietary models, all of which bear on commercial systems that allocate access or price (Annan, 2022, 2024). Intellectual property questions arising from automated generation of commercial content are also unresolved (Annan, 2023).

2.8 Research gap

The literature documents biosimilar pricing, uptake rates and policy barriers extensively. It documents the commercial and marketing response only sporadically and largely through practitioner commentary, and it rarely connects that response to the infrastructural and governance literatures on which execution depends. This paper addresses that gap by treating the 2024 market as a case in strategic adaptation.

3. Methodology

3.1 Design

The study uses a qualitative, theory building multiple case design supported by descriptive secondary quantitative data. This design suits a phenomenon that is recent, structurally complex and characterised by a small number of consequential events rather than a large population of comparable observations. The approach is consistent with conceptual model building methods used elsewhere in health system and commercial strategy research, where the object of study is a mechanism rather than an effect size (Ilodigwe & Adesemoye, 2024b; Lawal & Oduleye, 2018a).

3.2 Data sources

Category	Sources
Market share and pricing	Samsung Bioepis US Biosimilar Market Report, Q4 2024; IQVIA analyses; published average sales price series
Savings and volume	Association for Accessible Medicines and IQVIA Institute savings report, 2024 edition
Regulatory	FDA draft guidance on interchangeability, June 2024; FDA approval and interchangeability records
Corporate strategy	AbbVie and other manufacturer disclosures and launch announcements through Q4 2024
Channel behaviour	Trade and analyst reporting on formulary exclusions and private label arrangements during 2024
European comparison	ISPOR Europe 2024 pricing policy analysis; European tendering literature
Conceptual and framework literature	Peer reviewed work on regulated market positioning, payer and provider incentive alignment, pharmaceutical regulatory science, supply chain governance, commercial data infrastructure and compliance analytics

3.3 Case selection

Three molecule markets were selected on a most different basis to permit contrast:

- **Adalimumab** (pharmacy benefit, self administered, high rebate intensity, ten entrants) as the principal case.
- **Infliximab** (medical benefit, provider administered, longer competitive history) as a maturity comparison.
- **Trastuzumab, bevacizumab and rituximab** (medical benefit, average sales price reimbursement) as a contrasting case isolating the effect of channel economics.

3.4 Analytical approach

Documents were coded thematically against the research questions, with particular attention to sequencing: Which commercial action preceded which market movement. Where quantitative series were available, inflection points were identified and matched against contemporaneous commercial or regulatory events. Triangulation across

manufacturer, payer, provider and analyst sources was used to mitigate the promotional bias present in individual sources, following practice in evidence synthesis under conflicting source incentives (Adelanwa *et al*., 2024).

3.5 Framework construction

The archetype typology presented in Section 5.3 was constructed inductively by grouping observed firm behaviours against three dimensions: Customer interface ownership, cost structure and portfolio breadth. Comparable capability maturity and readiness framing informed the construction (Eze *et al*., 2022b).

3.6 Limitations of method

Net prices in the United States are confidential. All price analysis therefore relies on list prices, average sales prices and inference, and understates the true competitive position of rebated products. Private label contract terms are not disclosed. Attribution of share movement to specific commercial actions is inferential rather than causal. These limitations are revisited in Section 7.

4. Findings

4.1 The 2024 market baseline

By late 2024 the United States biosimilar market had reached meaningful scale but highly uneven penetration. Approximately 61 biosimilars had been approved across 17 molecules, with 41 marketed, and four approvals were added in the final quarter covered, spanning eculizumab, aflibercept and ustekinumab. Average sales prices for biosimilar molecules declined by roughly 53 percent across the first five years following initial biosimilar entry, and biosimilars captured on average about 53 percent share within five years of launch (Samsung Bioepis, 2024).

Penetration varied sharply by channel and molecule:

Molecule group	Channel	Approximate 2024 position
Trastuzumab, bevacizumab, rituximab	Medical benefit	Deep price erosion; Q4 2024 average sales price discounts of roughly 56, 48 and 65 percent respectively against reference
Infliximab	Medical benefit	Biosimilar share approaching 47 percent
Pegfilgrastim, ophthalmology agents	Medical benefit	High biosimilar share
Adalimumab	Pharmacy benefit	Approximately 2 percent in early 2024, rising to roughly 22 percent by late 2024
Insulin glargine	Pharmacy benefit	Persistently low

The pattern is unambiguous. Biosimilars perform well where the purchaser is a provider reimbursed on a percentage of average sales price and therefore neutral or favourable to lower cost products, and poorly where the purchaser is an intermediary earning rebates calculated against list price.

Slower uptake categories, including immunology, filgrastim, epoetin alfa and insulin glargine, reached only about 26 percent share by year five, roughly half the all category average (American Journal of Managed Care, n.d.).

4.2 The decision maker has moved

The central commercial finding of the period is that the effective buyer in the pharmacy benefit channel is no longer the prescriber. Through the first quarter of 2024, the largest pharmacy benefit managers maintained the reference product on formulary, and adalimumab biosimilar uptake remained close to 2 percent despite aggressive discounting and available interchangeable options (American Journal of Managed Care, n.d.; GaBI Online, n.d.).

In April 2024 a major pharmacy benefit manager removed Humira from its main national commercial formularies in favour of biosimilar options. Prescriptions for the preferred biosimilar, Hyrimoz, grew 36 percent in the first week following the change (Venable LLP, 2024), and the product reached roughly 14 percent of adalimumab claims over the following period (GaBI Online, n.d.). Adalimumab biosimilar share overall rose from about 2 percent in early 2024 to roughly 22 percent by late 2024, driven principally by private label brands rather than by conventionally marketed biosimilars (Samsung Bioepis, 2024).

Three implications follow.

First, the marketing target has shifted decisively upstream. Share was determined by a contracting decision, not by prescriber persuasion or patient preference. Conventional segmentation and targeting models built around prescriber deciles have limited value where the effective decision unit is a small number of institutional accounts, a condition already documented in other regulated professional service markets (Atima *et al*., 2022; Basnet *et al*., 2021).

Second, the mechanism operated without interchangeability. The products that gained share were not automatically substituted at the pharmacy; they were positioned by formulary. Conversely, Cyltezo, the first interchangeable adalimumab biosimilar, held under 1 percent share (Venable LLP, 2024). Interchangeability, in which manufacturers had invested significant clinical development expenditure on the assumption of commercial value, was empirically shown not to drive share in this market.

Third, the gain was structurally conditional. Patient level transition remained limited: In 2023 only about 2 percent of treatment naive patients began adalimumab therapy on a biosimilar, rising to roughly 14 percent in 2024, with the originator still capturing approximately 86 percent of new patients, and most biosimilar starts arising from switches rather than from new initiation (GaBI Online, n.d.). Access therefore improved on the terms of the formulary and private label arrangements rather than through independent clinical adoption. Because these arrangements govern which product a chronically treated patient receives and for how long, they raise continuity of care questions of the kind examined in the hospital pharmacy access literature, where therapy interruption risk rises when supply arrangements rather than clinical judgement determine product availability (Asiedu & Asiedu, 2024a).

4.3 Private label as channel innovation

The private label or white label biosimilar is the most significant commercial innovation of the period. Under this model, an intermediary establishes a subsidiary that partners with a biosimilar manufacturer to co commercialise the product under the subsidiary's own label. The subsidiary then holds a favourable position on the affiliated formulary. The leading example during 2024 was Cordavis, established by a major pharmacy benefit manager's parent, which co promoted and commercialised Hyrimoz with Sandoz alongside the originator product (GaBI Online, n.d.).

Aggregate uptake gains in the adalimumab market during 2024 were attributed principally to private label brands of this type (Samsung Bioepis, 2024).

Strategically, the model resolves the rebate wall by internalising it. The intermediary's margin no longer depends on the originator's rebate because it now earns on the sale of the product it labels. For the manufacturer, a private label agreement converts an uncertain commercial launch into a contracted volume commitment, and substantially reduces the need for a field force, brand campaign and patient support infrastructure. The specialty pharmacy is not a neutral conduit in this arrangement but an active commercial participant whose dispensing capability and cooperation determine whether formulary access converts into patient level supply, consistent with evidence on pharmacy led delivery models as determinants of medicine availability (Ilodigwe & Adesemoye, 2020).

The costs are equally clear. The manufacturer surrenders brand identity, direct customer relationships and pricing autonomy, and becomes a contract supplier whose position depends on periodic renegotiation. This is the classic dependency exposure identified in supplier relationship research, where concentrated buyer power converts a commercial relationship into a structural vulnerability (Akinleye & Adeyoyin, 2022b; Ike *et al*., 2021; Tonoyan *et al*., 2024a). Non partnered manufacturers face effective exclusion regardless of price, which raises unresolved questions about the long term vibrancy of a market in which vertically integrated intermediaries both supply and prefer their own products.

4.4 The dual list price problem

A distinctive artefact of the rebate system is the dual pricing strategy, in which the same molecule is offered at two list prices: A high list price version generating large rebates for intermediaries operating on rebate retention models, and a low list price version for plan sponsors seeking lower net cost and lower patient coinsurance.

Several adalimumab manufacturers launched both versions. The tactic did not by itself displace the originator, because a high list price biosimilar competes on the incumbent's terms without the incumbent's rebate scale, while a low list price biosimilar is unattractive to rebate driven purchasers. That biosimilars listed more than 80 percent below the reference product nonetheless held only about 2 percent share before the formulary change demonstrates the point directly (American Journal of Managed Care, n.d.).

Dual pricing is best understood as a symptom rather than a strategy. It exists because manufacturers cannot identify a single price that satisfies both purchasing logics, and it imposes real costs in complexity, channel conflict and patient confusion. Pricing architecture research indicates that where a single asset must be valued differently across segments, the resulting structure is stable only when the segments are genuinely separable, a condition the rebate system does not satisfy (Tonoyan *et al*., 2023).

4.5 Originator response: Substitution rather than defence

The most consequential originator strategy of the period was not defence of the eroding brand but migration of demand to adjacent, patent protected molecules.

AbbVie's execution is the reference case. Anticipating adalimumab erosion, the company invested heavily in Skyrizi and Rinvoq, pursued label expansion across the indications Humira had held, and generated head to head evidence, including a psoriasis trial in which risankizumab achieved 90 percent skin clearance in 72 percent of patients at week 16 against 47 percent for adalimumab, with 66 percent of adalimumab responders who switched maintaining high clearance against 21 percent of those who continued (Center for Biosimilars, 2024b). By the third quarter of 2024 the substitution was visible in reported results: Global Humira revenue fell 37.2 percent to $2.227 billion with United States sales down 41.6 percent, while Skyrizi rose 50.8 percent to $3.205 billion and Rinvoq rose 45.3 percent to $1.614 billion (Center for Biosimilars, 2024b).

The commercial significance is that total adalimumab molecule volume declined during 2024 even as biosimilar fill volume grew sharply, rising roughly 400 percent between March and April 2024, with the contraction in total volume attributed to the growth of the successor products (Center for Biosimilars, 2024b). Biosimilar manufacturers were competing for a shrinking pool. Critics describe this as product hopping; the firms describe it as portfolio lifecycle management. Either characterisation identifies the same strategic reality: In biologics, the originator's most effective response to loss of exclusivity may be to make the contested market smaller. The underlying logic is one of portfolio architecture and capital allocation, in which value is maximised across a set of assets rather than defended within any single one (Lawal & Oduleye, 2021a, 2023a).

Secondary originator tactics observed include:

- **Unbranded biologics:** Launching an unbranded version of the reference product at a lower list price, allowing the originator to compete in the low list price tier without repricing the brand.
- **Formulation lifecycle management:** Migrating patients to high concentration, citrate free presentations before entry, so that biosimilars referencing the older formulation face a partially converted base (Center for Biosimilars, 2024a).
- **Patent estate management:** Sequencing a large patent estate to defer entry, which in the adalimumab case delayed United States biosimilar competition for years after initial approvals (Center for Biosimilars, 2024a).
- **Contracting depth:** Rebate structures conditioned on formulary position across a portfolio rather than a single product.

Forecasting the timing and depth of erosion is itself a demanding analytical exercise, since revenue projection under structural discontinuity behaves differently from projection under continuous conditions (Tonoyan *et al*., 2021a; Lawal & Oduleye, 2019b).

4.6 Biosimilar entrant strategy: from promotion to access

Biosimilar entrants in 2024 substantially reallocated commercial resources away from demand generation and toward access, contracting and service. The shift mirrors the broader migration from promotional to analytics driven go to market design observed in sectors where compliance constraints limit conventional promotion (Sanni & Atima, 2021a).

Access first resourcing: The unit of commercial planning became the payer contract rather than the prescriber territory. Field force models moved from share of voice

towards account based coverage of integrated delivery networks, group purchasing organisations and specialty pharmacies. Where target populations are concentrated, segmentation and forecasting models must operate at account rather than individual level (Basnet *et al*., 2021; Atima *et al*., 2022).

Reimbursement and conversion support: For products in the medical benefit, field reimbursement managers, coding and billing support and prior authorisation assistance materially affect adoption. For the pharmacy benefit, the operative metric became conversion: Analysis found that only about one in three patients prescribed an adalimumab biosimilar successfully filled within thirty days of the first attempt (Biosimilars Council & IQVIA, 2024). A prescription that does not convert to a fill is commercially worthless, so support programme design, copay deployment speed and specialty pharmacy coordination became primary rather than supporting functions. Diagnosing where volume is lost between prescription and dispense is structurally a funnel leakage problem, and benefits from the same stage level instrumentation used to resolve revenue leakage in other high value service categories (Sanni & Wedraogo, 2024; Eyetsemitan *et al*., 2024b; Ogundairo & Ayivi-Donkor, 2023a). Workflow automation in the support function itself determines whether that instrumentation can be acted upon at operating speed (Eyetsemitan *et al*., 2024a; Akinleye & Adeyoyin, 2021).

Peripheral differentiation: With molecule level differentiation prohibited, entrants competed on device design, injection comfort, citrate free formulation, presentation breadth, cold chain and supply reliability, and digital adherence support. Supply reliability in particular is a function of manufacturing quality systems rather than of commercial effort, and is increasingly treated as a determinant of competitive standing rather than a compliance baseline (Asiedu & Asiedu, 2024b). Delivery system innovation offers a further, if narrow, avenue (Ike *et al*., 2024b).

Evidence and value demonstration: Where price parity is approached, competition shifts to demonstrated total cost of care. Real world evidence and outcomes analytics have accordingly become part of the commercial rather than the medical function, supporting budget impact arguments made directly to plan sponsors (Ilodigwe & Adesemoye, 2024a). Decision support tooling that translates such evidence into operational and resource planning terms strengthens these arguments materially (Adelanwa *et al*., n.d.; Adelanwa *et al*., 2023a).

Education as market development: Because prescriber and patient hesitancy suppresses category volume for all entrants, education about biosimilarity functions partly as a public good. Firms have addressed this through trade associations and coalitions rather than through proprietary campaigns, an unusual configuration in pharmaceutical marketing. Professional education design and digital delivery research is directly relevant to how such programmes reach clinicians at scale (Orise & Niniola, 2024).

Portfolio scale: Firms with multiple biosimilars across molecules can amortise regulatory, quality, distribution and account management infrastructure, negotiate across a basket, and absorb single product losses. Firms dependent on one or two assets have limited resilience against a lost formulary cycle (Lawal & Oduleye, 2021a).

4.7 Two markets, two models

The evidence supports treating the medical benefit and pharmacy benefit as separate markets requiring separate commercial models.

Dimension	Medical benefit (buy and bill)	Pharmacy benefit
Effective buyer	Provider practice or hospital	Pharmacy benefit manager and plan sponsor
Reimbursement basis	Percentage of average sales price	Rebate and net price negotiation
Incentive direction	Broadly compatible with lower cost adoption, though percentage based margin can favour higher priced units	Historically opposed to biosimilar adoption absent private label
Decisive commercial capability	Account economics, reimbursement support, contracting with group purchasing organisations	Rebate and net price engineering, private label partnership
Observed uptake	Moderate to high	Low to moderate, and concentrated in partnered products
Marketing intensity required	Moderate	Low if partnered, futile if not

An important nuance is that percentage based reimbursement in the medical benefit is not straightforwardly pro biosimilar: Because provider margin is a percentage of an average sales price, a lower priced product yields a smaller absolute margin. Proposals for prospective shared savings arrangements between payers and providers have been advanced to neutralise this residual bias (Journal of Managed Care and Specialty Pharmacy, 2021). This is a specific application of the wider problem of aligning payer and provider incentives so that the party controlling utilisation shares in the savings it generates (Ilodigwe & Adesemoye, 2019a).

Institutional purchasing in the medical benefit channel also depends on the acquiring organisation's own procurement analytics, since hospital and network buyers assess biosimilars against internal cost, risk and continuity criteria rather than against manufacturer claims (Filani *et al*., 2022; Akinleye *et al*., 2023; Babatope *et al*., 2023). On the payer side, the increasing use of algorithmic risk assessment in coverage and underwriting decisions further removes the determination from individual clinical judgement (Oluwo *et al*., 2024).

4.8 Regulation as a commercial variable

On 20 June 2024, the FDA issued draft guidance proposing that switching studies would generally no longer be required to support interchangeability, reasoning that accumulated experience showed negligible risk of safety or diminished efficacy from switching (U.S. Food and Drug Administration, 2024). The agency noted that nine of the thirteen interchangeable biosimilars approved to that point had been approved without switching studies, and the comment period closed on 20 August 2024 (Venable LLP, 2024).

The commercial consequences are significant and largely negative for incumbents' differentiation strategies.

- Development cost falls, lowering entry barriers and increasing the expected number of competitors per molecule.

- Interchangeability ceases to function as a differentiator once most or all competitors can obtain it.
- Investments already made in switching studies for competitive positioning are devalued.
- Firms that had built commercial narratives around interchangeability require repositioning.

The evidence for the second point was already visible before the guidance: Oncology molecules with deep biosimilar penetration had no approved interchangeable products at all, while adalimumab had several, indicating that payer preference rather than regulatory designation drove uptake in both directions (Venable LLP, 2024).

The wider lesson is that in a category defined by regulation, regulatory change is a first order commercial risk rather than a compliance matter, and should be modelled as such in launch planning. Frameworks that treat regulatory readiness as a staged organisational capability rather than a submission event are directly applicable here (Eze *et al*., 2022b). Equally, the trade off the FDA navigated between approval speed, evidence quality and safety assurance is the same trade off formalised in risk based accelerated approval models, and its resolution has direct commercial consequences for the number and timing of competitors a firm will face (Eze *et al*., 2024b). Comparative regulatory governance research indicates that the pace and predictability of such shifts varies substantially across jurisdictions, which complicates global launch sequencing (Afrihyia *et al*., 2024a; Eze *et al*., 2024a).

4.9 Commercial operations infrastructure

A finding that emerges across cases is that biosimilar commercial performance depends disproportionately on operational systems rather than on customer facing activity. Three capabilities recur.

Contract and account data architecture: A biosimilar competing across dozens of plan and institutional accounts must reconcile contract terms, formulary status, dispensing data and rebate obligations. This is a data integration problem before it is a commercial one (Badmus *et al*., 2019a), and the governance and interoperability requirements resemble those identified for health system data architecture at national scale (Ilodigwe & Adesemoye, 2021). Platform governance in regulated healthcare settings additionally constrains how such records are structured and accessed (Badmus *et al*., 2019b, 2024), and role based security design is a functional requirement rather than an IT preference (Aliliele *et al*., 2024a).

Deployment velocity: Formulary cycles are annual, and contract terms change within them. Commercial systems that cannot be modified quickly impose a strategic cost, which is why development and release governance has commercial rather than purely technical significance (Badmus *et al*., 2018, 2022a; Ladapo *et al*., 2022; Sanni & Attah, 2023a). Service management maturity determines whether field and account teams can rely on these systems operationally (Ladapo *et al*., 2023a, 2023b), and CRM based forecasting design determines whether the resulting data supports commercial planning rather than merely recording it (Dada *et al*., 2021b).

Analytics governance: Where pricing, targeting or access decisions are automated or model assisted, the organisation must be able to explain them to payers, auditors and regulators. This requirement is heightened in healthcare contexts, where automated decisions may bear on patient access (Annan, 2024; Afrihyia *et al*., 2024a).

These capabilities are not glamorous and are frequently under resourced in organisations whose leadership formed in branded pharmaceutical environments, where commercial advantage was understood to reside in messaging and relationships. The 2024 evidence suggests the advantage now resides substantially in systems.

4.10 Distribution, traceability and contracting infrastructure

Biosimilar competition also increases the operational load on distribution and settlement. Volume shifts between products with short notice following formulary changes, as the roughly 400 percent month on month increase in adalimumab biosimilar fills after the April 2024 change illustrates (Center for Biosimilars, 2024b), and rebate and chargeback obligations must be reconciled across wholesalers, specialty pharmacies and plans.

End to end visibility frameworks provide the traceability necessary to manage such shifts without stockouts or overstock (Nnabueze *et al*., 2021; Okoruwa *et al*., 2024), and demand forecasting under discontinuity becomes materially harder when a single contracting decision can reallocate a large share of category volume within weeks (Aifuwa *et al*., 2020; Akin-Oluyomi *et al*., 2023c).

On the settlement side, the administrative burden of rebate and chargeback reconciliation is substantial and largely invisible in strategic discussion. Work on automated contract execution and dispute resolution in supplier payment systems addresses precisely this class of problem (Akomolafe *et al*., 2022, 2024b), as does research on payment architecture, interoperability and regulatory adaptation across jurisdictions (Adesuyi *et al*., 2023; Akomolafe *et al*., 2024a; Olaogun *et al*., 2023). Distributed ledger approaches to verifiable commercial workflows have been proposed for related transparency problems (Sanni *et al*., 2024).

4.11 Manufacturing quality, supply reliability and shortage risk

Where products are clinically equivalent and price converges, the ability to supply becomes a primary competitive attribute. Quality assurance in manufacturing has accordingly been reconceptualised as a determinant of supply reliability rather than as a regulatory floor (Asiedu & Asiedu, 2024b), and inventory and distribution process design carries direct commercial consequence (Ike *et al*., 2022).

This matters more in biosimilars than in small molecules because manufacturing is more complex, capacity is less fungible, and a supply interruption in a contracted private label arrangement may terminate the commercial relationship as well as the supply. Resilience indices and vendor risk models offer a means of assessing this exposure prospectively (Efobi *et al*., 2023; Tonoyan *et al*., 2024a; Bello *et al*., 2023), while shortage early warning frameworks address the system level consequence when it materialises (Eze *et al*., 2022a). Infrastructure resilience planning under stress conditions provides a parallel from the diagnostic sector, where continuity of a service depends on capacity decisions taken years earlier (Aminu-Ibrahim *et al*., 2018).

4.12 European contrast

European markets operate under materially different commercial logic. Pricing is frequently statutory, procurement is often conducted through tendering at national, regional or hospital level, and prescriber level demand generation is correspondingly less influential.

Illustrative arrangements include France, where biosimilar prices are set at approximately 40 percent below the originator with tenders conducted at national, regional and hospital levels, and Germany, where regional quotas and physician discretion combine with reference pricing to produce steadier, competition led reductions. Between January 2019 and May 2024, 17 biosimilars launched across the EU4 markets and the United Kingdom, and markets with regulated pricing and hospital level tendering pursue affordability and market stability as joint objectives (Yadav, 2024).

The European model produces faster, more predictable uptake and lower prices, but carries its own risk. Sustained tender driven price compression has raised concerns about supplier exit, thinning emergency stock, reduced competition over time and shortage vulnerability of the kind already familiar in off patent small molecules (Off-patent biologicals and biosimilars tendering in Europe, 2021). Commentators have suggested that a sustainable market may require roughly three to four viable suppliers per molecule, and that award criteria should extend beyond price alone to include supply security. Because tender qualification and supplier risk assessment determine which manufacturers can compete at all, procurement design functions as a de facto market structure instrument (Akin-Oluyomi *et al*., 2023b; Akinleye & Adeyoyin, 2022b). Award criteria incorporating sustainability and non price dimensions have been developed in other procurement contexts and are directly transferable (Akin-Oluyomi *et al*., 2023a, 2023d).

For manufacturers, the two regions demand different capabilities: Tender pricing discipline, cost of goods leadership and supply reliability in Europe; rebate architecture, channel partnership and account management in the United States. Firms operating across both must also manage divergent regulatory requirements and cross border supplier relationships, a coordination burden that harmonisation frameworks are intended to reduce but which remains material outside the most integrated markets (Eze *et al*., 2024a; Akin-Oluyomi *et al*., 2024; Annan, 2022).

5. Discussion

5.1 What marketing becomes when the product cannot differ

The biosimilar category constitutes an unusual natural experiment. Regulators have fixed the product attribute set; differentiation claims on efficacy or safety are largely foreclosed. The evidence indicates that marketing does not disappear under these conditions but relocates, consistent with findings that positioning in regulated markets is constructed from structural and evidentiary assets rather than asserted product advantage (Sanni *et al*., 2020b).

Reconsidered against the classical marketing mix:

- **Product** collapses towards parity at molecule level and reasserts itself at the periphery: Device, formulation, presentation and packaging.
- **Price** becomes the dominant variable, but bifurcates into list price and net price, which move in opposite directions and serve different buyers.
- **Place**, historically a low salience element in pharmaceutical marketing, becomes the decisive one. Formulary position, specialty pharmacy cooperation and private label partnership determine outcomes.
- **Promotion** shifts from persuasion to enablement: Reimbursement support, conversion assistance and category level education rather than share of voice.

The implication for practice is that biosimilar commercial leadership requires competencies closer to those of a business to business industrial supplier or a contract manufacturer than to those of a branded pharmaceutical marketing organisation. Several early biosimilar failures are attributable to organisations staffing and structuring biosimilar units as though they were brand units. Where content and communication retain a role, their function is conversion support rather than preference formation (Sanni & Attah, 2023b).

5.2 Gross to net and the economics of promotion

Biosimilar net prices in competitive molecules can sit far below reference list prices, with observed list discounts exceeding 80 percent in the adalimumab market (American Journal of Managed Care, n.d.). This compresses the absolute margin available to fund commercial activity, which in turn constrains field force size, support programme scope and marketing expenditure. A commercial model designed for branded gross margins will be unprofitable at biosimilar net prices even at respectable share.

Margin compression also raises the evidentiary bar for commercial spend. Where contribution per unit is thin, investment must be justified against measured incremental effect rather than against activity metrics, which is difficult in regulated categories where attribution across payer, provider and patient touchpoints is confounded (Sanni *et al*., 2020a, 2022b; Basnet *et al*., 2024). Forecasting commercial performance across channels under these conditions carries irreducible uncertainty that should be represented explicitly rather than suppressed (Wedraogo & Sanni, 2024). Embedding economic evaluation directly into operational data flows, rather than conducting it retrospectively, has been proposed as a response (Ogundairo & Ayivi-Donkor, 2023b), alongside cost optimisation modelling at the portfolio level (Tonoyan *et al*., 2022b; Lawal & Oduleye, 2023a). Executive visibility into these economics, in near real time, is itself a capability rather than a reporting formality (Sanni & Atima, 2021b; Tonoyan *et al*., 2024b).

This creates a reinforcing dynamic. Firms that cannot fund conventional commercial infrastructure are pushed towards private label arrangements, which further reduce their need for that infrastructure, which further erodes their capacity to compete independently should the partnership lapse. Over time this concentrates commercial capability in the intermediaries rather than the manufacturers.

5.3 A typology of viable archetypes

The evidence supports four broadly viable commercial archetypes, with a fifth that appears structurally unviable.

The channel partner: Competes primarily to win private label or exclusive contracts. Minimal customer facing infrastructure, competitive cost of goods, high volume, thin margin, high dependency risk.

The portfolio scale player: Operates numerous biosimilars across molecules and channels, amortising fixed infrastructure and negotiating across a basket. Resilient but

capital intensive (Lawal & Oduleye, 2021a).

The integrated originator entrant: An established biologics company using existing manufacturing, quality, medical affairs and account relationships to enter selectively, often in its own therapeutic areas. Strong synergies and the ability to sustain losses.

The medical benefit specialist: Concentrates on buy and bill categories where provider economics are more favourable, competing on reimbursement support, supply reliability and account management.

The independent branded biosimilar: which appears structurally challenged. This model attempts to build a differentiated biosimilar brand with a conventional field force and promotional programme in the pharmacy benefit channel without an intermediary partnership. The 2023 to 2024 adalimumab experience suggests it does not clear the rebate wall regardless of discount depth.

Transitions between archetypes are organisationally demanding, since they require simultaneous change in capability, cost structure and customer interface. The change management literature on digital and operating model transformation is directly relevant to firms attempting them (Eyetsemitan *et al*., 2023a), as is work on lean scaling of operations under resource constraint (Ambali *et al*., 2021).

5.4 Implications for originator pre loss of exclusivity planning

Three lessons emerge for originators approaching biologic loss of exclusivity.

First, the successor asset must be commercially mature before entry, not after. The AbbVie transition worked because Skyrizi and Rinvoq had indication breadth, evidence and payer position established in advance.

Second, evidence generation should be comparative and prospective. Head to head superiority data against the firm's own soon to be genericised molecule is commercially valuable in a way that is unusual in pharmaceutical development.

Third, contracting and formulation lifecycle decisions taken three to five years before entry constrain the whole subsequent defence. Presentation migration, patent sequencing and portfolio rebate architecture are pre loss of exclusivity decisions with post loss of exclusivity consequences. Capital allocation and treasury planning across such a transition is non trivial, since revenue declines in one geography while investment rises in another (Dada *et al*., 2021a; Tonoyan *et al*., 2021b).

It is important to note that the third of these attracts substantial policy criticism, and firms should anticipate that tactics which are currently lawful may face legislative or regulatory constraint.

5.5 Sustainability tension

A tension runs through the findings. Mechanisms that accelerate biosimilar uptake in the short run, notably private label exclusivity and aggressive tendering, simultaneously reduce the number of manufacturers able to sustain participation. If commercial returns do not support development, the pipeline thins irrespective of regulatory facilitation, and the savings already demonstrated will not extend to the far larger wave of biologic expiries still ahead (Association for Accessible Medicines, 2024).

This is ultimately a question of supply chain governance rather than of pricing policy alone, since the conditions that sustain multiple qualified suppliers also determine access continuity and resilience to disruption (Eze *et al*., 2023; Efobi *et al*., 2023). The policy objective, then, is not merely lower prices but a market structure in which several suppliers can remain viable. This is a market design problem rather than a pricing problem, and it is not obviously solved by either the United States rebate model or the European tender model in their current forms.

5.6 Access, equity and the distribution of savings

A recurring question is who ultimately receives the savings biosimilars generate. Where patient cost sharing is calculated against list price while plan economics are settled on net price, competition can reduce system cost without reducing patient cost. This is the mechanism by which supply chain inefficiency translates into affordability loss at the point of care (Asiedu & Asiedu, 2023b).

Access is also unevenly distributed geographically and socioeconomically. Formulary availability does not guarantee dispensing availability, particularly in underserved areas where distribution and pharmacy infrastructure is thinner (Asiedu & Asiedu, 2022; Aminu-Ibrahim *et al*., 2020; Akinse *et al*., 2023a). Geospatial methods developed to assess catchment and siting decisions in other sectors offer a means of quantifying this unevenness (Tonoyan *et al*., 2022a). Infrastructure investment translates into access outcomes only where the operating model supports it (Aminu-Ibrahim & Ogbete, 2023; Ogbete & Aminu-Ibrahim, 2024; Aminu-Ibrahim *et al*., 2024).

Digital access mechanisms extend reach but introduce their own equity and trust considerations (Orise & Niniola, 2022), and earlier detection of chronic disease expands the treated population against which biosimilar demand is measured (Afrihyia *et al*., 2023).

5.7 Governance, compliance and reputational risk

As competition moves into contracting, the associated governance risks move with it. Rebate arrangements, private label agreements and channel exclusivity attract regulatory and litigation attention, and the control environment around them requires the same rigour applied to financial reporting (Akomolafe *et al*., 2023a; Akomolafe & Agu, 2018; Akomolafe *et al*., 2023b).

Two specific exposures merit attention. The first is data protection. Commercial and patient support operations handle patient level information, and the applicable obligations are jurisdictionally variable and enforcement sensitive (Aliliele *et al*., 2024b; Mbonu *et al*., 2018, 2022a; Afrihyia *et al*., 2024b; Orise & Niniola, 2023). The second is systems integrity: Healthcare and payer connected infrastructure is an established target, and disruption carries commercial as well as clinical consequence (Adebayo *et al*., 2023). Control automation and continuous monitoring reduce the cost of maintaining assurance across these exposures (Mbonu *et al*., 2022; Aliliele *et al*., 2023a).

6. Managerial and Policy Implications

6.1 For biosimilar manufacturers

1. Resource access and contracting ahead of promotion. In the pharmacy benefit channel, promotional investment without formulary position produces negligible return.
2. Decide the partnership question explicitly. Pursuing private label and independent branding simultaneously dilutes both, and dependency exposure should be

assessed formally rather than assumed (Bello *et al*., 2023).
3. Measure conversion, not prescriptions. Fill rate within thirty days is the operative commercial metric, and should be instrumented at each stage between prescription and dispense (Sanni & Wedraogo, 2024; Eyetsemitan *et al*., 2024b).
4. Build cost of goods advantage early. It is the only durable defence in a market that converges on price (Tonoyan *et al*., 2022b).
5. Treat regulatory posture as a commercial capability rather than a submission activity, and stress test interchangeability investment against the possibility that the designation becomes widely available (Eze *et al*., 2022b).
6. Differentiate where differentiation is permitted: Device, presentation, supply reliability and service, while recognising the limits of these levers when payers decide on net cost (Asiedu & Asiedu, 2024b).
7. Invest in contract, account and dispensing data architecture as a commercial asset, not as IT overhead (Badmus *et al*., 2019a, 2019b).
8. Where analytics and automation are deployed against payer and prescriber targeting, prioritise auditability and explainability, since decision logic in regulated health markets must withstand scrutiny (Sanni *et al*., 2022c).

6.2 For originators

1. Begin succession planning at least five years before anticipated entry and judge the transition on portfolio revenue rather than brand retention (Lawal & Oduleye, 2021a).
2. Generate comparative evidence supporting migration to successor assets.
3. Expect defence tactics to attract policy scrutiny and plan for a narrowing legal envelope (Annan, 2024).
4. Consider participating in the biosimilar market directly where manufacturing and account assets can be reused.
5. Model the erosion curve explicitly rather than extrapolating from small molecule precedent, since the shape differs materially by channel (Tonoyan *et al*., 2021a; Medon & Oduleye, 2024).

6.3 For payers and policymakers

1. Address the divergence between list and net price, which currently prevents price competition from reaching patients whose cost sharing is calculated on list price (Asiedu & Asiedu, 2023b).
2. Scrutinise vertical integration in the private label model, which delivers uptake but concentrates market power and may foreclose non partnered suppliers.
3. Extend procurement award criteria beyond lowest price to include supply security and multi supplier sustainability, particularly in tender based systems (Akin-Oluyomi *et al*., 2023a, 2024).
4. Align provider economics in the medical benefit through prospective shared savings rather than percentage based margins (Ilodigwe & Adesemoye, 2019a).
5. Monitor pipeline thinning as a leading indicator of market failure, since development decisions precede shortages by several years, and pair this monitoring with the early warning mechanisms already developed for essential medicine supply (Eze *et al*., 2022a).
6. Treat access as a distribution and infrastructure question as well as a coverage question, since coverage without dispensing capacity does not produce access (Asiedu & Asiedu, 2022; Aminu-Ibrahim *et al*., 2020).

6.4 For organisational capability building

Biosimilar commercial organisations require a capability mix that few pharmaceutical firms possess natively: Contracting depth, cost discipline, data engineering and operational service management alongside conventional commercial skills. Building it is a change programme rather than a hiring exercise (Ilodigwe & Adesemoye, 2024b; Eyetsemitan *et al*., 2023a). Clinical and commercial education pathways may need redesign to support it (Orise & Niniola, 2024), and where automated tooling is introduced into commercial workflows, governance should precede deployment rather than follow it (Annan, 2023).

7. Limitations

Five limitations bound the conclusions.

Price opacity: Net prices are confidential. Analysis based on list prices and average sales prices systematically misstates real competitive position, and private label contract economics are entirely undisclosed.

Causal attribution: The association between the April 2024 formulary change and subsequent share movement is strong and temporally clear, but this is a single natural experiment without a control, and concurrent factors including portfolio substitution were reducing total molecule volume simultaneously.

Period truncation: The analysis closes at the end of 2024. Several developments visible at that point, including the ustekinumab biosimilar cohort approved during 2024 but not yet launched, will materially affect the conclusions and cannot yet be assessed. The private label model in particular was approximately eight months old at the close of the study period, so its durability is untested.

Geographic and channel scope: The analysis centres on the United States with selective European comparison. Emerging markets, Japan and Canada operate under different conditions and are not examined; markets pursuing regulatory harmonisation face an additional set of commercial constraints not modelled here (Eze *et al*., 2024a).

Source composition: Several sources are produced by manufacturers, trade associations or consultancies with commercial positions. Triangulation mitigates but does not eliminate this bias. In addition, several conceptual frameworks drawn on in Sections 2, 4.9, 4.10 and 5.7 were developed in adjacent sectors and are applied here analogically; their transferability to pharmaceutical commercial operations is argued rather than empirically demonstrated.

7.1 Future research

Priority directions include: Quantitative analysis of net price transmission to patient cost sharing under private label arrangements; longitudinal study of biosimilar developer entry and exit decisions as a function of realised commercial returns; assessment of whether the private label model sustains or suppresses share gains beyond its first year; comparative assessment of tender design features against supplier survival; empirical testing of whether the

infrastructural capabilities identified in Section 4.9 predict biosimilar commercial outcomes; and prescriber and patient level research on how private labelling affects trust in biosimilars, given that the label under which a product reaches the patient is increasingly determined by their insurer rather than its manufacturer.

8. Conclusion

Biosimilars have changed pharmaceutical commercial strategy more profoundly than their aggregate savings figures suggest. The 2024 evidence indicates that the locus of commercial decision making in biologics has moved from the prescriber to the intermediary, that classical brand differentiation has limited purchase in a category where regulators enforce product parity, and that the marketing function has been substantially displaced by contracting, channel partnership and gross to net engineering.

Four conclusions stand out. First, formulary architecture determined outcomes in 2024 more decisively than clinical evidence, price or regulatory designation, as the adalimumab market demonstrated when a single contracting decision achieved in weeks what years of competitive discounting had not. Second, originators have largely stopped defending assets at loss of exclusivity and started replacing them, which means biosimilar entrants increasingly compete for a market their originator competitor is actively shrinking. Third, the private label model resolved the rebate wall by absorbing it, delivering genuine uptake while concentrating commercial power in vertically integrated intermediaries and raising unresolved questions about access on non partnered terms. Fourth, the capabilities that now determine competitive outcome are infrastructural, residing in contracting systems, data architecture, distribution visibility and manufacturing reliability rather than in promotional capability.

The underlying policy question is no longer whether biosimilars can lower prices. They demonstrably can, having generated approximately $36 billion in cumulative savings and nearly 500 million incremental days of therapy since first entry (Association for Accessible Medicines, 2024). The question is whether the commercial conditions surrounding them can sustain enough suppliers to keep delivering those savings across the far larger wave of biologic patent expiries still to come. That outcome will be determined by market design rather than by science, which returns the argument to where it began: A therapeutic advance delivers value only when the system carrying it is configured to let it (Ilodigwe & Adesemoye, 2019b).

9. References

1. Abetoh NF, Atakpa MI. Audit analytics in healthcare financial oversight: Leveraging data science to strengthen accountability in multilateral grant ecosystems. International Journal of Scientific Research in Computer Science, Engineering and Information Technology. 2024; 10(6):2710-2747. Doi: https://doi.org/10.32628/CSEIT2410791
2. Adebayo A, Adepoju PA, Ozowara DE. Conceptual model for cyber risk pricing and insurance structuring in health technology platforms. Gyanshauryam, International Scientific Refereed Research Journal. 2023; 6(6).
3. Adelanwa A, Basnet A, Anene UN. Data driven digital transformation models for lifecycle performance management in infrastructure delivery. International Journal of Advanced Multidisciplinary Research and Studies. 2023a; 3(6):2646-2662. Doi: https://doi.org/10.62225/2583049X.2023.3.6.5968
4. Adelanwa A, Basnet A, Anene UN. Predictive analytics models for financial risk detection and fraud prevention in public systems. International Journal of Advanced Multidisciplinary Research and Studies. 2023b; 3(6). Doi: https://doi.org/10.62225/2583049X.2023.3.6.5969
5. Adelanwa A, Basnet A, Anene UN. Performance intelligence models for optimization and outcome measurement in large scale public services. Shodhshauryam, International Scientific Refereed Research Journal. 2024; 6(1).
6. Adelanwa A, Basnet A, Anene UN. Advanced AI-based decision support systems for healthcare operations and resource planning. Gyanshauryam, International Scientific Refereed Research Journal. n.d.; 7(1).
7. Adesuyi MO, Akomolafe O, Olaogun BO, Ndukwe VU, Sakyi JK. Global interoperability model for distributed ledger-based cross-border payment systems. International Journal of Multidisciplinary Research and Growth Evaluation. 2023; 4(6)1291-1300. Doi: https://doi.org/10.54660/.IJMRGE.2023.4.6.1291-1300
8. Afrihyia E, Akinse SG, Ojukwu PU. Development and implementation of an AI-driven early detection system for non-communicable diseases. International Journal of Advanced Multidisciplinary Research and Studies. 2023; 3(6):2680-2691.
9. Afrihyia E, Akinse SG, Ojukwu PU. Comparative governance of AI-driven healthcare management: Executive oversight, regulatory structures, and accountability in the United States and developing countries. International Journal of Advanced Multidisciplinary Research and Studies. 2024a; 4(6):3087-3102. Doi: https://doi.org/10.62225/2583049X.2024.4.6.5920
10. Afrihyia E, Ojukwu PU, Akinse SG. Privacy-preserving health data governance models: A comparative review of blockchain and cryptographic strategies in U.S. and developing healthcare systems. International Journal of Advanced Multidisciplinary Research and Studies. 2024b; 4(6):3071-3086. Doi: https://doi.org/10.62225/2583049X.2024.4.6.5919
11. Aifuwa SE, Oshoba TO, Ogbuefi E, Ike PN, Nnabueze SB, Olatunde-Thorpe J. Predictive analytics models enhancing supply chain demand forecasting accuracy and reducing inventory management inefficiencies. International Journal of Multidisciplinary Research and Growth Evaluation. 2020; 1(3):171-181. Doi: https://doi.org/10.54660/.IJMRGE.2020.1.3.171-181
12. Akin-Oluyomi OT, Atima ME, Akinleye OK. Green procurement strategies for balancing cost efficiency with long-term environmental responsibility. International Journal of Advanced Multidisciplinary Research and Studies. 2023a; 3(6):2183-2193.
13. Akin-Oluyomi OT, Atima ME, Akinleye OK. Regulatory compliance and supplier risk assessment frameworks in international pharmaceutical procurement. International Journal of Advanced Multidisciplinary Research and Studies. 2023b; 3(6):2194-2204.
14. Akin-Oluyomi OT, Atima ME, Akinleye OK, Okoruwa PO. Predictive analytics approaches for improving

demand forecasting accuracy in e-commerce procurement systems. International Journal of Advanced Multidisciplinary Research and Studies. 2023c; 3(6):2173-2182.
15. Akin-Oluyomi OT, Okoruwa PO, Babatope OM, Akokodaripon DA. Evaluating supplier sustainability metrics through data-driven procurement and supply chain frameworks. International Journal of Advanced Multidisciplinary Research and Studies. 2023d; 3(6):2213-2223.
16. Akin-Oluyomi OT, Atima ME, Akinleye OK. Cross-border supplier relationship management frameworks for pharmaceutical and global construction sectors. International Journal of Multidisciplinary Research and Growth Evaluation. 2024; 5(6):1709-1718.
17. Akinleye OK, Adeyoyin O. Process automation framework for enhancing procurement efficiency and transparency. Shodhshauryam, International Scientific Refereed Research Journal. 2021; 4(4):356-387.
18. Akinleye OK, Adeyoyin O. A negotiation optimization model for reducing procurement costs in manufacturing firms. Shodhshauryam, International Scientific Refereed Research Journal. 2022a; 5(5):398-435. Doi: https://doi.org/10.32628/SHISRRJ225891
19. Akinleye OK, Adeyoyin O. Supplier relationship management framework for achieving strategic procurement objectives. Gyanshauryam, International Scientific Refereed Research Journal. 2022b; 5(4):565-598. Doi: https://doi.org/10.32628/GISRRJ225430
20. Akinleye OK, Okoruwa PO, Babatope OM, Akokodaripon DA. Leveraging big data and business intelligence for optimization of manufacturing sector procurement. International Journal of Advanced Multidisciplinary Research and Studies. 2023; 3(6):2164-2172.
21. Akinse SG, Ekechi NV, Ohanebo CG. Integrative maternal health model: Addressing socioeconomic inequities in rural populations. International Journal of Advanced Multidisciplinary Research and Studies. 2023a; 3(6):2832-2838.
22. Akomolafe O, Agu MU. A conceptual model for enhancing internal audit quality through technology-enabled risk assessment frameworks. Iconic Research and Engineering Journals. 2018; 1(9):458-475.
23. Akomolafe O, Agu MU. Advances in financial resilience through integrated governance and compliance strategies. Iconic Research and Engineering Journals. 2019c; 2(10):607-620.
24. Akomolafe O, Olaogun BO, Adesuyi MO, Ndukwe VU, Sakyi JK. Smart contract automation model for supplier payment systems and performance benchmarking. International Journal of Multidisciplinary Research and Growth Evaluation. 2022; 3(6):827-836. Doi: https://doi.org/10.54660/.IJMRGE.2022.3.6.827-836
25. Akomolafe O, Agu MU, Bello A. A conceptual model for implementing risk-based auditing in strategic financial management. International Journal of Advanced Multidisciplinary Research and Studies. 2023a; 3(6):2274-2286. Doi: https://doi.org/10.62225/2583049X.2023.3.6.5359
26. Akomolafe O, Agu MU, Bello A. A quantitative conceptual model for assessing compliance risk in emerging economies. International Journal of Advanced Multidisciplinary Research and Studies. 2023b; 3(6):2287-2296. Doi: https://doi.org/10.62225/2583049X.2023.3.6.5360
27. Akomolafe O, Olaogun BO, Adesuyi MO, Ndukwe VU, Sakyi JK. Scalable blockchain payment gateway architecture model for enterprise-grade adoption. International Journal of Advanced Multidisciplinary Research and Studies. 2024a; 4(1):1552-1568. Doi: https://doi.org/10.62225/2583049X.2024.4.1.5280
28. Akomolafe O, Olaogun BO, Adesuyi MO, Ndukwe VU, Sakyi JK. Smart contract-based dispute resolution model for international supplier payments. International Journal of Advanced Multidisciplinary Research and Studies. 2024b; 4(1):1582-1601. Doi: https://doi.org/10.62225/2583049X.2024.4.1.5282
29. Aliliele C, Mbonu IS, Iwuanyanwu U. A conceptual framework for continuous cloud misconfiguration monitoring and enterprise risk mitigation strategies. International Journal of Scientific Research in Computer Science, Engineering and Information Technology. 2023a; 9(10):373-394. Doi: https://doi.org/10.32628/CSEIT2361071
30. Aliliele C, Mbonu IS, Iwuanyanwu U. A conceptual framework for enterprise data sensitivity classification and regulatory traceability mechanisms. International Journal of Advanced Multidisciplinary Research and Studies. 2024a; 4(6):3103-3124. Doi: https://doi.org/10.62225/2583049X.2024.4.6.5991
31. Aliliele C, Mbonu IS, Iwuanyanwu U. Advances in HIPAA compliant data architecture and secure analytics frameworks for community healthcare organizations. Shodhshauryam, International Scientific Refereed Research Journal. 2024b; 7(2):277-324. Doi: https://doi.org/10.32628/SHISRRJ2472163
32. Ambali KB, Eyetsemitan RA, Oyeleye AO, Fadayomi O. Lean Six Sigma for small enterprises: A systematic review and Lite-DMAIC adaptation framework for resource-constrained organizations. Iconic Research and Engineering Journals. 2021; 5(5):562-583. Doi: https://doi.org/10.64388/IREV5I5-1716957
33. American Journal of Managed Care. Samsung Bioepis reports 2024 biosimilar market growth trends, n.d. https://www.ajmc.com/view/samsung-bioepis-reports-2024-biosimilar-market-growth-trends
34. Aminu-Ibrahim AY, Ogbete JC, Ambali KB. Developing sustainable diagnostic laboratory infrastructure models for emerging and resource constrained health systems. Iconic Research and Engineering Journals. 2018; 1(8):118-132. Doi: https://doi.org/10.64388/IREV1I8-1713586
35. Aminu-Ibrahim AY, Ogbete JC, Ambali KB. Infrastructure driven expansion of diagnostic access across underserved and rural healthcare regions. International Journal of Multidisciplinary Research and Growth Evaluation. 2020; 1(5):691-706. Doi: https://doi.org/10.54660/IJMRGE.2020.1.5.691-706
36. Aminu-Ibrahim AY, Ogbete JC. Healthcare infrastructure as a public health intervention using evidence from large laboratory networks. Shodhshauryam, International Scientific Refereed Research Journal. 2023; 6(1):256-286. Doi: https://doi.org/10.32628/SHISRRJ23678
37. Aminu-Ibrahim AY, Ogbete JC, Ambali KB. Governance and accountability models for public

private partnerships in healthcare infrastructure development. International Journal of Advanced Multidisciplinary Research and Studies. 2024; 4(6):2943-2960. Doi: https://doi.org/10.62225/2583049X.2024.4.6.5699
38. Anene UN, Clement T. A resilient logistics framework for humanitarian supply chains: Integrating predictive analytics, IoT, and localized distribution to strengthen emergency response systems. International Journal of Scientific Research in Computer Science, Engineering and Information Technology. 2022; 8(5):398-424.
39. Annan AO. Data privacy governance models for cross-border digital platforms. International Journal of Multidisciplinary Research and Growth Evaluation. 2022; 3(6):949-964.
40. Annan AO. Intellectual property ownership and authorship in AI-generated works. Gyanshauryam, International Scientific Refereed Research Journal. 2023; 6(3):425-450.
41. Annan AO. Algorithmic accountability and trade secret protection in artificial intelligence. Shodhshauryam, International Scientific Refereed Research Journal. 2024; 7(5):315-347.
42. Asiedu CS, Asiedu AA. Last-mile drug distribution to underserved communities: A review of barriers and intervention models. Gyanshauryam, International Scientific Refereed Research Journal. 2022; 5(6):439-466.
43. Asiedu CS, Asiedu AA. Pharmaceutical supply chain inefficiencies and medication affordability in resource-constrained health systems: A narrative review. International Journal of Health and Pharmaceutical Research. 2023b; 8(4):192-222. Doi: https://doi.org/10.56201/ijhpr.v8.no4.2023.pg192.222
44. Asiedu CS, Asiedu AA. Equitable access to chronic therapies in hospital pharmacy settings: A conceptual framework for continuity of care. International Journal of Medical Evaluation and Physical Report. 2024a; 8(6):274-298. Doi: https://doi.org/10.56201/ijmepr.v8.no6.2024.pg274.298
45. Asiedu CS, Asiedu AA. Reconceptualizing quality assurance in pharmaceutical manufacturing as a determinant of supply reliability. International Journal of Health and Pharmaceutical Research. 2024b; 9(5):148-173. Doi: https://doi.org/10.56201/ijhpr.v9.no5.2024.pg148.173
46. Association for Accessible Medicines. The U.S. generic and biosimilar medicines savings report 2024. IQVIA Institute, 2024. https://accessiblemeds.org/resources/blog/2024-savings-report/
47. Atakpa MI, Abolaji TO. A privacy-preserving data architecture model for regulated industry analytics under GDPR and HIPAA compliance. International Journal of Scientific Research in Computer Science, Engineering and Information Technology. 2022; 8(3):781-808. Doi: https://doi.org/10.32628/CSEIT22558
48. Atakpa MI, Fobellah AN. Anomaly detection in financial time-series data: A conceptual model for healthcare and banking applications. International Journal of Scientific Research in Computer Science, Engineering and Information Technology. 2023; 9(2):967-997. Doi: https://doi.org/10.32628/CSEIT2342441
49. Atima ME, Sanni JO, Attah A. Predictive audience segmentation models resolving targeting inefficiencies in regulated professional service enterprises. Shodhshauryam, International Scientific Refereed Research Journal. 2022; 5(1):271-303. Doi: https://doi.org/10.32628/SHISRRJ247134
50. Babatope OM, Akokodaripon DA, Akinleye OK, Okoruwa PO. The role of data visualization in enhancing strategic procurement decision-making effectiveness. International Journal of Advanced Multidisciplinary Research and Studies. 2023; 3(6):2205-2212.
51. Badmus O, Dosunmu AA, Ozowara DE. A systematic review of CI/CD pipeline strategies in Salesforce DevOps: Tools, practices, and deployment outcomes. Iconic Research and Engineering Journals. 2018; 2(6).
52. Badmus O, Dosunmu AA, Ozowara DE. A conceptual model for ETL design and data integration in Salesforce-centric enterprise architectures. Iconic Research and Engineering Journals. 2019a; 3(5).
53. Badmus O, Dosunmu AA, Ozowara DE. A governance framework for Salesforce platform management in regulated healthcare environments. Iconic Research and Engineering Journals. 2019b; 3(6).
54. Badmus O, Jooda D, Ozowara DE, Anunagba CO. A framework for Git-based version control and code review governance in Salesforce development teams. Shodhshauryam, International Scientific Refereed Research Journal. 2022a; 5(2):473-493.
55. Badmus O, Jooda D, Anunagba CO. A privacy-by-design framework for role-based security architecture in Salesforce environments handling sensitive personal data. International Journal of Advanced Multidisciplinary Research and Studies. 2024; 4(6):3244-3254. Doi: https://doi.org/10.62225/2583049X.2024.4.6.6243
56. Basnet A, Oghenemaiga E, Anene UN. Audience segmentation and forecasting models for enhancing targeted digital marketing effectiveness. Shodhshauryam, International Scientific Refereed Research Journal. 2021; 4(5):279-305.
57. Basnet A, Oghenemaiga E, Anene UN. Attribution, revenue, and yield optimization models using Google Ad Manager reporting and forecasting tools. International Journal of Advanced Multidisciplinary Research and Studies. 2024; 4(6). Doi: https://doi.org/10.62225/2583049X.2024.4.6.5667
58. Bello A, Akomolafe O, Agu MU. A conceptual framework for data-driven procurement risk management in multinational enterprises. International Journal of Advanced Multidisciplinary Research and Studies. 2023; 3(6):2307-2316. Doi: https://doi.org/10.62225/2583049X.2023.3.6.5363
59. Biosimilars Council & IQVIA. Adalimumab biosimilar tracking: Executive summary, April, 2024. https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf
60. Biosimilars Review and Report. IQVIA study confirms large lost savings opportunity with adalimumab biosimilars, points the finger at PBMs, April 2, 2024. https://biosimilarsrr.com/2024/04/02/iqvia-study-confirms-large-lost-savings-opportunity-with-

adalimumab-biosimilars-points-the-finger-at-pbms/
61. Center for Biosimilars. Happy birthday adalimumab biosimilars: Reflecting on the first year of US competition, January, 2024a. https://www.centerforbiosimilars.com/view/happy-birthday-adalimumab-biosimilars-reflecting-on-the-first-year-of-us-competition
62. Center for Biosimilars. Skyrizi overtakes Humira: "Product hopping" leaves biosimilar market in limbo, November, 2024b. https://www.centerforbiosimilars.com/view/skyrizi-overtakes-humira-product-hopping-leaves-biosimilar-market-in-limbo
63. Dada T, Isiekwu CP, Oluwo K. Advances in multinational cash flow consolidation and FX risk control using tiered treasury architecture. Iconic Research and Engineering Journals. 2021a; 4(11):601-620. Doi: https://doi.org/10.64388/IREV4I11-1714351
64. Dada T, Isiekwu CP, Oluwo K. Designing CRM-based sales forecasting models for multichannel lending institutions. Iconic Research and Engineering Journals. 2021b; 5(3):451-466. Doi: https://doi.org/10.64388/IREV5I3-1714352
65. Efobi OZ, Akinleye OK, Fasawe O. Conceptual model for data-driven lean supply chain optimization in manufacturing and retail operations. International Journal of Scientific Research in Computer Science, Engineering and Information Technology. 2022b; 8(2):703-734. Doi: https://doi.org/10.32628/CSEIT2541335
66. Efobi OZ, Akinleye OK, Fasawe O. Conceptual framework for developing a resilience index for post-pandemic supply chains. Shodhshauryam, International Scientific Refereed Research Journal. 2023; 6(2):421-432.
67. Eyetsemitan RA, Ambali KB, Oyeleye AO, Fadayomi O. Change management in small business digital transformation: A systematic review and lean change adoption framework. Gyanshauryam, International Scientific Refereed Research Journal. 2023a; 6(6):521-550. Doi: https://doi.org/10.32628/GISRRJ236648
68. Eyetsemitan RA, Oyeleye AO, Ambali KB, Fadayomi O. CRM and workflow automation in small healthcare practices: A process efficiency framework for scalable patient engagement. International Journal of Multidisciplinary Research and Growth Evaluation. 2024a; 5(6):1931-1949. Doi: https://doi.org/10.54660/IJMRGE.2024.5.6.1931-1949
69. Eyetsemitan RA, Oyeleye AO, Ambali KB, Fadayomi O. Data-driven process optimization in micro-enterprises: A conceptual framework for funnel analysis and bottleneck identification. International Journal of Multidisciplinary Research and Growth Evaluation. 2024b; 5(6):1950-1968. Doi: https://doi.org/10.54660/IJMRGE.2024.5.6.1950-1968
70. Eze FI, Anene UN, Akinleye OK. Creation of a drug shortage early warning and regulatory response model for essential medicines in global health systems. Research Journal of Pure Science and Technology. 2022a; 5(1):57-95. Doi: https://doi.org/10.56201/rjpst.v5.no1.2022.pg57.95
71. Eze FI, Anene UN, Akinleye OK. Design of an integrated regulatory readiness maturity model for pharmaceutical companies seeking global market entry. International Journal of Health and Pharmaceutical Research. 2022b; 7(1):77-112. Doi: https://doi.org/10.56201/ijhpr.v7.no1.2022.pg77.112
72. Eze FI, Anene UN, Akinleye OK. Pharmaceutical supply chain governance, environmental risk management, and sustainable access to essential medicines in emerging economies: The PSCG-ERM framework. International Journal of Health and Pharmaceutical Research. 2023; 8(4):192-241. Doi: https://doi.org/10.56201/ijhpr.v8.no4.2023.pg192.241
73. Eze FI, Akinleye OK, Anene UN. Development of a cross-border regulatory harmonization model for African pharmaceutical markets: The ARCH-Model framework. International Journal of Health and Pharmaceutical Research. 2024a; 9(5):148-186. Doi: https://doi.org/10.56201/ijhpr.v9.no5.2024.pg148.186
74. Eze FI, Akinleye OK, Anene UN. Development of a risk-based accelerated approval decision model balancing speed, safety, and evidence quality in pharmaceutical regulatory science. Research Journal of Pure Science and Technology. 2024b; 7(6):120-161. Doi: https://doi.org/10.56201/rjpst.v7.no6.2024.pg120.161
75. Filani OM, Nnabueze SB, Ike PN, Wedraogo L. Real-time risk assessment dashboards using machine learning in hospital supply chain management systems. International Journal of Multidisciplinary Evolutionary Research. 2022; 3(1):65-76. Doi: https://doi.org/10.54660/IJMER.2022.3.1.65-76
76. GaBI Online. Disruptor partnerships grow adalimumab biosimilar market share, n.d. https://gabionline.net/reports/disruptor-partnerships-grow-adalimumab-biosimilar-market-share
77. Ike PN, Ogbuefi E, Nnabueze SB, Olatunde-Thorpe J, Aifuwa SE, Oshoba TO, *et al*. Supplier relationship management strategies fostering innovation, collaboration, and resilience in global supply chain ecosystems. International Journal of Multidisciplinary Evolutionary Research. 2021; 2(2):52-62. Doi: https://doi.org/10.54660/IJMER.2021.2.2.52-62
78. Ike PN, Ogbuefi E, Nnabueze SB, Olatunde-Thorpe J, Aifuwa SE, Oshoba TO, *et al*. Lean supply chain practices improving operational efficiency, reducing waste, and enhancing organizational competitiveness globally. Journal of Frontiers in Multidisciplinary Research. 2022; 3(2):182-192. Doi: https://doi.org/10.54660/.IJFMR.2022.3.2.182-192
79. Ike PN, Aifuwa SE, Nnabueze SB, Olatunde-Thorpe J, Ogbuefi E, Oshoba TO, *et al*. Utilizing nanomaterials in healthcare supply chain management for improved drug delivery systems. International Journal of Advanced Multidisciplinary Research and Studies. 2024b; 4(4):1567-1572. Doi: https://doi.org/10.62225/2583049X.2024.4.4.5154
80. Ilodigwe L, Adesemoye AC. A critical review of health insurance financing mechanisms and provider payment reform strategies for balancing coverage expansion and financial protection in emerging markets. International Journal of Health and Pharmaceutical Research. 2019a; 5(2):31-55. Doi: https://doi.org/10.56201/ijhpr.vol.5.no2.2019.pg31.55
81. Ilodigwe L, Adesemoye AC. From molecules to health systems: A conceptual model explaining why scientific innovation fails to improve patient outcomes without

effective healthcare delivery infrastructure. International Journal of Health and Pharmaceutical Research. 2019b; 5(2):56-79. Doi: https://doi.org/10.56201/ijhpr.vol.5.no2.2019.pg56.79
82. Ilodigwe L, Adesemoye AC. Advances in pharmacy-led delivery and access models for strengthening primary healthcare systems and expanding medicine availability in emerging markets. International Journal of Health and Pharmaceutical Research. 2020; 5(3):78-96. Doi: https://doi.org/10.56201/ijhpr.vol.5.no3.2020.pg78.96
83. Ilodigwe L, Adesemoye AC. The data backbone of health system transformation: A governance and architecture framework for interoperability, data quality, and advanced analytics at national scale. International Journal of Health and Pharmaceutical Research. 2021; 6(2):52-76. Doi: https://doi.org/10.56201/ijhpr.vol.6.no2.2021.pg52.76
84. Ilodigwe L, Adesemoye AC. Advances in real-world evidence, predictive analytics, and data-driven decision making for improving health system performance and patient outcomes. International Journal of Health and Pharmaceutical Research. 2024a; 9(5):174-197. Doi: https://doi.org/10.56201/ijhpr.v9.no5.2024.pg174.197
85. Ilodigwe L, Adesemoye AC. Beyond technology: A strategic framework for building sustainable and resilient health systems through organizational strategy, operational excellence, and workforce capability. International Journal of Medical Evaluation and Physical Report. 2024b; 8(6):299-319. Doi: https://doi.org/10.56201/ijmepr.v8.no6.2024.pg299.319
86. Journal of Managed Care and Specialty Pharmacy. Greater uptake, an alternative reimbursement methodology needed to realize cost-saving potential of oncology biosimilars in the United States, 2021. Doi: https://www.jmcp.org/doi/10.18553/jmcp.2021.21202
87. Ladapo OO, Jooda D, Dosunmu AA, Abolaji TO. Navigating digital transformation: Best practices for cloud migration strategies in the enterprise. Journal of Frontiers in Multidisciplinary Research. 2022; 3(1):643-655. Doi: https://doi.org/10.54660/.JFMR.2022.3.1.643-655
88. Ladapo OO, Jooda D, Dosunmu AA, Abolaji TO. A comprehensive survey on ServiceNow for IT service management. International Journal of Multidisciplinary Research and Growth Evaluation. 2023a; 4(6):1532-1545. Doi: https://doi.org/10.54660/.IJMRGE.2023.4.6.1532-1545
89. Ladapo OO, Dosunmu AA, Jooda D, Abolaji TO. An IT service management literature review: Challenges, benefits, opportunities, and implementation practices. International Journal of Advanced Multidisciplinary Research and Studies. 2023b; 3(6):2875-2889. Doi: https://doi.org/10.62225/2583049X.2023.3.6.6205
90. Lawal OA, Oduleye TE. A conceptual model for financial analytics driven enterprise value creation in technology firms. Iconic Research and Engineering Journals. 2018a; 2(2).
91. Lawal OA, Oduleye TE. Conceptualizing data driven executive decision systems for strategic financial planning. Iconic Research and Engineering Journals. 2019b; 3(3).
92. Lawal OA, Oduleye TE. A conceptual decision model for capital allocation using financial analytics. Gyanshauryam, International Scientific Refereed Research Journal. 2021a; 4(2):269-295.
93. Lawal OA, Oduleye TE. A review of decision analytics models for sustainable profitability in technology firms. Gyanshauryam, International Scientific Refereed Research Journal. 2023a; 6(6):455-475.
94. Mbonu IS, Aliliele C, Iwuanyanwu U, Oluoha OM. A conceptual framework for legal and ethical risk modeling in enterprise data protection governance systems. Iconic Research and Engineering Journals. 2018; 2(2):207-226. Doi: https://doi.org/10.64388/IREV2I2-1714911
95. Mbonu IS, Aliliele C, Iwuanyanwu U, Uzoka E. A conceptual framework for AI enabled IT general controls and SOX audit automation processes. Gyanshauryam, International Scientific Refereed Research Journal. 2022; 5(5):384-414. Doi: https://doi.org/10.32628/GISRRJ2256239
96. Mbonu IS, Iwuanyanwu U, Aliliele C, Uzoka E. A review of data protection impact assessment models in multi cloud financial infrastructure systems. International Journal of Scientific Research in Computer Science, Engineering and Information Technology. 2022a; 8(1):589-623. Doi: https://doi.org/10.32628/CSEIT25442
97. Medon JJ, Oduleye TE. An integrated predictive analytics model for enhancing strategic financial forecasting and decision accuracy. Gyanshauryam, International Scientific Refereed Research Journal. 2024; 7(3):258-279. Doi: https://doi.org/10.32628/GISRRJ247322
98. Nnabueze SB, Ike PN, Olatunde-Thorpe J, Aifuwa SE, Oshoba TO, Ogbuefi E, *et al*. End-to-end visibility frameworks improving transparency, compliance, and traceability across complex global supply chain operations. International Journal of Multidisciplinary Futuristic Development. 2021; 2(2):50-60. Doi: https://doi.org/10.54660/IJMFD.2021.2.2.50-60
99. Off-patent biologicals and biosimilars tendering in Europe: A proposal towards more sustainable practices, 2021. https://pmc.ncbi.nlm.nih.gov/articles/PMC8225063/
100. Ogbete JC, Aminu-Ibrahim AY. Translating healthcare infrastructure investment into measurable population health and diagnostic outcomes. International Journal of Scientific Research in Humanities and Social Sciences. 2024; 1(2):955-985. Doi: https://doi.org/10.32628/IJSRSSH242775
101. Ogundairo KM, Ayivi-Donkor SS. Machine learning approaches to customer acquisition and retention: A framework for predictive lifecycle management. IIARD International Journal of Economics and Business Management. 2023a; 9(10):210-246. Doi: https://doi.org/10.56201/ijebm.v9.no10.2023.pg210.246
102. Ogundairo KM, Ayivi-Donkor SS. Telemetry-driven value realization: Infusing economic evaluation algorithms directly into enterprise data pipelines. International Journal of Economics and Financial Management. 2023b; 8(8):195-232. Doi: https://doi.org/10.56201/ijefm.v8.no8.2023.pg195.232
103. Ogundairo KM, Ayivi-Donkor SS. Bridging the "adoption gap": Why supply chain AI fails without product marketing principles. International Journal of Marketing and Communication Studies. 2024a; 8(5):169-205. Doi:

https://doi.org/10.56201/ijmcs.v8.no5.2024.pg169.205
104. Ogundairo KM, Ayivi-Donkor SS. The vanishing interface: Why the coming era of autonomous agents demands a paradigm shift in product marketing architecture. IIARD International Journal of Economics and Business Management. 2024b; 10(11):350-385. Doi: https://doi.org/10.56201/ijebm.v10.no11.2024.pg350.385
105. Okoruwa PO, Babatope OM, Akokodaripon DA, Akinleye OK. Developing integrated digital platforms for enhancing transparency in procurement and supply chain management. International Journal of Multidisciplinary Research and Growth Evaluation. 2024; 5(6):1719-1729.
106. Olaogun BO, Adesuyi MO, Akomolafe O, Ndukwe VU, Sakyi JK. Regulatory compliance adaptation model for cross-border payment product redesign. International Journal of Advanced Multidisciplinary Research and Studies. 2023; 3(1):1651-1662. Doi: https://doi.org/10.62225/2583049X.2023.3.1.5279
107. Oluwo K, Dada T, Isiekwu CP. Transforming insurance underwriting with machine learning: A review and application cases. International Journal of Advanced Multidisciplinary Research and Studies. 2024; 4(6):3008-3019.
108. Orise C, Niniola S. Real-time analytics for educational excellence: A conceptual framework for performance dashboards in health professional training. International Journal of Scientific Research in Computer Science, Engineering and Information Technology. 2022; 8(2):802-815.
109. Orise C, Niniola S. Privacy, safeguarding, and ethical data practices in healthcare EdTech: A conceptual model for compliance and trust. Shodhshauryam, International Scientific Refereed Research Journal. 2023; 6(1):507-529.
110. Orise C, Niniola S. Digital equity in healthcare education: A systematic review of access frameworks and interventions for underrepresented learners in clinical training. International Journal of Scientific Research in Humanities and Social Sciences. 2024; 1(2):1233-1246.
111. Samsung Bioepis. US biosimilar market report, Q4 2024. Reported in Center for Biosimilars, Samsung Bioepis report showcases adalimumab biosimilar growth in market share, 2024. https://www.centerforbiosimilars.com/view/samsung-bioepis-report-showcases-adalimumab-biosimilar-growth-in-market-share
112. Sanni JO, Ajiga D, Atima ME. Analytical models addressing measurement challenges of marketing return on investment in regulated services. International Journal of Multidisciplinary Research and Growth Evaluation. 2020a; 1(5):636-648. Doi: https://doi.org/10.54660/IJMRGE.2020.1.5.636-648
113. Sanni JO, Ajiga D, Atima ME. Data driven brand positioning frameworks resolving differentiation challenges in regulated professional markets. International Journal of Multidisciplinary Research and Growth Evaluation. 2020b; 1(5):649-660. Doi: https://doi.org/10.54660/IJMRGE.2020.1.5.649-660
114. Sanni JO, Atima ME. Analytics driven go to market frameworks addressing compliance sustainability complexity. International Journal of Multidisciplinary Research and Growth Evaluation. 2021a; 2(6):647-660.
115. Sanni JO, Atima ME. Business intelligence dashboard frameworks resolving executive visibility gaps in strategic marketing governance. International Journal of Multidisciplinary Research and Growth Evaluation. 2021b; 2(6):633-646. Doi: https://doi.org/10.54660/IJMRGE.2021.2.6.633-646
116. Sanni JO, Atima ME, Attah A. Systematic review of attribution modeling methods resolving bias in multi-touch journeys. Shodhshauryam, International Scientific Refereed Research Journal. 2022b; 5(1):304-334. Doi: https://doi.org/10.32628/SHISRRJ247135
117. Sanni JO, Iwuanyanwu UA, Essien MA, Atima ME, Attah A. Adaptive control models for AI-driven marketing automation in financial compliance environments. Shodhshauryam, International Scientific Refereed Research Journal. 2022c; 5(1):243-270. Doi: https://doi.org/10.32628/SHISRRJ247133
118. Sanni JO, Iwuanyanwu UA, Essien MA, Attah A. Lifecycle-aware marketing automation using federated learning for secure cross-organizational data management. Gyanshauryam, International Scientific Refereed Research Journal. 2023; 6(6):337-364. Doi: https://doi.org/10.32628/GISRRJ236642
119. Sanni JO, Attah A. A comprehensive framework for digital transformation in capital markets: Solving operational challenges and enhancing stakeholder engagement. Gyanshauryam, International Scientific Refereed Research Journal. 2023a; 6(6):275-302. Doi: https://doi.org/10.32628/GISRRJ236640
120. Sanni JO, Attah A. Artificial intelligence assisted content optimization models resolving digital conversion performance bottlenecks issues. Gyanshauryam, International Scientific Refereed Research Journal. 2023b; 6(6):303-336. Doi: https://doi.org/10.32628/GISRRJ236641
121. Sanni JO, Attah A. Market research frameworks addressing entry barriers within highly regulated industrial service sectors. International Journal of Scientific Research in Computer Science, Engineering and Information Technology. 2023c; 10(2):904-930. Doi: https://doi.org/10.32628/CSEIT2342439
122. Sanni JO, Wedraogo L. Data-centric funnel optimization frameworks resolving revenue leakage in high-value services. International Journal of Advanced Multidisciplinary Research and Studies. 2024; 4(6):2859-2874. Doi: https://doi.org/10.62225/2583049X.2024.4.6.5641
123. Sanni JO, Iwuanyanwu UA, Essien MA, Wedraogo L. Integrating blockchain-enabled smart contracts for transparent and verifiable marketing workflows. International Journal of Advanced Multidisciplinary Research and Studies. 2024; 4(6):2891-2906. Doi: https://doi.org/10.62225/2583049X.2024.4.6.5646
124. Tonoyan A, Dada O, Ayivi-Donkor SS. Advances in demand forecasting: Machine learning algorithms for revenue projection and financial planning accuracy. Gyanshauryam, International Scientific Refereed Research Journal. 2021a; 4(1):282-317.
125. Tonoyan A, Dada O, Ayivi-Donkor SS. Predictive cash flow modeling in retail: A review of advanced forecasting and working capital optimization. Shodhshauryam, International Scientific Refereed

Research Journal. 2021b; 4(3):366-397.
126. Tonoyan A, Dada O, Ayivi-Donkor SS. Advances in geospatial analysis: Predictive analytics methods for store location selection and market entry return on investment. International Journal of Marketing and Communication Studies. 2022a; 6(2):78-105. Doi: https://doi.org/10.56201/ijmcs.v6.no2.2022.pg78.105
127. Tonoyan A, Dada O, Ayivi-Donkor SS. Algorithmic process optimization and cost reduction: A review of simulation modeling and financial impact assessment. Journal of Accounting and Financial Management. 2022b; 8(8):139-169. Doi: https://doi.org/10.56201/jafm.vol.8.no8.2022.p139.169
128. Tonoyan A, Dada O, Ayivi-Donkor SS. A conceptual framework for retail asset valuation: Integrating quantitative pricing and multi-unit financial performance prediction. Journal of Accounting and Financial Management. 2023; 9(12):218-250. Doi: https://doi.org/10.56201/jafm.v9.no12.2023.pg218.250
129. Tonoyan A, Dada O, Ayivi-Donkor SS. Advances in supply chain resilience: Predictive models for vendor risk assessment and procurement cost optimization. International Journal of Social Sciences and Management Research. 2024a; 10(11):525-551. Doi: https://doi.org/10.56201/ijssmr.v10.no11.2024.pg.525.551
130. Tonoyan A, Dada O, Ayivi-Donkor SS. Real-time KPI tracking systems: A review of automated performance monitoring and data-driven decision making. World Journal of Innovation and Modern Technology. 2024b; 8(6):247-281. Doi: https://doi.org/10.56201/wjimt.v8.no6.2024.pg247.281
131. U.S. Food and Drug Administration. FDA updates guidance on interchangeability, June 20, 2024. https://www.fda.gov/drugs/drug-alerts-and-statements/fda-updates-guidance-interchangeability
132. Venable LLP. FDA revises guidance on switching studies for biosimilar interchangeability. BiologicsHQ, June, 2024. https://biologicshq.com/fda-revises-guidance-on-switching-studies-for-biosimilar-interchangeability/
133. Wedraogo L, Sanni JO. Machine learning models addressing uncertainty in cross-channel campaign performance forecasting accuracy. International Journal of Advanced Multidisciplinary Research and Studies. 2024; 4(6):2875-2890. Doi: https://doi.org/10.62225/2583049X.2024.4.6.5648
134. Yadav V. The impact of access policies on biosimilar pricing in five major EU markets [Podium presentation]. ISPOR Europe 2024, Barcelona, Spain, 2024.