Capgemini invent



From Biosimilar Development to Market Leadership: The Power of Connected Execution



The Biosimilar Opportunity… and the Execution Reality

The Biosimilar opportunity is created by patent expiry, but market leadership is determined by how effectively organizations convert analytical confidence into regulatory approval, predictable manufacturing, reliable supply and adoption.

More than $96 billion of Biologic revenue is expected to face Biosimilar competition, supported by nearly 200 active development programs worldwide. However, unlike traditional generics, Biosimilars require a Totality of Evidence approach that combines analytical, clinical, manufacturing and regulatory evidence to demonstrate Biosimilarity. This creates a unique execution paradox: development programs must become faster and leaner, while quality and supply expectations remain rigorous. In addition, regulatory pathways and market-access models vary across geographies, requiring molecule, market and regulator-specific launch strategies. Success, therefore, depends not only on scientific rigor, but also on consistent execution across development, manufacturing, supply and commercialization.

Biosimilars: From Approval to Advantage

Why the next decade of biosimilar competition will be won or lost after approval.

The race has changed

Patent expiry opens the door. What happens next decides who walks through it.

The US Food and Drug Administration (FDA) has approved 76 biosimilars since 2015, generating more than $56 billion in cumulative US healthcare savings, yet market share still sits below 20%. The European Medicines Agency (EMA) has approved 86 biosimilars since 2006 and recommended 41 more in 2025 alone; IQVIA estimates cumulative European savings near €75 billion and over 7 billion additional treatment days.

The next wave: ustekinumab, denosumab, aflibercept, tocilizumab, and omalizumab is larger, more complex, and will draw more simultaneous entrants than the first.

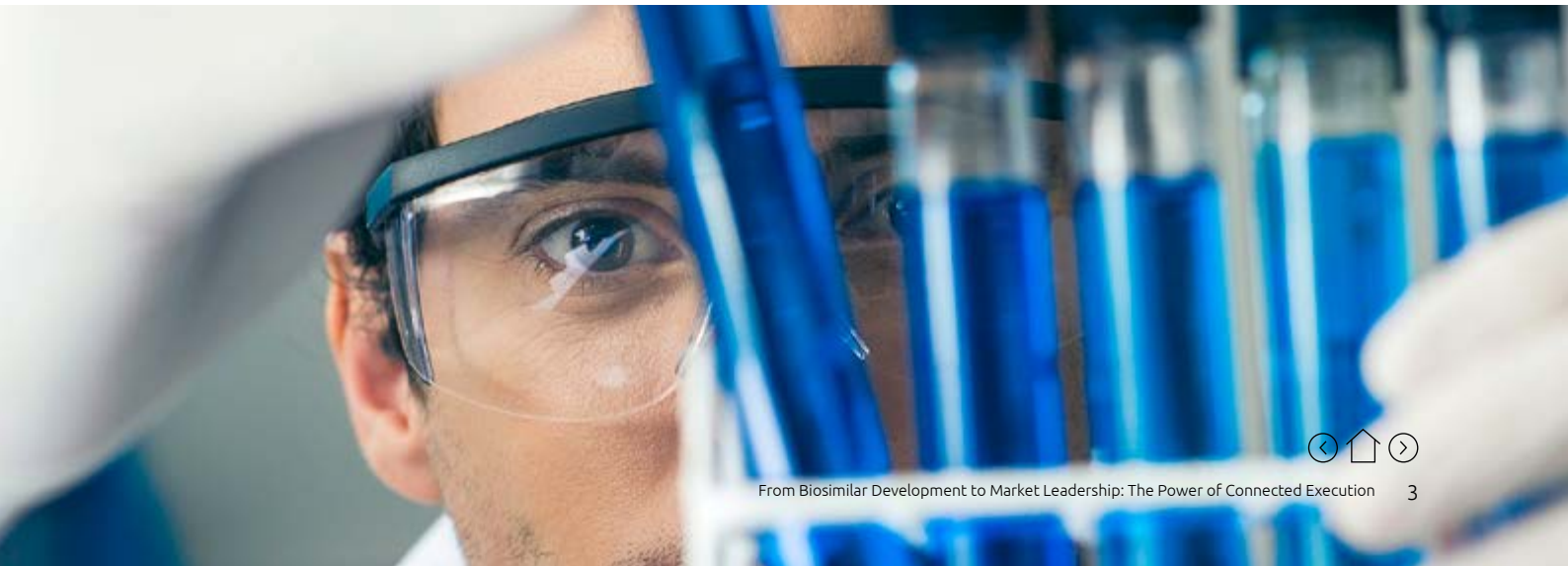
The gap between approved and adopted is where the real race now happens.

The bottleneck is moving

Regulators are converging on risk-based, analytical-first evidence. The EMA's tailored clinical approach and revised World Health Organization(WHO) guidance increasingly allow robust analytical and functional comparability, paired with PK data, to substitute for large comparative efficacy trials. FDA has moved away from routinely requiring switching studies for interchangeability.

This is good for patients and for speed. It also means more companies will reach approval at the same time. Where AI is genuinely earning its place here is in accelerating that analytical work itself: pattern detection across comparability data, faster method development, and enhanced analytical insight, rather than replacing scientific judgment.

As evidence requirements evolve, competitive bottlenecks increasingly shift downstream, toward manufacturing, supply and market execution.



The value chain is now one system

Winning repeatedly means connecting stages that most organizations still run separately:

Select the molecule ⟶ Develop the evidence ⟶ Prove biosimilarity ⟶ Transfer the process ⟶ Manufacture and Supply reliably ⟶ Access payers and tenders ⟶ Adopt and earn real confidence.

A molecule chosen without a manufacturing-fit view creates downstream execution challenges. A dossier without a transfer-ready process does little to accelerate launch readiness. A launch without secured access rarely translates into commercial success. Each break in the chain shows up later as delay, rework, supply risk, slower adoption or lost market share, reinforcing the need for connected end-to-end execution.

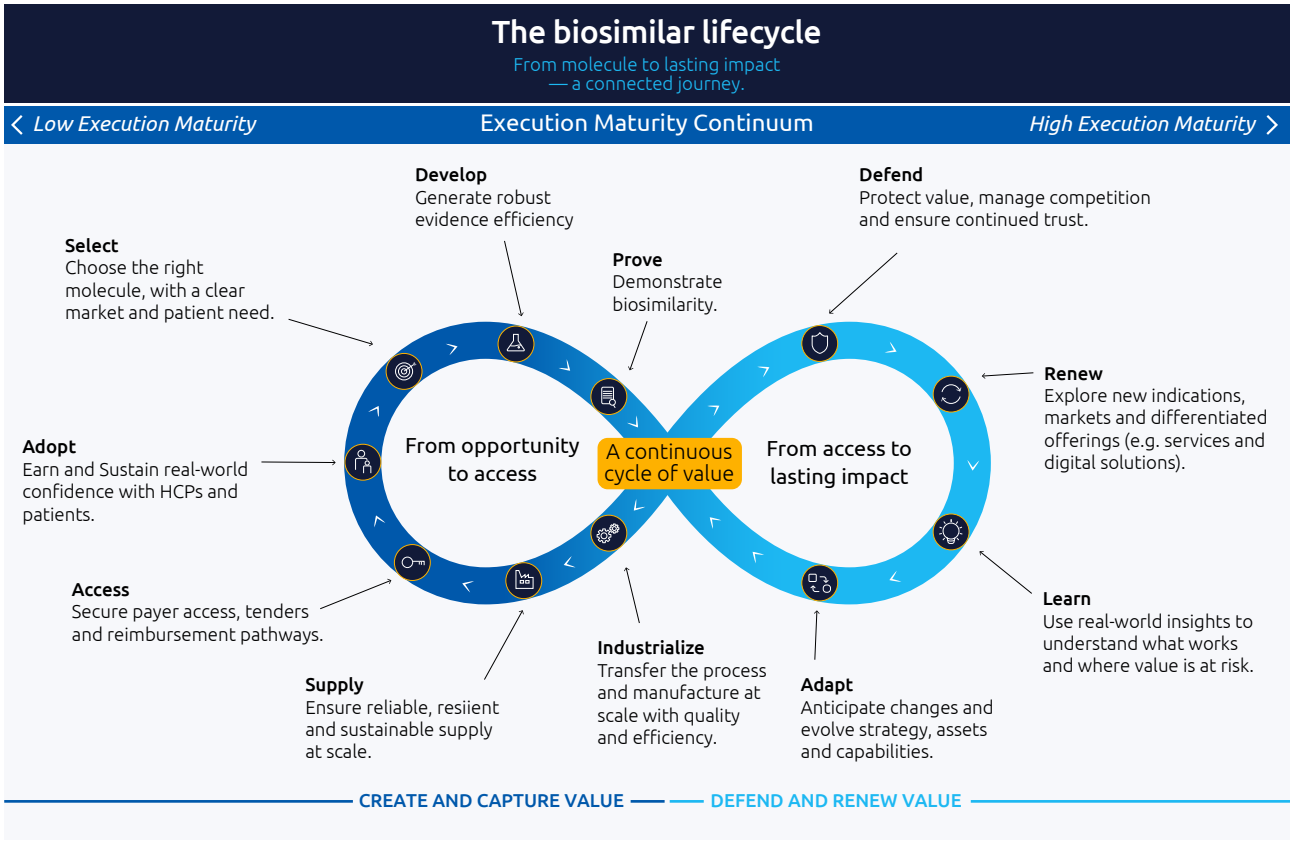


Figure 1: *The biosimilar lifecycle: From molecule to lasting impact – a connected journey.*

Geography and trust change the game

There is no single global playbook.

In the United States, biosimilar uptake is strongly shaped by payer and PBM decisions. The Humira and Stelara experiences show that availability alone is insufficient: formulary placement, contracting, pricing and switching policies materially influence the pace of adoption. In Europe, national tenders and procurement dominate, and Europe is itself not one market: Germany's payer economics, France's hospital/community split, the UK's centrally-guided NHS switching (which identified up to £1 billion in five-year savings), and the Nordics' tender-driven procurement each demand different execution, not just different paperwork.

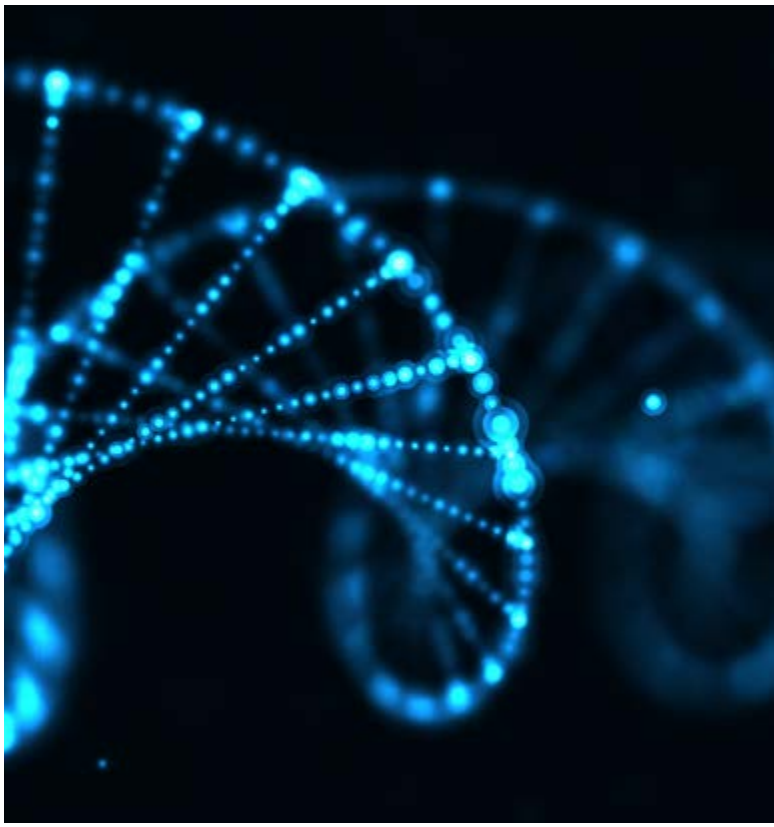
Beyond the United States and Europe, emerging markets follow yet another set of rules. Affordability, local production strategies, healthcare infrastructure, regulatory maturity and cold-chain resilience can be as important as payer access or tender success. In many of these markets, biosimilars are not only a substitution opportunity but also a vehicle for expanding patient access to biologic therapies. This creates a different competitive equation, where execution across manufacturing, supply, partnerships and trust-building becomes as important as price itself.

Trust has to be built, not assumed. The clinical evidence on switching is genuinely reassuring. A review of etanercept switching across 18 studies, and a meta-analysis of inflammatory bowel disease switching across 37 studies and more than 10,800 patients, both found comparable efficacy, safety and immunogenicity. What the evidence does not show is that any single education tactic causes adoption by itself; confidence typically builds alongside payer and pricing signals, real-world evidence, and reliable supply. Medical affairs' role is to connect scientific evidence to that confidence, not promotion, but trust infrastructure.

Reliable availability is no longer a back-office metric; it is part of the product promise.

From time-to-market to time-to-value

Speed matters, but sustainable value requires development, manufacturing, supply and market-access readiness to progress together. The organizations that capture value aren't necessarily the first to gain approval; they are the ones whose manufacturing, supply and access work is ready by the time approval arrives, so the interval between eligibility and real market share stays short.



From execution to connected execution

Taken together, the previous three sections point to a clear conclusion: the scientific bottleneck is moving downstream, the value chain behaves as one interconnected system, and trust and supply now sit inside the commercial equation rather than outside it.

The logical consequence is a model where evidence, decisions and consequences travel across molecule strategy, development, manufacturing, supply, access and adoption, instead of stopping at each function's border. Call this Connected Execution: not a department, a standalone technology, or a piece of software, but the discipline of managing the entire value chain as a single connected system.

Capgemini's point of view is that Biosimilar success depends on connecting strategy, evidence, manufacturing, supply, and commercialization through a unified execution model. The Capgemini Biosimilar Execution Framework integrates six critical execution domains: Portfolio & Molecule Strategy, Analytical & Development Excellence, Clinical & Regulatory Strategy, Tech Transfer & Manufacturing, Quality & Supply Resilience, and Market Access & Adoption, creating a connected pathway from molecule selection to commercial success.

The framework is anchored by a digital, data and AI-enabled execution spine that enables end-to-end evidence continuity, governed decision-making, and lifecycle-wide visibility. Structured decision gates, including Evidence Gate, Filing Readiness, Transfer Clearance, Release Approval, and Launch Go/No-Go, ensure that product, process, quality, regulatory, supply, and commercial evidence are continuously connected, assessed, and translated into informed execution decisions.

The framework aligns execution excellence, enabling organizations to transition from functionally optimized operations to scalable, data-driven Biosimilar leadership capable of delivering sustainable competitive advantage.

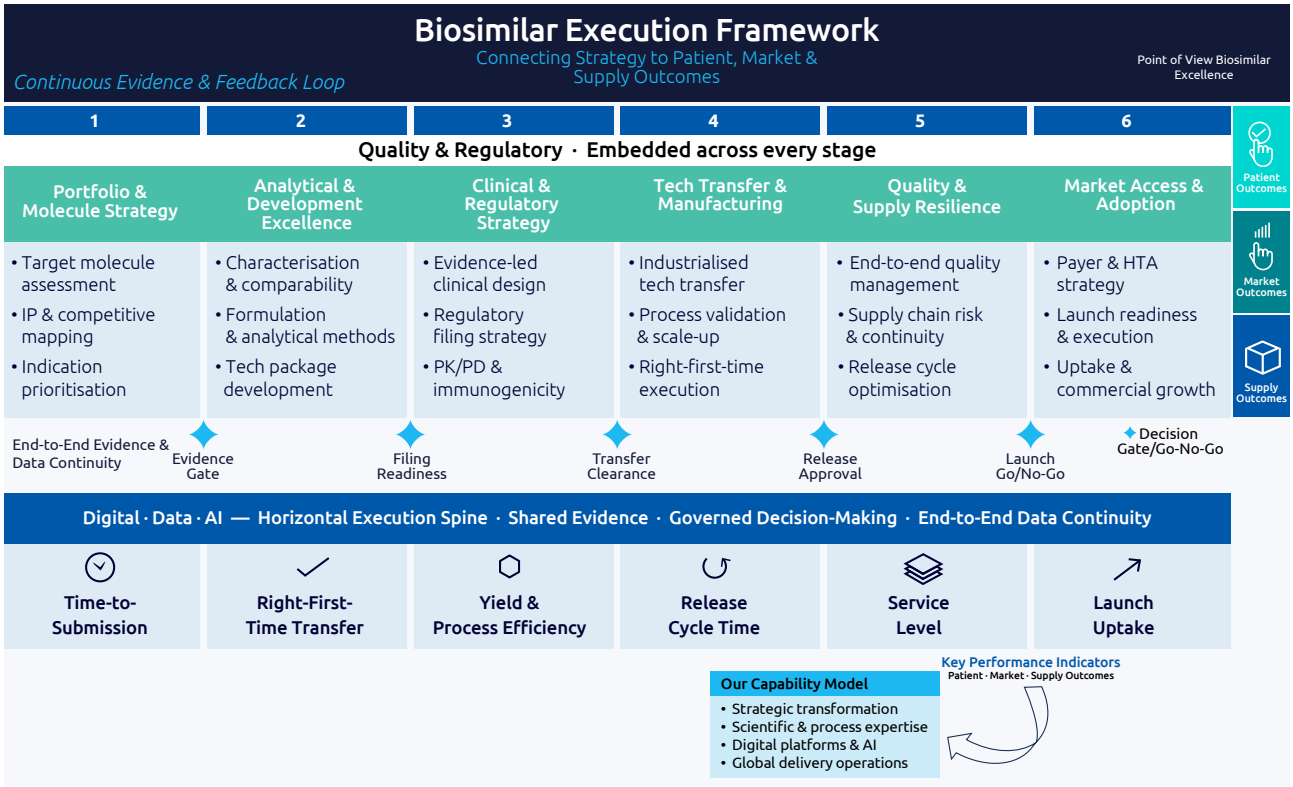


Figure 2: Connected Biosimilar Execution Framework: linking portfolio strategy, development, evidence, manufacturing, supply and commercialization through a governed digital and data spine.

From launch success to lifecycle value management

Adoption is only the beginning of the next phase of value creation, where a different set of disciplines comes into play.

Defend value. Track new entrants, price and margin erosion, tender renewal cycles, and shifts in clinical practice or regulation, before they arrive as a surprise.

Renew value. Established practice already includes new presentations, devices and formulations. Evidence increasingly supports pursuing additional indications and differentiated access strategies where justified. More emerging, and less proven, territory includes patient-support ecosystems, digital HCP/patient experience, and partnerships with public-health bodies or NGOs in specific markets. These sit on a spectrum from established to exploratory, and should be treated that way.

Learn and adapt. Real-world evidence, pharmacovigilance and competitive intelligence should feed back into the next molecule and portfolio decision, closing the loop rather than ending it.

Underlying all of this is a broader discipline: as AI and other technologies accelerate innovation across biopharma, the pace of competitive and scientific change may increase. Organizations therefore need continuous sensing of competitive, scientific, regulatory and market signals so that portfolio and lifecycle decisions can adapt proactively, rather than being forced to react.



Building a repeatable competitive capability

Long-term advantage comes from building a repeatable capability that combines lifecycle insight, connected data, scalable platforms, resilient operations and continuous learning across molecules and markets.

This progression drives faster decisions, stronger regulatory confidence, greater supply resilience and sustained market leadership.

Each stage of maturity reflects a distinct evolution in how Biosimilar organizations manage evidence, risk, decision-making, and execution across the product lifecycle:

- **Fragmented:** Functions operate in silos with manual evidence assembly, limited visibility across teams and reactive issue resolution, often resulting in delays and rework due to compliance gaps
- **Connected:** Integrated workflows and shared data create evidence continuity across functions, improving collaboration and execution consistency.
- **Predictive:** Organizations leverage risk-based analytics and data-driven forecasting to anticipate challenges before they occur.
- **Adaptive:** AI-enabled insights and continuous monitoring support dynamic decision-making, allowing organizations to adjust strategies proactively and respond rapidly to emerging risks and opportunities.
- **Scaled Leadership:** Mature organizations industrialize successful launch and operating models, replicating best practices across geographies to achieve sustainable growth, scalability and competitive advantage.

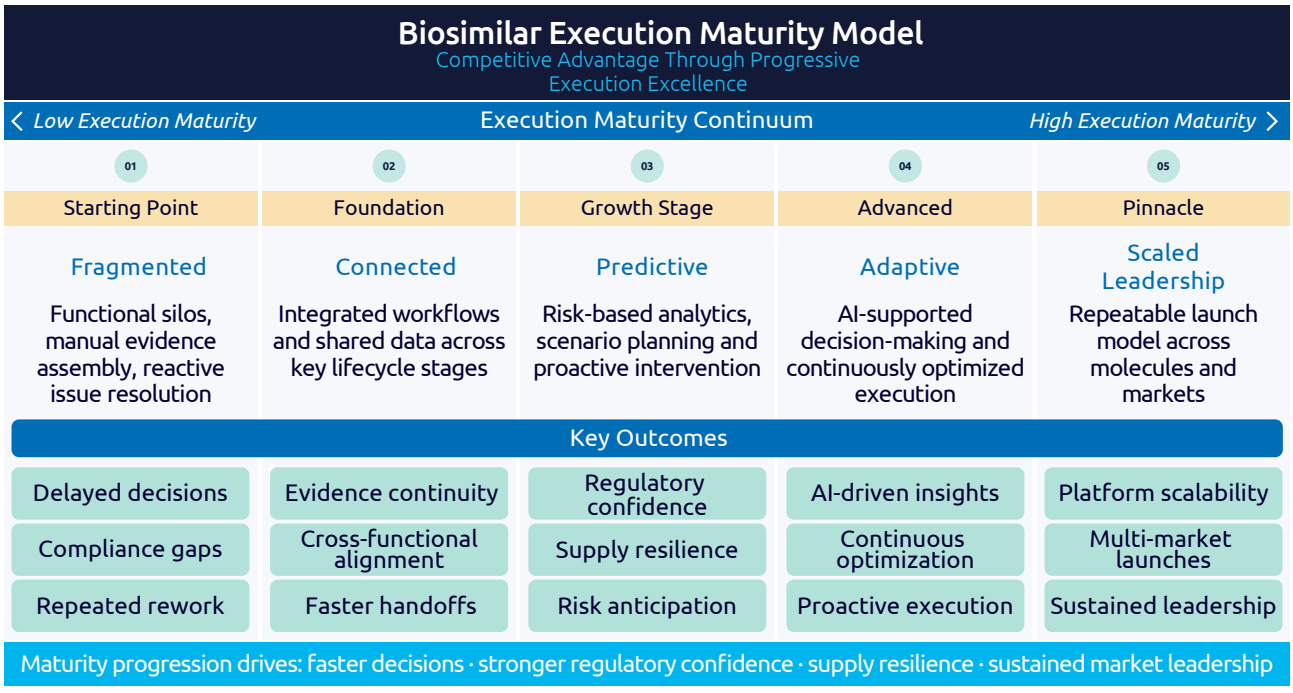


Figure 3: *Competitive advantage for Biosimilar organizations. Biosimilar Execution Maturity: from fragmented delivery to predictive, repeatable, adaptive and scalable market leadership.*

Sustainable value

The affordability and access case is well evidenced: tens of billions in documented savings and billions of additional treatment days represent real headroom for healthcare systems, though how much translates into genuine equity still depends on reimbursement design and reinvestment. The environmental case is more nuanced: biosimilars are not inherently greener. Footprint, including energy, water, waste, cold chain, packaging and logistics, has to be designed and measured, not assumed. The industrial case is real too: biomanufacturing capability, technology-transfer skills and regional resilience are genuine, evidenced outcomes of a maturing industry, distinct from any claim about net employment.

How connected knowledge creates reusable value

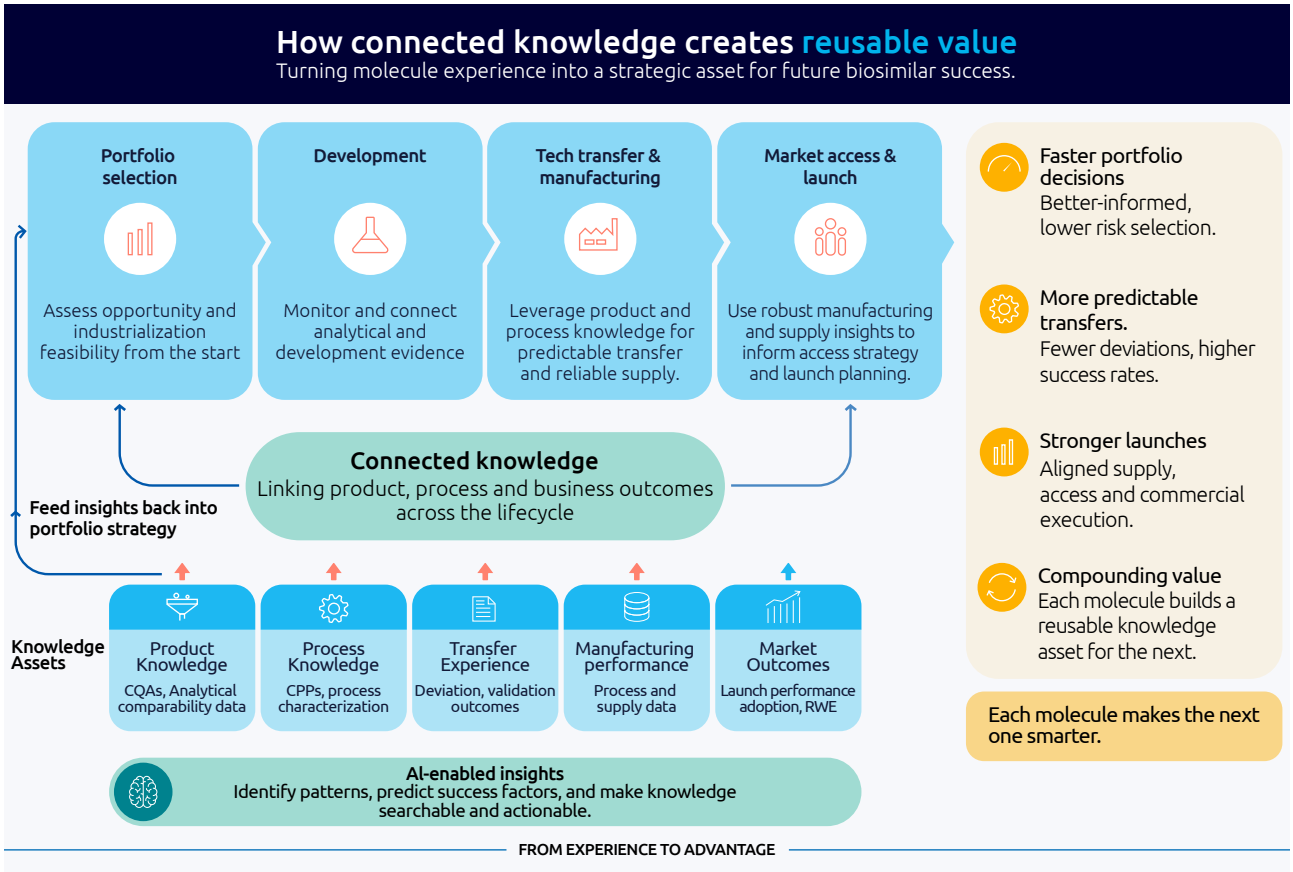


Figure 4 shows how connected knowledge creates compounding value across the biosimilar lifecycle. By linking product, process, transfer, manufacturing and commercial knowledge through a common digital and AI-enabled foundation, organizations can make better portfolio decisions, improve transfer predictability, strengthen launches and continuously reuse learning from one molecule to the next.

Capgemini's perspective on how biosimilar organizations can redefine value creation

Winning in Biosimilars is no longer determined by excellence within individual functions, but by the ability to orchestrate decisions, evidence, processes, and outcomes across the product lifecycle. As competition intensifies and regulatory expectations evolve, organizations must operate through an integrated execution model that connects molecule strategy, clinical development, manufacturing, commercial operations, supply resilience, and regulatory and quality excellence.

Capgemini's Connected Biosimilar Operating Model comprises six interconnected pillars supported by a common digital, data and AI foundation. Each pillar contributes to a specific stage of the Biosimilar journey, while the digital backbone enables evidence continuity, shared governance, integrated workflows, and data-driven decision-making across the enterprise.

Together, these pillars form a unified execution engine that helps biosimilar organizations accelerate development, increase regulatory confidence, strengthen manufacturing and supply resilience, and enhance commercial performance.

Figure 5 illustrates how the six pillars are connected through a shared digital, data and AI foundation, enabling integrated workflows, aligned governance and common KPIs across the biosimilar lifecycle.

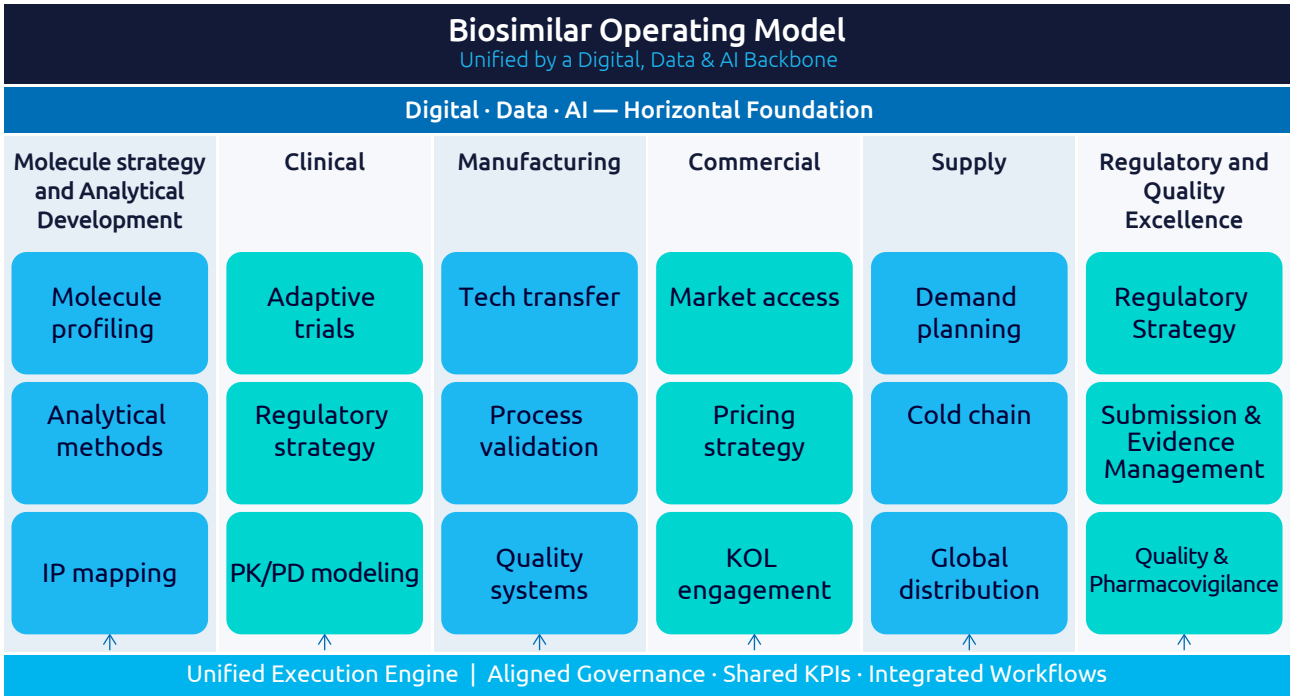


Figure 5: *Pillars of a winning Biosimilar Organization*

Conclusion

The future of biosimilar competitiveness depends less on completing any single stage well and more on building the capability to connect decisions, evidence and outcomes across the lifecycle. In a market where analytical comparability, technology transfer, manufacturing reliability, supply continuity, market access and physician confidence all shape the value ultimately captured, these are no longer independent milestones; together they form a continuous value-creation system:

Learn from every molecule, every transfer, every manufacturing campaign, every launch and every market, and turn that experience into reusable knowledge that continuously improves both the lifecycle of existing products and the choices made for the next generation of biosimilars.

This matters because biosimilar value does not stand still. Price pressure intensifies as competition expands. Supply reliability can determine access and tender performance. Clinical experience can reshape adoption. New therapies can progressively erode the value of an established molecule. And every market creates new evidence about what drives success and what destroys it.

Organizations that are able to connect these signals and turn them into reusable knowledge can move from optimizing individual biosimilar launches to building a repeatable capability for competing across molecules, markets and generations of products.

Ultimately, the next biosimilar leaders will not be distinguished by their ability to prove biosimilarity alone, but by their ability to repeatedly convert biosimilarity into adoption, adoption into value, and value into long-term competitive advantage.

Create connected value. Capture it. Defend it. Renew it.

References

- FDA (U.S. Food and Drug Administration) | FDA Moves to Accelerate Biosimilar Development and Lower Drug Costs | Regulatory modernization of biosimilar development, streamlining of evidence requirements, and biosimilar market status.

  Link: https://www.fda.gov/news-events/press-announcements/fda-moves-accelerate-biosimilar-development-and-lower-drug-costs

- FDA (U.S. Food and Drug Administration) | FDA Updates Guidance on Interchangeability | Updated approach to biosimilar interchangeability and reduced reliance on switching studies.

  Link: https://www.fda.gov/drugs/drug-alerts-and-statements/fda-updates-guidance-interchangeability

- FDA (U.S. Food and Drug Administration) | Considerations for Demonstrating Interchangeability with a Reference Product: Update | Scientific and regulatory expectations for interchangeable biosimilars.

  Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-update

- EMA (European Medicines Agency) | Biosimilar Medicines: Overview | EU biosimilar regulatory framework, approval principles, and scientific rationale.

  Link: https://www.ema.europa.eu/en/human-regulatory-overview/biosimilar-medicines-overview

- EMA & Heads of Medicines Agencies (HMA) | Biosimilar Medicines Can Be Interchanged | Scientific confirmation of interchangeability for EMA-approved biosimilars.

  Link: https://www.ema.europa.eu/en/news/biosimilar-medicines-can-be-interchanged

- EMA (European Medicines Agency) | Human Medicines in 2025 | Annual review highlighting biosimilar recommendations and market evolution in Europe.

  Link: https://www.ema.europa.eu/en/news/human-medicines-2025

- EMA (European Medicines Agency) | Reflection Paper on a Tailored Clinical Approach in Biosimilar Development | Transition toward risk-based, analytical-first biosimilar development with reduced need for comparative efficacy trials.

  Link: https://www.ema.europa.eu/en/reflection-paper-tailored-clinical-approach-biosimilar-development

- WHO (World Health Organization) | Guidelines on Evaluation of Biosimilars | Global principles for biosimilar evaluation and regulatory convergence.

  Link: https://www.who.int/publications/m/item/guidelines-on-evaluation-of-biosimilars

- WHO (World Health Organization) | Biosimilars Regulatory Resources | WHO framework supporting science-based and risk-based biosimilar development.

  Link: https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards/sbp

- IQVIA Institute | Unlocking Biosimilar Potential | Healthcare savings, patient access expansion, and uptake of biosimilars in Europe.

  Link: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/unlocking-biosimilar-potential-2026

- IQVIA Institute | Generic and Biosimilar Economics in a Payer-Engineered Market | Impact of payer and formulary decisions on biosimilar adoption in the U.S. market.

  Link: https://www.iqvia.com/locations/united-states/blogs/2026/05/generic-and-biosimilar-economics-in-a-payer-engineered-market

- IQVIA Institute | Biosimilar Sustainability Scorecards for Europe 2026 | Market sustainability, competition, tendering practices, and long-term supply resilience.

  Link: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilar-sustainability-scorecards-for-europe-2026

- Advances in Therapy (Springer Nature) | Clinical and Real-World Evidence on Etanercept Biosimilar Switching: A Narrative Literature Review of Efficacy and Safety | Review of clinical and real-world evidence evaluating the impact of switching between originator and biosimilar etanercept.

  Link: https://link.springer.com/article/10.1007/s12325-025-03367-5

- Revista Española de Enfermedades Digestivas / PubMed | Biosimilar Switching in IBD: Safety, Efficacy and Immunogenicity in 10,812 Patients – A Systematic Review and Meta-analysis | Meta-analysis of 37 studies assessing outcomes following biosimilar switching in inflammatory bowel disease.

  Link: https://pubmed.ncbi.nlm.nih.gov/41247367/

- Pharmaceuticals (MDPI) | Advances in Biosimilars: A Systematic Review of Machine Learning Applications | Review of AI and machine-learning applications across biosimilar development, manufacturing, analytical comparability, and pharmacovigilance.

  Link: https://www.mdpi.com/1424-8247/19/5/745

- UK Government | Life Sciences Sector Plan | UK life sciences strategy, innovation policy, and healthcare system transformation relevant to biologics and biosimilars.

  Link: https://www.gov.uk/government/publications/life-sciences-sector-plan/life-sciences-sector-plan



Authors



Amit Patil
Director
amit.j.patil@capgemini.com



Malik Belattar
Director
malik.belattar@capgemini.com

Key Contributor



Dr Sarika Vanarse
Senior Director
sarika.vanarse@capgemini.com

About Capgemini Invent

As the digital innovation, design and transformation brand of the Capgemini Group, at Capgemini Invent we enable CxOs to envision and shape what's next for businesses. Located in over 40 studios and more than 70 offices around the world, we are a 13,500 strong team of strategists, data scientists, product and experience designers, brand experts and technologists who develop new digital services, products, experiences and business models for sustainable growth.

Capgemini Invent is an integral part of Capgemini, an AI-powered global business and technology transformation partner, delivering tangible business value. We imagine the future of organizations and make it real with AI, technology and people. With our strong heritage of nearly 60 years, we are a responsible and diverse group of over 420,000 team members in more than 50 countries. We deliver end-to-end services and solutions with our deep industry expertise and strong partner ecosystem, leveraging our capabilities across strategy, technology, design, engineering and business operations. The Group reported 2025 global revenues of €22.5 billion.

www.capgemini.com

Make it real.

©2026 Capgemini. All rights reserved. This presentation contains information that may be privileged or confidential and is the property of the Capgemini Group.