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THRIVE FUTURES ARCHITECTURE™

Healthcare and Biopharma Futures: Vantage Point 1

Launch Excellence 2035

Winning in an Era of Exponential Change

Four futures for the U.S. launch environment, and what they change about turning a medicine into a viable business.



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Executive route: Introduction, Executive Summary, and Sections 3–5. Sections 1 and 2 are the evidence route.

Introduction

The pharmaceutical industry is being reshaped at its foundations. Artificial intelligence, genomics, and more precise diagnostics are converging with pressure on affordability, new ways of delivering care, and a changing role for patients. Together, these forces will reshape healthcare delivery and payment systems and the biopharma R&D and commercial models. They change what the biopharma industry can discover, whom it can treat and when, and how scientific progress becomes clinical and commercial value.

In discovery, AI-assisted screening can search vast libraries of compounds, while generative models design new molecules for researchers to test.^{1,2} AlphaFold and related advances in predicting protein structures and molecular interactions are expanding the possibilities for understanding and targeting disease.^{3,4} Together, these capabilities could produce a surge in candidates entering development. More candidates will not automatically mean more approved medicines. But, at the minimum, they could intensify competition for capital, clinical-trial participants and, ultimately, a differentiated place in treatment.

In parallel, medicine is moving toward greater precision. A familiar diagnosis can conceal different molecular drivers and different responses to treatment. Genomics, biomarkers, and richer patient information are making it possible to match therapies more closely to the biology and circumstances of the people receiving them. The opportunity is not only to develop more medicines, but to intervene more selectively and, where the evidence supports it, earlier. Whether that precision becomes routine or remains concentrated in particular diseases, populations, and care settings is one of the uncertainties ahead.⁵

The information surrounding treatment is changing, too. In the AMA's 2026 survey, 72 percent of respondents to its practice-use question reported incorporating at least one listed AI use case.⁶ Pew Research Center's June 2026 survey found that 34 percent of U.S. adults had used a chatbot for at least one of eight health purposes, and 22 percent for treatment information.⁷ AI is entering the work of clinicians and the deliberations of patients. How much authority it acquires, and who remains accountable for its influence, are different questions.

This exploration follows these forces into four plausible futures for the U.S. pharmaceutical market in 2035. It examines how scientific advances and changing care economics could reshape the biopharma business model, commercial strategy, and the capabilities required for successful launch. Each world combines a lived experience of healthcare with structured analysis of the choices facing the organizations bringing medicines to patients.

These worlds are thinking tools, not predictions. Each describes a dominant pattern; none assumes a uniformly transformed system. The report is U.S.-focused: it explores U.S. treatment decisions, care arrangements, access, and commercial economics. Its driving forces apply globally, and THRIVE will publish Europe and Asia editions of this report later in Q4 2026; email launch@thrive-co.com to receive a copy of the international editions. Elements of the worlds can coexist and partially overlap across assets, indications, payer populations, networks, and routes to care. A portfolio can face several combinations at once; applying the scenarios does not require choosing one world for the whole company. The people and scenes in 2035 are fictional, no probability is assigned to any world, and present-day developments are sourced in the endnotes.

This report is a starting point for strategic decisions, not a prescription for a company's investment plan. It defines the commercial issues and choices emerging from change, exposes assumptions, and offers guideposts for the questions to ask, options to prepare, and commitments to test. The ten questions at the end set an agenda for applying these ideas to a specific launch or portfolio.

Read with a real medicine, portfolio, or launch plan in mind, but also with a sense of possibility. What new paths to patients could these changes open? Which partnerships could turn scientific promise into better care? What could your organization begin learning, testing, and building today to lead in the markets taking shape? Exploring these futures is an invitation to look beyond today's assumptions, recognize opportunities before they become obvious, and act while there is room to shape them. The ambition reaches beyond preparing for change. It is to help translate the extraordinary possibilities of science into better outcomes for patients and enduring value for the businesses that serve them.

This edition is written through the lens of launch leaders and the functions that support them: commercial, medical, value and access, regulatory, supply, business development, and launch excellence, in global biopharma and in biotechs preparing a first launch. The horizon is 2035, with signals observable between 2026 and 2030. THRIVE's Futures of Biopharma work extends to broader questions of strategy, portfolios, care models, and organizational capability. Request a THRIVE Futures Briefing to explore the implications most relevant to your situation. Contact Eliette Krakora, Founder and CEO of THRIVE Consulting, at launch@thrive-co.com.

The future belongs to those who can hear it coming, prepare for it, and proactively shape what comes next.

When the Market Changes as Profoundly as the Medicine

A medicine can succeed scientifically and enter a market whose rules have changed. This exploration asks what happens when advances in discovery and R&D meet new decision systems, affordability constraints, competing care models, and AI-informed and -enabled stakeholders. Its purpose is not to predict the most likely future. It is to reveal choices that a launch strategy built only around today's healthcare system and market environment could miss.

What Is Happening

Ten forces are already in motion, and every future contains them. The table on the next page sets them out. Four of them change what a medicine is and how it is judged. AI is widening the front of discovery and tying candidates more tightly to defined populations. New modalities and delivery formats are changing how a medicine acts and where it can be given. Routine care and daily life generate data that can become decision-grade evidence. Pricing pressure has become a lifecycle planning issue, with Medicare negotiation reaching physician-administered drugs and most-favored-nation terms announced for Medicaid.^{8,9}

The other six change the market a medicine enters. Detection starts earlier. AI enters the treatment decision on both the clinician's and the patient's side of the desk. Care moves beyond the hospital into organizations that combine navigation, delivery, and coverage. Targeted therapies redefine the treatable population inside common diagnoses. Patients arrive informed, with preferences shaped by new sources. Prevention becomes an explicit ambition of health systems.

Across these forces, the launch commercial model is becoming more complex. Reliable, reimbursed use depends on evidence, delivery design, and negotiation. Data and delivery capability can become competitive assets held by organizations the developer neither owns nor controls. And the frame in which a medicine is judged can widen from the product to the total cost and result of care, so that a better-delivered existing treatment, a preventive program, or a lower-cost alternative becomes a serious competitor.

Evidence infrastructure, delivery capability, and relationships therefore matter more to commercial advantage. How much each matters, who controls it, and what it costs to combine them around a defined population differ across the four worlds.

One interpretation runs through this report. More launches may need the diagnostic-led patient identification and subgroup evidence associated with rare disease, without inheriting rare-disease pricing or a bespoke commercial model. Scale would come from reusing those capabilities across many defined populations and assets. This is THRIVE's reading of the forces, not a forecast that every medicine becomes a rare-disease product.

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Driving Forces

Many forces are converging to reshape the future of healthcare, with significant implications for how medicines are developed and commercialized. They are already in motion, and every one of the four worlds contains them. For this report, THRIVE selected ten driving forces that it expects to reshape the biopharma commercial model and, with it, the launch excellence model. The selection prioritizes changes to the relevant patient population, competition, evidence, delivery, the route to care, and how commercial value is earned. Section 1 profiles each force with current illustrations and with what those illustrations do not prove.

DRIVING FORCE	WHAT IS CHANGING	IMPLICATION FOR LAUNCH
F01 AI expands target discovery and accelerates candidate design	Machine learning helps choose targets, predict structures, generate molecules, and predict responders. The interval from hypothesis to credible candidate shrinks, and candidates are tied more tightly to defined populations; China-origin candidates widen the field of rivals.	More entrants and narrower populations: track competitors by stage, test whether the advantage survives, and plan responder identification before launch.
F02 New modalities and drug-device combinations expand how medicines work and reach patients	Cell and gene therapies, RNA medicines, degraders, and multispecifics widen how medicine acts; formulation and devices change where and by whom it is given.	Build launch archetypes around the actual treatment pathway; compare the whole delivered proposition, not the molecule alone. For device-dependent therapies, launch readiness should encompass the medicine, delivery system and supporting service.
F03 Richer real-world, wearable, and patient-generated data move toward decision-grade evidence	Records, claims, registries, sensors, and patient reports can answer defined questions; whether decision-makers accept them is a separate uncertainty.	Specify the decisions before choosing data; secure definitions, access rights, and analysis responsibilities early.
F04 Pricing pressure, affordability constraints, and new payment models	Negotiation, reference pricing, purchasing arrangements, value assessment, and payment redesign reconcile clinical value with finite budgets, in market-specific ways.	Model price, funded reach, delivery cost, and cash timing under the actual agreement; hold an affordable-scale option.
F05 Earlier risk identification, AI-assisted detection, and a different starting point for care	AI-supported imaging, molecular testing, and monitoring make relevant information visible earlier or in a different setting.	Distinguish at-risk, eligible, funded, and reachable populations; build diagnostic and referral partnerships around the gaps.
F06 AI enters the treatment decision, on both sides of the desk	AI systems help clinicians and patients summarize evidence and navigate treatment; some functions are advisory, others act within bounded workflows.	Audit how product information is represented in clinical and patient-facing tools; map each tool's authority before assigning it an objective.
F07 Care moves beyond the hospital through connected services and new care organizations	Home, virtual, and hybrid services redistribute care; organizations assemble navigation, delivery, coverage, and follow-up in new combinations.	Map services and handoffs, not only sites and prescribers; test who pays for the supporting work.

DRIVING FORCE	WHAT IS CHANGING	IMPLICATION FOR LAUNCH
F08 Targeted therapies and precision medicine redefine the treatable population	Treatment decisions link to validated characteristics of a person's disease; one diagnosis divides into groups, one target connects organs.	Define the tested population, threshold, and diagnostic pathway together; forecast the selected population, not the umbrella diagnosis.
F09 Patients arrive informed, with treatment preferences shaped by new information sources	Conversational AI brings research and comparisons to patients before and between visits, without guaranteeing accuracy or control.	Start AEO (answer engine optimization) on marketed products; keep evidence, risks, and approval status intelligible through intermediaries.
F10 From reactive treatment toward prevention and sustained health	Health systems invest in intervening before illness and sustaining health between visits; movement is uneven and reach is not yet population-wide.	Test how earlier intervention changes incidence, duration, and escalation; identify who sustains engagement and who gains financially.

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What Is Open: Ten Uncertainties

The driving forces are a given; the scope and speed with which they transform the biopharma model are not. Beyond that question of magnitude and pace, there are additional uncertainties that can play out in different directions, and the universe of them is large. Out of that universe, THRIVE selected the ten it expects to shape the biopharma commercial model most profoundly. Each is a condition that could settle on a spectrum between two poles by 2035, and each pole changes something concrete about launch. For this report, THRIVE selected two of the ten, the Tx decision channel and the payment currency, as the primary scenario axes; the four worlds in Section 3 are built from them. The other eight are not dropped: they specify the conditions inside each world, and Section 2 profiles all ten with the signals that would move them.

UNCERTAINTY	THE TWO POLES	IMPLICATION FOR LAUNCH
U01 Tx decision channel	System-governed. An institutional pathway establishes the presumptive treatment sequence; departures require justification. Distributed. Clinicians and patients retain meaningful discretion among competing recommendations.	Determines whom the launch sells to: a physician's judgment, or a pathway position earned with evidence in the form it ingests and re-earned as evidence changes.
U02 Payment currency	Paid for outcomes. A material share of payment depends on results verified after treatment. Paid by price and volume. Payment depends primarily on units supplied at an agreed net price.	Determines when revenue is known, at the sale or after results are verified, and whether the forecast is a volume model or an actuarial one.
U03 Registry and real-world evidence	Broader decision-specific acceptance. Fit-for-purpose registries and RWE play a primary-evidence role in a wider range of regulatory, payer, and pathway decisions. Selective acceptance. Primary-evidence acceptance stays concentrated in specific questions; other uses are supportive.	Decides whether post-approval evidence can move a label, a pathway position, or a payment, and how quickly a competitor's registry can undercut a trial result.
U04 Reach of price regulation and negotiation	Expansion and spillover. Medicare negotiation, most-favored-nation reference pricing, and related legislation widen and spill into commercial pricing. Bounded reach. Negotiation and reference pricing stay narrower, program by program, with limited spillover.	Sets the price corridor and whether a benchmark constrains other contracts; shapes indication sequencing and the value of a premium position.

UNCERTAINTY	THE TWO POLES	IMPLICATION FOR LAUNCH
U05 Integrated care organizations	Consequential role. Integrated organizations hold a material patient relationship in selected populations. More limited role. They remain a margin around conventional insurance and practice.	Determines whether a consequential customer holds the continuing patient relationship, and whether the company is its supplier, its partner, or, where it delivers care itself, its competitor for that relationship.
U06 One-time therapies at scale	Viable at breadth. Manufacturing cost, delivery, and payment models let one-time therapies reach populations well beyond the most severe. Confined to severity. Cost, delivery requirements, and funding keep them limited to the most severe patients and a few centers.	Determines whether a one-time therapy is a specialist-center product or a mass-market option, and so the reachable population, the delivery model, and the business case.
U07 AI-regulation climate	More enabling. Clinical and payer AI can operate within frameworks that permit consequential use. More constrained. Law, professional resistance, or public concern limits consequential use.	Decides which consequential functions AI may perform and under whose accountability. The regulatory setting is specified within each world as a scenario assumption.
U08 AI discovery translation	Pipeline-transforming impact. Discovery gains change the volume, timing, or differentiation of approved medicines. Limited downstream impact. Development constraints absorb most gains; the pattern of approvals stays similar.	Sets the pace at which credible competitors arrive and the length of the window in which differentiation is commercially distinctive.
U09 Data Ownership	Connected under workable rights. Usable data connect through national, platform-level, or interoperable infrastructure under workable access and reuse terms. Fragmented or restricted. Separate holders, incompatible content, or restrictive rights keep data costly to assemble.	Decides whether a pathway has a spine to run on, who verifies benefit, and whose terms govern the evidence a launch needs.
U10 Precision beyond oncology	Broad reach. Biomarker-guided treatment extends into primary care and wider disease areas. Specialist concentration. Access and implementation stay concentrated in specialist centers and selected conditions.	Decides whether a biomarker-defined subgroup is found in primary care or in specialist centers, and with it the size of the reachable population.

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Two Questions, Four Worlds

The two axes were chosen because each has high consequences for launch and materially different plausible outcomes, and because together they separate futures that would otherwise look alike. One concerns authority. The other concerns money.

TX DECISION CHANNEL

Does an institutional pathway govern the treatment sequence, or do clinicians and patients retain meaningful discretion among competing recommendations?

PAYMENT CURRENCY

Does a material share of payment depend on verified results after treatment, or primarily on units supplied at an agreed net price?

The two questions create four plausible U.S. markets in 2035. They are illustrations of the range, not predictions, and an organization cannot prepare for different markets unless it has first imagined them. The other eight uncertainties are specified inside each world. In this set, the system-governed worlds assume regulators permit continuous pathway updates within accountable rules, and the distributed worlds assume tighter limits on delegated AI authority. That is a selected configuration, not a law. Elements of several worlds can coexist across an organization's assets and

populations; the worlds are drawn apart so that each commercial logic can be seen clearly. Under each world below: what the market looks like, and the two things launch success depends on in it.

Four Worlds, and What Launch Success Depends On in Each

Algorithmic Order

System-governed Tx decisions · Paid for outcomes

Pathways organize care and tie payment to verified results. Scientific success brings reach, and dependence on the organization that governs treatment.

Pathway position. A place earned with evidence the pathway can ingest and continuously reassessed by AI, with human veto and documented override rights.

Outcome ownership. A deliberate decision about which parts of the care that produce the result the company takes responsibility for, because payment depends on them.

Precision Islands

Distributed Tx decisions · Paid for outcomes

Competing networks organize prevention and continuing care around results. Clinicians and patients keep treatment choice; access depends on coverage and willingness to engage.

A package that travels. The medicine plus the diagnostics, monitoring, and support that produce the outcome, tailored to the targeted networks.

Network sequencing. Which networks to enter, in which order, and how to reduce contracting and deployment costs through reuse.

The Waiting Room

System-governed Tx decisions · Paid by price and volume

The system identifies more treatable need than budgets and capacity can absorb. Companies compete to make useful care affordable at the scale the system can see.

Benefit-based patient definition. Showing where the incremental benefit is unmistakable before the payer draws the funded tier.

Affordable-scale design. A price, delivery model, and channel planned around the full identified population, with funded reach and delivery capacity tested before launch.

Many Doors

Distributed Tx decisions · Paid by price and volume

Care stays episodic and transactional. Clinicians, patients, payers, and their tools have more information, but make separate judgments that shape treatment.

Route economics. Knowing which routes generate additional demand, which redistribute it, and what each contributes after costs.

Coherence across advisers. One evidence-grounded value story, accurately represented in the physician's tool, the patient's adviser, and the care service.

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What It Means for Launch

Four lessons hold across the worlds. First, the critical gate to viable adoption changes: an earned position with performance terms, a workable threshold and price agreement, a repeatable network arrangement, or route-specific coverage and adoption. None of these gates guarantees delivered treatment, and the dangerous assumption is that the route from evidence to adoption to revenue that carried the last medicine will carry the next one. Second, the reachable population is not the eligible population. The gap exists in every world; what changes is its size and what sets it: pathway placement, funded tiers, network participation, delivery capacity, and the patient's ability and willingness to proceed. Third, decision-system readiness is a shared foundation. Institutional pathways, network tools, and personal advisers all place demands on a medicine's evidence, and the audience for scientific information is no longer limited to the audience it was written for. Fourth, the launch stays cross-functional and the launch lead owns it; which functions carry the decisive work is what changes.

The same advance faces a different commercial test in each world. Hold one medicine constant, aimed at a more precisely defined population and simpler to administer. In Algorithmic Order the test is whether verified contribution earns and keeps pathway position, and what outcome responsibility comes with it. In The Waiting Room it is whether the complete proposition lets the budget and the delivery system treat more of the appropriate population. In Precision Islands it is whether the medicine-plus-care package, designed for the networks the company has chosen to target, reproduces its results and economics in each of them. In Many Doors it is whether the medicine wins the relevant clinical and patient decisions through routes that generate worthwhile incremental treatment. Section 4 runs two invented medicines, a recurring cardiovascular therapy and a one-time cell therapy, through all four tests.

What to Start Now: Seven No-Regret Moves That Hold Across Worlds

The four worlds differ in what decides adoption and what gets paid for. Seven actions create value in all of them. They are recurring disciplines rather than an execution order, and they build the eight success factors before the market chooses which of them matters most. Each has an accountable owner and a concrete output, set out in Section 5. Taken together, they are the launch organization a company would want to have regardless of which world arrives.

01

Rehearse, monitor, and adapt. Test current plans against all four worlds; connect signals to an accountable response. Output: an assumptions map of what could change the population, comparator, differentiation window, and business case.

02

Build evidence that earns trust. Answer meaningful clinical and value questions; map evidence to each decision it must support; stay explicit about uncertainty. Output: an evidence-to-decision map with unresolved requirements and credible alternatives.

03

Build AEO and decision-system readiness. Learn on marketed products how AI tools represent the evidence, then carry accurate information and monitoring into launch. Output: a maintained question set, representation checks, named owners, and escalation routes.

04

Design access for affordable scale. Test price, delivery requirements, and reachable treatment together; hold an affordable-scale case beside the premium case. Output: an affordable-scale business case covering the medicine and its supporting care.

05

Build with patients, not only for them. Let experience, burden, and access barriers shape the proposition. Output: a patient-tested account of the burdens that prevent appropriate use and the changes that address them.

06

Choose ecosystem roles and partners. Decide what the company will provide, who is responsible for the rest, and what continues when a patient or partner leaves. Output: a responsibility and continuity map for care, data, verification, and financial exposure.

07

Rehearse delivery and accountability. Test capacity and handoffs, assign decision rights, and reuse the learning across launches. Output: a rehearsal showing who acts, what changes, and what continues when the original plan breaks.

What to Watch, and When to Commit

The no-regret moves build foundations. Beyond them sit investments whose payoff depends on the market: contract and evidence operations as a standing competency, a second price tier and delivery model, a partnership organization built for replication, and a cross-channel engagement model. Do not make these commitments merely because a scenario is plausible. Prepare and test the options; commit when the asset's evidence, economics, and observed conditions justify the investment. Watch combinations, not isolated headlines: a single contract announcement, application launch, or denied claim rarely distinguishes one future from another.

WORLD	THE COMBINATION THAT SAYS IT IS TAKING SHAPE	ONE CONTINGENT INVESTMENT IT WOULD JUSTIFY
Algorithmic Order	Pathways gain practical authority, and a material share of payment is actually reconciled against later results.	Pathway integration and performance settlement as a standing competency: contract, evidence, and data teams that can earn placement and reconcile payment against results, plus ownership of defined care steps the payment depends on, such as monitoring or patient support.
The Waiting Room	Identification expands, fixed-price terms persist, and lower-total-cost propositions win funded use.	A second price tier and delivery model for the full identified population, with supply that flexes under budget caps.
Precision Islands	Networks organize prevention and continuing care; performance agreements replicate while treatment choice remains personal.	A partnership organization: network steering seats, a contract team, and delivery packages designed for each targeted network.
Many Doors	Care stays episodic and payment unit-linked while several separate advice and access decisions materially shape treatment.	A cross-channel evidence and engagement model with route-specific delivery and measurement of incremental treatment.

Section 5 sets out the pilot that precedes each of these commitments, the larger commitment itself, and the exposure it creates if the world does not arrive.

Where to Take the Exploration Further

These four worlds are one way to look at the future, not the only one. They rest on two primary uncertainties chosen from ten, and a different choice of axes would produce a different and equally legitimate set. The most appropriate selection depends on the decision the scenarios are meant to serve. This report takes the vantage of the launch excellence function and the launch leader. The same forces and uncertainties, read from the vantage of regulatory, supply, medical, or a portfolio committee, would stress different uncertainties and demand different adaptations from those functions. Those readings are not developed here. They are the natural next step for an organization that wants the whole enterprise, not only the launch function, to be ready for more than one future.

Ten questions in Section 5 are the place to begin that conversation. Request a **THRIVE Futures Briefing** to work through them for a specific launch, a portfolio, or the organization as a whole: launch@thrive-co.com.

SECTION 1

The Forces Every Future Contains

Of the many developments reshaping healthcare, THRIVE selected the driving forces and critical uncertainties with the most significant implications for the biopharma commercial model and, by extension, Launch Excellence. This is not an exhaustive inventory. The selection prioritizes changes to the relevant patient population, competition, evidence, delivery, the route to care, and how commercial value is earned.

Driving forces are developments already in motion. Their presence does not imply uniform speed, reach, or consequences. Richer real-world data is a force; how that data is accepted as evidence is an uncertainty. AI-assisted candidate generation is a force; how successfully those candidates translate through development is an uncertainty. The forces apply globally but are not uniformly expressed; a country-specific policy is an illustration of a broader force, not its definition. This chapter provides a brief definition of each of the forces and select illustrations of early manifestations.

F01

AI expands target discovery and accelerates candidate design

Machine-learning systems help researchers choose a target, predict protein shapes, generate and optimize molecules and, increasingly, predict which patients will respond. The interval from hypothesis to credible candidate shrinks, and the candidate is tied more tightly to a defined population. Biology, clinical validation, regulation, and payment still constrain it.

Rentosertib enters phase 3, September 2026. Insilico reports that rentosertib, its investigational candidate for idiopathic pulmonary fibrosis, is the first with both an AI-discovered target and an AI-generated compound to report randomized phase 2a results and enter phase 3. The first patient was dosed in China on September 10, 2026.^{2,10} It is not the first AI-associated molecule in the clinic; DSP-1181 entered phase 1 in January 2020 and was later discontinued.¹¹

A measurable clinical pipeline. An ASCO 2026 abstract identified 117 AI-enabled therapeutic assets from 63 companies that had entered interventional trials by July 2025.¹² Xaira reports a preclinical antibody lead reached in seven weeks from DNA synthesis, with target reagents prepared in advance, and a functional antibody against a receptor its conventional methods had failed to address.¹³ Lila describes a discovery loop that generates its own experimental data, having tested more than 950,000 mRNA sequences.¹⁴

Implication for launch. Separate target creation, candidate nomination, clinical progression, and approval in competitor tracking. Test whether the product's advantage survives more entrants and whether identifying its responder population must begin before launch. More launches may need diagnostic-led identification and subgroup evidence without inheriting rare-disease pricing or a bespoke commercial model.

What this does not prove. These illustrations do not establish future phase 3 success, improved clinical conversion, or lower end-to-end development cost. Rentosertib's phase 2a was small and short; the Xaira and Lila results are company-reported.

F02

New modalities and drug-device combinations expand how medicines work and reach patients

Cell and gene therapies, RNA medicines, protein degraders, and multispecific antibodies widen the ways medicine can act on disease.¹⁷ Formulation and device innovation change how a therapy is administered. A new mechanism, a new formulation, and a novel device alter different parts of the commercial proposition.

An oncology medicine gains a subcutaneous route. FDA approved subcutaneous pembrolizumab (Keytruda Qlex) in September 2025: delivery changed around an established mechanism, and the administration route became part of the launch proposition.¹⁸ **An autoinjector changes where treatment can begin.** Leqembi Iqlik's subcutaneous autoinjector was approved in July 2026 as a starting-dose option for early Alzheimer's disease; selection, training, and follow-up become part of making that delivery proposition work.¹⁹

A medicine creates a new treatment workflow. FDA approved J&J's INLEXZO in September 2025 for specified BCG-unresponsive bladder cancers.⁶⁴ The gemcitabine-releasing system remains in the bladder for three weeks; trained

providers must insert and remove it.⁶⁴ Delivery therefore includes a repeat procedure, not simply dispensing a medicine.

Site readiness becomes part of availability. Delcath announced HEPZATO KIT's first U.S. commercial treatment in January 2024.⁶⁵ Its liver-directed melphalan treatment requires certified settings, trained radiology, perfusion and anesthesia teams, and specified equipment to circulate and filter blood outside the body.⁶⁵

Device evidence can delay the medicine. ONAPGO's April 2024 complete response letter included device performance-testing deficiencies, alongside separate drug-product quality issues.⁶⁶

Ownership becomes a selective strategic choice. West announced the sale of SmartDose 3.5 mL manufacturing and supply rights and associated facilities to AbbVie in January 2026, reporting completion in July.⁶⁸

Implication for launch. Build launch archetypes around the actual treatment pathway: testing, administration, monitoring, supply, and patient support. For device-dependent therapies, launch readiness should encompass the medicine, delivery system and supporting service.⁶³ Clinical eligibility alone does not define the reachable market: trained users, equipped sites, reliable consumables and workable payment arrangements also matter. Compare the entire delivered proposition with alternatives, including an established product with a better route. Looking toward 2035, the strategic question is which delivery capabilities a company must own, secure through partners or coordinate through the care system.

What this does not prove. Authorization of a modality or format does not demonstrate commercial scale, better adherence, payer parity, or freedom from monitoring.

F03

Richer real-world, wearable, and patient-generated data move toward decision-grade evidence

Routine care and daily life generate information beyond the controlled trial: records, claims, registries, sensor measurements, and patient reports. Data become evidence through a question, an appropriate design, and credible analysis. Whether a regulator, payer, or pathway accepts that evidence for a particular purpose is a separate uncertainty (U03).²²

A home-worn sensor becomes a primary endpoint. EMA qualified stride velocity 95th centile, measured with a wearable sensor, as a primary endpoint in a specified Duchenne muscular dystrophy trial context, the first digital primary endpoint qualified for any indication.²³

A registry supports a regulatory decision. FDA's record of approvals using real-world evidence includes Prograf's lung-transplant indication, supported in part by a non-interventional study using a national transplant registry.²⁴

Implication for launch. Specify the intended decisions before choosing data sources. Establish outcome definitions, patient coverage, missing-data handling, access rights, and analysis responsibilities early. Distinguish a dataset that can describe care from one that can estimate the medicine's incremental effect.

What this does not prove. More observations do not remove confounding, selection bias, or missingness. One qualified endpoint and one registry-based approval do not establish broad acceptance for approval, comparative value, or payment.

F04

Pricing pressure, affordability constraints, and new payment models

Across markets, the cost of innovation meets finite budgets, an aging population, chronic-disease burden, and competing claims on public and household spending. Responses include negotiation, purchasing arrangements, value assessment, payment redesign, and alternative routes to access. The legal mechanisms and resulting payment models remain market-specific.

U.S. negotiation reaches another part of the market. CMS selected drugs for the third Medicare negotiation cycle in January 2026, the first to include Part B medicines, with prices effective in 2028.⁸ Second-cycle prices, effective 2027, include semaglutide at \$274 for a 30-day supply against a 2024 list price of \$959.²⁵ In August 2026 the White House

reported MFN agreements with 26 manufacturers covering 89 percent of the branded market, including guarantees on new launches. In September it announced MFN-level rebates for all 50 state Medicaid programs through participating manufacturers under GENEROUS.^{9, 26} CMS finalized GLOBE, a mandatory Part B rebate model using international benchmarks, with planned waivers for manufacturers in GENEROUS.²⁷

England buys availability, not prescriptions. NHS England's antimicrobial subscription model pays an annual amount based on a product's value to the health service rather than doses used: successful stewardship need not mean weak commercial demand under the contract.²⁸

Implication for launch. Model price, funded reach, delivery cost, and cash timing under the actual agreement. Test which parts of value the payer recognizes, who carries the cost before benefit appears, and whether a smaller margin can support a viable broader population. Build an affordable-scale option without assuming either automatic discounting or automatic volume growth.

What this does not prove. These examples do not show that outcomes-based payment will dominate or that every net price will fall. A subscription is not contingent on individual outcomes. Medicare and Medicaid expansion do not themselves prove commercial-price spillover; that is U04.

F05

Earlier risk identification, AI-assisted detection, and a different starting point for care

AI-supported imaging, molecular testing, and continuous monitoring can make clinically relevant information visible earlier or in a different care setting. Some tools estimate future risk; others detect an existing finding. The force is a changing starting point for investigation. It is not yet a universal shift to earlier treatment.

The mammogram has a second job. CureMetrix's cmAngio helps radiologists detect breast arterial calcification, an incidental finding separately studied as a cardiovascular-risk marker. FDA cleared V1.6 in April 2025 and V2.0 in July 2026; the clearance is not a cardiovascular-risk claim.²⁹ Clarity's Allix5, marketed as Clarity Breast and authorized in May 2025, estimates five-year breast-cancer risk.³⁰ Everlywell announced a nationwide, clinician-ordered launch in October 2026 at \$249 self-pay; its product page notes that availability varies by state.³¹

Implication for launch. Map who receives the finding, who confirms it, and what evidence makes an intervention appropriate. Distinguish the at-risk, clinically eligible, funded, and reachable populations. Build diagnostic and referral partnerships around the gaps between those groups rather than converting every positive signal into forecast demand.

What this does not prove. Device authorization does not establish improved outcomes from earlier identification. Risk prediction is not diagnosis, and diagnosis is not drug eligibility.

F06

AI enters the treatment decision, on both sides of the desk

AI systems help clinicians and patients summarize evidence, assess options, and navigate the steps around treatment. Some functions remain advisory; others are tested within bounded workflows. The force is their growing presence in the decision environment, not a universal transfer of authority.

A bounded task becomes a test of delegation. Utah's Doctronic pilot, announced in January 2026, permits AI participation in routine prescription renewals, not new prescriptions. The state's Phase 1 status requires licensed-practitioner authorization of each renewal; later direct submission to pharmacists requires state approval.³² FDA's clinical decision support guidance distinguishes certain non-device support functions from software subject to device oversight.³³ In the AMA's 2026 survey, 72 percent of respondents to its practice-use question reported at least one listed AI use case.⁶

Implication for launch. Audit how permitted product information is found and represented in clinically relevant and patient-facing questions. Separate answer-engine visibility from formal engagement with a pathway owner; neither automatically produces adoption. Map the authority of each tool before assigning a commercial objective to it.

What this does not prove. A pilot, a guidance document, or self-reported use does not establish system-wide autonomous treatment. Permission to summarize evidence is not permission to prescribe.

F07

Care moves beyond the hospital through connected services and new care organizations

Home, virtual, community, and hybrid services redistribute care across settings, while organizations assemble navigation, delivery, coverage, and follow-up in new combinations. Care outside a hospital can remain fragmented, and coordinated care need not be owned by one company. **F07** concerns where and how care is organized; **F10** concerns the goal of preventing illness.

Navigation and primary care are brought together. Included Health agreed in July 2026 to acquire Firefly Health and described Firefly as part of its business in October, combining navigation, primary care, and health-plan capabilities around the patient relationship.³⁴ CMS estimates 14.3 million Medicare beneficiaries in accountable-care arrangements in 2026.³⁵ England's 10 Year Health Plan names the shift from hospital to community as an institutional strategy.³⁶

Implication for launch. Map services and handoffs, not only sites and prescribers. Test whether the treatment can be delivered safely in each setting and who pays for the supporting work. Distinguish an announced partnership from an operational pathway with accountable people, accessible data, and capacity to treat.

What this does not prove. Moving care out of hospital does not prove lower total cost or better continuity. Combining organizations does not by itself establish a functioning integrated model.

F08

Targeted therapies and precision medicine redefine the treatable population

Precision medicine links a treatment decision to validated characteristics of a person's disease. One diagnosis can divide into groups with different responses; one biological target can connect cancers in different organs. Modality describes how a therapy works; precision describes whom it is for. The force is established in selected settings; how far it spreads is **U10**.

A biological feature crosses tumor categories. FDA granted accelerated approval to Enhertu in April 2024 for previously treated HER2-positive (IHC3+) solid tumors regardless of organ: the biomarker is part of the market definition.³⁷

A common diagnosis contains a selected group. Nucala was approved in May 2025 for adults with inadequately controlled COPD with an eosinophilic phenotype. Precision is not synonymous with oncology or with rare disease.³⁸

Implication for launch. Define the tested population, the clinical threshold, and the diagnostic pathway together. Forecast the tested and appropriately selected population, not everyone carrying the umbrella diagnosis. Commercial economies of scale may come from reusing diagnostic, evidence, and delivery capabilities across defined populations rather than rebuilding a launch model for each one.

What this does not prove. A biomarker does not automatically predict benefit, and a targeted drug does not make all biomarker-positive patients suitable for treatment. Wider testing can reveal uncertainty as well as opportunity.

F09

Patients arrive informed, and with treatment preferences shaped by new information sources

Patients encounter research, treatment comparisons, and personal interpretations before or between visits. Conversational AI makes information accessible without knowing which paper to search. The force is a change in the sources and timing of patient understanding; it does not imply that information is accurate or that the patient controls treatment.

Treatment information is already a reason to use a chatbot. Pew found that 34 percent of U.S. adults had used a chatbot for at least one of eight health purposes and 22 percent for treatment information.⁷ KFF found 19 percent had used AI to compare physical-health treatment options in the past year.³⁹ OpenAI's Health in ChatGPT, launched in July 2026, lets U.S. users connect Apple Health and supported medical records with permission.⁴⁰

Implication for launch. Make accurate, balanced evidence discoverable where stakeholders and decision makers seek answers. Start with on-market products: audit visibility and representation in AI, including benefits, risks, limitations, and approval status. Use the findings to strengthen permitted information and address material inaccuracies through appropriate channels, without manipulating independent recommendations. Keep communications appropriate to their audience and regulatory status. For investigational programs, preserve scientific exchange without preapproval promotion; AI discoverability creates no exemption.⁴¹

What this does not prove. Surveyed use is not proof of changed prescribing or better decisions. The surveys ask different questions over different periods; their percentages are not one trend series.

F10

From reactive treatment toward prevention and sustained health

Healthcare is developing more ways to intervene before illness, prevent complications, and sustain health between visits. The change concerns what care aims to achieve and how it is organized over time, not merely finding a signal earlier. Movement is uneven: reactive care remains necessary, and prevention programs do not establish population-wide reach.

A medicine that prevents rather than treats. WHO recommended injectable lenacapavir for HIV prevention in July 2025 and CDC issued U.S. recommendations in September; the twice-yearly approach embeds a preventive medicine in testing, access, and follow-up, and its commercial proposition depends on reliably reaching people before infection.^{42, 43} England's plan names the shift from sickness to prevention as one of three organizing ambitions.³⁶

When the evidence arrives before the payment pathway. In the CHALLENGE trial, 889 patients with resected colon cancer after adjuvant chemotherapy were assigned to three years of structured exercise or health-education materials. Disease-free survival, the primary endpoint, improved; estimated eight-year overall survival, a secondary endpoint, was 90.3 percent versus 83.2 percent.⁶⁰ A Canadian public-payer analysis estimated a program cost of C\$2,917 and C\$1,589 lower total direct healthcare cost per participant over five years in its base case, in 2024 Canadian dollars. Savings were uncertain: the program was both more effective and less costly in 53 percent of resampled analyses.⁶¹

The delivery problem remains: someone must fund trained coaches, make participation practical, and sustain the service. The New York Times reports that UPMC plans exercise-oncology coverage for breast cancer patients in its employee health plan from 2027. That is a planned benefit for a defined population, not universal access. UPMC already provides individualized in-person and virtual exercise support.⁶²

THRIVE's interpretation. Better-organized supportive care can change the standard against which a new medicine's contribution is assessed. Clinical value becomes accessible care only when an organization can deliver it and make the economics work.

Implication for launch. Test how earlier intervention changes incidence, progression, treatment duration, and escalation in the specific category. Identify who can sustain engagement and who benefits financially from prevention. Build the medicine's role within a wider program where justified, without assuming every developer should become a care provider or that prevention is automatically cost-saving.

What this does not prove. A prevention policy is not demonstrated implementation. The colon-cancer trial and planned breast-cancer benefit concern different populations; the trial does not establish benefit across all cancers or support replacing cancer treatment. Paying for an intervention because it improves outcomes is not the same as making payment contingent on verified outcomes.

SECTION 2

What Is Open: Ten Uncertainties

Ten uncertainties describe consequential conditions that remain open, consolidated from the wider set surfaced in the research and assessed for their impact on launch and how open they remain. The Tx decision channel and the payment currency are the two scenario axes; the other eight specify additional conditions within the worlds and are not mechanically determined by those axes. The overview table in the Executive Summary pairs each uncertainty with its two poles and its launch consequence. The profiles that follow distinguish a trend's presence from its translation into authority, accepted evidence, funded access, or useful scale.

U01 · Scenario axis 1

Tx decision channel: who governs the treatment decision?

This concerns authority, not whether AI is present. A pathway can govern treatment while people oversee rules and exceptions; an adviser can be highly influential without governing the decision. Neither the number of tools nor the number of organizations determines the pole. Continuous AI reassessment within accountable rules is a scenario possibility, not a current operating model.

Delegation starts with a bounded task. Utah's Doctronic pilot tests AI participation in prescription renewal within explicit conditions.³² CMS's WISeR model uses technology in the review of selected services while requiring licensed clinical review for any non-payment recommendation: automation and decision authority are separated by task.⁴⁴

Implication for launch. Map actual decision rights, override routes, evidence requirements, and update mechanisms. Do not infer governance from software adoption alone. **Signals:** toward system governance, pathway departures become conditional on justification in routine care; toward distributed discretion, clinicians and patients continue to select among competing advice in practice.

U02 · Scenario axis 2

Payment currency: how much of payment depends on results after treatment?

The distinction is whether later performance materially changes payment for the treated population. Outcomes can affect prescribing and future negotiation under either pole. Installments do not necessarily put payment at risk, and a care organization can profit from prevention while buying medicines at fixed prices.

Outcome-linked terms, and unit prices, both advance. The CMS Cell and Gene Therapy Access Model organizes outcomes-based agreements for two sickle-cell gene therapies across 32 states, D.C., and Puerto Rico.⁴⁵ The third Medicare negotiation cycle resets unit-price economics for Part B medicines from 2028, distinct from any later clinical-outcome reconciliation.⁸

Implication for launch. Model which payment is at risk, for which patients, over what observation period, and under whose verification. Keep clinical monitoring, pathway reassessment, and financial settlement on their own clocks. **Signals:** toward outcomes, repeated completed settlements with material revenue at risk beyond a narrow set of therapies; toward units, negotiation and volume contracts remain the main mechanism despite richer outcome measurement.

U03

Registry and real-world evidence: how broadly accepted for consequential decisions?

F03 concerns richer data; this uncertainty concerns what decision-makers accept that data to establish. Approval, label expansion, pathway placement, and reimbursement are different decisions, and acceptance in one does not confer acceptance in the others.

A precedent and a moving boundary. Prograf's lung-transplant indication was supported in part by a registry study.²⁴ In November 2025, before final meeting minutes, uniQure said it believed FDA no longer agreed that its phase 1/2 data compared with an external control could serve as primary evidence for AMT-130. In June 2026, the sponsor reported that FDA would accept its three-year analysis as the primary basis for an accelerated-approval application, which it submitted in September. The evidentiary position changed during development; submission is not approval.⁴⁶

Implication for launch. Secure alignment on the intended regulatory, payer, and pathway decisions. Test comparability, confounding, and endpoint relevance before relying on external controls. **Signals:** toward broader acceptance, repeated primary-evidence decisions outside exceptional settings; toward selective acceptance, continuing limits on observational comparisons despite increasing data availability.

U04

Reach of price regulation and negotiation: how far do public prices travel?

Public prices now arise through more than one mechanism: statutory Medicare negotiation, most-favored-nation reference pricing set by agreement and by model rule, and state and federal legislation. The presence of a public price does not establish that another payer adopts it, and a different payment model need not use that price at all. The question is how far any of these benchmarks spreads across payers, channels, indications, or countries.

Benchmarks multiply; spillover is not yet documented. Medicare negotiation now reaches Part B; MFN-level Medicaid rebates have been announced for all 50 states; and TrumpRx offers public direct-to-consumer cash prices.^{8, 26, 9} England's antimicrobial subscription shows another response: changing the unit of value rather than extending a unit-price benchmark.²⁸

Implication for launch. Map explicit price references and exclusions for each product. Stress-test the business case against spillover from negotiation and from reference pricing alike, without presenting either as already observed. **Signals:** toward spillover, documented commercial contracts explicitly adopting external benchmarks, or legislation extending them; toward bounded reach, durable exclusions and compartmentalized terms.

U05

Integrated care organizations: how consequential will they become?

F07 describes new settings and combinations of services. This uncertainty asks whether those organizations achieve durable reach and influence over the care proposition. That does not require one mandated treatment ranking: an integrated network can coordinate prevention and outcomes while retaining clinician and patient choice.

Strategic expansion and an economic counter-signal. Included Health described Firefly as part of its business in October 2026, bringing more of the care relationship together.³⁴ CVS Health reported a \$5.7 billion goodwill impairment in its Health Care Delivery business for 2025: assembling care assets and making their economics work are different achievements.⁴⁷

Implication for launch. A consequential organization can be a customer, a partner, or, where the developer chooses to deliver part of the care itself, a competitor for the patient relationship; its prevention programs and managed use of existing therapies can also substitute for a new medicine without competing with it directly. Assess continuity, retention, delivery capacity, evidence capability, and unit economics alongside population size. Distinguish network integration from decision authority, and a care organization's outcome incentives from performance-linked medicine payment. **Signals:** toward consequence, repeatable care results and viable economics across populations; toward limitation, exits, weak retention, or bespoke operating costs.

U06

One-time therapies at scale: will technology and economics make them viable for broader populations?

The uncertainty is whether advances in manufacturing, delivery, and payment let one-time therapies reach populations well beyond the most severe patients at an economically viable cost. Qualified treatment sites and workable referral routes are part of making that reach possible. A one-time treatment is also not a one-step journey: testing, referral, collection, manufacturing, conditioning, administration, and long-term follow-up may all determine access, and a single dose does not guarantee a cure. Payment for outcomes (**U02**) interacts with this uncertainty without deciding it.

A one-time therapy aims at a common disease. VERVE-102, an in vivo base-editing therapy that inactivates PCSK9 in the liver, produced a mean LDL cholesterol reduction of 62 percent in the highest-dose cohort after a single infusion in a phase 1 study of 35 adults with heterozygous familial hypercholesterolemia or premature coronary disease. Reductions appeared durable through follow-up, which reached at least one year in 15 participants.⁴⁸

THRIVE's point of view. VERVE-102 will not replace statins as first-line treatment in the broader hypercholesterolemia patient population. The question is whether, and under which circumstances, a one-time option could reach broader adoption, for example on the order of today's injectable PCSK9 inhibitors. Cost competitiveness, including manufacturing and delivery, will strongly influence its place in therapy; physical access in the form of certified treatment centers is another critical element.

Collections and infusions are different milestones. Vertex reported 147 first cell collections and 64 Casgevy infusions globally in 2025, separate annual flows that make visible a journey with more than one gate.⁴⁹ The CGT Access Model's outcomes agreements address part of the access problem; they do not create treatment slots or manufacturing capacity, or lower the cost of producing the therapy.⁴⁵

Implication for launch. Model the business case at the unit cost and delivery model the technology can actually reach, not only at the price a severe population will bear. Build forecasts through the actual treatment gates; distinguish stocks, flows, and lags. Use the least scalable necessary step to challenge the rollout plan. **Signals:** toward breadth, falling manufacturing cost per treatment, simpler delivery outside specialist centers, and payment models that fund broader populations; toward severity, persistent cost and delivery requirements, local-only capability, or commercial retreat despite authorization to a severe population niche.

U07

AI-regulation climate: how much authority will AI be permitted to exercise?

The uncertainty is about the scope and stability of permission, not simply more or fewer rules. A rigorous framework can enable deployment by clarifying responsibility; permissive rules can leave liability unresolved. Restrictions on denial decisions do not necessarily restrict approvals, documentation, or clinical advice. In this scenario set, Algorithmic Order and The Waiting Room assume permission for continuous AI pathway updates within accountable rules. Precision Islands and Many Doors assume tighter limits on delegated AI authority. These are selected combinations, not a universal deduction: enabling regulation can also coexist with distributed treatment choice.

States allocate decision rights by function. Washington's SB 5395 permits certain AI processing and approvals while retaining licensed review for medical-necessity denials.⁵⁰ Colorado replaced its 2024 AI Act with an automated-decision-making regime. From 2027, covered deployers face notice, explanation, and human-review requirements, the latter where commercially reasonable. HIPAA-covered entities and business associates have a statutory exemption subject to conditions; compliant insurers are deemed compliant.⁵¹ A December 2025 executive order directs federal challenges to conflicting state AI laws; FDA's CDS guidance retains a conditional route for decision support.^{52 33}

Implication for launch. Keep Medical, Regulatory, Legal, Access, and Digital aligned on the intended use of each system. Monitor permissions and liability rather than authorization counts. **Signals:** toward enabling use, clear and durable permissions with credible review; toward constraint, enforceable limits, adverse events, or sustained resistance that changes deployment decisions.

U08

AI discovery translation: how much does a wider funnel change output?

F01 concerns changes already visible in target exploration and candidate design. **U08** concerns translation into useful medicines. Volume, speed, and success probability are separate variables: more candidates can increase absolute approvals even if success rates stay unchanged. The size of that increase depends on trial capacity, funding, biology, and comparative benefit.

A cohort reaches the stages where translation can be assessed. Of the 117 AI-enabled assets identified in the ASCO 2026 abstract, about half had completed phase 1 and fewer than one in ten had completed phase 2 as of December 1, 2025.¹² Rentosertib's phase 3 start is a specific program advancing, not a resolution of the class question.¹⁰

Implication for launch. Track defined cohorts by stage, disclosure date, comparator, and meaningful differentiation. Separate faster candidate generation from faster development and higher clinical success. **Signals:** toward pipeline-transforming impact, repeated late-stage benefits and material changes in approved volume or differentiation; toward limited impact, attrition, funding, or trial bottlenecks absorbing most gains.

U09

Data Ownership: connected under workable rights, or costly to assemble?

Technical connectivity, legal access, usable content, and permission to reuse evidence are different requirements.

A public route and a private one. CMS launched the first wave of Health Tech Ecosystem tools in April 2026 after organizational commitments to patient-centered exchange.⁵³ A Tempus-associated preprint describes a multimodal patient model trained on a 1.67-million-patient oncology cohort, illustrating what an assembled dataset makes possible and who controls it.⁵⁴

Implication for launch. Secure rights, quality requirements, continuity arrangements, and verification responsibilities before relying on partner data. Do not confuse a retrospective association with a causal estimate of treatment benefit. **Signals:** toward connection, operational reusable data under sustainable access terms; toward fragmentation, restrictive terms, incompatible definitions, or security incidents that materially constrain use.

U10

Precision beyond oncology: how far will biomarker-guided care spread?

F08 describes targeted treatment already present in selected diseases. **U10** asks how far validated testing and matched care spread. A test must be ordered, interpreted, funded, and connected to an intervention with meaningful benefit.

A blood test moves toward primary care; a biomarker misses the outcome test. FDA cleared Lumipulse's blood-based Alzheimer's assessment in May 2025 for symptomatic patients in specialized care; Roche reports that Elecsys pTau217, cleared in August 2026, is labeled for primary as well as specialty care.^{55, 56} In September 2026 Novartis reported that pelacarsen lowered lipoprotein(a) but did not meet Lp(a)HORIZON's primary cardiovascular endpoint, a concrete counter-signal to assuming that moving a marker produces the intended outcome.⁵⁷

Implication for launch. Link the biomarker proposition to outcomes, label criteria, test workflow, coverage, and capacity. Forecast actual testing and referral rather than assuming prevalence equals access. **Signals:** toward breadth, routine funded testing linked to demonstrated treatment benefit in community care; toward concentration, uncertain clinical utility, restricted test access, or persistent specialist dependence.

SECTION 3

Four Futures

A Map of Four Futures

The worlds diverge on two questions. One is about who decides treatment. The other is about what gets paid for. Neither says how advanced any technology becomes; how far diagnostics, connected information, and new care models reach is specified inside each world and does not follow from the axes.

Tx decision channel: System-governed. Institutional pathways establish the presumptive treatment sequence. A clinician who wants to prescribe outside it documents the exception and may have to defend it; a new medicine is not an option until the pathway lists it.

Payment currency: Paid for outcomes. A material share of what is paid depends on results verified after treatment. A payment can be earned, withheld, adjusted, or returned, so the company is paid for what the medicine did, not only for what was dispensed.

Tx decision channel: Distributed. Clinicians and patients keep meaningful discretion among competing recommendations. A clinician can act on an AI adviser's ranking or disregard it, and the patient can bring a recommendation of their own; a new medicine competes for that judgment one decision at a time.

Payment currency: Paid by price and volume. Payment depends primarily on units supplied at an agreed net price. Outcomes still shape demand and future negotiations; they do not routinely change what is paid for patients already treated.

The other eight uncertainties are specified inside each world. In this set, Algorithmic Order and The Waiting Room assume regulators permit continuous pathway updates within accountable rules; Precision Islands and Many Doors assume tighter limits on delegated AI authority. These are selected combinations, not a claim that enabling regulation must centralize treatment decisions, or that distributed choice requires regulatory constraint. Each world page states its assumed conditions.

The distinctions are worth holding onto, because familiar arrangements can sit on either side of them. An insurer can benefit from better prevention while still buying medicines at fixed prices. An installment schedule need not depend on treatment success. A competitive market can contain several organizations that each tightly govern clinical choice; a network that mandates its own algorithmic sequence is a system-governed pocket inside a distributed market. Subscription and availability arrangements add commercial variety without automatically linking payment to verified outcomes.

Algorithmic Order

System-governed Tx decisions · Paid for outcomes

The medicine works. Its place in the system is another question.

How do we earn a place in the pathway, and keep it in a constantly evolving algorithm?

The Waiting Room

System-governed Tx decisions · Paid by price and volume

The patient has been found. The money has not.

How do we demonstrate which patients benefit most and make effective treatment affordable at scale?

Precision Islands

Distributed Tx decisions · Paid for outcomes

Prevention is organized. Treatment remains a personal choice.

How do we deliver value across networks that organize prevention, measure results, and retain treatment choice?

Many Doors

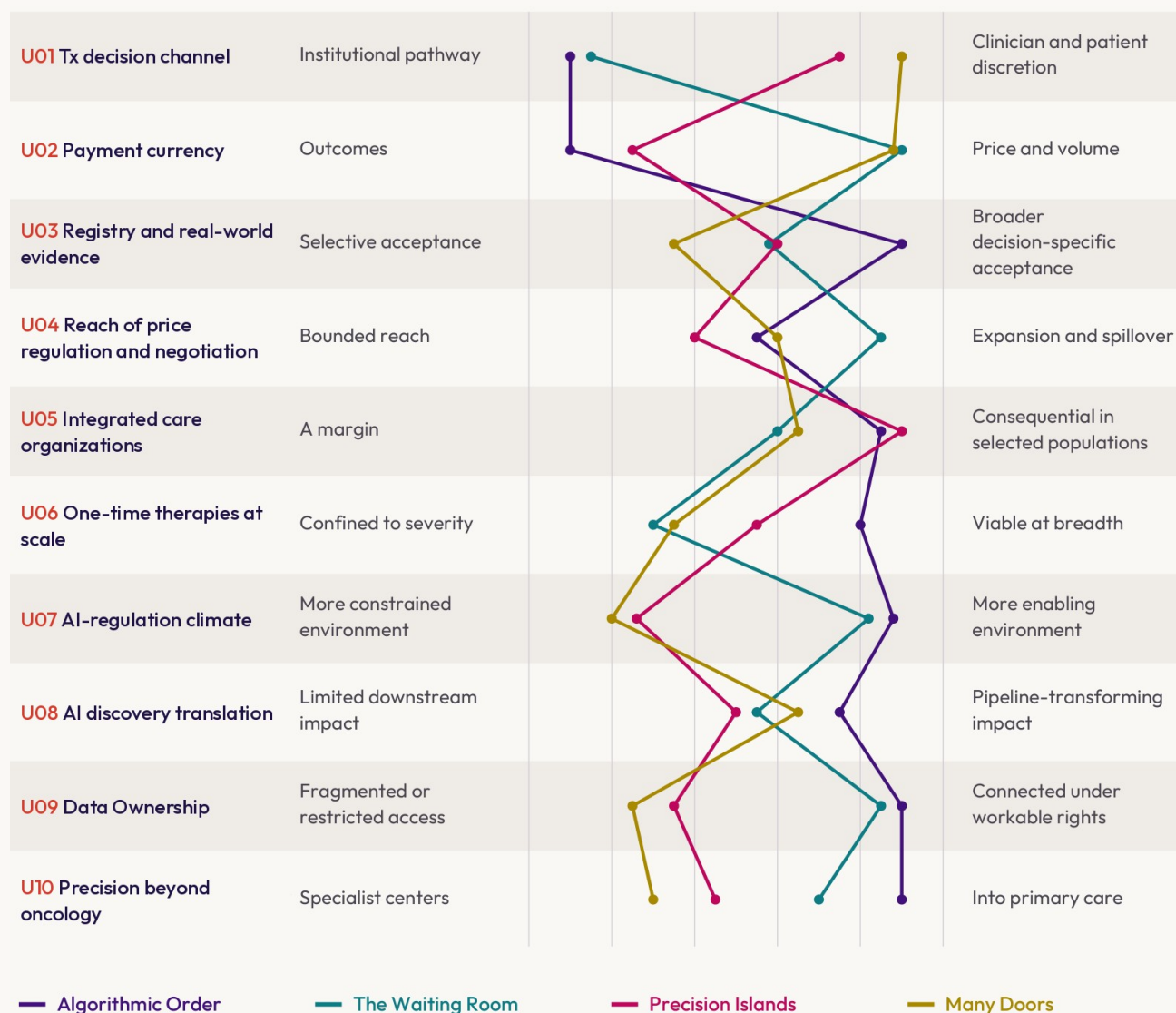
Distributed Tx decisions · Paid by price and volume

Care remains episodic. The sources of influence multiply.

How do we establish a compelling value proposition across the many sources that shape treatment?

Four Futures Across Ten Uncertainties

The chart describes the overall pattern of reach and market conditions in each U.S. world, not the most advanced institution inside it. Strong capability within a network can coexist with limited reach beyond its members. Rows 1 and 2 are the scenario axes. The other eight positions are analytical judgments about conditions consistent with each world's logic, placed relative to the other worlds. They are not measurements, and they are meant to be argued with. The care patterns of the worlds are explicit scenario assumptions, not automatic consequences of the axes: Precision Islands emphasizes competing networks accountable for prevention and results over time; Many Doors emphasizes episodic, transactional care with distributed sources of information and influence.



Row 7 retains the regulatory settings selected for these scenarios, not a universal coupling: the system-governed worlds assume an enabling climate and the distributed worlds tighter limits on delegated authority. Connected data within Precision Islands do not imply wider reusable access. Many combinations of the ten uncertainties remain possible.

The same advance can face a different commercial test in each world. The four tests are compared in Section 4.

THE SYSTEM GOVERNS THE DECISION × PAID FOR OUTCOMES

Algorithmic Order

The medicine works. Its place in the system is another question.

By 2035, much of U.S. care is organized through institutional pathways that connect diagnosis, treatment, and follow-up. Organizations combining coverage and delivery use connected records, home monitoring, and more precise diagnostics to identify need earlier. Clinicians remain responsible for patients, but following the pathway is the default; a departure requires a documented reason. This world assumes an enabling AI-regulation climate (U07): law and professional practice permit continuous pathway updates within accountable rules.



A material share of payment depends on results verified after treatment. The same infrastructure supports ongoing comparison between a new medicine, a competing product, and better delivery of an established treatment. A therapy can reach a substantial population quickly, yet its position and commercial terms remain open to reassessment.

For patients, the promise is coordinated care and less of the journey to assemble themselves. The trade-off is a shorter list of institutionally preferred choices. For biopharma, scientific success does not ensure commercial leadership. Developers must choose whether to remain specialist suppliers, take responsibility for part of the care around a medicine, or help build the care business itself.

A MOMENT IN 2035 · SCENARIO FICTION

She is looked after. She has little say.

Three weeks ago, she felt perfectly well. Now, after an alert, confirmatory tests, and a specialist appointment arranged by her care organization, she is due to start cancer treatment on Monday. Nothing has been left for her to organize. But she has read about another medicine that would mean fewer visits, and she brings the article to her oncologist. "The pathway doesn't support that option for your profile," he explains. "We can request an exception, but I don't see the evidence that would get it approved." He shows her why the recommended treatment ranks first. She understands the reasoning. She had thought her preference would count for more. As she leaves, Monday's appointment appears on her phone, followed by transport, monitoring, and follow-up. She accepts the schedule.

What launch success depends on. Pathway position: a place earned with evidence the pathway can ingest and continuously reassessed by AI; updates follow defined evidence thresholds, with human veto and documented override rights. **Outcome ownership:** a deliberate decision about which parts of the care that produce the result the company takes responsibility for, because payment depends on them.

WHO GAINS

Organizations coordinating care; developers with distinctive, measurable benefit or reliable delivery advantages.

WHO IS EXPOSED

Interchangeable suppliers; products whose benefit cannot be demonstrated under the relevant terms; commercial models unable to engage pathway governance.

Who Owns the Result?

A registry safety signal moves the medicine from first line to third for patients over 75 across a network of four million lives, overnight. Finance asks what the re-ranking means for performance-linked revenue. By the time the launch team opens its morning dashboard, new-start projections have changed. The obligations attached to patients already treated have not.

Settlement follows the endpoint. Some measures allow frequent reconciliation; durable remission needs years of observation. Hospitalizations avoided require an agreed comparison, not merely an admission count. Data show what happened, but do not settle which party caused it.

The developer controls its medicine, not every appointment, support service, or treatment site. A specialist-supplier model works where the contribution is distinctive and becomes exposed when an alternative delivers a similar result on better terms. Precision can also create reach a specialist developer could not assemble alone: one shared infrastructure can find a biologically defined population across a large network. The opportunity is broader reach without rebuilding every local patient-finding function; the vulnerability is dependence on the operator that controls access to that infrastructure.

The Position Must Be Earned Again

The launch begins with a choice about responsibility. Evidence must support the pathway's clinical comparison and the performance agreement. Diagnostics, supply, support, and follow-up must make the promised result deliverable. An earned position opens a route to patients; it does not create capacity or guarantee sustained use.

AI continuously evaluates registry results, safety signals, and comparative evidence. Validated changes within pre-authorized rules update the pathway when evidence thresholds are met. Clinical stewards can veto or reverse updates, and clinicians document patient-specific overrides. Launch teams monitor representation, placement, and delivered care as the evidence evolves.

Pathway reassessment, regulatory claims, and payment settlement use different standards and clocks. Contracts must specify what remains due for patients already treated when placement changes: monitoring, data continuity, verification, and any later adjustment. The launch lead brings the decisions together; Launch Excellence makes dependencies visible and carries learning across assets.

QUESTION	IN THIS WORLD
Who finds the patient, and how early	The pathway, in primary care and at home, often before symptoms; the clinician confirms.
Who decides which treatment	The pathway sets the sequence; the clinician confirms or documents an exception.
Who prescribes	The clinician, inside the pathway; departures are reviewed.
What is paid for	A material share depends on verified post-treatment results; settlement timing follows the endpoint.
Discovery to patient	Earlier investigation reveals patients sooner; access still requires evidence, an earned position, and delivery capacity.
How fast the market moves	Use can expand quickly once capacity is ready; positions change as evidence and alternatives develop.

Early indicators (scenario fiction). 2027: CMS makes registry enrollment a condition of coverage for two oncology indications under performance terms. 2029: an integrated care organization publishes the first pathway ranking with settlement terms attached. 2032: two-thirds of covered lives in the ten largest U.S. metros are managed under a certified pathway. 2034: most new specialty launches enter under performance-linked terms in at least one large network.

Signals already observed. CMS's CGT Access Model runs outcomes-based arrangements across 32 states, D.C., and Puerto Rico: an operating contracting mechanism, not proof of completed settlement for a broad market.⁴⁵ WISer separates technology-assisted review from licensed decision authority; it is task-specific automation, not formulary governance.⁴⁴ FDA's registry-supported Prograf approval shows a registry answering a defined question, not a dataset adequate for all decisions.²⁴

THE SYSTEM GOVERNS THE DECISION × PAID BY PRICE AND VOLUME

The Waiting Room

The patient has been found. The money has not.

The system can identify treatable need earlier and more precisely. Institutional pathways combine clinical evidence with coverage rules to establish the expected treatment sequence. Clinicians can see who could benefit, which treatment is recommended, and which option the patient's plan will fund. As in Algorithmic Order, this world assumes an enabling AI-regulation climate (U07); here the algorithm governs access against a budget rather than reconciling payment against results.



Payment remains predominantly tied to units at negotiated prices. Outcomes may be measured well without determining payment after treatment. Budgets and delivery capacity do not expand as quickly as the population now identified. Risk tiers, exceptions, and restrictions make the gap between clinical need and funded care visible.

The commercial opportunity is not only to defend a premium in a smaller population. Companies compete to make worthwhile treatment affordable for more people, through better patient selection, credible lower-cost alternatives, simpler administration, or better use of existing care. Employer programs and other routes help some patients obtain treatment sooner, but can widen differences in access. The strongest proposition shows where benefit is greatest and what it takes to deliver it at a sustainable scale.

A MOMENT IN 2035 · SCENARIO FICTION

Knowing earlier does not mean receiving the recommended treatment earlier.

An AI read of her routine mammogram flags risk two years before it would otherwise have been found. Further tests confirm it; she tells her daughter they have caught it in time. Her doctor recommends a treatment, then opens the pathway: she meets the clinical criteria, but not the plan's funded risk tier. The status reads, "eligible, not funded this cycle." "So you think I should have it?" she asks. He does. He starts an available alternative and files an exception. Six weeks later, the refusal arrives while she is making dinner. Her sister, insured through a different employer, has already started the recommended medicine. The alternative is helping. She puts the two messages side by side: the care system's recommendation and the insurer's refusal. Both carry her name.

What launch success depends on. Benefit-based patient definition: showing where the incremental benefit is unmistakable before the payer draws the funded tier. **Affordable-scale design:** a price, delivery model, and channel planned around the full identified population, with funded reach and delivery capacity tested before launch rather than assumed.

WHO GAINS

Developers with credible affordable-scale propositions; care organizations that make identified need treatable; therapies with clearly demonstrated incremental benefit.

WHO IS EXPOSED

Premium propositions without sufficient differentiation; diagnostic models that depend on unfunded follow-up; plans built only to protect price.

The Competitor With a Different Price of Admission

Inside the developer of the preferred therapy, one team proposes a familiar defense: focus on the patients for whom the strongest price can be justified. Another asks what happens if a competitor makes useful treatment affordable for the much larger population the system has identified.

The payer declines the premium proposal, then reopens the discussion when a competing package reduces administration and monitoring requirements. The comparison is no longer only benefit per patient. It is how many appropriate patients the available budget and workforce can actually treat. A lower acquisition price is one route; a simpler delivery model or more reliable use of established treatment is another.

The alternative need not be better on every measure. It must offer a credible balance of benefit, safety, delivery, and total cost. Not every developer should discount: a substantial incremental benefit may sustain a premium. Equally, a small population provides no immunity from difficult funding choices.

Define Benefit First. Then Design for Scale.

Benefit-based patient definition comes first. Medical and evidence teams must show where the incremental benefit is unmistakable, by patient profile and against available alternatives, before the payer draws the funded tier. This is not a narrower population chosen simply to protect a price.

Affordable-scale design follows. Model price, administration, monitoring, support, and channel together for the full identified population. Prepare an affordable-scale case alongside the premium case before launch. Test whether simpler delivery or different terms actually fund more treatment; preparing an option is not a commitment to discount.

Launch Excellence brings benefit and delivery economics into the same review. A funded tier is a gate, not the result: the plan must turn it into treated patients, including those unable to travel or sustain the proposed monitoring, and still work after the next competitor responds. The affordable challenger wins only if savings become delivered care rather than another nominally covered option.

QUESTION	IN THIS WORLD
Who finds the patient, and how early	The pathway finds risk and initiates confirmation in primary care and at home; clinical eligibility and the funded tier remain separate.
Who decides which treatment	The pathway ranks by cost-effectiveness at the negotiated price; the clinician confirms within the funded tier.
Who prescribes	The clinician, inside the pathway, with prior authorization automated against the budget.
What is paid for	Units at negotiated net prices under population-level budgets; outcomes shape future negotiations, not payment for this year's patients.
Discovery to patient	Review can be shorter for some products; funded access takes longer, and a waiting list is normal.
How fast the market moves	Fast to identify, slow to fund; the affordable alternative moves fastest.

Early indicators (scenario fiction). 2028: a national payer imposes a population-level budget cap on an AI-identified early-stage cancer indication. 2029: a lower-cost entrant displaces the first-line position in a diagnostically expanded cardiovascular indication within a year. 2031: investors price a premium for affordable-scale pipelines. 2033: patient groups in three states bring a coordinated legal challenge over eligible-but-unfunded status.

Signals already observed. The third Medicare negotiation cycle includes Part B medicines from 2028, changing unit-price economics without making payment contingent on outcomes.⁸ cmAngio flags breast arterial calcification and Clairity estimates breast-cancer risk from screening mammograms; neither authorization establishes drug eligibility or improved outcomes from acting earlier.^{29, 30} Subcutaneous pembrolizumab shows that administration can change around an established mechanism; the commercial question is what the entire delivery model makes affordable and reachable.¹⁸

CLINICIANS AND PATIENTS KEEP THE DECISION × PAID FOR OUTCOMES

Precision Islands

Prevention is organized. Treatment remains a personal choice.

Competing care networks organize prevention, treatment, and follow-up around results over time. Employer-linked plans, regional insurer-provider partnerships, specialist networks, and new entrants connect information and services for their members. Clinicians and patients retain meaningful choice among treatments and competing advisers. Integration does not require obedience to one institutional ranking. This world assumes tighter limits on delegated AI authority (U07): algorithms inform and rank, people decide, and consequential decisions remain accountable to licensed clinicians.



Networks benefit when better care improves outcomes and avoids unnecessary expenditure. They also use performance-linked agreements for medicines where results can be measured reliably. Earlier intervention, ongoing monitoring, and support become part of the proposition. A therapy competes on its contribution to that proposition, not just its clinical profile in isolation.

The best experience is not equally available to everyone. Coverage, affordability, geography, and practical support affect access; willingness to participate, share information, and engage in prevention affects use. Highly engaged patients can still lack access, while well-covered patients may decline intrusive monitoring. For pharma, the opportunity is to build partnerships that deliver meaningful results and can be repeated beyond the first successful network.

A MOMENT IN 2035 · SCENARIO FICTION

Care follows her life, but membership determines who gets that support.

The nurse calls while she is walking her dog. Her home readings have changed, and the team wants to understand why before the next scheduled visit. She admits she has stopped taking the afternoon dose on days she cares for her father. Nobody lectures her. At a video appointment, she and her physician compare two covered options, including the one her personal adviser suggested. They choose a plan she believes she can sustain; the network arranges follow-up and checks back the next week. For once, she does not have to start the story again with each person she speaks to. Her brother asks how he can get the same support. He is just as willing to participate, but neither of the plans available through his employer includes the network.

What launch success depends on. A package that travels: the medicine plus the diagnostics, monitoring, and support that produce the outcome, tailored to the targeted networks. **Network sequencing:** which networks to enter, in which order, and how to reduce contracting and deployment costs through reuse; track replication speed, cost, and quality.

WHO GAINS

Networks that deliver prevention and continuing care; developers with repeatable evidence and delivery propositions; patients able and willing to participate.

WHO IS EXPOSED

One-off partnership models that cannot travel; patients excluded by coverage or practical barriers; products whose results depend on unsupported local conditions.

The Second Network Is the Harder Sale

The first partnership works. Patients receive the medicine, follow-up is reliable, and the agreed results justify payment. The second network asks who will supply monitoring. It has fewer staff, different devices and data, and a different patient population. The proposition works. The company has not yet shown that it travels. The second network accepts the clinical case; its contracting team asks what happens when a member leaves before the outcome is verified. The first agreement had never needed to answer that question.

A material share of revenue depends on performance in defined populations. Agreements can run on network data without a shared national infrastructure, but evidence does not become easy merely because a contract exists. Prevention creates an additional competitive test: better use of an established therapy or an earlier intervention can change demand for a new medicine, in either direction.

The islands are boundaries of coverage, continuity, economic accountability, and trust, not simply incompatible IT. Data may be connected within a network yet unavailable for reuse outside it. A program that works for well-supported participants also has to show how it serves people with less time, fewer resources, or greater clinical complexity.

Build the Partnership to Travel

The market map shows partner populations and delivery capabilities as well as accounts and territories. Decide which networks to target, and design the package for each of them: their members, their devices and data, their staff, and their contracting terms. The package is not built for the first partner and then offered to the next; it is built for the set of networks the launch intends to reach. Membership is not the medicine's reachable market. The team needs to know who is eligible, funded, willing and able to participate, and supported by sufficient treatment capacity.

Work with the targeted partners early enough to shape evidence and delivery. Define what must remain consistent across them: clinical claims, safety requirements, performance measures, and minimum support. Let the rest adapt to each network where the evidence and economics allow it. Test each deployment before scaling, and track the cost and quality of replication, not only contracts.

Specify the handover when coverage changes: who continues support, who may use earlier records, who verifies the endpoint, and which party retains financial responsibility. Test the reusable core in a different population before calling the package scalable. Coordination must preserve meaningful patient and clinician choice rather than hardening into a mandatory treatment sequence. Launch Excellence carries the standards and the learning across assets.

QUESTION	IN THIS WORLD
Who finds the patient, and how early	Networks investigate earlier among participating members; access and engagement vary within and outside them.
Who decides which treatment	Clinician and patient choose among recommendations; network coordination does not dictate one sequence.
Who prescribes	The clinician, directly; developers reach clinicians through medical and evidence teams and through the network.
What is paid for	Performance verified on the network's data, contract by contract; units at net price where no contract exists.
Discovery to patient	Variable: fast inside a contracted network, slow outside.
How fast the market moves	Network by network; a launch is a sequence, and replication sets the pace.

Early indicators (scenario fiction). 2027: first performance contract signed between an employer-sponsored care plan and a developer on the plan's own outcome data. 2029: a quarter of new performance contracts replicate a template first executed in another network. 2031: a prevention-led network and two developers publish outcome-adjusted results for a joint cardiovascular program. 2033: investors value developers on contracted covered lives and replication rate.

Signals already observed. Included Health reported Firefly as part of its business in October 2026; care benefits remain unproven.³⁴ CVS's \$5.7 billion impairment illustrates integration risk.⁴⁷ The New York Times reports planned 2027 exercise-oncology coverage for breast cancer patients in UPMC's employee plan: organized prevention within a benefit boundary, not outcome-contingent payment.⁶² Public and private data routes do not guarantee reuse rights.^{53 54}

CLINICIANS AND PATIENTS KEEP THE DECISION × PAID BY PRICE AND VOLUME

Many Doors

Care remains episodic. The sources of influence multiply.

Care remains predominantly episodic and transactional. Patients, clinicians, and payers have more information, but no organization routinely assembles it into continuous care for most people. A clinical visit, a coverage decision, a diagnostic test, and a prescription may still be handled separately. Medicines are paid for mainly through units at agreed net or cash prices.



Technology advances around those arrangements. Personal AI advisers, clinical tools, virtual services, employer programs, and membership offerings create more sources of advice and more routes to treatment. Some coordinate care well; most do not reorganize the wider system. Clinicians and patients keep the treatment decision while weighing recommendations that reflect different information and priorities. As in Precision Islands, this world assumes tighter limits on delegated AI authority (U07): tools advise, while clinicians and patients retain the treatment decision.

For pharma, the challenge is to establish a coherent value proposition across these distributed judgments. A medicine must make clinical sense to the prescriber, practical sense to the patient, and economic sense to the payer, while being represented credibly in the tools each uses. Competition can enter through a new product, better delivery of an existing treatment, or a service that changes how patients consider their options.

A MOMENT IN 2035 · SCENARIO FICTION

She has more information and more options. Connecting them is still her job.

By Thursday, she has three recommendations about switching medicines. Her physician favors her current medicine, her insurer prefers another, and her adviser flags a competitor with a dosing schedule that fits her working day. Her membership service's wearable observations are not in her physician's record. She uploads the summary, requests another conversation, and compares costs. Her doctor agrees the competitor is appropriate. A manufacturer's cash channel makes it affordable. By Friday, the switch is complete, within a week. The developer's access dashboard has not moved; the formulary position is unchanged. She is pleased, but surprised by how much of her week it has taken. Before closing her laptop, she adds a reminder to tell the membership service that her treatment has changed.

What launch success depends on. Route economics: knowing which routes generate additional demand, which redistribute it, and what each contributes after costs: physician, care service, employer plan, cash channel. **Coherence across advisers:** one evidence-grounded value story, accurately represented in the physician's tool, the patient's adviser, and the care service, with the context each decision requires.

WHO GAINS

Developers that establish credible value across clinical, patient, and payer decisions; services that remove meaningful treatment barriers.

WHO IS EXPOSED

One-message strategies; plans that mistake coverage or AI visibility for demand; channels that add cost without improving treatment access.

The Value Proposition Has Many Audiences

The familiar commercial model persists, but a single message does not travel unchanged through every decision. The clinician examines comparative benefit and safety. The patient weighs burden, convenience, and trust. The payer examines affordability and alternatives. Their advisers and tools may draw on different evidence and arrive at different recommendations.

The manufacturer's direct channel reports strong growth. Finance discovers that some orders came from patients who previously used another reimbursed route. The channel has changed; the treated population has not grown by the same amount. The team must separate improved access from redistribution, and both from channel activity that adds cost without improving sustained treatment.

A coherent proposition is not a different truth for each audience. It is the same credible clinical case, expressed with the evidence and context needed for each decision. More credible products can shorten the window of differentiation. Integrated care challengers exist, but remain pockets. Episodic care is a condition of this world, not an inevitable consequence of unit pricing.

Connect the Decisions That Lead to Treatment

The team maps how people recognize need, seek advice, obtain a prescription, secure funding, and start treatment. It tests the proposition with clinicians, patients, payers, and relevant services. The task is not to be present at every door; it is to understand which combinations matter for this medicine.

AEO and decision-tool monitoring start with accurate, current evidence and representative questions. Test what different systems say, whose needs are being missed, and whether the answer helps the next step in care. Visibility is not the same as adoption, and adoption is not the same as sustained benefit.

Follow the patient across routes without double-counting starts. Compare contribution after channel and service costs, test which handoffs fail, and identify who receives treatment changes. A one-time therapy still requires a qualified center, funding, and follow-up. Launch Excellence links the reviews so strength in one part does not conceal a failed handoff elsewhere. A seamless prescription transaction is not proof that anyone owns the continuing care relationship.

QUESTION	IN THIS WORLD
Who finds the patient, and how early	Clinicians, patient advisers, and care services identify need at different times; follow-up is not routinely connected.
Who decides which treatment	Clinician and patient, informed by several sources; payers and services make separate access and delivery decisions.
Who prescribes	The clinician, reached by field, digital, and peer channels, and by the patient who arrives with a request.
What is paid for	Units at negotiated, referenced, or cash prices; outcomes shape demand and future negotiations.
Discovery to patient	Review can be faster; access depends on the route the patient takes and its handoffs.
How fast the market moves	New information and competitors move quickly; adoption depends on several separate decisions and handoffs.

Early indicators (scenario fiction). 2028: fewer than 10 percent of performance-based pilot contracts renewed or scaled. 2029: a chronic medicine gains substantial uptake through a combination of clinical advice, employer services, and a manufacturer channel. 2031: membership-based care services cover a tenth of commercially insured adults in the largest metros. 2033: a lower-cost entrant gains share by aligning evidence, convenience, and payer terms across separate channels.

Signals already observed. Pew and KFF report substantial self-reported use of chatbots for health and treatment information: an information channel, not a measured prescription-switching rate.^{7,39} Most-favored-nation agreements, TrumpRx cash prices, and permission-based consumer AI add routes whose relevance depends on the patients they add and the handoffs they complete.^{9,40} New routes and formats change the proposition around a medicine without reorganizing care into a continuous, accountable system.^{18,19}

SECTION 4

The Scenarios in Practice: Implications for Launch

One Medicine, Four Commercial Tests

Hold one advance constant: a medicine aimed at a more precisely defined population, with simpler administration. Its biology does not change across these worlds. The commercial test does.

WORLD	THE TEST	WHAT THE TEST TURNS ON
Algorithmic Order	Does verified contribution earn and sustain pathway position, and what outcome responsibility accompanies that position?	Shared infrastructure can extend reach; the operator controls placement and evidence access. Distinctive priorities: pathway position; outcome ownership.
The Waiting Room	Does the complete proposition let the budget and the delivery system treat more of the appropriate population?	The challenger changes price, staffing, administration, and follow-up together. Distinctive priorities: benefit-based patient definition; affordable-scale design.
Precision Islands	Can the medicine-plus-care package, designed for the targeted networks, reproduce its results and economics in each of them?	Replication must carry responsibilities and continuity, not only clinical claims. Distinctive priorities: a package that travels; network sequencing.
Many Doors	Does it win the relevant clinical and patient decisions through routes that generate worthwhile incremental treatment?	Convenience and more routes create opportunity, but channel growth is not automatically market growth. Distinctive priorities: route economics; coherence across advisers.

Two Medicines, Four Launch Environments

Two invented assets make the tests concrete. Each is held constant; only the market changes. The question for each cell is which part of the business case no longer holds.

Kairozi is an invented once-monthly subcutaneous therapy that slows early-onset heart failure in adults with a specified molecular signature. The eligible group sits within a larger cardiovascular population. Earlier identification changes the entry point, not Kairozi's clinical profile: model the path from risk signal to confirmatory testing, the molecular signature, funding, capacity, initiation, and sustained use. Better delivery of existing cardiovascular care may delay escalation for some people while better case finding identifies others; neither effect should be assumed from prevalence alone.

Soteris is an invented one-time cell therapy for severe, treatment-refractory lupus, intended to produce durable remission. Durability remains uncertain. Specialist delivery and follow-up are necessary in every world; a new commercial arrangement does not remove those requirements, and a change of payer or network does not end a treated patient's need for follow-up.

Kairozi: A Recurring Medicine

WORLD	THE SUCCESS FACTOR TESTED	WHERE THE CASE FAILS
Algorithmic Order	Pathway position. Earn and renew placement with subgroup registry evidence; the testing pathway must identify the molecularly defined group, since a general risk flag is not placement evidence. Outcome ownership. Define the monitoring and support the company will deliver and how those responsibilities affect settlement.	Registry results weaken placement, or missed monitoring reduces the measured benefit. Placement changes cut new starts while outcome responsibilities for treated patients continue.
The Waiting Room	Benefit-based patient definition. Establish where incremental benefit is clearest. Affordable-scale design. Test whether price, monthly administration, and support let the budget reach the full identified population; model test access and monthly delivery as well as the net medicine price.	The premium case protects a narrow funded tier while a credible alternative reaches more patients. A lower price also fails if administration, support, or capacity still prevents affordable scale.
Precision Islands	A package that travels. Specify diagnostics, monitoring, and support around the medicine for each targeted network. Network sequencing. Order deployments to test different populations and delivery systems while reducing contracting costs; test a second population with different support needs and retention patterns.	The first network's results depend on staff, devices, or engagement the next cannot reproduce. Bespoke contracting costs prevent replication; a member moves before the endpoint is verified and the contract has not allocated continuity.
Many Doors	Route economics. Assess each route's cost and contribution; distinguish additional demand from channel shifts; deduplicate starts across reimbursed and cash routes. Coherence across advisers. Make the same evidence useful to physician, patient, and care-service tools.	The cash or service route shifts existing demand without improving contribution. Conflicting advice prompts a switch while access measures stay stable; channel activity is mistaken for sustained treatment.

The recurring-treatment case tests affordable-scale design and route economics most sharply: can the proposition fund sustained use across the identified population, and does each route improve access or contribution after costs, rather than merely redistribute transactions?

From Risk Signal to Sustained Treatment

Build a workable route from a routine-care risk signal to confirmation of the molecular signature: who orders the test, which laboratory performs it, who pays, who receives the result, and who completes the referral. Measure loss and delay at each step. A positive risk flag is not treatment eligibility, and a completed test is not a treatment start.

Test two opposing effects together. Better delivery of established cardiovascular care may delay the need for Kairozi, while better case finding may identify more appropriate patients. Establish incremental value against that optimized care. Design initiation and ongoing support around patients' daily lives; track persistence separately from evidence of clinical benefit.

Soteris: A One-Time Specialist Therapy

WORLD	THE SUCCESS FACTOR TESTED	WHERE THE CASE FAILS
Algorithmic Order	Pathway position. Align registry evidence with placement and reassessment. Outcome ownership. Specify responsibility for specialist delivery, long-term follow-up, and uncertain durability before accepting performance-linked terms; keep regulatory evidence, placement thresholds, and long-term settlement separate.	A pathway position does not create a treatment slot. The company carries durability or follow-up exposure it cannot control, price, or verify when payment is reconciled; a data feed disappears while the follow-up obligation persists.
The Waiting Room	Benefit-based patient definition. Establish unmistakable incremental benefit in the eligible group. Affordable-scale design. Fit total treatment cost, funding, and specialist capacity to the identified population; match the initiation budget to the least scalable necessary delivery step.	Clinical eligibility exceeds the funded or deliverable population. A compelling benefit case cannot overcome a budget requirement or specialist-capacity constraint the launch model has not addressed.
Precision Islands	A package that travels. Make specialist delivery, monitoring, and long-term verification transferable to each targeted network. Network sequencing. Choose networks that can adopt those responsibilities; specify how data rights and follow-up transfer when membership changes.	The second network cannot supply compatible monitoring or sustain follow-up. A network can reproduce the infusion but not the long-term verification; rebuilding arrangements contract by contract interrupts continuity.
Many Doors	Route economics. Cost the referral, funding, and center route that delivers treatment. Coherence across advisers. Align clinician, patient, and care-service understanding of eligibility, benefit, risks, and follow-up; make the specialist pathway executable, not merely visible.	Interest and clinical eligibility grow, but advice, funding, and center capacity never form an executable plan. More referrals or engagement add cost without producing additional treatment slots.

The one-time-treatment case tests outcome ownership and a package that travels most sharply: can responsibility for delivery and durable benefit be verified, funded, and transferred across networks?

A Treatment Slot Is Not a Complete Care Plan

Qualify a treatment site against the tasks, staffing, monitoring, and follow-up this therapy requires, not simply whether a contract is signed. Track confirmed eligibility, funded treatment plans, booked capacity, completed treatment, and ongoing follow-up as distinct gates.

Before treatment, agree who continues care when coverage changes, who can use earlier records, and who funds and verifies follow-up. Neither data rights nor financial obligations transfer automatically. A shared registry is one possible arrangement; linked records with agreed rights are another. Plan continuity of clinical follow-up across the handoff, whether payment is fixed or depends on later results.

SECTION 5

What to Do Next

A scenario exercise becomes useful when it leads to action. The starting point is a clearer account of what the existing plan depends on.

The critical gate to viable adoption changes.

What the worlds change is where the launch's commercial logic is tested most sharply: an earned position with performance terms, a workable threshold and price agreement, a repeatable network arrangement, or route-specific coverage and adoption. None of these gates guarantees delivered treatment or sustainable economics. The dangerous assumption is that the route from evidence to adoption to revenue that carried the last medicine will carry the next one.

The reachable population is not the eligible population.

The gap exists in every world. In Algorithmic Order it is set by pathway placement and the operator's capacity; in The Waiting Room by the funded tier; in Precision Islands by which networks have contracted and who participates; in Many Doors by the routes the plan built and the handoffs between them. A forecast built on epidemiology alone overstates reach in all four. Where relevant, distinguish people flagged for investigation, confirmed cases, clinically eligible patients, funded patients, and those who actually start and sustain treatment.

Decision-system readiness is a shared foundation.

Patients already use chatbots for treatment information.⁷ Institutional pathways, network tools, and personal advisers make different demands on evidence. THRIVE's interpretation is that AI answers can extend research beyond its intended audience and strengthen patient participation. AEO is a launch-readiness imperative: make credible evidence discoverable and monitor its context, risks, uncertainty, and approval status. Google's guidance supports discoverability in its AI features.⁵⁸

The launch stays cross-functional, and the launch lead owns it.

Evidence and contract governance; patient selection and affordable-scale design; prevention partnerships and replication; value across distributed decisions. Which functions carry the decisive work changes, but the launch remains cross-functional.

What this asks of Launch Excellence.

Launch Excellence provides a shared way to expose assumptions, test readiness, and learn across launches. It ensures that evidence, engagement, access, and delivery fit together without taking over every specialty, and it helps build reusable commercial capabilities across assets: diagnostic partnerships, subgroup evidence, delivery packages, data access, and the ability to operate different contracts. More specifically defined populations may require capabilities associated with rare disease without supporting an expensive bespoke launch each time. The accountable launch lead runs the launch; senior leaders choose the commitments and provide the decision rights to act. Launch Excellence is a strategy discipline in every world; fragmented care creates a particularly demanding coordination task. A first-time biotech may have no separate function; the same work still needs named owners, a shared view of evidence and delivery requirements, and a practical way to resolve cross-functional dependencies before they become launch barriers.

Seven No-Regret Moves

Certain actions can create value no matter how the future takes shape. These are recurring disciplines, not a prescribed execution order. They can run in parallel; the scale and form of investment should remain proportionate to the asset and the evidence. The moves build the eight factors before the market chooses which of them matters most.

1. Rehearse, monitor, and adapt

Accountability: Launch Excellence and Insights, with launch leads. Prepares for all eight success factors.

Test current launch plans against all four worlds and the alternatives each medicine must beat. Maintain a shared view of signals, patient experience, uptake, and safety; assign thresholds and owners for revisiting assumptions. Test earlier identification, narrower responder populations, prevention, and simpler delivery of existing treatment as changes to the market, not only as competitor announcements. Separate candidate volume, development speed, regulatory timing, and comparative benefit.

Concrete output: a short assumptions map showing what could change the population, comparator, differentiation window, and business case.

2. Build evidence that earns trust

Accountability: Medical, Clinical, and HEOR, with Access. Prepares for all eight success factors.

Design clinical and real-world evidence around consequential treatment questions, relevant subgroups, and practical outcomes. Map evidence to regulatory claims, clinical choice, payer access, pathway placement, and performance settlement separately. Test transfer across patient populations and care settings; plan a credible alternative when primary-evidence acceptance is uncertain. Bring clinicians into the scientific dialogue early; update the case when experience challenges it.

Concrete output: an evidence-to-decision map, with unresolved requirements and credible alternatives.

3. Build AEO and decision-system readiness

Accountability: Digital and Commercial, with Medical, Regulatory, and Legal; Launch Excellence connects the learning. Prepares for pathway position; coherence across advisers.

Start AEO (answer engine optimization) with one or two on-market products. Make truthful, balanced, current product information accessible and intelligible to the AI tools patients and clinicians use, within the rules for its audience and purpose. Audit representative questions and check that answers preserve benefits, risks, evidence limitations, and approval status. Address material inaccuracies through appropriate channels; the aim is informed independent judgment, not manipulated recommendations. Apply existing medical, legal, and regulatory controls. For investigational programs, keep scientific exchange distinct from promotion; discoverability does not create a preapproval-promotion exemption.⁴¹ Keep patient-facing representation and formal pathway engagement separate. Repeat the checks after material evidence, label, or system changes.

Concrete output: a maintained question set, representation checks, named owners, and escalation routes.

4. Design access for affordable scale

Accountability: Launch lead, Access, HEOR, and Finance. Prepares for affordable-scale design; benefit-based patient definition.

Model price, delivery intensity, and service requirements together. Test which patients benefit most and what terms make treatment reachable. Prepare an affordable-scale alternative where relevant without committing to a discount or assuming that volume guarantees value. Cost testing, confirmation, referral, administration, monitoring, support, and capacity. Identify who pays before benefit appears and test whether apparent savings become funded, deliverable care.

Concrete output: an affordable-scale business case covering the medicine and its supporting care.

5. Build with patients, not only for them

Accountability: Patient Engagement and Medical, with the launch team. Prepares for all eight success factors.

Bring patients and caregivers into evidence priorities, care design, and support decisions. Test treatment and monitoring burdens, privacy preferences, and access barriers. Include people with limited time, caregiving responsibilities, digital access, and willingness to share information, not only highly engaged participants. Use their experience to improve the proposition, rather than treating engagement only as a route to uptake.

Concrete output: a patient-tested account of the burdens that prevent appropriate use and the changes that address them.

6. Choose ecosystem roles and partners

Accountability: Commercial leadership and launch leads, with Access and Legal. Prepares for outcome ownership; a package that travels.

Decide where the company will supply a medicine, partner in delivery, or provide part of the ongoing service, and select partners accordingly. Agree who supplies diagnostics, care, data, and verification, with explicit responsibilities and continuity arrangements. Assess partner economics, data-use rights, continuity, and exit arrangements. Specify who retains obligations when the patient changes coverage, the partner leaves, or access to a dataset is interrupted.

Concrete output: a responsibility and continuity map for care, data, verification, and financial exposure.

7. Rehearse delivery and accountability

Accountability: Launch lead and Operations; Launch Excellence coordinates. Prepares for network sequencing; route economics.

Bring evidence, access, supply, patient support, and partner readiness into one review. Test demand shifts, capacity limits, and failed handoffs before scale-up. Simulate an abrupt pathway change, a demand shift, loss of data access, and a second deployment that cannot reproduce the first. Make clear which commitments continue even when new treatment starts stop. Assign decision rights and escalation owners, and reuse what is learned in later launches.

Concrete output: a rehearsal showing who acts, what changes, and what continues when the original plan breaks.

The future commercial model depends not only on discovering a better medicine, but on finding the appropriate population, delivering a proposition that works in its care setting, demonstrating the right result, and building economics that can be repeated. The worlds place control, cost, and responsibility for those tasks in different hands.

Test via Pilots, Commit Deliberately

Some capabilities help in several worlds. What becomes contingent is their scale, organizational form, and timing. A pilot can reveal whether a larger commitment is justified without requiring the company to declare that one future has won. Preparing an option is different from paying to build the whole future around it. Keep the medicine constant, change the market, then ask which part of the business case no longer holds.

WORLD	PILOT	LARGER COMMITMENT MOST JUSTIFIED UNDER THIS MARKET LOGIC	EXPOSURE CREATED BY THE COMMITMENT
Algorithmic Order	Test one pathway-integration and performance-settlement arrangement with one operator, on the operator's own data; learn what the outcome exposure means. Rehearse an evidence-triggered placement change while obligations for treated patients continue.	Contract, evidence, and data operations as a standing competency, plus ownership of defined care steps the payment depends on, such as monitoring or patient support.	Interchangeable inside the pathway, or a capability built for a world that stayed a pilot.
The Waiting Room	Test reach, not only willingness to discount: one affordable-scale proposition with one regional payer or integrated organization. Measure the change in appropriate patients actually treated, including the supporting workforce and capacity.	A second price tier and delivery model for the clinically eligible population; supply that flexes under caps; managed access built as infrastructure.	Margin given away for reach that a cap then limits anyway.
Precision Islands	Test the second deployment early: one performance contract written as a template from the start, with a replication plan. Include different support needs and a member who changes coverage before verification.	A partnership organization: network steering seats, program enablement, a contract team, and a delivery package the company supplies.	Replication that does not travel; a package built for a network that switches partners.
Many Doors	Test whether one coherent value proposition works across clinical, patient, and payer decisions in a selected care route. Deduplicate patients and compare contribution after route and service costs.	A cross-channel evidence and engagement model, with route-specific delivery and measurement of incremental treatment.	Duplicated engagement, conflicting representations, or channel shifts without sufficient additional treatment or return.

Watch for Consequences, Not Headlines

WORLD	THE COMBINATION TO WATCH	WHAT WOULD WEAKEN THE CASE	DECISION TO REVISIT
Algorithmic Order	An evidence-triggered pathway change alters treatment in practice; a material share of payment is actually reconciled against later results. Track the continuing exposure on previously treated patients.	A major data breach or serious AI failure causes patients, clinicians, or regulators to retreat from pathway authority; or performance terms expose little revenue.	How much to invest in pathway integration, evidence operations, and responsibility for care.
The Waiting Room	A lower-total-cost proposition increases appropriate funded treatment, but a persistent funding or capacity gap still governs access. Savings relieve the constraint without removing it.	Affordable treatment and delivery capacity durably close the funding and capacity gap across the relevant population.	The balance between premium positioning, affordable reach, and the delivery model.
Precision Islands	Results and viable delivery economics repeat across different populations; data and support continue through member transitions, while clinician and patient choice remains meaningful.	Partnerships cannot repeat their results, exclude too many patients, or harden into mandatory treatment pathways.	Which partners to prioritize, and how much of the support offering to build for reuse.
Many Doors	A route produces incremental treatment and sustained use with worthwhile contribution after costs; a more convenient transaction does not necessarily create continuous care.	Care becomes predominantly longitudinal and coordinated, with substantial performance-linked pharmaceutical payment.	Which value judgments and handoffs to support, and which channels create additional treated patients.

A signal earns its place on the dashboard when it could change a launch decision. Set decision thresholds for the asset rather than borrowing a national percentage: a route that matters to a cardiovascular launch may be irrelevant to a specialist cell therapy, and a performance agreement matters when enough revenue is exposed to change the business case. Keep an observation date, evidence status, relevant population, business-case implication, and response owner for each signal. A negative result or failed deployment can be as informative as adoption.

Ten Questions Worth Exploring

These questions begin a working conversation, not a readiness scorecard. Apply them to a defined asset or portfolio decision; the answers may differ across populations and routes.

- 1 Which combinations of these worlds are emerging across our priority assets, indications, and payer populations, and where does our plan assume a more uniform market?
- 2 Which elements of evidence infrastructure, delivery capability, and relationships become more decisive to our competitive advantage in each world, and where should we build, partner, or secure access?
- 3 Which of our next five launches depends on a commercial assumption that fails in another plausible world, and which investment or resource decision does that expose?
- 4 For those launches, which of the eight success factors are demonstrated in the plan, which are assumed, and what must we learn before committing further?
- 5 How would earlier identification, more targeted treatment, prevention, or better delivery of existing care change our reachable population, comparator, and value proposition?
- 6 Can we serve more precisely defined populations with viable economics without assuming rare-disease pricing or rebuilding a bespoke commercial model for each launch?
- 7 Whose decisions determine whether our evidence becomes treatment and revenue, including AI-mediated recommendations, and where do our engagement and readiness plans miss that authority?
- 8 Which roles, partnerships, data rights, and continuing obligations should we own, share, or avoid, and what happens when the patient, partner, or pathway changes?
- 9 Which commitments are justified now, which options should we test first, and what evidence or market signal would cause us to accelerate, redirect, or stop?
- 10 What capabilities can we reuse across launches, what should we stop to free resources, and who has authority to turn these questions into decisions within our existing governance?

EXPLORE WHAT THIS MEANS FOR YOU

Request a THRIVE Futures Briefing to apply these questions to a specific launch or portfolio: identify the decisions at stake, challenge assumptions, and examine the options. Europe and Asia editions will be published later in Q4 2026. Contact launch@thrive-co.com.

About This Report

The method.

Scenario planning is not about predicting the future. Its purpose is to build the capacity to navigate deep uncertainty by constructing valid alternative models of it: to expand the future rather than narrow it, to reveal the hidden assumptions a linear plan rests on, to increase strategic degrees of freedom, and to build resilience by remembering the future before it arrives. THRIVE Futures Architecture™ is THRIVE's scenario planning method for decisions under deep uncertainty. It moves from what is given (the driving forces) to what is open (the critical uncertainties, assessed and consolidated), to the uncertainties selected as axes, to the worlds those axes define, and then to the response for a specific decision-maker. The worlds are built so that a strategy or plan can be tested against each of them; the value lies in what holds across all four and in what only one or select worlds demand.

Development notes.

Launch Excellence 2035: Winning in an Era of Exponential Change was developed by Eliette Krakora, THRIVE Consulting, in September 2026 and expanded in October 2026. The worlds build on THRIVE's December 2025 first scenario set on the same subject,⁵⁹ augmented by structured research of secondary sources and insights from expert talks. Present-day observations are cited to the sources listed in the endnotes; company reports and survey populations are identified where relevant, and the endnote text records what each source does and does not establish. Generative AI tools (Claude, Perplexity, ChatGPT) and THRIVE's proprietary scenario engine, the THRIVE Futures Architect™, supported research, exploration, drafting, and editing. The author directed the scenario design and selected, revised, and validated the final scenario logic, conclusions, and recommendations. The author remains responsible for the content. An integrated review edition with the full illustration bank and evidence register is maintained separately.

What is observed, interpreted, and imagined.

The scenarios are structured thought experiments to support strategic planning and leadership dialogue. They are not predictions, and no probability is assigned to any of them. Future people, scenes, dialogue, company decisions, and dated future headlines are fictional. Kairozi and Soteris are invented comparison assets. Named institutions in future scenes do not imply claims about their current strategy or performance. Present-day developments are sourced observations; company-reported figures and expert statements are identified as such. THRIVE's interpretations and points of view draw on professional experience in launch strategy, scenario planning, and pattern recognition across engagements. They are identified as judgments, not study findings, and are intended to be tested against the reader's situation.

Scenario use and disclaimer.

These scenarios are structured thought experiments developed to support strategic planning and leadership dialogue. They are not predictions, forecasts, or representations of what will occur, and no probability is assigned to any scenario. Actual developments may differ materially from those described. Future people, scenes, dialogue, events, company decisions, and dated future headlines are fictional; present-day observations are separately identified and sourced. This material is provided for informational and discussion purposes only and does not constitute investment, legal, medical, regulatory, financial, or other professional advice. No representation or warranty, express or implied, is made as to the accuracy or completeness of any future-oriented assumption or outcome. Readers remain responsible for their own decisions and should not rely on these materials as a substitute for independent judgment or professional advice.

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Endnotes

Sources are identified by the reference numbers used in the text. Each entry records the source, its date, and its scope. The source labels link to the cited material.

- 1 Stokes JM, et al. A Deep Learning Approach to Antibiotic Discovery. *Cell*. 2020;180(4):688-702. A foundational example of AI-assisted screening, not a 2026 adoption estimate.
[Publisher](#) · [PubMed](#)
- 2 Xu Z, et al. A generative AI-discovered TNIK inhibitor for idiopathic pulmonary fibrosis: a randomized phase 2a trial. *Nature Medicine*. 2025;31:2602-2610. 71 participants, 12 weeks; safety was the primary endpoint.
[Source](#)
- 3 EMBL-EBI. AlphaFold Database update, February 17, 2026. More than 200 million predicted structures for catalogued protein sequences; coverage is not therapeutic validation.
[Source](#)
- 4 Abramson J, et al. Accurate structure prediction of biomolecular interactions with AlphaFold 3. *Nature*. 2024;630:493-500. Predictions are not validated therapies.
[Source](#)
- 5 National Cancer Institute. Biomarker Testing for Cancer Treatment. Explains matching some cancer treatments to biomarkers and the limits of such matching. GSK's Nucala approval in eosinophilic COPD (May 22, 2025; note 38) provides a non-oncology example.
[NCI](#) · [Non-oncology example](#)
- 6 American Medical Association. 2026 Physician Survey on Augmented Intelligence. Fielded January 15 to February 2, 2026; practice-use base n=1,342. 72 percent reported at least one listed use. Self-reported.
[Source](#)
- 7 Pew Research Center. From Diagnoses to Treatments: Why Americans Use AI Chatbots for Health. August 25, 2026. n=3,488 U.S. adults, fielded June 22 to 28, 2026. Ever-use for any of eight health purposes: 34 percent; treatment information: 22 percent of all adults. Self-reported use, not verified treatment change.
[Source](#)
- 8 CMS. Selection of drugs for the third cycle of Medicare drug price negotiation, January 27, 2026; manufacturer participation fact sheet, March 13, 2026. First cycle to include Part B drugs; prices effective 2028.
[Selection](#) · [Participation fact sheet](#)
- 9 White House. Fact sheet on additional manufacturer pricing agreements, August 31, 2026: 26 agreements covering 89 percent of the branded market, MFN prices on new launches, TrumpRx.gov launched February 2026. Administration-reported.
[Source](#)
- 10 Insilico Medicine. First patient dosed in GENESIS-IPF-3, September 10, 2026. Phase 3 conducted in China; rentosertib remains investigational.
[Source](#)
- 11 Sumitomo Dainippon Pharma. DSP-1181 enters phase 1, January 30, 2020: an early AI-designed molecule in human trials. Sumitomo Pharma, Q3 FY2021 presentation, January 31, 2022, slide 15, records discontinuation after phase 1 did not reach expected criteria.
[Trial entry](#) · [Discontinuation](#)
- 12 Haque W, et al. Clinical-stage AI-enabled therapeutic assets: An industry-wide analysis of scale, clinical progression, and company characteristics. *J Clin Oncol*. 2026;44(16 suppl):11072. 117 assets from 63 companies entering interventional trials through July 1, 2025; progression assessed to December 1, 2025. Phase completion is not a success rate.
[Source](#)
- 13 Xaira Therapeutics. De novo design of progressable antibodies to therapeutic targets, October 2, 2026. Company technical disclosure: XA-1 lead in seven weeks from DNA synthesis with target reagents prepared in advance; XA-4 antagonists at a difficult GPCR. Preclinical and company-reported.
[Source](#)
- 14 Lila Sciences. Inside Lila's RNA discovery engine, August 28, 2026. More than 950,000 mRNA sequences designed, built and tested; selected constructs advanced to animal studies. Company-reported preclinical work.
[Source](#)
- 15 BioNTech. Completion of the Biotheus acquisition, February 3, 2025; BioNTech and Bristol Myers Squibb global partnership for BNT327, June 2, 2025. China-origin innovation reaching global development; investigational asset.
[Biotheus acquisition](#) · [BNT327 partnership](#)
- 16 Reuters. China biotech licensing boom to hit record in 2026 as pipeline swells, February 13, 2026, citing PharmCube. The \$137.7 billion figure covers Greater China and headline terms including potential milestones; not independently audited.
[Source](#)
- 17 FDA. Approved Cellular and Gene Therapy Products, reviewed September 2026, supports the cell and gene therapy examples. FDA's 2022 Amvuttra label describes an RNA-interference medicine; NCI's blinatumomab entry describes a bispecific T-cell engager. Protein degradation is illustrated in notes 20 and 21. These sources establish modality examples, not commercial scale.
[Cell and gene list](#) · [RNA label](#) · [Bispecific example](#)
- 18 FDA. Approval of pembrolizumab and berahyaluronidase alfa-pmrh (Keytruda Qlex) for subcutaneous use, September 19, 2025. A delivery-format example.
[Source](#)
- 19 Eisai and BioArctic. FDA approval of Leqembi Iqlik subcutaneous autoinjector as a starting dose for early Alzheimer's disease, July 13, 2026. Home administration does not remove selection or safety-monitoring requirements.
[Source](#)

- 20 FDA. Approval of vepdegestrant (Veppanu) for ESRI-mutated advanced breast cancer with Guardant360 CDx as companion diagnostic, May 1, 2026. Median PFS 5.0 versus 2.1 months on fulvestrant.
[Source](#)
- 21 Arvinas. Second-quarter 2026 results, August 4, 2026. The company describes Veppanu as the first FDA-approved PROTAC (heterobifunctional) protein degrader. Arvinas and Pfizer licensed exclusive global development, manufacturing, and commercialization rights to Rigel.
[Source](#)
- 22 FDA. Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products. Final guidance, August 2023. Requirements for specific uses, not blanket acceptance. FDA guidance concerns regulatory decisions, not payer or pathway acceptance.
[Source](#)
- 23 Servais L, et al. Evidentiary basis of the first regulatory qualification of a digital primary efficacy endpoint. Scientific Reports, 2024; EMA qualification 2023. SV95C qualified in a defined Duchenne context, not a general endorsement of wearable data. The EMA opinion qualifies the outcome measure in a specified context, not a particular wearable device.
[Study](#) · [EMA opinion](#)
- 24 FDA. CDER drug approvals that used real-world evidence. Agency record reviewed October 2, 2026. Prograf lung-transplant indication, July 2021, supported by a transplant-registry study.
[Source](#)
- 25 CMS. Negotiated prices for 15 additional Part D drugs effective 2027, November 25, 2025, and IPAY 2027 fact sheet. The semaglutide group is listed at \$274 for a 30-day supply against a 2024 list price (WAC) of \$959. The comparison is not with the prior net price. CMS also published first-cycle prices effective 2026.
[Announcement](#) · [2027 price table](#)
- 26 White House. Fact sheet on the GENEROUS Medicaid payment model, September 18, 2026. Announces rebates from participating manufacturers so all 50 state Medicaid programs can access MFN-level prices; the release does not establish completed implementation. The \$64.3 billion decade saving is an administration estimate.
[Source](#)
- 27 CMS. GLOBE finalized September 30, 2026; final rule published October 2 and effective November 30. Selected Part B drugs and areas covering about 25 percent of Original Medicare beneficiaries. Data collection begins January 2027; performance runs April 2027 to March 2032, with payment through March 2034. CMS intends quarterly participation waivers for manufacturers participating in GENEROUS. As of October 5, 2026, GUARD remained proposed, with its final rule under OMB review.
[GLOBE](#) · [GUARD](#) · [OMB review](#) · [Final rule](#)
- 28 NHS England. Antimicrobial products subscription model: guidance on commercial arrangements, 2024. Annual payment based on value to the health service, delinked from volume; not contingent on individual patient outcomes.
[Source](#)
- 29 FDA. cmAngio V1.6, K250754, April 10, 2025; V2.0, K260980, July 30, 2026. The V1.6 documentation describes assistance in detecting and localizing incidental breast arterial calcification, not an authorized cardiovascular-risk estimate. Iribarren C, et al. Circ Cardiovasc Imaging. 2022;15:e013526, separately studies its association with cardiovascular risk in postmenopausal women.
[V2.0 record](#) · [V1.6 indication](#) · [Clinical association](#) · [V2.0 indication](#)
- 30 FDA. De Novo authorization DEN240047, Allix5 (marketed as Clarity Breast), May 30, 2025. Estimates five-year breast-cancer risk from screening mammograms; explicitly not a cancer diagnosis.
[Source](#)
- 31 Everlywell. Clarity Breast cancer 5-year risk assessment, product page and October 1, 2026 launch release. Company-announced nationwide, clinician-ordered launch; product page lists \$249 self-pay and says availability varies by state.
[Product page](#) · [Launch release](#)
- 32 Utah Department of Commerce. Doctronic renewal pilot announcement, January 6, 2026, and Office of AI Policy pilot page. The undated status describes Phase 1, requiring licensed-practitioner authorization for each renewal; the last listed public report is May 19, 2026. Direct-to-pharmacist renewal requires state approval. No new prescriptions or treatment-plan changes are permitted in this pilot. The stated term is October 2025 to October 2026; no dated notice confirms its October phase or renewal.
[Announcement](#) · [Pilot conditions](#)
- 33 FDA. Clinical Decision Support Software, final guidance, January 2026, and town hall, March 11, 2026. Non-device criteria are function-specific; not blanket approval of clinical AI.
[Source](#)
- 34 Included Health. July 28, 2026 Firefly acquisition agreement and October 1, 2026 Included Health Plans launch. The October release describes Firefly as embedded in Included Health; it does not state the exact closing date. Firefly's earlier figures of more than 20,000 people served and a 15 percent reduction in total care cost against a risk-adjusted benchmark are company-reported, not independently established care benefits.
[July announcement](#) · [October update](#)
- 35 CMS. 2026 Medicare Accountable Care Organization Initiatives Participation Highlights, February 4, 2026. An estimated 14.3 million beneficiaries, compared with 13.7 million a year earlier.
[Source](#)
- 36 UK Government. 10 Year Health Plan for England, July 3, 2025. Three shifts: hospital to community, analogue to digital, sickness to prevention. Policy direction, not completed transformation.
[Source](#)

- 37** FDA. Accelerated approval of fam-trastuzumab deruxtecan-nxki for unresectable or metastatic HER2-positive (IHC3+) solid tumors, April 5, 2024. Previously treated patients with no satisfactory alternative.
[Source](#)
- 38** GSK. Nucala approved by US FDA for adults with inadequately controlled COPD and an eosinophilic phenotype, May 22, 2025. Company-reported approval.
[Source](#)
- 39** KFF. Health Information and Trust Tracking Poll, March 25, 2026. n=1,343 U.S. adults, fielded February 24 to March 2. Past-year health-AI use: 32 percent; comparing physical-health treatments: 19 percent; privacy concern: 77 percent. Measures differ from Pew and should not be read as one series.
[Source](#)
- 40** OpenAI. Health in ChatGPT, July 23, 2026. More than 300 million people weekly is a global company figure; record connection is a permission-based, company-reported rollout.
[Source](#)
- 41** 21 CFR 312.7(a). Promotion of investigational drugs. Restricts preapproval promotion while preserving scientific exchange. Not an AEO-specific exemption.
[Source](#)
- 42** WHO. WHO recommends injectable lenacapavir for HIV prevention, July 14, 2025.
[Source](#)
- 43** CDC. Recommendation for injectable lenacapavir for HIV pre-exposure prophylaxis. MMWR, September 18, 2025.
[Source](#)
- 44** CMS. WISer model, 2026 to 2031. Original Medicare, six states, selected services; technology-assisted review with licensed clinical review for non-payment recommendations. Not a drug-formulary model.
[Source](#)
- 45** CMS. Cell and Gene Therapy Access Model, frequently asked questions. Current program page reviewed October 2, 2026: 32 participating states plus the District of Columbia and Puerto Rico; outcomes-based agreements for Casgevy and Lyfgenia. The July 2025 announcement cited 33 states and is historical.
[Current program FAQ](#) · [Historical announcement](#)
- 46** uniQure. AMT-130 regulatory updates, November 3 and December 4, 2025; March 2, June 17, and September 2, 2026. The sponsor first reported doubt that externally controlled phase 1/2 data could be primary evidence; its December and March accounts of FDA minutes confirmed that position. In June it reported that the three-year analysis would be acceptable as the primary basis for an accelerated-approval BLA, with confirmatory-study alignment sought. It announced submission on September 2. These are sponsor accounts of FDA interactions, not public FDA decisions. Submission does not establish acceptance for filing or approval.
[November 2025](#) · [December minutes](#) · [March minutes](#) · [June update](#) · [September submission](#)
- 47** CVS Health. Fourth-quarter and full-year 2025 results, February 2026. \$5.7 billion goodwill impairment in the Health Care Delivery reporting unit. A counter-signal on economics, not proof that integrated care fails.
[Source](#)
- 48** Vafai SB, et al. In Vivo Base Editing of PCSK9 with VERVE-102 for Hypercholesterolemia. N Engl J Med. 2026;395:648-659. Published May 25, 2026. Phase 1, 35 participants, single infusion; mean LDL reduction was 62 percent in the highest-dose cohort. Reductions appeared durable through follow-up; 15 participants had at least one year. Sponsor-funded study; not an approval, cardiovascular-outcomes trial, or cost finding.
[Publisher](#) · [PubMed abstract](#)
- 49** Vertex Pharmaceuticals. Fourth-quarter and full-year 2025 results, February 12, 2026. 147 first cell collections and 64 Casgevy infusions globally in 2025. Separate annual flows, not a conversion rate.
[Source](#)
- 50** Washington Legislature. SB 5395, chapter 157, Laws of 2026, signed March 23, 2026; generally effective June 11, with sections 3 and 7 effective January 1, 2027. Includes licensed review of relevant prior-authorization denials and permits certain AI processing and approvals. Companion March 25 explanation is from Sen. Tina Orwall, Washington Senate Democrats.
[Orwall release](#) · [Session law](#)
- 51** Colorado General Assembly. SB 26-189, Automated Decision-Making Technology, 2026; requirements from January 1, 2027. Covers consequential decisions across specified domains. Covered employers face notice, explanation, and human-review duties, the latter where commercially reasonable. HIPAA-covered entities and business associates have an exemption subject to statutory conditions; compliant insurers are deemed compliant. See section 6-1-1708.
[Bill record](#) · [Session law](#)
- 52** White House. Executive Order 14365, Ensuring a National Policy Framework for Artificial Intelligence, December 11, 2025. Directs challenges to certain state AI laws; does not itself nullify them.
[Source](#)
- 53** CMS. First wave of Health Tech Ecosystem tools, April 9, 2026. Pledges and initial tools, not universal operational interoperability or external data rights.
[Source](#)
- 54** Vorontsov E, et al. A multimodal foundation model for longitudinal patient representation and scalable insight generation in oncology. arXiv 2608.24688, August 25, 2026. Tempus-associated research on a 1.67-million-patient cohort; retrospective, not clinical utility.
[Source](#)
- 55** FDA. FDA clears first blood test used in diagnosing Alzheimer's disease, May 16, 2025. Lumipulse, for symptomatic patients in specialized care; not population screening.
[Source](#)

- 56** FDA 510(k) K261686, Elecsys Phospho-Tau (217P) Plasma: decision August 19, 2026; Roche announcement August 24. FDA's indications cover amyloid-pathology assessment in adults 55 and older with cognitive decline, alongside other clinical information, without specifying a care setting. Primary- and specialty-care use is Roche's framing. The FDA decision summary notes lower positive predictive value in low-prevalence primary care and the need for clinical assessment; this is not stand-alone diagnosis or asymptomatic screening. [FDA record](#) · [Decision summary](#) · [Roche announcement](#)
- 57** Novartis. Lp(a)HORIZON phase III topline results for pelacarsen, September 4, 2026. Lp(a) was lowered; the primary cardiovascular endpoint was not met. Sponsor topline; full results pending. [Source](#)
- 58** Google Search Central. AI features and your website. Guidance for Google AI Overviews and AI Mode: standard search fundamentals apply, with no special markup or guaranteed inclusion. Supports web accessibility, not the report's broader strategic AEO recommendations or clinical-tool governance. [Source](#)
- 59** THRIVE Consulting. December 2025 scenario set and PHLEX London workshop, presented at the Pharmaceutical Launch Excellence Summit, London, December 1, 2025.
- 60** Courneya KS, et al. Structured Exercise after Adjuvant Chemotherapy for Colon Cancer. *N Engl J Med.* 2025;393:13-25. Published online June 1, 2025. CHALLENGE randomized 889 patients after surgery and adjuvant chemotherapy to three years of structured exercise or health-education materials. Disease-free survival was primary; overall survival was secondary, with findings consistent with longer survival. The studied population was stage III or high-risk stage II colon cancer, not all cancers. [Trial abstract](#)
- 61** Chan KKW, et al. Structured Exercise Program After Adjuvant Chemotherapy for Colon Cancer: A Cost-Utility Analysis of the CHALLENGE Trial. *J Clin Oncol.* 2026;44:2130-2139. Published online May 31, 2026. Canadian public-payer base case: five years, 1.5 percent discounting, 2024 Canadian dollars. Program cost C\$2,917 per participant; total direct healthcare cost C\$1,589 lower per participant, already including program cost. Both more effective and less costly in 53 percent of bootstrap samples; below C\$50,000 per quality-adjusted life-year in 80 percent. Not U.S. plan economics. [Economic analysis](#)
- 62** Agrawal N. It Can Keep Cancer in Remission. Why Is No One Talking About It? *The New York Times*, October 6, 2026. Reports planned 2027 exercise-oncology coverage for breast cancer patients in UPMC's employee health plan, not universal coverage or an outcome-contingent payment contract. UPMC describes its individualized in-person and virtual service. The planned benefit is reported journalism, not a reviewed benefit document. [Article](#) · [UPMC service](#)
- 63** FDA. Application of Human Factors Engineering Principles for Combination Products: Questions and Answers. Final guidance, September 2023, Q3-Q8. Addresses the complete combination product and its user interface, including packaging, labeling and training where applicable; nonbinding guidance, not a universal training mandate. [FDA guidance](#).
- 64** FDA. Approval of gemcitabine intravesical system (INLEXZO), September 9, 2025; prescribing information, September 2025, §§1-2. Indicated for adults with BCG-unresponsive non-muscle-invasive bladder cancer with carcinoma in situ, with or without papillary tumors. Each system remains in place for three weeks; trained providers insert and remove it. [FDA approval announcement](#); [FDA prescribing information](#).
- 65** Delcath Systems. U.S. launch and first commercial treatment using HEPZATO KIT, January 16, 2024. Company-reported launch, not the original approval date. FDA-hosted Hepatic Delivery System instructions, 2024 label file, pp. 4-7, document REMS certification, team training and specified extracorporeal equipment. [Delcath launch announcement](#); [FDA-hosted system instructions](#).
- 66** FDA. ONAPGO, NDA 214056, Summary Review; final review signed January 31, 2025. Background, Product Quality and CDRH discussion document the April 5, 2024 complete response letter, including device performance-testing deficiencies and separate drug-product quality concerns. The final review found the resubmitted device information acceptable. [FDA summary review](#).
- 67** Supernus Pharmaceuticals. FDA approval of ONAPGO (apomorphine hydrochloride), February 4, 2025. Approved for motor fluctuations in adults with advanced Parkinson's disease. Company announcement describes nurse education and access support planned for launch; it does not independently establish successful implementation or coverage. [Supernus approval announcement](#).
- 68** West Pharmaceutical Services. Agreement to sell SmartDose 3.5 mL manufacturing and supply rights and associated facilities to AbbVie, January 12, 2026; completion reported July 1, 2026. Company-reported transaction; other SmartDose versions remained with West. The transaction establishes selective internalization, not proof that ownership improves performance or that bottleneck removal was AbbVie's stated motive. [West agreement announcement](#); [West completion announcement](#).

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