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Multidisciplinary Process for the Review of Existing & Emerging Biosimilars

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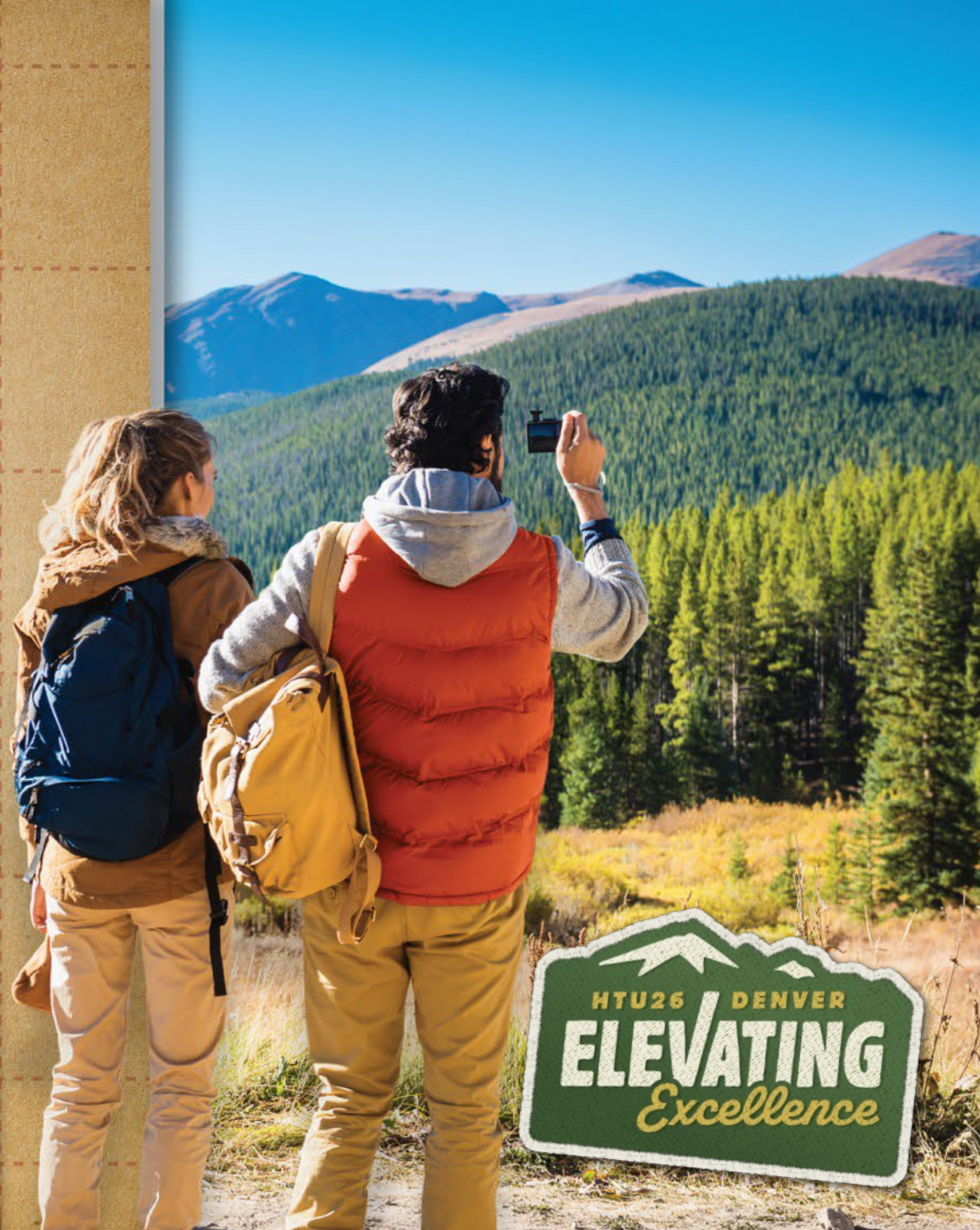
CE Deadline: 08/31/26



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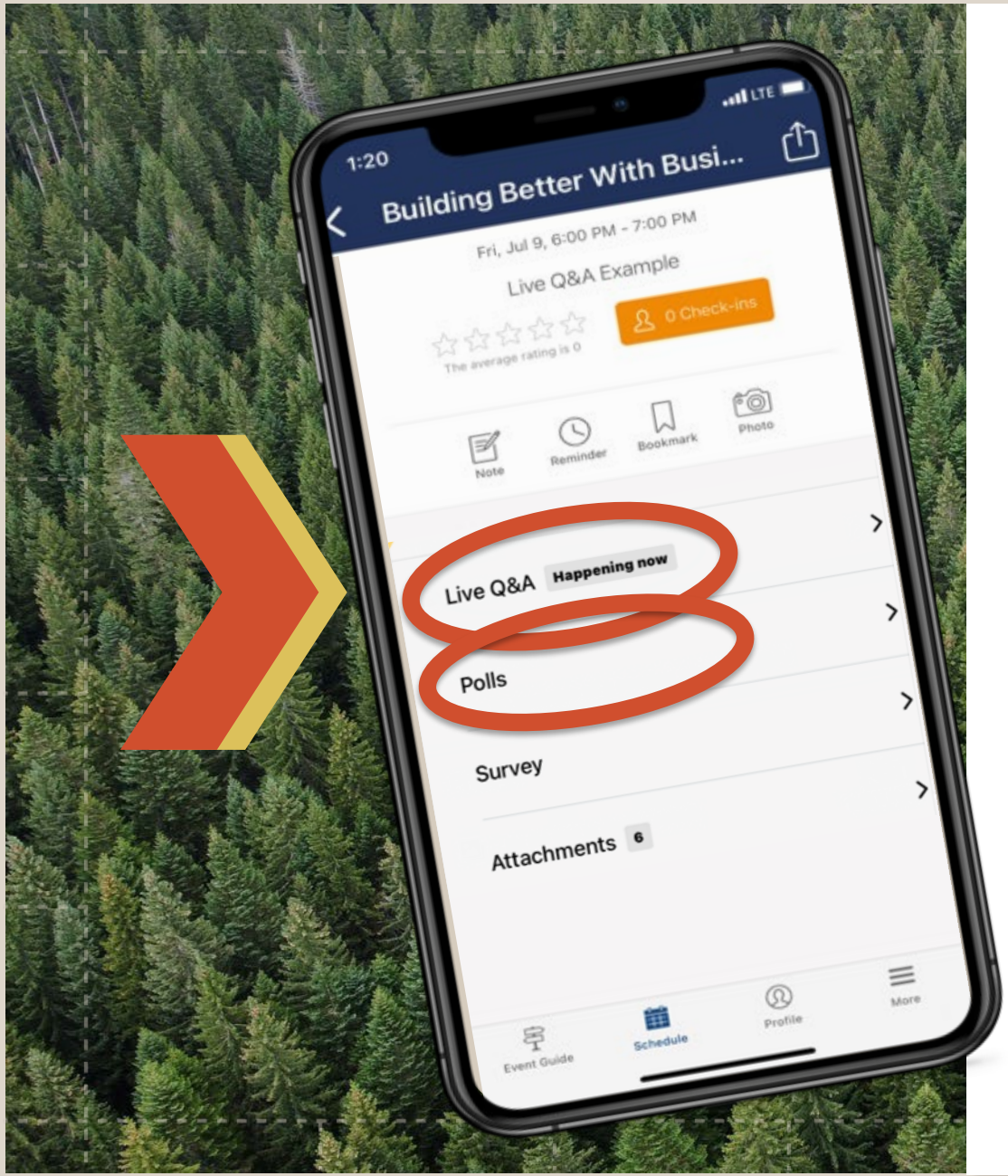

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Multidisciplinary Process for the Review of Existing & Emerging Biosimilars

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Scripps Health

CE Deadline: 08/31/26

Disclosures

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Learning Objectives

At the end of this session, participants should be able to:

- Identify work group team members critical for a successful multidisciplinary biosimilar review process.
- Recognize required task delegation to team members based upon their expertise.
- Recall some of the tools available for biosimilar clinical and financial comparisons.

Outline

Scripps at a Glance	Sherrie Todd
What is a Biologic?	Angela Rosenblatt
From Science to Strategy	Sherrie Todd
From Decision to Go Live	Angela Rosenblatt
Real-life Example	Sherrie Todd

About Scripps Health

Scripps

$5 BILLION
IN REVENUE

18,500
EMPLOYEES

3,500
PHYSICIANS
2,000 IN INDEPENDENT PRACTICE

Tax-exempt, Integrated Health Care System in San Diego, California

Operating two of the three Level 1 trauma centers in SD – of six total

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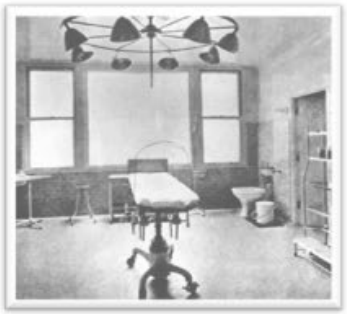
Scripps | 100 YEARS OF CARING

HISTORICAL LEGACY

Miss Ellen Browning Scripps

Scripps Memorial Hospital & Metabolic Clinic, 1924



Mother Mary Michael Cummings & Sisters Of Mercy

St. Joseph's Hospital, 1890
Named Mercy Hospital, 1924

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- Throughout San Diego County
- From the upper north to near the border of Mexico

What is a biologic?

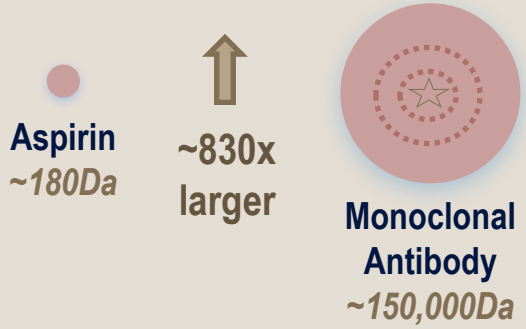
- Biologics are **complex, large-molecule proteins** derived from living cells—bacteria, yeast or mammalian cell lines. Unlike traditional drugs made through chemical synthesis, biologics are manufactured through biological processes.

Monoclonal Antibodies **Insulins** **Growth Factors** **Vaccines** **Gene Therapies**

~2% of U.S. Prescriptions → **~46%** of Total Drug Spend

$$$$$$$$$

MOLECULAR SCALE



Biologics are far too large and complex to replicate through simple chemical synthesis

Source: IQIVA Institute. Biosimilars in the United States 2023–2027: Competition, Savings, and Sustainability. January 2023

What Is a Biosimilar?

A biosimilar is **highly similar** to an already-approved reference (originator) product with **no clinically meaningful differences** in safety, purity, potency.

Highly Similar

Not identical, but with no clinically meaningful differences in safety, purity or potency compared to the originator biologic.

01

Same Mechanism

Shares the same mechanism of action, route of administration, dosage form and strength as the reference product.

02

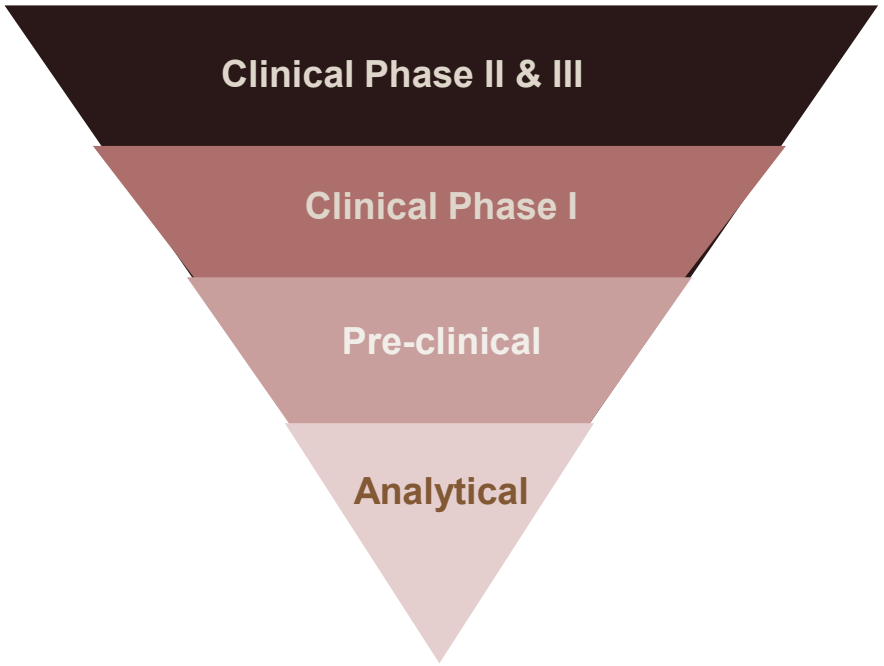
Rigorous Testing

Requires extensive analytical, functional and clinical comparability studies before FDA approval can be granted.

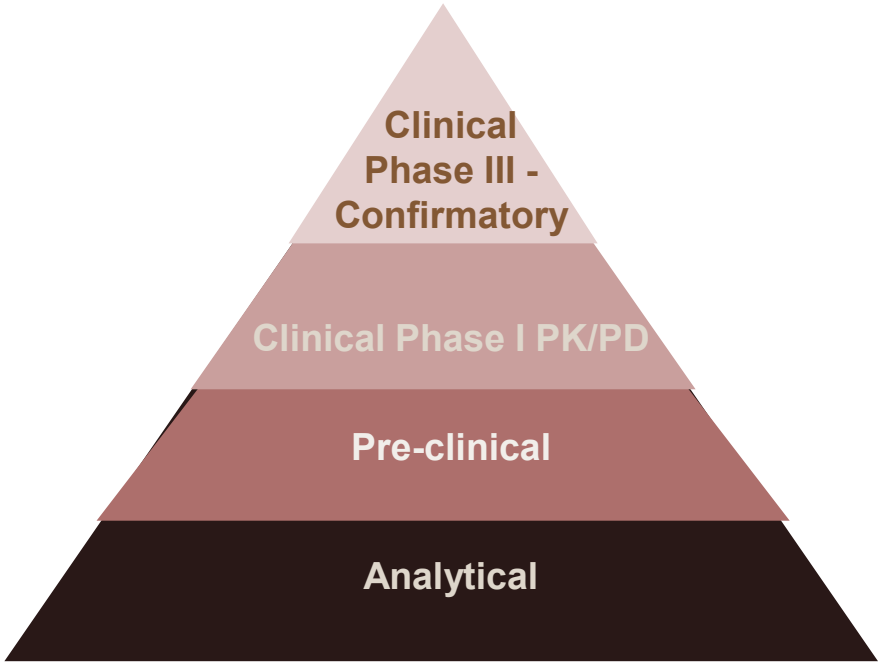
03

Source: FDA. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product. Guidance for Industry, April 2015

FDA Standpoint: Totality of the Evidence



Reference Medicine Development
Main goal is to determine the clinical effect for each indication (standard 351a regulatory pathway)



Biosimilar Development
Main goal is to establish similarity to reference medicine (standard 351k regulatory pathway)

Source: Cohen HP. Eng Development & Policy. 2018.

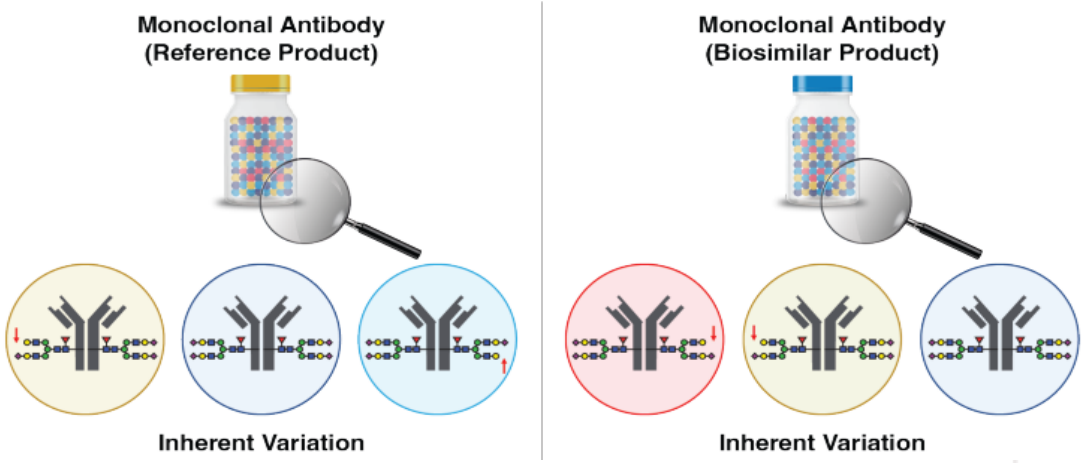
One of These Things is not Like the Other

Biologic variability means no two batches—even of the same product—are identical. Biosimilars are held to the same quality standards as the reference biologic.

Source: https://www.timeout.com/newyork/things-to-do/nycs-best-television-shows-the-top-25-gotham-series

The Originator Isn't Even Identical to Itself

- Living cell manufacturing produces inherent molecular micro-heterogeneity in every batch
- Originator products drift over time as manufacturers make process changes – no two batches or lots are identical
- FDA requires manufacturers to demonstrate consistency within an acceptable range of variability
- Biosimilars must fall within this same range of acceptable variability



- Every lot of a biologic—even the originator—varies slightly.
- Biosimilars must fall within this same natural range.

Source: FDA Biosimilars Info Sheet, Level 2: Regulatory and Scientific Concepts — "Variation in Biological Products." Available at www.fda.gov/biosimilars.

Why Everyone Gets Confused at First

The Terminology Trap

- Biosimilar ≠ Bio-identical ≠ Interchangeable
- FDA approval ≠ Formulary approval
- Every payer has different rules

The Process Puzzle

- Naming conventions are a puzzle (INN + suffix)
- Extrapolation of indications is counterintuitive
- Switching vs. transitioning vs. interchange

That’s exactly why Scripps built a structured workgroup to sort it all out!

Generics vs. Biosimilars

Category	Generic Drugs	Biosimilars
Similarity standard	**Identical** active ingredient (bioequivalent to reference drug)	**Highly similar** – no clinically meaningful differences in safety, purity or potency
Manufacturing	Chemical synthesis – reproducible, identical copies	Biological manufacturing – inherent batch-to-batch variability
Approval pathway	Hatch-Waxman Act	351(k) pathway
Substitution	Automatic (AB-rated) – pharmacy level substitution standard	Requires interchangeability
Regulatory trend	Mature, well-established framework	Evolving – FDA considering streamlines interchangeability standard

Interchangeable biosimilars **CAN** be substituted at the pharmacy level without prescriber intervention, similar to generics. As of 2025, the FDA is re-evaluating interchangeability requirements to further streamline biosimilar access.

Source: FDA. *Questions and Answers on Biosimilar Development and the BPCI Act.* Guidance for Industry, Rev. 3, March 2026. www.fda.gov/biosimilars.

Interchangeability: What it Means vs. What's Changing

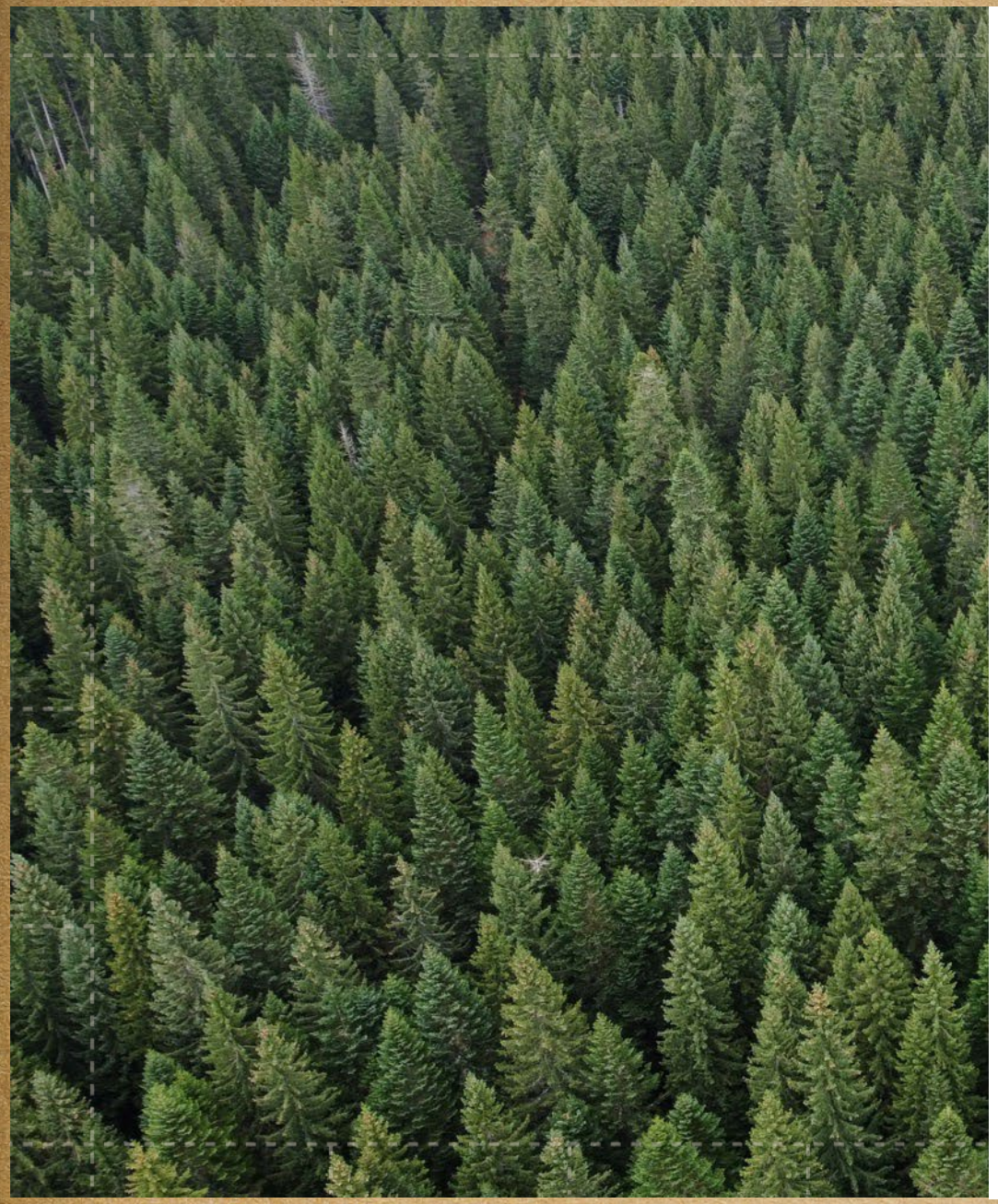
What Interchangeability Means Today

- Allows pharmacy-level substitution (state law permitting)
- Requires switching studies showing no impact on safety or efficacy
- Unique to the U.S
  - 47 states allow substitution
  - EU: member states decide; no extra testing
  - Japan and Iran: automated substitution
  - 24 interchangeable biosimilars approved in the U.S.

What's Changing

- October 2025 FDA Draft Guidance
  - May eliminate comparative efficacy studies
  - May remove switching study requirements
- March 2026 Draft Q&As
  - Updated scientific expectations
  - Signals streamlined pathway
- Implication: Interchangeability may become easier to achieve and less distinct from standard biosimilarity

Source: Pharmaceutical Innovations & Novel Drug Approvals with Implications on Health System Practice; Health Trust presentation 4/2/2026



From Science to Strategy

How Scripps Health Built a Multidisciplinary Biosimilar Review Process

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Why a multidisciplinary review?

Biosimilar evaluation requires cross-functional expertise—not just pharmacy.

Clinical Complexity

Biosimilars require scientific evaluation beyond simple therapeutic equivalence—analytical, functional and immunogenicity data demand expert review.

Financial Impact

Significant cost implications for drug spend, reimbursement rates, 340B program savings and payer contract negotiations.

Operational Readiness

EMR order set builds, inventory management, nursing workflows and infusion center logistics all require coordination.

Stakeholder Alignment

Physician buy-in, patient communication and staff education are essential for successful adoption and trust.

Regulatory Navigation

Payer mandates, interchangeability status and prior authorization requirements vary widely and demand specialized knowledge.

Source: Berkowitz SA, et al. Analytical tools for characterizing biopharmaceuticals. Nat Rev Drug Discov. 2012; ASHP Guidelines on Formulary Management, 2023

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Committee Makeup & Governance

Clinical Team

Therapeutic area expertise, evidence review, clinical evaluation

Director of Pharmacy Purchasing

Procurement strategy, vendor management, contract negotiation, 340B impact

Pharmacy Operations

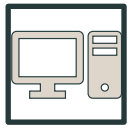
Workflow coordination, implementation logistics, day-to-day operations

Finance

Cost modeling, reimbursement analysis, payer impact and contracts

Prior Authorization Team

Authorization workflows, coverage landscape



Informatics

EMR build, order sets

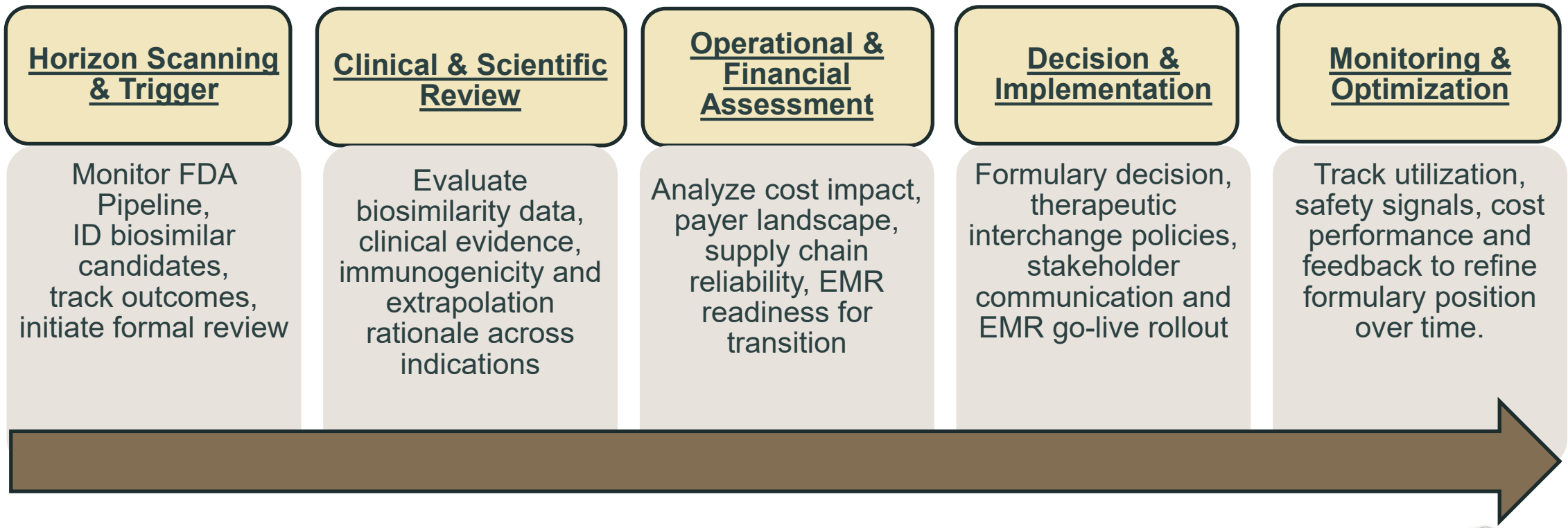
Reports to: Pharmacy & Therapeutics (P&T) Committee

Meeting Cadence: Quarterly or as triggered by pipeline events

Decision Framework: Consensus-based → P&T recommendation and approval

Scripps Biosimilar Review Workflow

A Structured Framework From Identification to Optimization



Horizon Scanning & Trigger

PHASE 1

- Monitor FDA Biosimilar Pipeline
  - Track anticipated approval dates, landscape
- Identify Emerging Competition
  - Flag therapeutic categories with growing biosimilar options
  - Review HealthTrust landscape tools
- Assess Payer Signals and Market Intel
  - Evaluate early payer coverage decisions, reimbursement trends and commercial mandates

Deliverables:

- Pipeline Tracking Report
- Trigger Notification: Alert to Biosimilar Review Committee when trigger criteria are met

Responsible Parties:

- Director of Purchasing
- Clinical team

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Clinical & Scientific Review

PHASE 2

- Review FDA approval package
  - Analytical, functional, clinical biosimilarity data
- Evaluate totality of evidence
- Assess immunogenicity data and switching studies
- Review real-world evidence and post-marketing safety surveillance data
- Compare biosimilar candidates within the therapeutic class
- Review HealthTrust tools – biosimilar and payer landscape

Deliverables:
- Clinical Review Summary
- Recommendation to Committee

Responsible Parties:
- Clinical team
- Pharmacy operations

Operations & Financial Assessment

PHASE 3

- Pharmacoeconomic Analysis
  - Acquisition cost, reimbursement modeling, 340B program impact, total cost of care assessment
- Contract Management Assessment
- Infusion Center/Clinic Workflow Evaluation
- Payer Landscape Mapping
- Electronic Medical Record (EMR) Readiness Evaluation

Deliverables:
- Financial impact model
- Operational readiness checklist
- Payer coverage matrix

Responsible Parties:
- Director of Purchasing
- Finance
- PA team
- Pharmacy operations
- Informatics

Decision & Implementation

PHASE 4

From committee recommendation to clinical go-live

- Prepare and present recommendation to P&T Committee → formulary decision
  - Including therapeutic interchange protocols, if needed
- Develop and execute stakeholder communication plan (physicians, pharmacists, operators, nursing, patients)
- Build and validate EMR order sets, orderables and clinical decision support
- Staff education

Deliverables:
- P&T decision
- Communication toolkit
- EMR go-live confirmation
- Education materials

Responsible Parties:
- Clinical team
- PA team
- Pharmacy Operations
- Informatics

Tools that Support Biosimilar Clinical, Financial & Operational Review

- Clinical Tools:
  - GPO Monographs
  - Comparative Evidence Summaries
- Financial Tools:
  - GPO pricing dashboards
  - Published CMS ASP rates
  - Patient billing and revenue tools
  - 340B ceiling price database
- Operational Tools:
  - EMR order set build tools
  - Patient identification reports
  - Workflow mapping
- Payer Tools:
  - Payer landscape tools
  - PA requirement databases
  - Denial/appeal analytics

FROM DECISION TO GO-LIVE

90-day Implementation Roadmap

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Planning Phase – Month 1

Biosimilar Committee

Clinical Coordinator

Monitor biosimilar product availability and reimbursement. Determine biosimilar strategy and scope based on care setting and/or insurance plan.

→ Desired dispensible eRx exists?

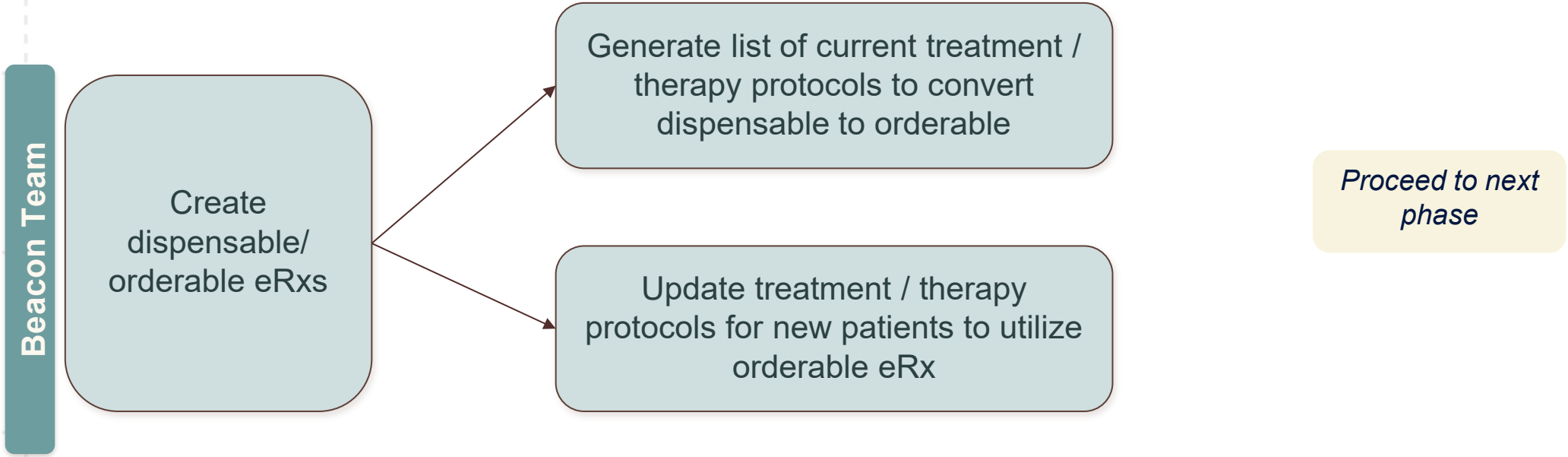
Yes → Orderable eRx exists?

Yes, proceed to next phase

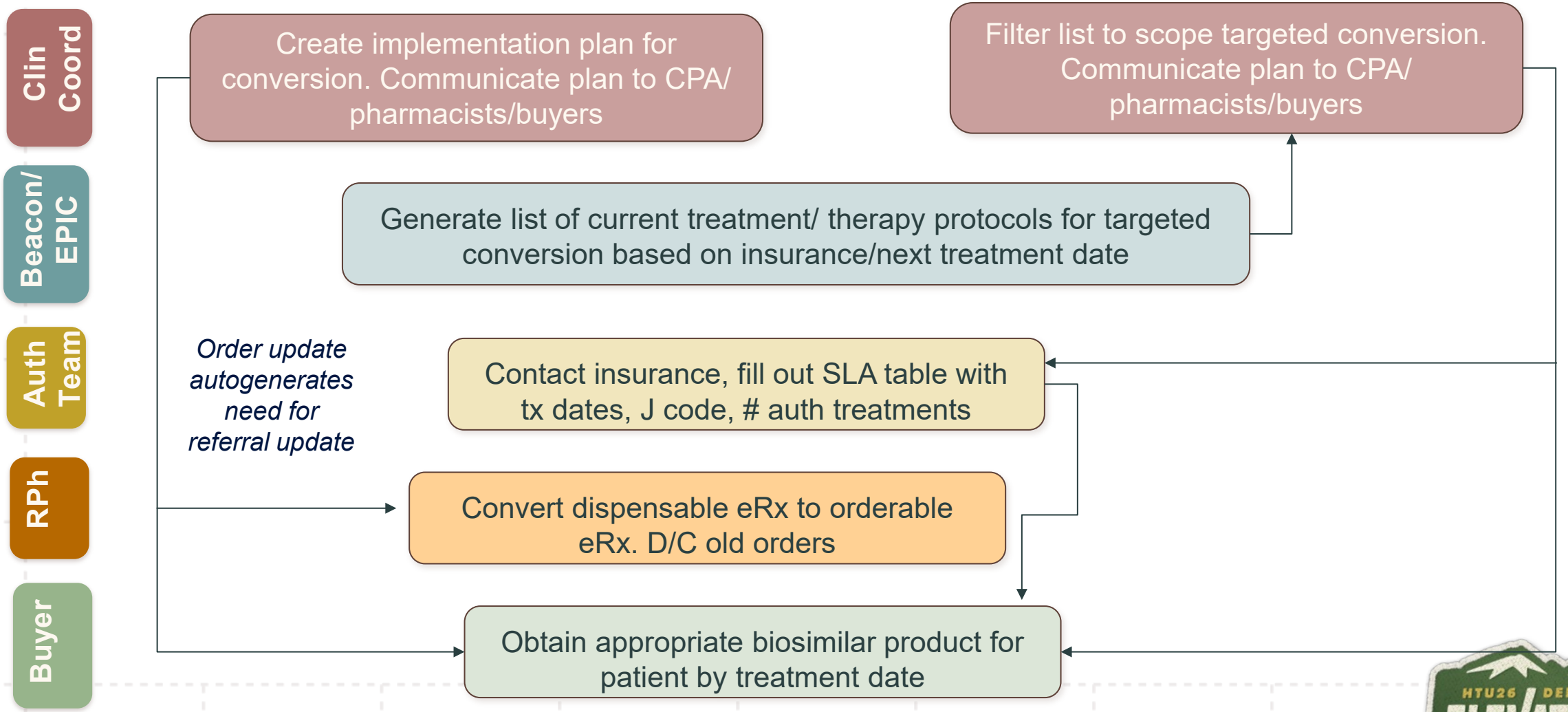
No → Place eRx gatekeeper form for creation of new dispensable eRx

No → Place Beacon Fast Pass for creation of new orderable eRx

Systems Evaluation/ Addressing EHR Build Needs – Month 2



Implementation – Month



Monitoring & Optimization

PHASE 5

Continuous tracking, feedback loops and data-driven formulary refinement

- Track biosimilar utilization rates and conversion metrics
- Analyze financial performance against projected savings targets
- Assess payer reimbursement trends and contract performance
- Adjust formulary position and interchange protocols, as needed

Deliverables:

- Quarterly performance dashboard
- Optimization recommendations

Responsible Parties:

- Clinical team
- Director of Purchasing

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REAL LIFE EXAMPLE

Trastuzumab and its biosimilars

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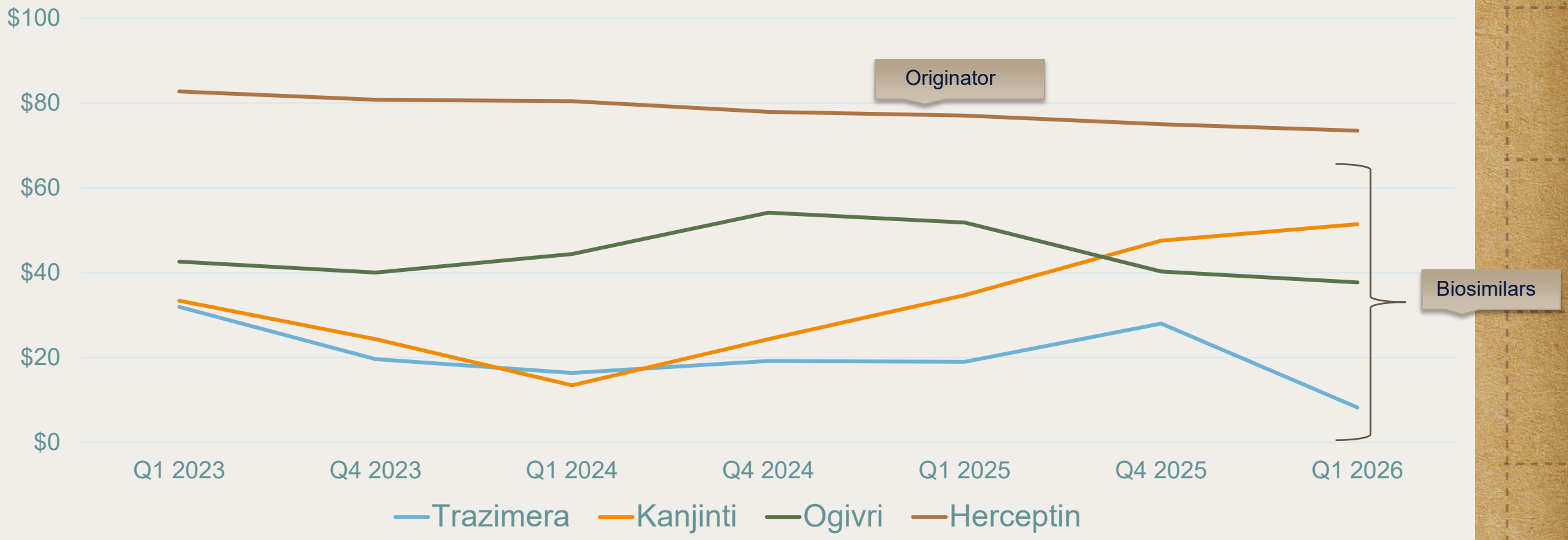
Trastuzumab & Biosimilars - ASP Changes (2023-2026)



One Size Does Not Fit All

Payor?

- Medicare
- Managed Care
- Commercial
- Medi-Cal
- Self-Pay

Settings and Contracts?

- Physician owned
- HOPD
- 340B
- Inpatient

Insurance Coverage Scene

TRASTUZUMAB BIOSIMILAR 2025 -BLUE SHIELD OF CA							
PLAN / Payers	J9355 - HERCEPTIN	Q5116 - TRAZIMERA	Q5117 - KANJINTI	Q5114 - OGIVRI	Q5113 - HERZUMA	Q5112 - ONTRUZANT	Q5146-HERCESSI
Blue Shield of CA		x	x				
https://www.blueshieldca.com/content/dam/bsca/en/provider/auth/BSC-med-benefit-drug-policy/trastuzumab-COMM-UMRx-provider.pdf (STILL DOES NOT INCLUDE CRITERIA FOR THE LATEST BIOSIMILAR HERCESSI)							
TRASTUZUMAB BIOSIMILAR 2025 - BLUE SHIELD MEDICARE							
PLAN / Payers	J9355 - HERCEPTIN	Q5116 - TRAZIMERA	Q5117 - KANJINTI	Q5114 - OGIVRI	Q5113 - HERZUMA	Q5112 - ONTRUZANT	Q5146-HERCESSI
Blue Shield Medicare		X	X				
https://www.blueshieldca.com/content/dam/bsca/en/provider/auth/BSC-med-benefit-drug-policy/trastuzumab-COMM-UMRx-provider.pdf (STILL DOES NOT INCLUDE CRITERIA FOR THE LATEST BIOSIMILAR HERCESSI)							
TRASTUZUMAB BIOSIMILAR 2025- BLUE SHIELD MEDICAID / MEDI-CAL							
PLAN / Payers	J9355 - HERCEPTIN	Q5116 - TRAZIMERA	Q5117 - KANJINTI	Q5114 - OGIVRI	Q5113 - HERZUMA	Q5112 - ONTRUZANT	Q5146-HERCESSI
Blue Shield Medicaid (Promise)		X	X	X	X	X	
https://www.blueshieldca.com/content/dam/bsca/en/provider/auth/Medi-Cal-med-benefit-drug-policy/trastuzumab-MCAL-UMRx-provider.pdf (STILL DOES NOT INCLUDE CRITERIA FOR THE LATEST BIOSIMILAR HERCESSI)							
TRASTUZUMAB BIOSIMILAR 2025 - ANTHEM BLUE CROSS COMMERCIAL							
PLAN / Payers	J9355 - HERCEPTIN	Q5116 - TRAZIMERA	Q5117 - KANJINTI	Q5114 - OGIVRI	Q5113 - HERZUMA	Q5112 - ONTRUZANT	Q5146-HERCESSI
Blue Cross Anthem Commercial	X		X				
https://www.anthem.com/ms/pharmacyinformation/clinicalcriteria/TrastuzumabAgentsStepTherapy.pdf (STILL DOES NOT INCLUDE CRITERIA FOR THE LATEST BIOSIMILAR HERCESSI)							
TRASTUZUMAB BIOSIMILAR 2025 - ANTHEM BLUE CROSS MEDICARE							
PLAN / Payers	J9355 - HERCEPTIN	Q5116 - TRAZIMERA	Q5117 - KANJINTI	Q5114 - OGIVRI	Q5113 - HERZUMA	Q5112 - ONTRUZANT	Q5146-HERCESSI
Blue Cross Anthem Medicar e	X		X				
https://www.anthem.com/ms/pharmacyinformation/clinicalcriteria/TrastuzumabAgentsStepTherapy.pdf (STILL DOES NOT INCLUDE CRITERIA FOR THE LATEST BIOSIMILAR HERCESSI)							
TRASTUZUMAB BIOSIMILAR 2025 - ANTHEM BLUE CROSS MEDICAID							
PLAN / Payers	J9355 - HERCEPTIN	Q5116 - TRAZIMERA	Q5117 - KANJINTI	Q5114 - OGIVRI	Q5113 - HERZUMA	Q5112 - ONTRUZANT	Q5146-HERCESSI
Blue Cross Anthem Medicaid			X				
https://www.anthem.com/ms/pharmacyinformation/clinicalcriteria/TrastuzumabAgentsStepTherapy.pdf (STILL DOES NOT INCLUDE CRITERIA FOR THE LATEST BIOSIMILAR HERCESSI)							

Data was accumulated by the prior authorization team member using payor websites.

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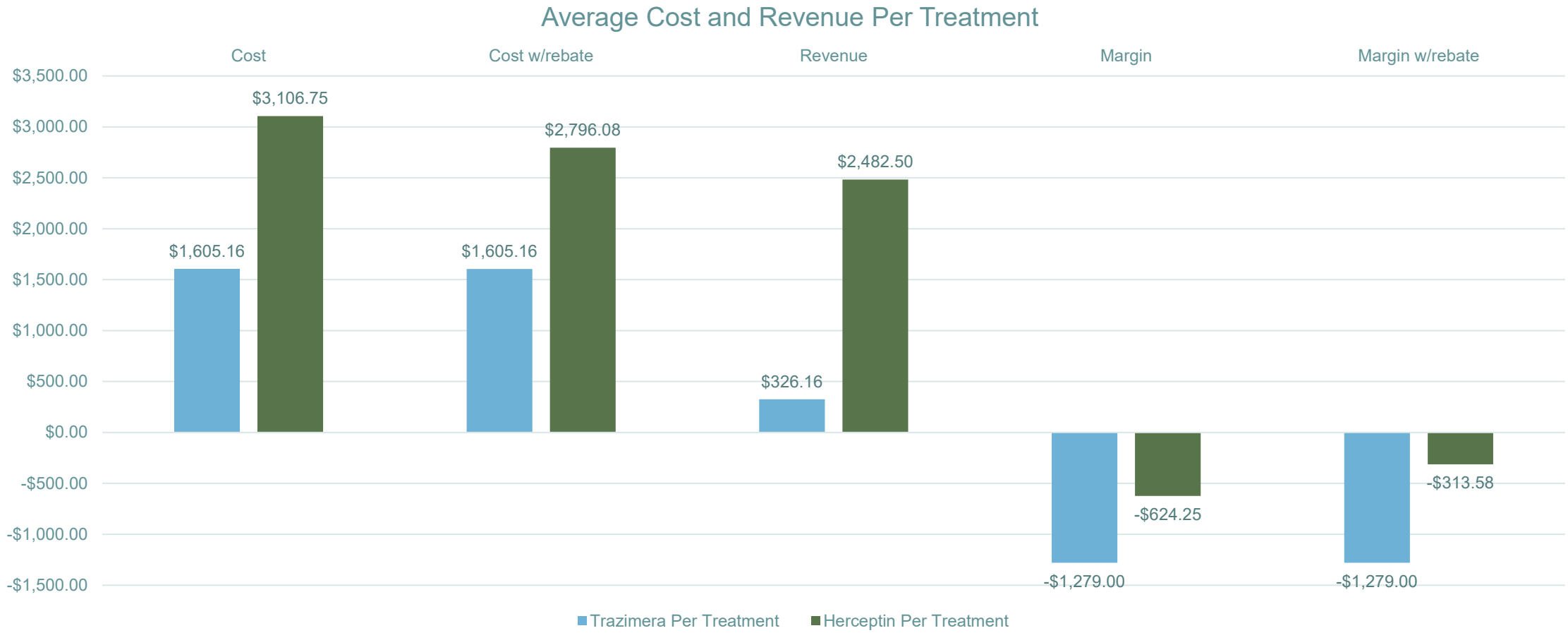
Trastuzumab Clinic Data Dec. 2025 – Feb. 2026

Primary Payer	MEDICARE				
Row Labels	**Sum of Procedure Quantity**	**Sum of Revenue**	**Sum of Total Cost**	**Sum of Net revenue**	**Average of Revenue as Percent of Cost**
Herceptin	510	$36,881.26	$36,740.74	$140.52	100.4%
Trazimera	2516	$20,060.24	$98,853.64	-$78,793.40	19.9%
Grand Total	**3026**	**$56,941.50**	**$135,594.38**	**-$78,652.88**	**33.7%**

Primary Payer	(Multiple Items)				
Row Labels	**Sum of Procedure Quantity**	**Sum of Revenue**	**Sum of Total Cost**	**Sum of Net revenue**	**Average of Revenue as Percent of Cost**
Kanjinti	357	$23,141.42	$31,398.63	-$8,257.21	75.5%
Ogivri	544	$18,650.33	$32,586.33	-$13,936.00	60.6%
Trazimera	2206	$47,179.06	$86,673.74	-$39,494.68	58.3%
Grand Total	**3107**	**$88,970.81**	**$150,658.69**	**-$61,687.88**	**60.8%**

Medicare Patients – Transition From Trazimera to Herceptin



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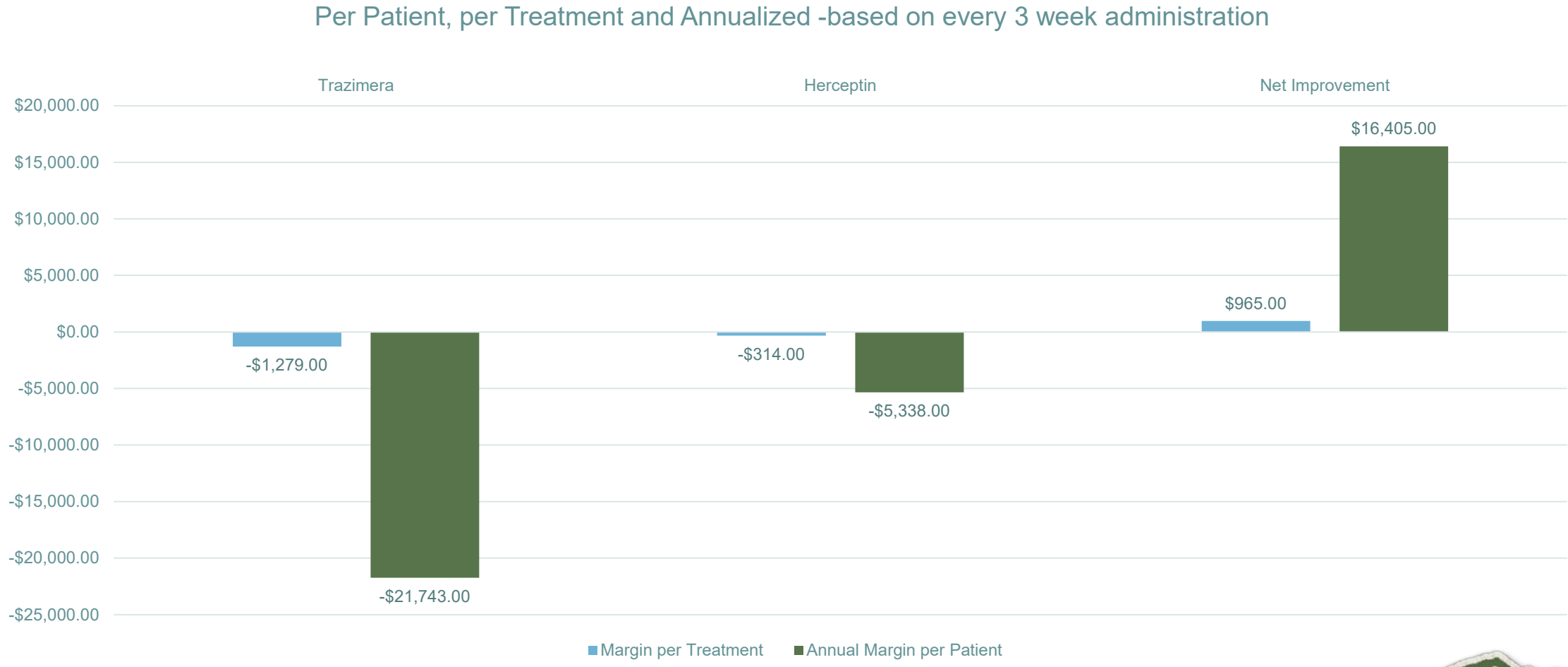
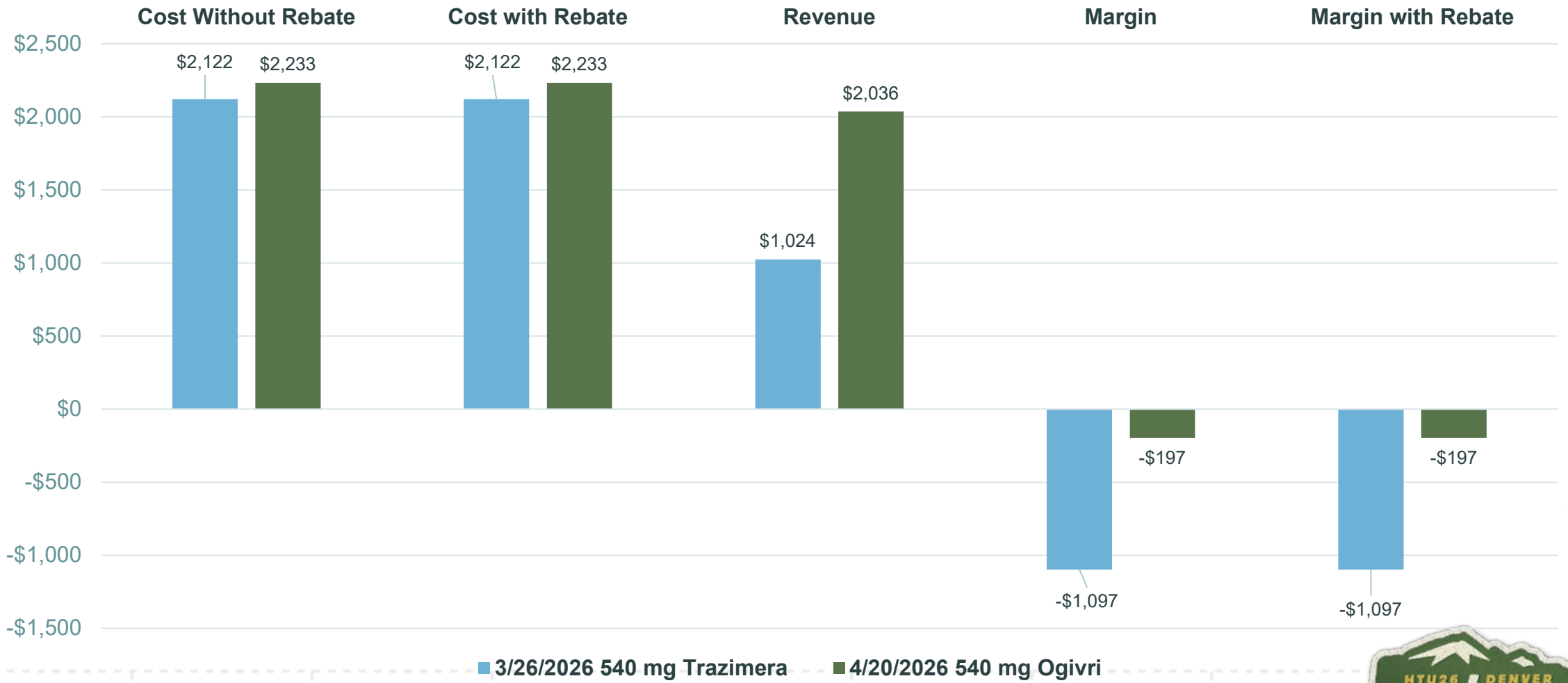
Medicare Patients – Bottom Line
Transition From Trazimera to Herceptin



Source: Scripps Health Internal Data. Not for reuse without permission from Scripps Health.

Medi-Cal Managed Care Patient – Transition From Trazimera to Ogivri



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Committee Decisions to Date

	Medicare		Commercial		Inpatient		340B	
Originator Product Generic	**Preferred**	**Backup**	**Preferred**	**Backup**	**Preferred**	**Backup**	**Preferred**	**Backup**
Bevacizumab	MVASI	Zirabev	MVASI	Zirabev	MVASI	Zirabev	MVASI	Zirabev
Denosumab	Jubbonti	Stoboclo	Jubbonti	Stoboclo	N/A		Jubbonti	Stoboclo
Denosumab	Wyost	Xgeva	Wyost	Xgeva	N/A		Wyost	Xgeva
Epoetin alfa	Retacrit	Procrit	Retacrit	Procrit	Retacrit	Procrit	Retacrit	Procrit
Infliximab	Generic Infliximab		Inflectra	Generic Infliximab	Renflexis		Inflectra	Renflexis
Rituximab	Truxima	Rituxan	Truxima	Rituxan	Ruxience		Ruxience	Truxima
Tocilizumab	Actemra	Tyenne	Actemra	Tyenne	Tyenne		Tyenne	Actemra
Trastuzumab	Herceptin		Ogivri	Trazimera	Kanjinti		Trazimera	Ogivri

Assessment Question 1

Which of the following are critical group members for a successful multidisciplinary biosimilar review process?

A. Supply Chain Logistics and Nursing Education
B. Marketing and Patient Experience
C. Clinical Team, Purchasing, Pharmacy Operations, Finance
D. Credentialing and Medical Staff

Response: Assessment Question 1

A. Supply Chain Logistics and Nursing Education
B. Marketing and Patient Experience
C. Clinical Team, Purchasing, Pharmacy Operations, Finance
D. Credentialing and Medical Staff

Assessment Question 2

Which task is most appropriately delegated to the Informatics team during biosimilar review?

A. Conducting immunogenicity literature review
B. Building and validating EMR order sets and therapy plans
C. Negotiating acquisition cost
D. Completing payer prior authorizations

Response: Assessment Question 2

A. Conducting immunogenicity literature review
B. Building and validating EMR order sets and therapy plans
C. Negotiating acquisition cost
D. Completing payer prior authorizations

Assessment Question 3

Which resource provides clinical monographs and contracting insights to support biosimilar evaluation?

A. FDA Medwatch
B. USP Compounding Standards
C. DEA Controlled Substance Schedules
D. Group Purchasing Organization (GPO) tools

Response: Assessment Question 3

A. FDA Medwatch
B. USP Compounding Standards
C. DEA Controlled Substance Schedules
D. Group Purchasing Organization (GPO) tools

Assessment Question 4

A payer mandates a biosimilar switch but only for patients with commercial insurance. Medicare patients must remain on the reference product. Which team must design the operational workflow?

A. Supply chain
B. Informatics, prior authorization, pharmacy operations
C. Clinical educators
D. Finance

Response: Assessment Question 4

A. Supply chain
B. Informatics, prior authorization, pharmacy operations
C. Clinical educators
D. Finance

Assessment Question 5

A physician questions whether a biosimilar's immunogenicity profile is appropriate for a specific patient population. What team is responsible for reviewing and validating the clinical evidence?

A. Informatics
B. Pharmacy Operations + PA Team
C. Supply chain + nursing
D. Clinical team

Response: Assessment Question 5

A. Informatics
B. Pharmacy Operations + PA Team
C. Supply chain + nursing
D. Clinical team

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