2023 HEALTHTRUST UNIVERSITY CONFERENCE

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To Switch or Not To Switch: Successful Pharmacist-led Biosimilar Utilization

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HEALTHTRUST® UNIVERSITY CONFERENCE

Meet the Presenters

Sarah Hogue, PharmD
Director Oncology Pharmacy
St. Luke's Health System

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Director, Infusion Services Pharmacy
St. Luke’s Health System

Katie Vuong, PharmD, BCPS
Senior Director of Clinical Pharmacy Services
St. Luke’s Health System

Disclosures

- Dr. Hogue was an advisory board member of TG Therapeutics, AstraZeneca and Seagen in the past 24 months. All relevant financial relationships have ended and have been mitigated.
- No other speakers or planners have relevant financial relationships with ineligible companies to disclose.

Note: This program may contain the mention of suppliers, brands, products, services or drugs presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes and should not be perceived as an endorsement of any particular supplier, brand, product, service or drug.

Learning Objectives

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

1. Recognize methods by which pharmacists can obtain provider prescriber support to drive increased utilization of biosimilars.
2. Recall how pharmacist education interventions can help patients avoid nocebo-related treatment failure.
3. Identify strategies to create or update an adoption plan for biosimilars.

St. Luke’s Health System Medical Centers

St. Luke’s Boise

St. Luke’s Elmore

St. Luke’s Jerome

St. Luke’s Magic Valley

St. Luke’s McCall

St. Luke’s Meridian

St. Luke’s Nampa

St. Luke’s Wood River

St. Luke's Health System – Idaho

- Serving Southern Idaho, Eastern Oregon & Northern Nevada
- $420M Drug Budget
- 340B Qualified (DSH & non-DSH)
- 8 Infusion Centers
- 5 Oncology Infusion Centers

Source: stlukesonline.org

Key Definitions

Biologic: A diverse category of large, complex molecules produced through recombinant DNA technology in a living system and are more complicated to characterize than small molecule drugs.

Reference Product: A single biological product approved by the FDA based on, among other things, a full complement of safety and efficacy data.

Biosimilar: A biological product that is highly similar to and has no clinically meaningful differences from the FDA-approved reference product.

- Same expected benefits and risks as their reference products
- Approved by FDA after rigorous evaluation
- Some biosimilar(s) may be approved for interchangeability

Source: U.S. FDA. Overview of Biosimilar Products; FDA: Rockville, MD, USA, 2023.

Key Definitions, *continued*

Extrapolation: A concept in which a biosimilar product is approved for an indication without direct studies in that indication.

- All available data and information in biosimilar application
- FDA's previous finding of safety and efficacy for other approved indications for the reference product
- Knowledge and consideration of various scientific factors for each indication

Interchangeability: An interchangeable biosimilar may be substituted for the reference product without the intervention of the prescribing healthcare provider.

- Additional FDA approval process in which the manufacturer must show no decrease in ineffectiveness or increase in safety risk associated with switching
- Depends on state pharmacy laws

Source: U.S. FDA. Biosimilar Product Regulatory Review and Approval; FDA: Rockville, MD, USA, 2023.
Source: U.S. FDA. Interchangeable Biological Products; FDA: Rockville, MD, USA, 2023.

National Trends in Drug Expenditure & Current Policy

- In 2022, overall pharmaceutical expenditures in the U.S. grew 9.4% compared to 2021, for a total of $633.5 billion
- Expect overall drug spend to rise by 6% to 8% in 2023
- Factors restraining drug expenditures
  - Traditional generic drugs
  - Biosimilars
- Public Policy
  - Build Back Better Act
  - Inflation Reduction Act
  - Advancing Education on Biosimilars Act of 2021

Sources:
Dustzina, S., Huskamp, H. Impending Relief for Medicare Beneficiaries – The Inflation Reduction Act. *N Engl J Med.* 2022; 387:1437-1439. DOI: 10.1056/NEJMp2211223
Tichy, E. et al. National Trends in Prescription Drug Expenditures and Projections for 2023. *Am J Health-Syst Pharm*. 2023. DOI: 10.1093/ajhp/zxad086

U.S. Biosimilar Market & Future Projections

- Biosimilars projected to lower spending on biologics by $38.4 billion from 2021 to 2025
  - Downward pressure on reference biologic prices
  - New biosimilar entry
- Forcing factors that could shape the direction of biosimilar uptake and future development
  - Patent ligation
  - Rebate trap
  - Dissemination of misleading information
  - Reimbursement policies by the federal government
  - FDA approval requirements and regulations

Sources:
Mulcahy, A., Buttorff, Christine, Finegold, Kenneth, et al. Projected US savings from biosimilars 2021-2025. *Am J Manag Care*. 2022;28(7):329-335. DOI:10.37765/ajmc.2022.88809.
Mehr, Stanton. Biosimilar Report: The US Biosimilar Market: A History of Growth and Towards a Sustainable Future. 2023 Edition. Copyright 2023 by SM Health Communications LLC. Accessed 6/7/23.

Approach to Biosimilar Initiative Implementation

Biosimilar Workgroup

- Pharmacy Leaders
- System Formulary Lead
- SL PBM
- SL Health Plan
- 340B
- Purchasing
- Pharmacy Educator
- Informatics

Market Review

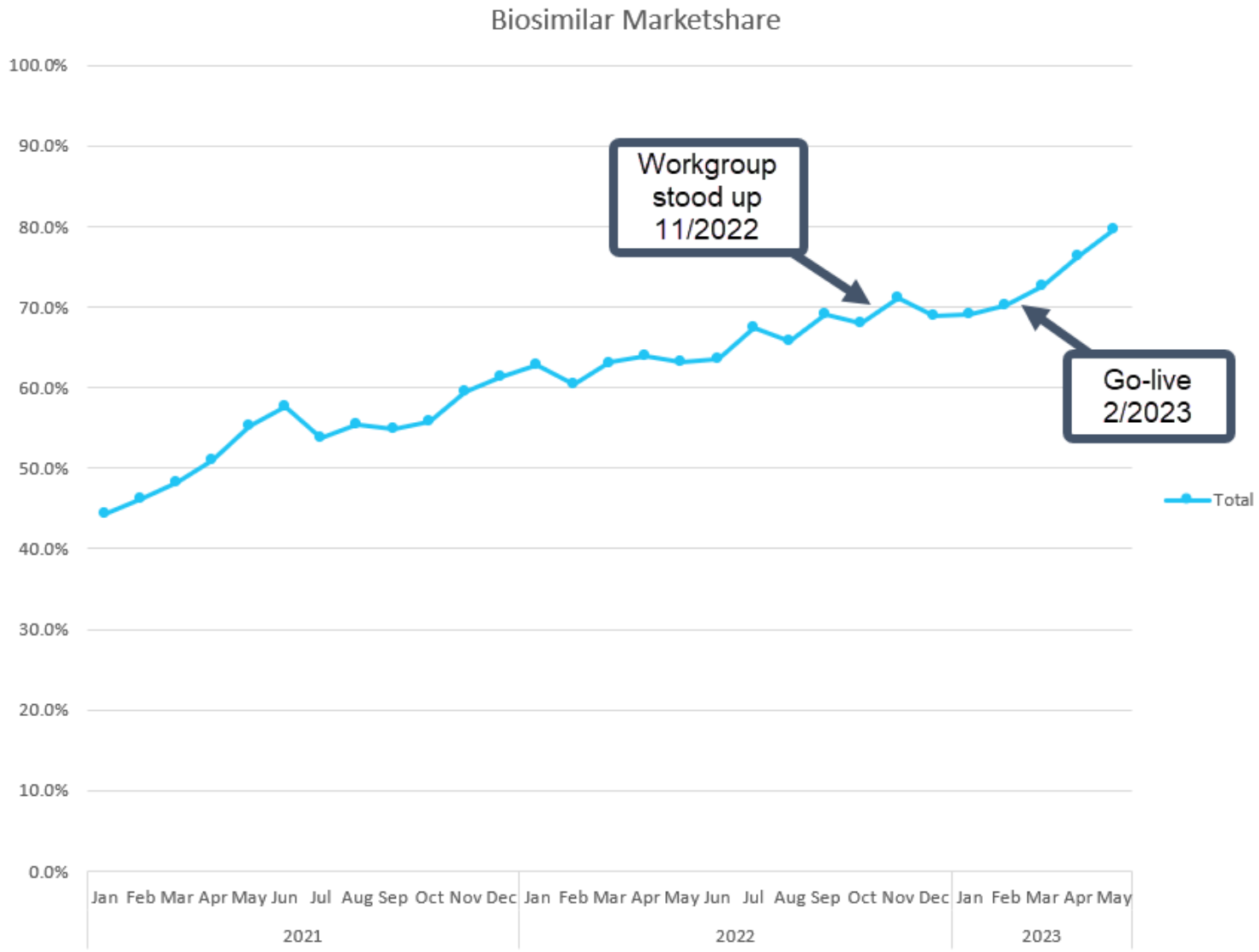
- Payer Policy
- Payer Mix
- Reimbursement
- Rebates
- Contracts

Clinical Review

- Physician Champions
- Provider & Nursing Stakeholders
- Pharmacy & Therapeutics
- Governing body approval

Operations

- Staff & patient education
- Benefits investigation
- Prior authorization
- Informatics
- Purchasing
- Revenue Cycle
- Data & Analytics
- Monitor & measure by workgroup



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Biosimilar Use in Non-Oncology Infusion

Pharmacist-led Biosimilar Use in SLHS Non-Oncology Infusion

- SLHS Infusion Pharmacy Team
  - 14 pharmacists
  - 3 technicians
  - Review all incoming orders
  - Transcription of orders from external providers
  - Clinical support of authorization and scheduling teams
- Payer Mandated Biosimilar Use
  - Ongoing for the past 3+ years
  - Providers reluctant, but resigned
    - PEDS GI elects peer to peer appeal regularly

Resident MUE Project

- Reviewed biosimilar use of infliximab and rituximab in 2 locations and found biosimilar use ~38%
- Primarily payer mandated utilization
- Medicare recipients nearly 100% reference product utilization

Biosimilar Workgroup

- Assembled to develop a strategy for reducing drug costs by leveraging biosimilar utilization
- Support from SLHS C-Suite operational and clinical leaders
- Notices to all providers outlining potential savings and expectations
- Pharmacist educator presented educational materials on biosimilars to internal provider groups

Pharmacist-led Biosimilar Conversion Process – New Start Patients

Generic Therapy Plan – Rituximab

Pharmacy will determine product based on system and payer formulary and clinical history.

MEDICATION

- ❑ Rituximab 1,000mg IV Day 1 and Day 15. Repeat every 6 months
- ❑ Rituximab 375mg/m2 weekly IV X 4 weeks
- ❑ Rituximab- Dose_____ Route_____ Frequency_____

Source: Chart/data property of St. Luke's. Please do not reproduce without permission.

Generic Therapy Plan – Infliximab

Pharmacy will determine product based on system and payer formulary and clinical history.

MEDICATIONS

INFLIXIMAB

LOADING DOSE:

❑ _____MG infliximab IV infusion **OR** ❑ _____MG/KG infliximab IV infusion

❑ To be given week 0, 2, and 6

❑ Other schedule

MAINTENANCE DOSE:

❑ _____ MG infliximab IV infusion **OR** ❑ _____MG/KG infliximab IV infusion

FREQUENCY: ❑ Every 4 weeks ❑ Every 6 weeks ❑ Every 8 weeks ❑ Other: _____

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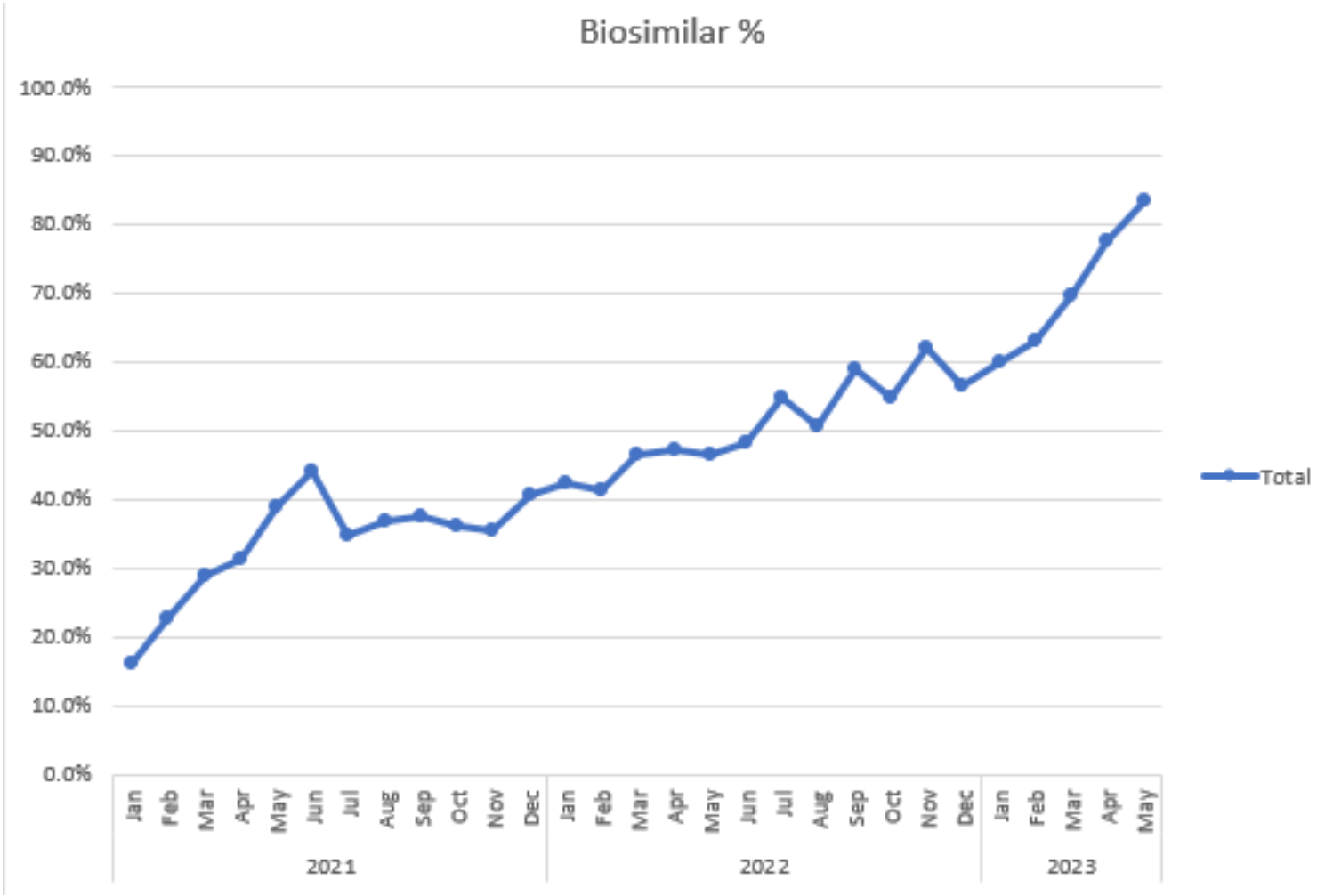
Results – Infliximab & Rituximab New Starts



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Pharmacist-led Biosimilar Conversion Process – Existing Therapy Patients

Patient Contact Message – Infliximab

Dear @PREFNAME@ ,

Your provider wanted to give you an update about your Remicade® (infliximab). If you are no longer receiving Remicade® at St. Luke's Health System, please disregard this letter.

Your infliximab (Remicade®) order has been updated to a biosimilar brand name, {Blank Single:19197::"Renflexis","Inflectra","Avsola","infliximab"}. While the brand is being updated, your {Blank Single:19197::"Renflexis","Inflectra","Avsola","infliximab"} dose, frequency, and infusion time will be the same as Remicade®.

A biosimilar is a biologic medicine that is equal to the original biologic medicine in terms of safety, purity, potency, and effectiveness. You should expect the same safety and efficacy between {Blank Single:19197::"Renflexis","Inflectra","Avsola","infliximab"} and Remicade®. Also, the amount you pay for {Blank Single:19197::"Renflexis","Inflectra","Avsola","infliximab"} may be less than what you pay for Remicade®.

If you have any questions or concerns, please review the FDA Biosimilar Fact Sheet link below or contact the St. Luke's Infusion clinical pharmacists at 208-706-0646 for a phone appointment.

The St. Luke's Heathcare Team is here to help you get the most benefit from your medications and is available to answer any questions you may have about this change. If you have any questions or concerns, please do not hesitate to call.

Sincerely,

St. Luke's Health System

https://www.fda.gov/drugs/biosimilars/patient-materials

Results – Infliximab & Rituximab Conversions

Drug	Infliximab	Rituximab
Complete	89	28
In Process	5	5
Refused	24	10
Not Started	10	55

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Pharmacist-led Biosimilar Initiative – Challenges

- External Providers
  - All adult GI providers serving 3 large infusion centers
- Pediatric Providers
  - Slightly altered workflow requested
- Authorization Capacity for Conversions
  - Completed when ordered close to expiring

Pharmacist-led Biosimilar Initiative

Inpatient Start Workflow

- Placeholder orders entered
- Consult directed to infusion pharmacist
- Preferred biosimilar selected
- Orders entered
- Therapy plan updated
- Patient treated
- Extremely positive provider/pharmacist feedback

Oncology

Sarah Hogue, PharmD

Director Pharmacy Oncology

St. Luke's Cancer Institute

- 5 locations in Idaho
  - Boise
  - Meridian
  - Nampa
  - Twin Falls
  - Fruitland
- Pediatrics
- Blood & Marrow Transplant Program
- Clinical Research

St. Luke's Cancer Institute (SLCI)

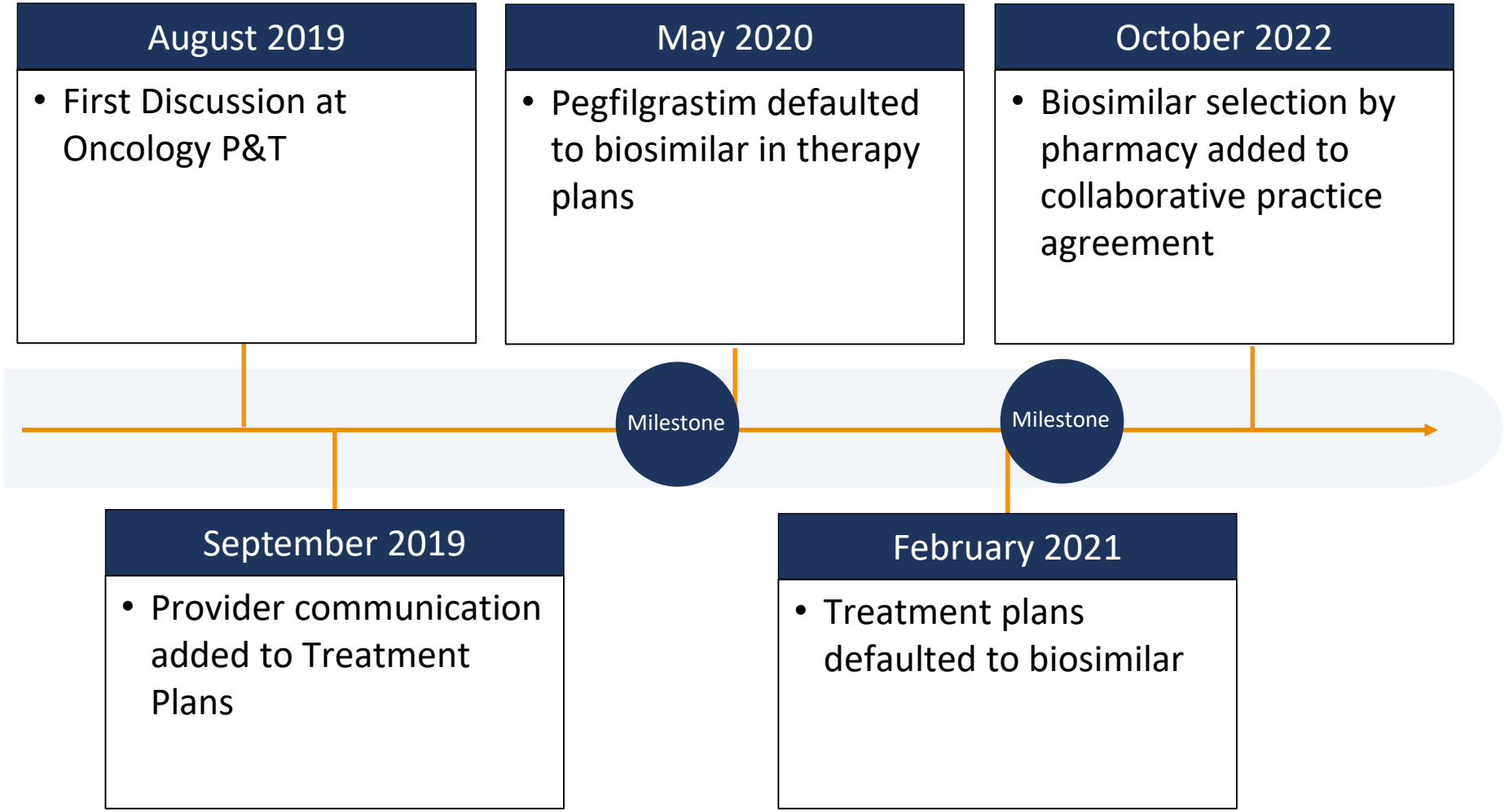
Pharmacy Team

- **Oncology Outpatient Infusion**
  - 15 pharmacists
  - 17 technicians
  - 2 pharmacy externs
- **Oncology Specialty Pharmacy**
  - 8 pharmacists
  - 8 technicians
- 3 Blood and Marrow Transplant Pharmacists
- 1 Inpatient Oncology Pharmacist
- 2 Pediatric Oncology Pharmacists
- 2 Clinical Research Pharmacists
- 3 PGY-2 Oncology Residents

SLCI Pharmacy Practice

- Moderate Oncology Pharmacy & Therapeutics Subcommittee
  - Maintain system formulary for all oncology related medications
- Global Collaborative Practice
  - Anti-emetics
  - Infusion reactions
  - Over the counter medications
  - Pre-medication
  - Anticoagulation
  - Oral chemotherapy
- BMT Pharmacists Credentialled Medical Staff

Oncology Biosimilar Adoption Timeline



Biosimilar Conversion in Oncology

- August 2019
  - Kanjinti® (trastuzumab-anns) entered market and reviewed at Onc P&T
    - Build biosimilar in background of treatment plans
    - Providers request auto substitution of biosimilar by pharmacy
      - If allowed by insurance
  - Pegfilgrastim Class Reviewed at Onc P&T
    - Build all currently available biosimilars in background
    - Due to payer preference, all biosimilars will need to be carried by each location

Biosimilar Conversion in Oncology

- August 2019
  - Provider communication added to Treatment Plans
    - "This protocol contains one or more medications for which a biosimilar is available. Pharmacy will switch to the preferred product automatically. If you feel this patient requires the original brand-name (innovator) medication, please contact the pharmacy and PFAs before the first dose of medication is administered"

- Treatment & therapy plans still default to innovator product

Results

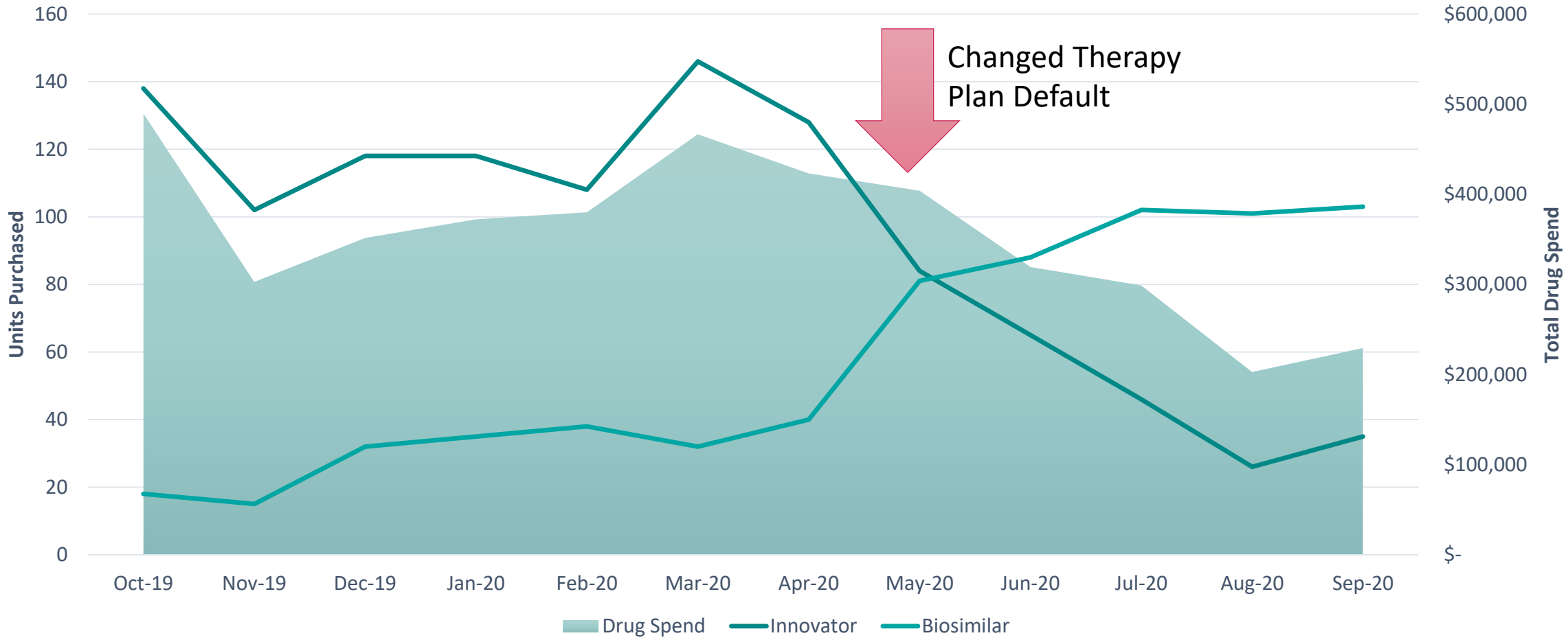
- Only new treatment plans contained provider communication
- Pharmacy unable to switch patients without new order from provider
- Difficult to find biosimilar in Electronic Health Record (EHR)
- Provider hesitancy to switch mid-treatment

- **SLOW UPTAKE**

Biosimilar Conversion in Oncology

- May 2020
  - Oncology P&T Subcommittee discussion
    - Utilizing biosimilars is in best interest financially
    - Must consider payer preference
    - All new treatments would request formulary biosimilar
    - Allow patients already on treatment to continue with originator product (unless mandated by insurance to switch)
- Update pegfilgrastim therapy plan to default to formulary preferred biosimilar
- Treatment plans still default to innovator product
  - Rituximab, Trastuzumab, Bevacizumab

Pegfilgrastim Use & Drug Spend – Fiscal Year 2020



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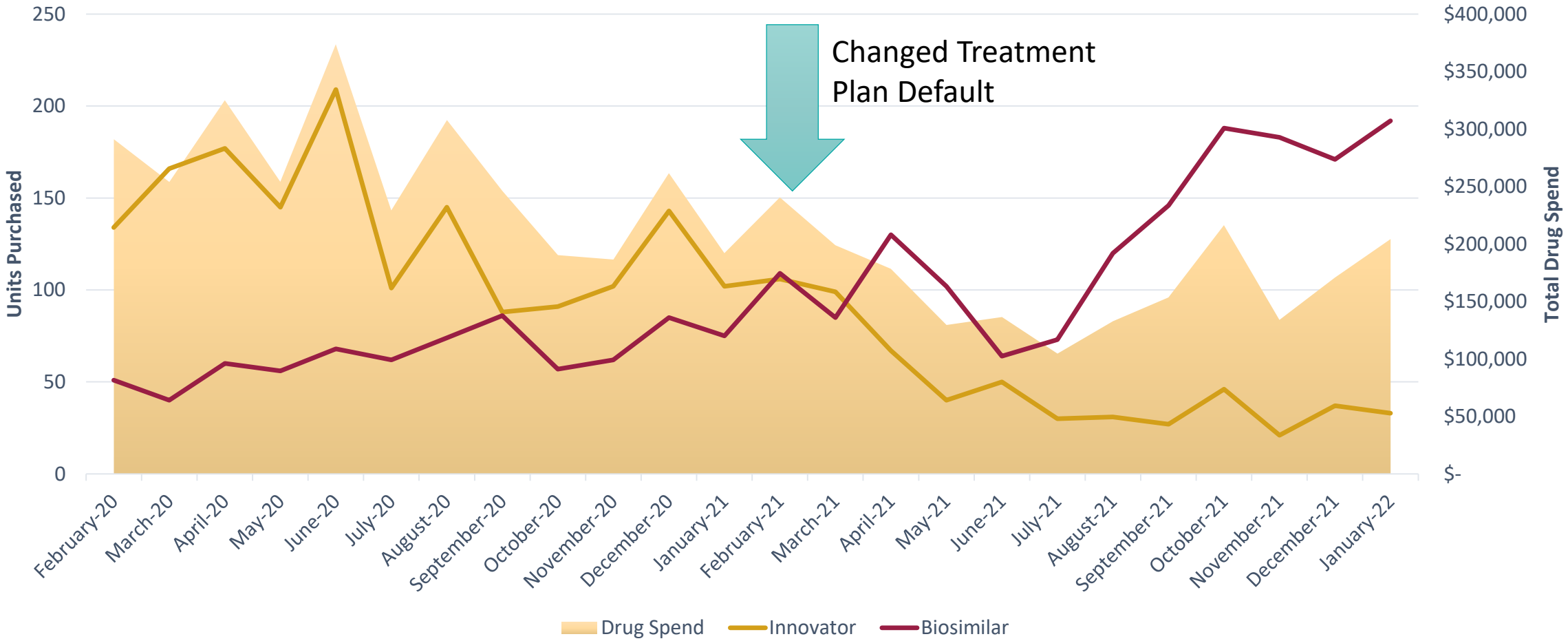
Success!

February 2021

- Treatment plans updated to default to the formulary preferred biosimilar
  - Rituximab
  - Bevacizumab
  - Trastuzumab

Bevacizumab Purchases & Drug Spend



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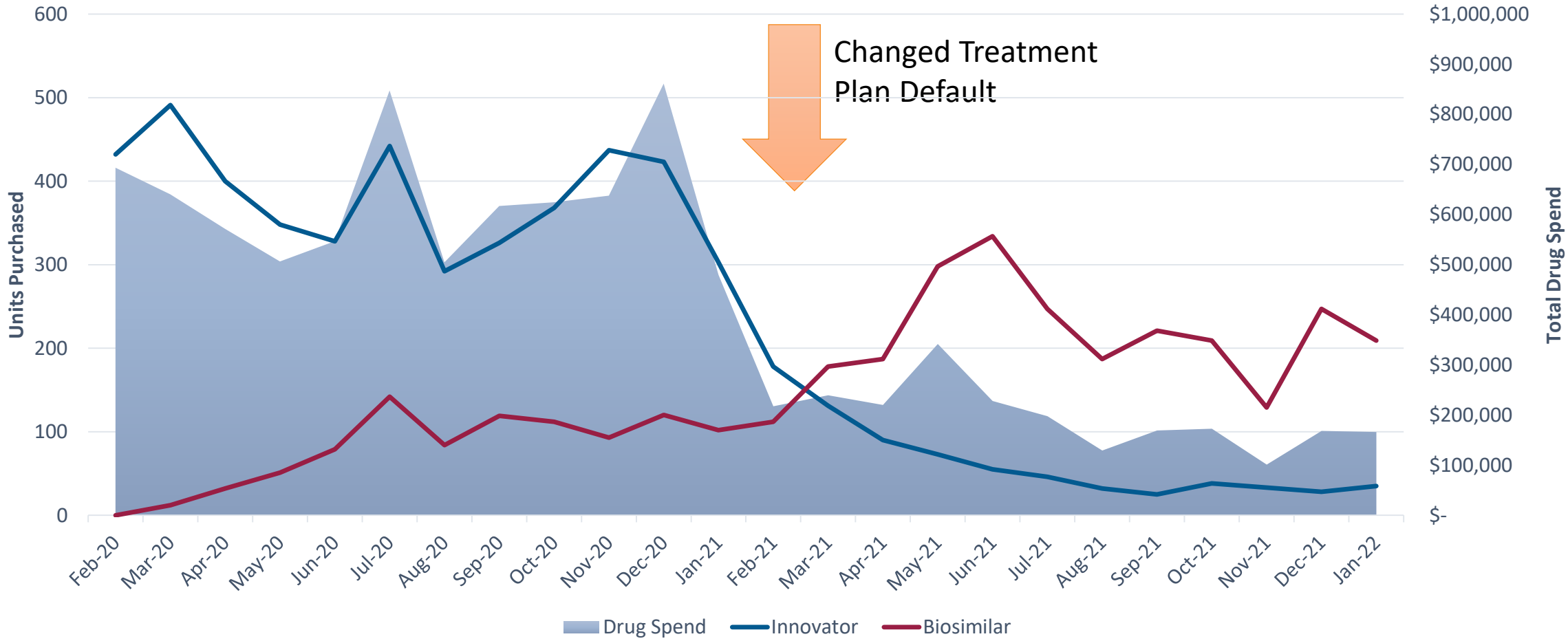
Rituximab Purchases & Drug Spend



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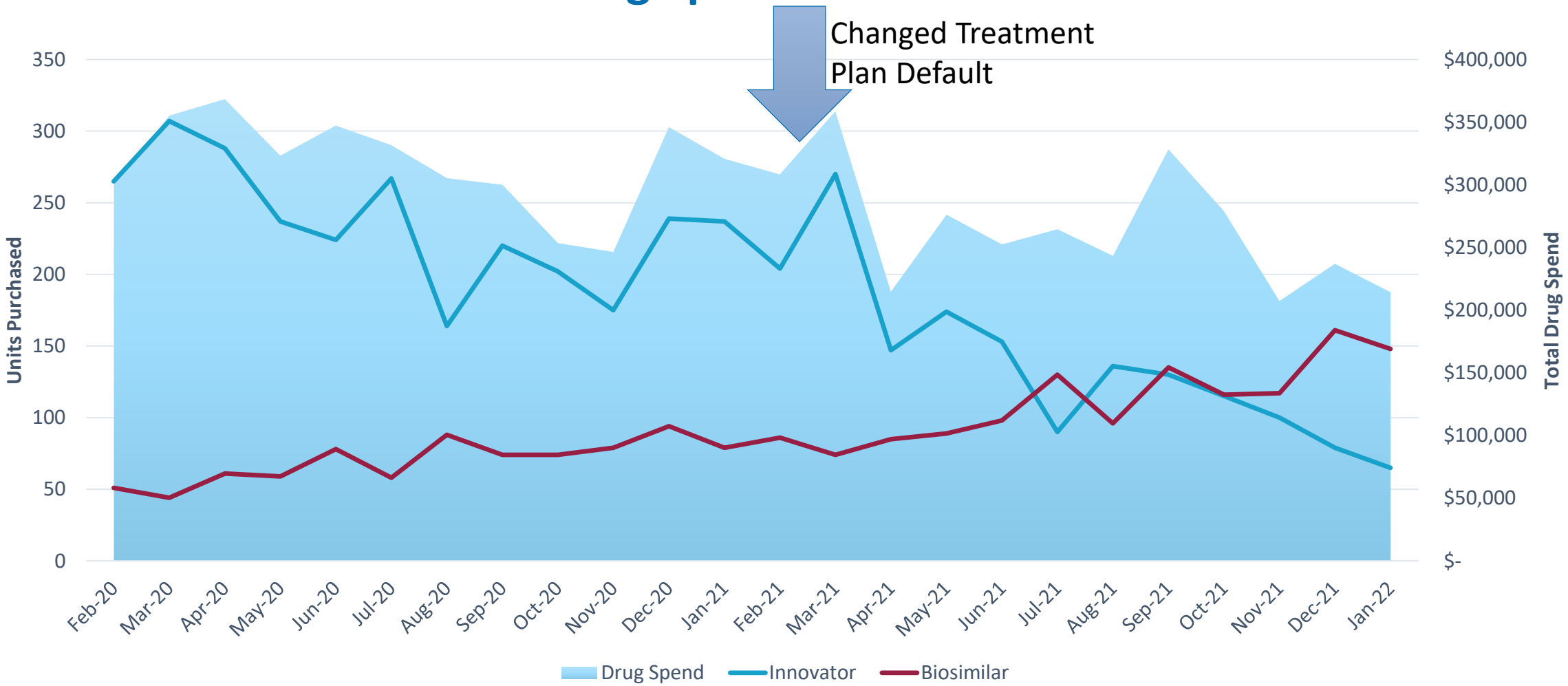
Trastuzumab Purchases & Drug Spend



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Results

- Rituximab & Bevacizumab
  - Increased biosimilar usage
  - Significant cost savings

- Trastuzumab
  - Continued reluctance to switch mid-treatment
    - Existing treatment plans did not contain provider communication

- **Success**

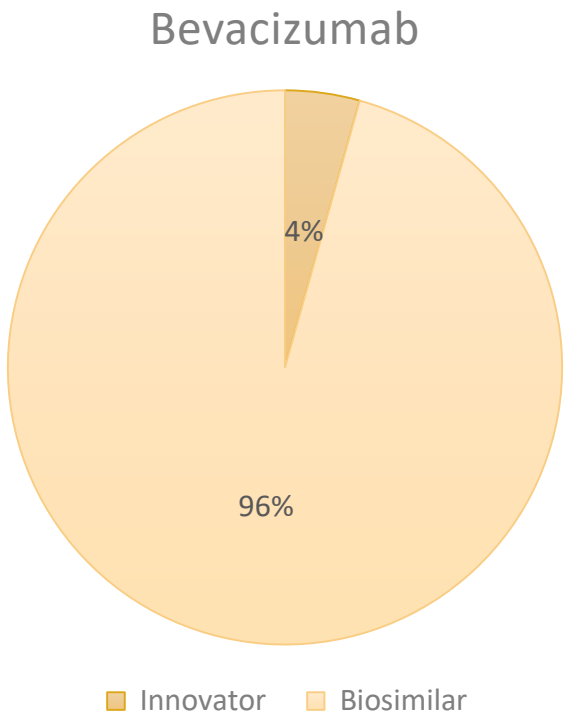
Collaborative Practice Agreement

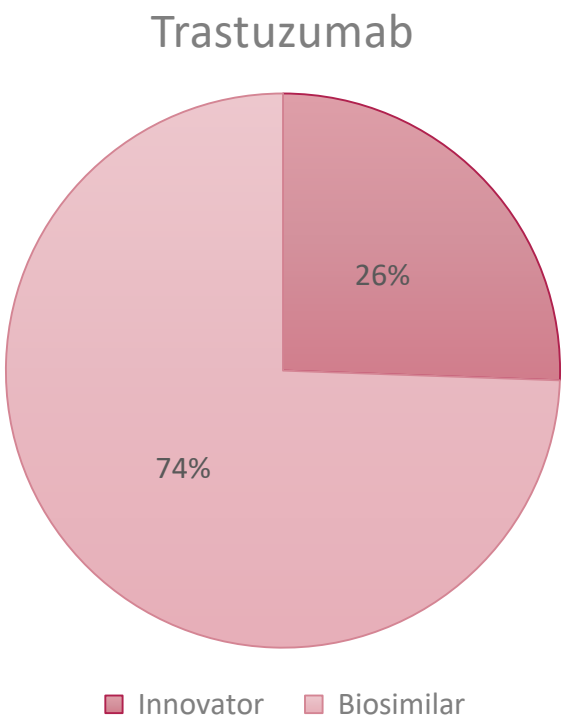
- October 2022
  - Biosimilars added to Oncology Collaborative Practice Agreement

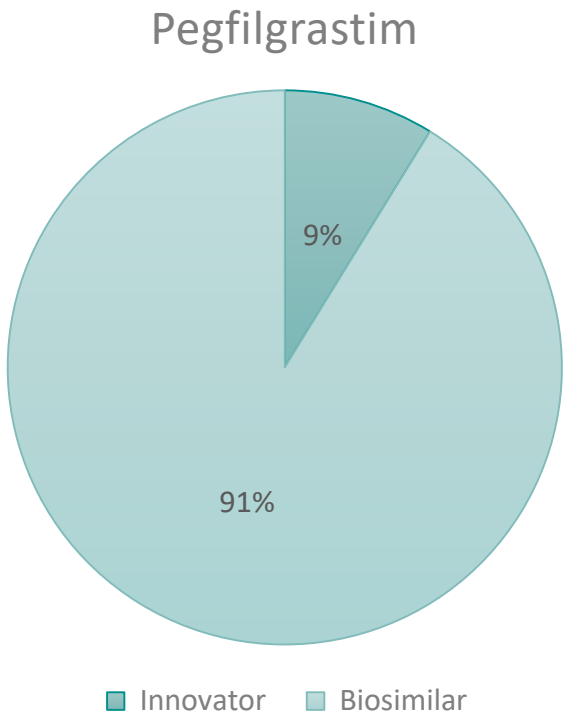
- Drug Therapy Management for Adult Oncology Patients
  - Selection of appropriate biosimilar
    - "Select appropriate biosimilar per system P&T guidance, and when applicable, payer preference"

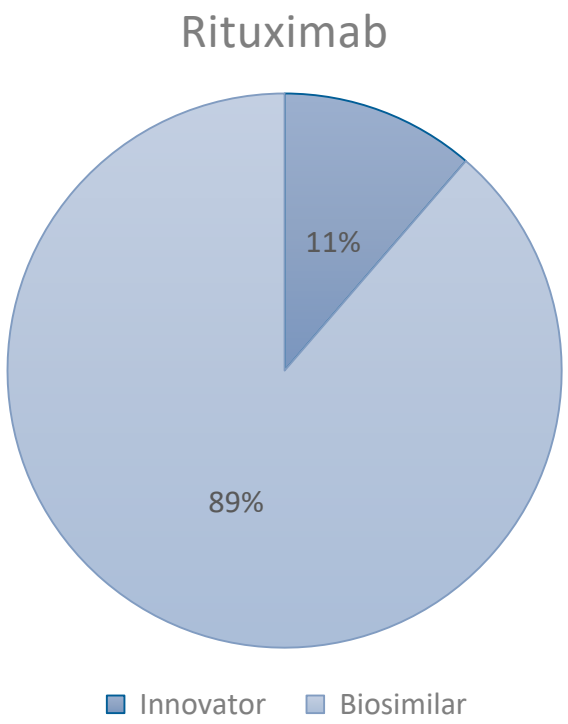
- Removed biosimilar communication from all Oncology Treatment Plans

Current Purchases – May 2023









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Assessment Question 1:

To drive increased utilization of biosimilars, pharmacists can obtain prescriber support by utilizing all of the following methods except:

A. Provide them with the clinical data describing the efficacy of biosimilars
B. Just tell them we are doing it regardless of what the prescriber would like to do
C. Show them the potential cost savings with the utilization of biosimilars
D. Inform them that payers are requiring biosimilars

Assessment Question 1, answer

To drive increased utilization of biosimilars, pharmacists can obtain prescriber support by utilizing all of the following methods except:

A. Provide them with the clinical data describing the efficacy of biosimilars

B. Just tell them we are doing it regardless of what the prescriber would like to do

C. Show them the potential cost savings with the utilization of biosimilars

D. Inform them that payers are requiring biosimilars

Assessment Question 2:

Pharmacist education can help patients avoid nocebo-related treatment failures by the following:

1. Informing patients that biosimilars are different than the originator product and thus could have different effects
2. Listening to patients concerns and answering their questions regarding biosimilars
3. Patient education is not necessary because the prescriber will tell the patient that it is equally efficacious
4. Discussing with patients what a biosimilar is and the evidence supporting the use in their indication

A. Both 1 and 3
B. Both 1 and 4
C. Both 2 and 4
D. Both 2 and 3

Assessment Question 2, answer

Pharmacist education can help patients avoid nocebo-related treatment failures by the following:

1. Informing patients that biosimilars are different than the originator product and thus could have different effects
2. Listening to patients concerns and answering their questions regarding biosimilars
3. Patient education is not necessary because the prescriber will tell the patient that it is equally efficacious
4. Discussing with patients what a biosimilar is and the evidence supporting the use in their indication

A. Both 1 and 3
B. Both 1 and 4
C. Both 2 and 4
D. Both 2 and 3

Assessment Question 3:

A pharmacist can use the following strategies to create or update an adoption plan for biosimilars:

A. Update treatment/therapy plans to default to the system-preferred biosimilar and place a statement regarding pharmacy switching to appropriate biosimilar
B. Discuss biosimilar interchange by pharmacists at P&T
C. Create a collaborative practice agreement allowing pharmacist interchange of biosimilars
D. All of the above

Assessment Question 3, answer

A pharmacist can use the following strategies to create or update an adoption plan for biosimilars:

A. Update treatment/therapy plans to default to the system-preferred biosimilar and place a statement regarding pharmacy switching to appropriate biosimilar
B. Discuss biosimilar interchange by pharmacists at P&T
C. Create a collaborative practice agreement allowing pharmacist interchange of biosimilars
D. All of the above

Challenges

- Provider Hesitancy
  - Especially in the beginning
  - Mid treatment switch
- Electronic Medical Record/Ordering
- Payer Preferences
- Fridge Space

References

- U.S. FDA. Overview of Biosimilar Products; FDA: Rockville, MD, USA, 2023.
- U.S. FDA. Biosimilar Product Regulatory Review and Approval; FDA: Rockville, MD, USA, 2023.
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- Mehr, Stanton. Biosimilar Report: The US Biosimilar Market: A History of Growth and Towards a Sustainable Future. 2023 Edition. Copyright 2023 by SM Health Communications LLC. Accessed 6/7/23.

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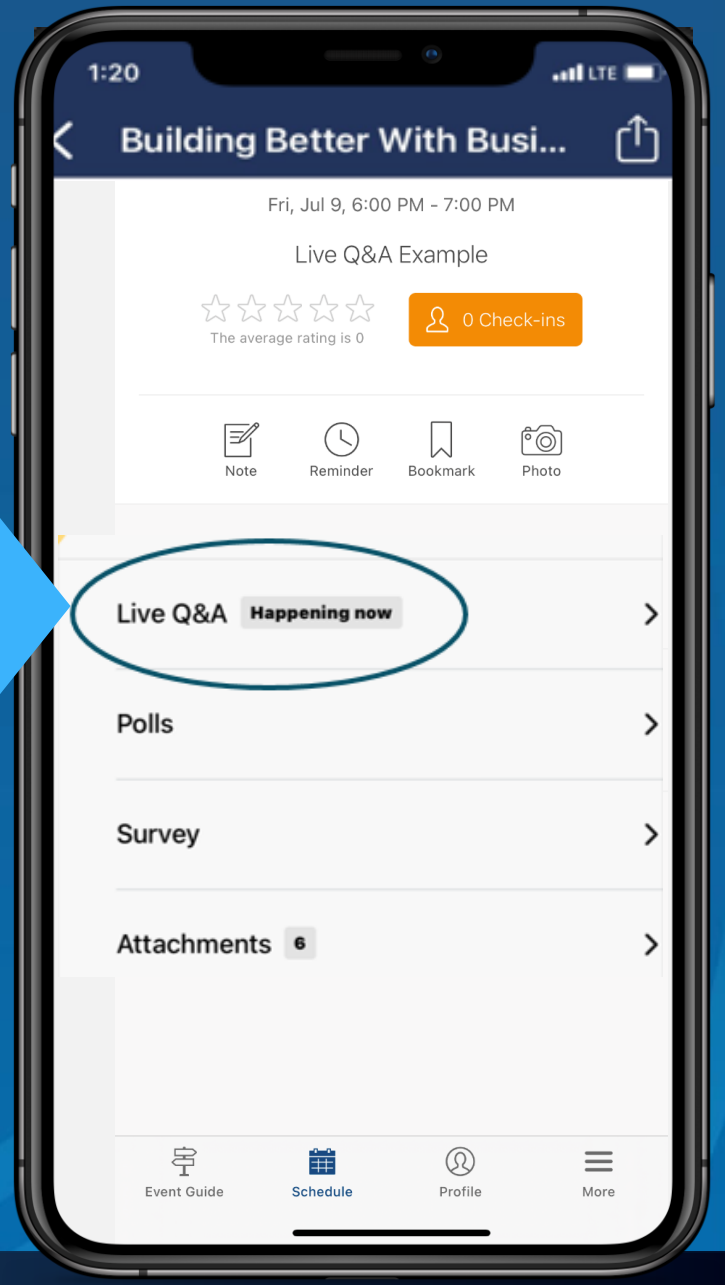
- Select session name
- Click on “Live Q&A,” then “Ask a Question”
- Type your question & hit “Submit”
- Send in any time; Qs will be held until the end of the session



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Thank you...

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Sarah Hogue, PharmD (hogues@slhs.org)

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