# Best Practices for the Implementation of Biosimilars

Written in collaboration with: David M. Waterhouse, MD, MPH,
Director, Phase I Research Unit OHC (Oncology Hematology Care) Cincinnati, Ohio.

## An efficient implementation process is an important factor to help realize the benefits of biosimilars.

The U.S. biosimilar landscape shows many signs of growth, spurring innovation and progress within the U.S. healthcare system.[1] However, despite the U.S. implementation of a pathway for biosimilar approval in 2010, their uptake and usage remain slower than that of Europe. On a global scale, Europe has taken the lead regarding the implementation of biosimilars into medical institutions and independent practices, increasing treatment options, patient access, and cost savings.[1]

## The Benefits of Biosimilars

Oncology has one of the highest uptakes of biosimilars into clinical practice in the U.S., accounting for the largest percentage of biosimilars in the market.[2]

When surveyed, most oncologists were comfortable prescribing a biosimilar to their patients.[3]

As a result, the cumulative savings in drug spend for classes with biosimilar competition is estimated to have been $21 billion over the past 6 years in the U.S.[4]

**Executive Summary:**

The best practices outlined in this white paper are based on key findings from a 2022 Fresenius Kabi survey on the successful implementation of biosimilars into an institution. Recommendations were developed based on the responses of decision-makers at 33 medical sites, including large health systems and private clinics of which 97% of the institutions have biosimilars approved in their formulary. Some of the elements that led to streamlined implementation, included:[5]

- Expediting the formulary review process where possible.
- Confirming efficient IT support and incorporating EMR/EHR integration early.
- Ensuring appropriate stakeholder involvement with proper communication, education, and assessment of the economic impact to the institution.
- Establishing an automatic substitution process that can be handled by the pharmacy.
- Incorporating the eliminations of re-sign from providers.
- Confirming adequate inventory setup.

A recent study conducted at Providence St. Joseph Health System found that the organization saved over $26 million due to its adoption of biosimilars after just two years.

The savings were determined by calculating the decrease in expenditures on biologics, advancements in operational and workflow procedures, and enhancements to the financial status of the health system as a whole.[6] This type of analytical assessment is being adopted and expanded as more biosimilars are being introduced.

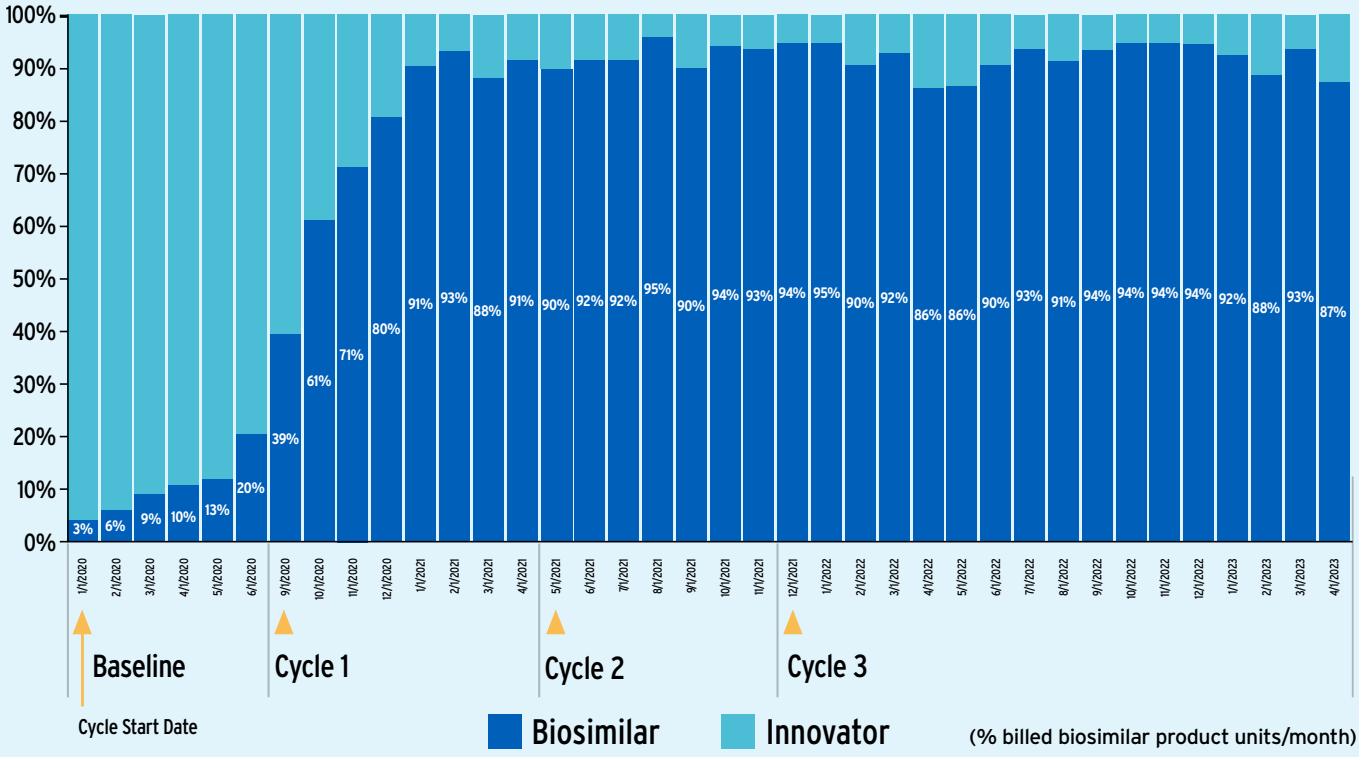
Why, then, has the U.S. yet to reach its full potential in implementing biosimilars? Barriers such as lengthy approval times, IT integration, and inventory management stifle progress and limit access. However, it has been shown that these obstacles can be lessened based on best practices identified at medical institutions and practices of all sizes, allowing them to take advantage of the benefits of biosimilars.[7]

## Expediting the Formulary Review Process as an Accepted Process

The formulary review process can be lengthy and tedious. However, the acceptance of biosimilars has begun to change this trend. The FDA thoroughly reviews all approved biosimilars to evaluate their efficacy and safety, ensuring no clinically meaningful difference between the biosimilar and its reference product.[8]

*Figure 1.*

**Pharmacy-Driven Implementation[9]**



A new approach that has helped institutions accelerate the approval of biosimilars into their formularies is the adoption of blanket approval for biosimilars. With this process, facilities could implement an automatic approval process once the FDA approves a biosimilar. Based on average Pharmacy and Therapeutics (P&T) Committee review times, implementing this new process could save weeks to months.

## Efficiency Can be Driven by the Pharmacy

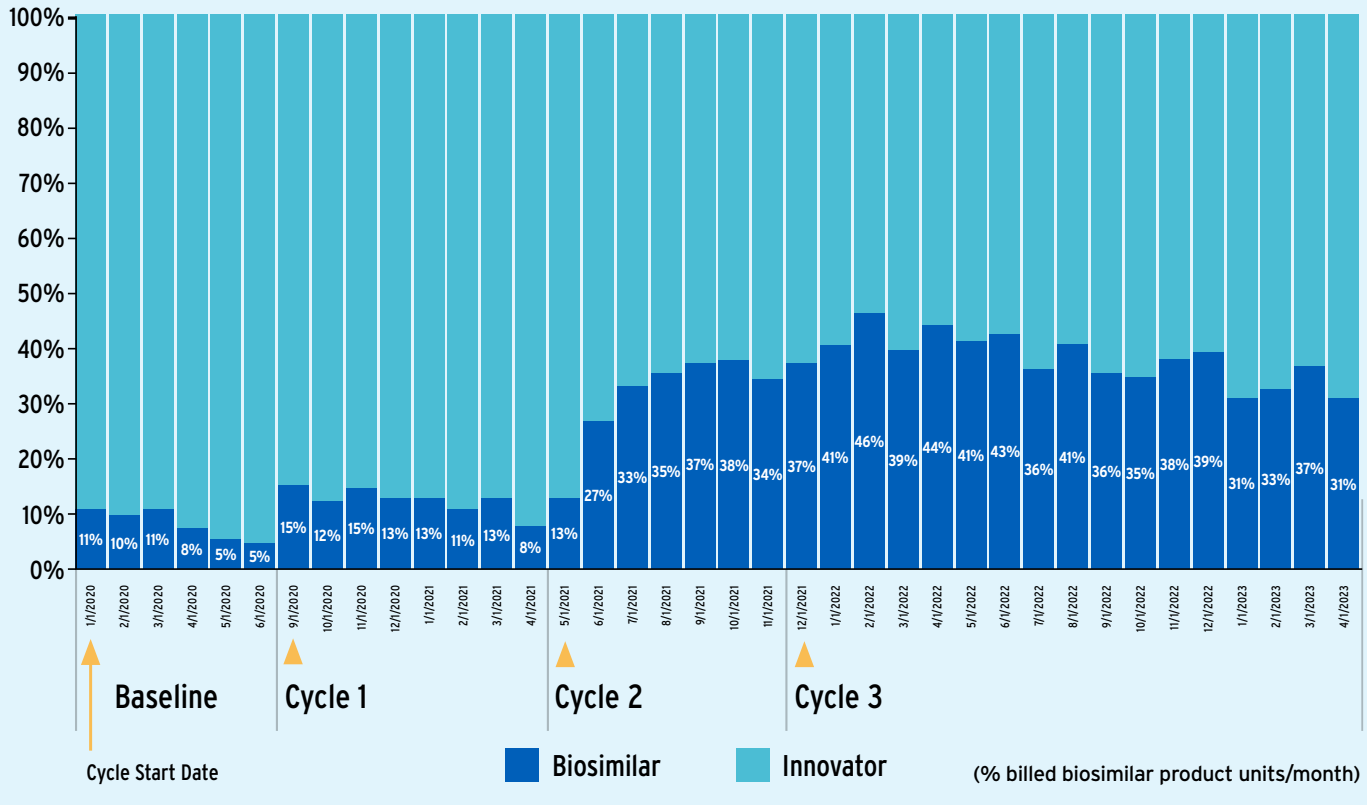
Through an analytical comparison between pharmacy-driven and physician-driven implementation in large medical institutions, researchers observed that physicians had less time for patient care when their attention was directed to back-end medication substitution processes. Physicians were also less likely to utilize biosimilars effectively and preferred to prescribe the less cost-efficient reference product.[9] (Figures 1 and 2)

In this instance, pharmacy-driven implementation was shown to be more efficient than physician-driven implementation. By introducing a thorough standardization of training by the pharmacy, the adoption of biosimilars was expedited while lowering clinic interruptions for physicians.[9]

A pharmacy-driven approach gives the pharmacist the ability to adopt new biosimilars into formulary and ensure they are ready for dispensing as quickly as possible, while the physician can focus on patient care and prescribing the most effective treatment.

**Physician-Driven Implementation[9]**

*Figure 2.*



It was also thought that the choice of biosimilar may have been influenced by differences in drug administration options, but that was not the case. It seems that other factors, such as payer incentives, may be playing a bigger role in biosimilar decisions. Research is ongoing to determine if additional factors are influencing decisions.

## Institutional Differences Based on Size

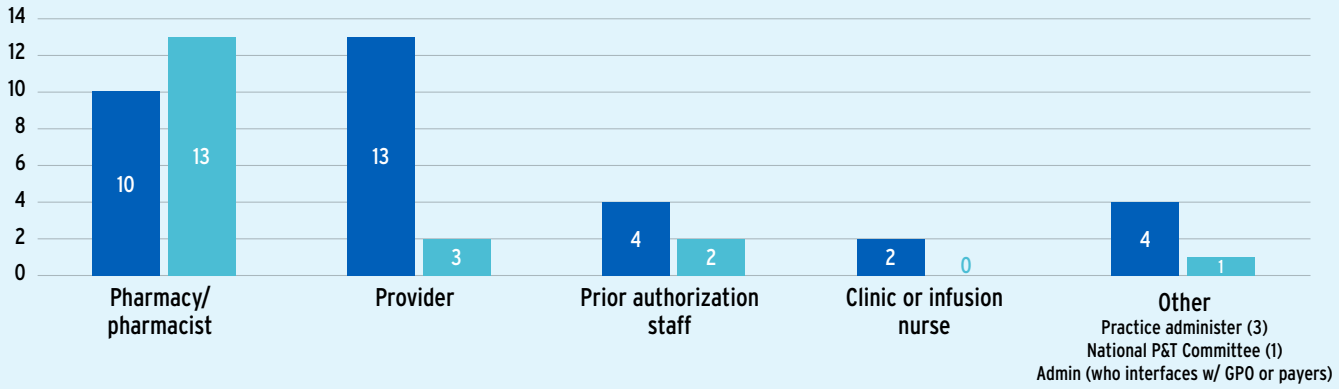
By examining a variety of health institutions ranging from large, integrated systems to smaller, standalone centers, informative data was uncovered for varied practices based on organizational size.

Survey results indicated that biosimilar implementation is more often initiated by pharmacy in smaller medical institutions, where-as it's initiated by both pharmacy and providers in larger health systems. (Figure 3)

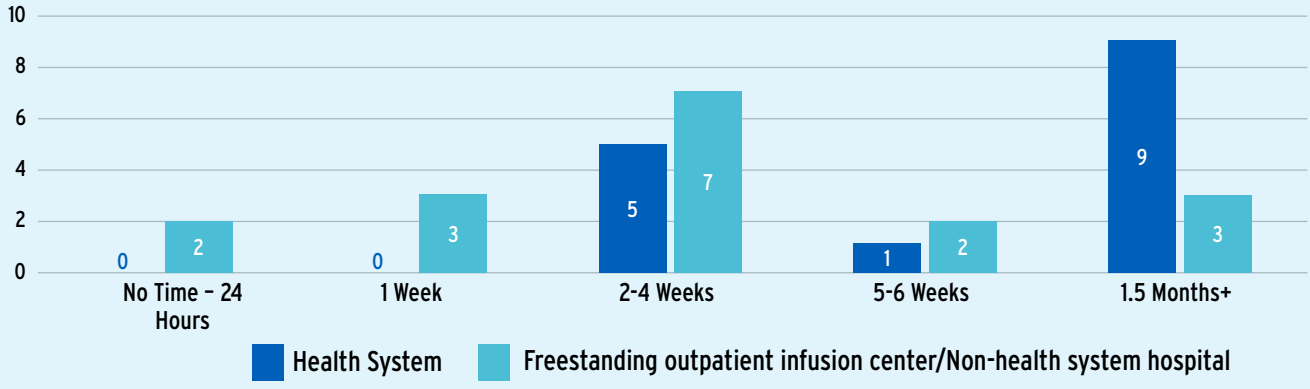
Furthermore, data showed that larger health systems faced prolonged periods to integrate biosimilars into their formularies and should anticipate encountering additional barriers due to institutional size.[5]

*Figure 3.*

**Which team member initiates adding a new biosimilar to formulary?[5]**




**How long does it take your team to fully integrate a biosimilar drug from initial P&T review to a ready-to-dispense product on shelf?[5]**



Data also illustrates an inverse correlation between the size of an institution and its willingness to revise current implementation protocols to capitalize on efficiency-improving strategies, with smaller establishments tending to be less likely to revise their current protocols.[5] (Figure 4)

Revisions to the implementation process that both large and small institutions should consider for greater efficiency:

- Creating an automatic or expedited approval process for FDA-approved biosimilars so that a full P&T review is not needed for all future biosimilar products.
- Assembling a multidisciplinary team of experts in pharmacy, finance, and formulary management to identify the gaps in processes or barriers to overcome.
- Forgoing re-consent for switching with biosimilars to help reduce obstacles and interruptions.
- Ensuring wholesale allocation.
- Collaborating with the authorization team.
- Developing parallel workflows, when possible, to make processes more streamlined.
- Giving priority to products with significant cost savings over projects with less economic impact.
- Enabling pharmacy to own this process and continue to drive it forward.

Institutions have been placing a larger emphasis on using an economic comparison model to evaluate the impact of switching or adding a new biosimilar to formulary.

Some factors to consider for the evaluation include:

- Total projected reimbursement through analysis of the payer mix.
- Trends in average sales price (ASP) and drug cost over time.
- Purchase history and drug utilization data.
- Intangible factors, such as organizational friction, employee time, etc.

*Figure 4.*

**Have you revised your implementation process to shorten the time frame?[5]**

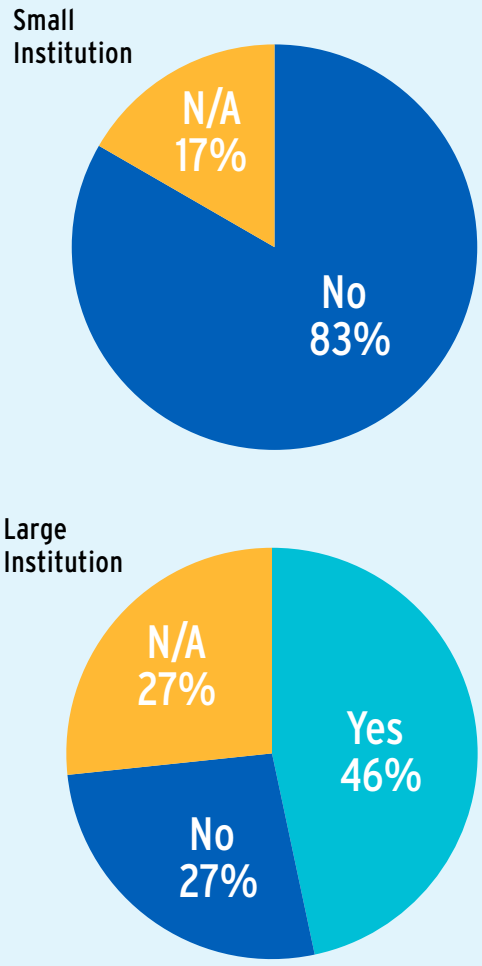
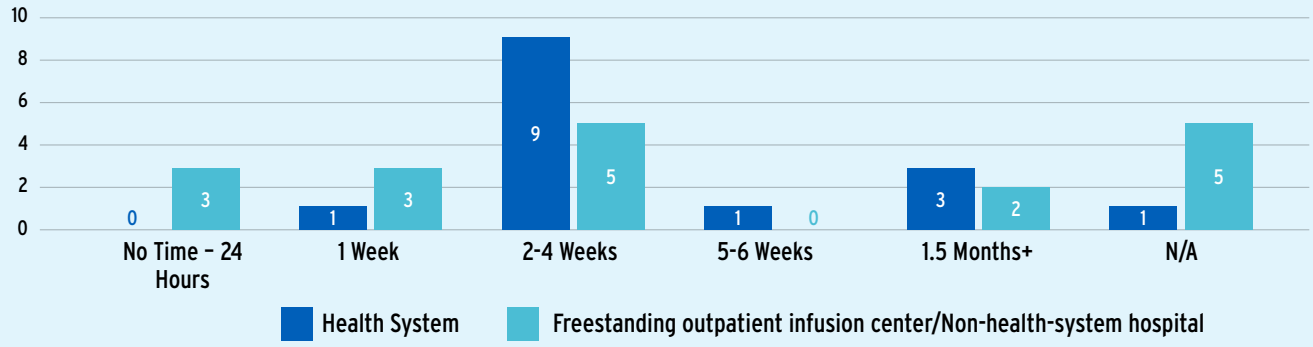


*Figure 5.*

**How much time does Internal Setup, including protocol revisions, inventory stocking, and EMR Integration, require?[5]**




Assessing this level of data can empower decision-makers to weigh the potential savings of biosimilar adoption and tailor their decisions to the unique needs of their institution or clinic.

## Effectively Streamlining Internal Setup

Critical challenges faced by the medical institutions that were shown to hinder the quick adoption of biosimilars included IT systems, EHR/EMR integration, inventory management, and protocol formations. The research subsequently highlighted how healthcare providers could use best practices (shown below) to overcome such obstacles.

Data showed that the majority of the workload is within the first two to four weeks of implementation in large and small institutions.

This information highlights how advance planning is vital for institutions to effectively manage their operations within this time frame using the recommendations identified by study participants. (Figure 5)

## Placing Emphasis on Education and Communication

Education and communication are some of the most crucial steps in implementation and should not be overlooked.

| **Obstacle** |
| --- |
| The creating and updating of protocols requires a high level of awareness, time, and communication among staff. |
| **Advice from Study Participants** |
| Develop a system that allows for a preferred biosimilar but retains the ability to switch easily based on payer mandates. |
| **Recommendations to Consider** |
| 1. Create a preferred biosimilar auto-substitution handled by the pharmacy to allow for easy switching based on payer mandates.<br>2. Establish SOPs that all staff can utilize to effectively communicate standardized practices. Allocate resources to ensure the SOPs are kept up to date.<br>3. If two or more biosimilar options are available, ask the pharmacy to create a template for physicians to sign off on.<br>4. Create a dedicated biosimilars build team who can update old protocols with new preferred biosimilars. |

**Obstacle**

Inventory management requires a high level of attention to ensure products are stocked and utilized properly.

**Advice from Study Participants**

Build direct therapeutic index for your system-preferred biosimilars.

**Recommendations to Consider**

1. Ensure the utilization or return of unused stock.
2. Confirm adequate stocking and storage space is available.
   - Ensure availability at wholesaler.
   - Identify stocking locations and adequate storage space.
   - Stock based on scheduled patients three days out.
3. Give sufficient notice to all staff of the conversion kickoff date.
   - Have all staff education materials ready.
4. Ensure that EHR automation is built.
   - Orders are set in place and ready to be used.
   - Set minimums and maximums.
   - Billing and coding information is in place.

**Obstacle**

IT being its own department with competing properties can make communication a challenge. EHR/EMR build-outs can be time-consuming and complex.

**Advice from Study Participants**

EHR/EMR integration should begin early, so that updates have an opportunity for protocol testing and usability to ensure that there are no errors and patient safety is preserved.

**Recommendations to Consider**

1. Contact IT prior to the initiation of implementation and ensure their schedule is aligned with the project's scope. This can be paralleled with P&T review.
2. IT and EHR/EMR should be one of the first priorities when kicking off implementation.
   - Ensure time for protocol testing.
   - Utilize generic names within the protocol.
   - Ensure regular updates about the biosimilar of choice.
3. Have software across various locations to support the aligned launch date.

All associated stakeholders, such as physicians, advance practice providers, pharmacists, treatment nurses, and others should be well-educated and informed on upcoming changes, so the process will not be slowed down with unnecessary oversights.

Institutions that established a process where PAs are involved earlier in the process and alerted well in advance of a new biosimilar being added have allowed them to plan accordingly while avoiding unnecessary obstacles.

Moreover, automatic authorization for healthcare professional or payer-preferred products can minimize the challenges of redundant processes.[5]

Furthermore, effective communication between clinicians and patients can be an essential component of a successful biosimilar program. If physicians are unfamiliar or unaware of the benefits of biosimilars, their patients will remain the same. Patient education may be a critical piece in the successful implementation of biosimilars.

With the implementation of biosimilars, manufacturers should be chosen carefully. Choosing a drug manufacturer with effective onboarding tools and support can make a difference in successful implementation. Research various companies to weigh their available resources before opting for one that provides superior solutions.

## Recommendations for educating staff include:[5]

- Begin education early in the process to allow all staff to be well-informed on handling new processes and procedures.
- If possible, shorten any following education based on the staff's prior knowledge of similar processes and procedures. Consider educating based on the new product information only and not the basic drug information.
- Educate staff as needed to ensure they are up-to-date on all new information.
- Use a manufacturing partner that offers a robust support program that provides educational resources for patients and HCPs, making the onboarding of biosimilars a smoother process.
- Make use of easily accessible online resources for clinicians by providing e-Learning or utilizing a learning management system.
- Leverage numerous channels of communication such as email or learning management systems.
- Consider organizing personalized training for each department with each new biosimilar adoption.

## Key Factors to Consider

Three ways that may improve the adoption process and ease implementation for biosimilars:[5]

1. Understand the similarities and communicate any potential advantage of the biosimilar compared to a reference or other biosimilars.
2. Do not underestimate the education component required of both staff and patients in making biosimilar implementation a success.
3. Start EMR/EHR integration early to aid in education, protocol testing, patient safety, safety testing of new protocols, etc.

**References: 1.** IQVIA Institute. Biosimilars in the United States 2020-2024: competition, savings, and sustainability. September 2020. Updated September 29, 2020 Accessed July 12, 2022. www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states- 2020-2024. **2.** Nahleh Z, Lyman GH, Schilsky RL, et al. Use of Biosimilar Medications in Oncology. *JCO Oncol Pract*. 2022;18(3):177-186. doi:10.1200/OP.21.00771 **3.** Oskouei ST, Gajra A, Jeune-Smith Y, Fortier S. Oncologists' perceptions and utilization of US therapeutic oncology biosimilars. *The American Journal of Accountable Care*. 2022;10(4):6-14. doi:10.37765/ajac. 2022.89283 **4.** 2022 Biosimilar Trends Report. Amgen Biosimilars. Accessed August 31, 2023. https://www.amgenbiosimilars.com/commitment/2022-Biosimilar-Trends-Report. **5.** Data on File Fresenius Kabi USA, LLC. 2022. **6.** Humphreys S. Real-world evidence of a successful biosimilar adoption program. *Future Oncology*. 2022;18(16):1997-2006. doi:10.2217/fon-2021-1584. **7.** Shah B, Haumschild R. Biosimilars: Realizing the potential in the US. *Fresenius Kabi*. November 2022. **8.** Ciccarello C, Leber MB, Leonard MC, et al. ASHP guidelines on the pharmacy and Therapeutics Committee and the formulary system. *American Journal of Health-System Pharmacy*. 2021;78(10):907-918. doi:10.1093/ajhp/zxab080. **9.** Waterhouse DM, Ward P, Drosick DR, Burdette C, Davies D, Mendenhall MA. Sustainable integration of FDA approved biosimilars: Pharmacy versus Physician driven change. 2023. *JCO Oncol Pract*. 09/2023 doi: 10.1200/OP 2300309d