Best Practices for the Implementation of Biosimilars

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An efficient implementation process is the critical building block to realize the benefits of biosimilars.

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

The Benefits of Biosimilars

Oncology has one of the highest uptakes of biosimilars into clinical practice in the US, 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, it is estimated that biosimilars in oncology have saved over $13 billion over ten years.[2]

Executive Summary:

Through a survey involving 33 US medical institutions of variable sizes, the findings highlighted keen insights into best practices for the successful implementation of biosimilars into these institutions. 97% of the institutions have biosimilars approved in their formulary. Some of the key elements that have been shown to help streamline implementation include: [6]

- 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 after just two years, the organization saved over $26 million due to its adoption of biosimilars.

The savings were determined by calculating the decrease in expenditure on biologics, advancements in operational and workflow procedures, and enhancements to the financial status of the health system as a whole.[4] This type of analytical assessment is being adopted and expanded as more biosimilars are being introduced.

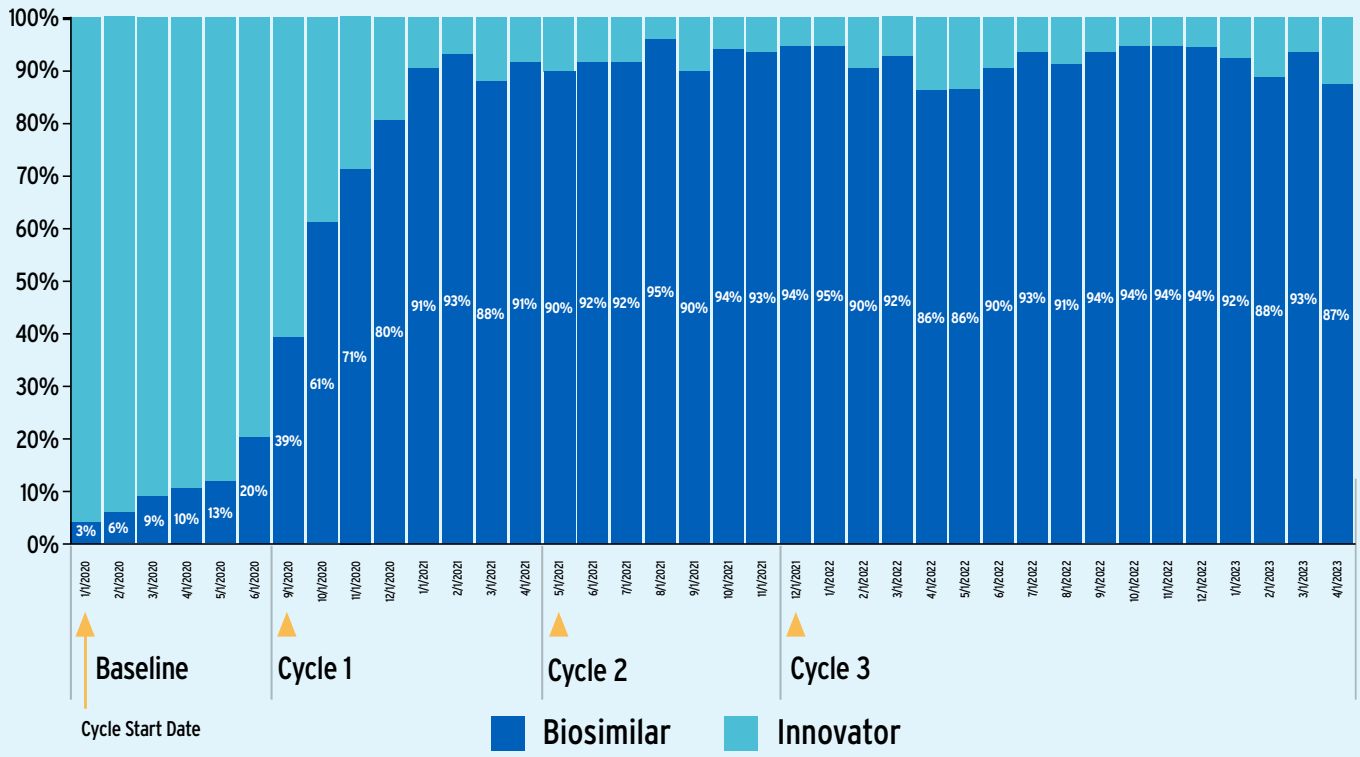
Why, then, has the US yet to reach its full potential in implementing biosimilars? Barriers such as lengthy approval times, IT integration, and inventory management stifle progress and limit access however, these obstacles can be resolved through best practices applied by medical institutions and practices of all sizes, allowing them to take advantage of the benefits of biosimilars.[5]

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 guarantee their efficiency and safety, ensuring no clinically meaningful difference between the biosimilar and its reference product.[7]

Figure 1.

Pharmacist-Driven Implementation



Waterhouse DM, Ward P, Drosick DR, Burdette C, Davies D, Mendenhall MA. *Sustainable integration of FDA approved biosimilars: Pharmacy versus Physician driven change.* 2023.[8]

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 P&T review times, implementing this new process could save weeks to months.

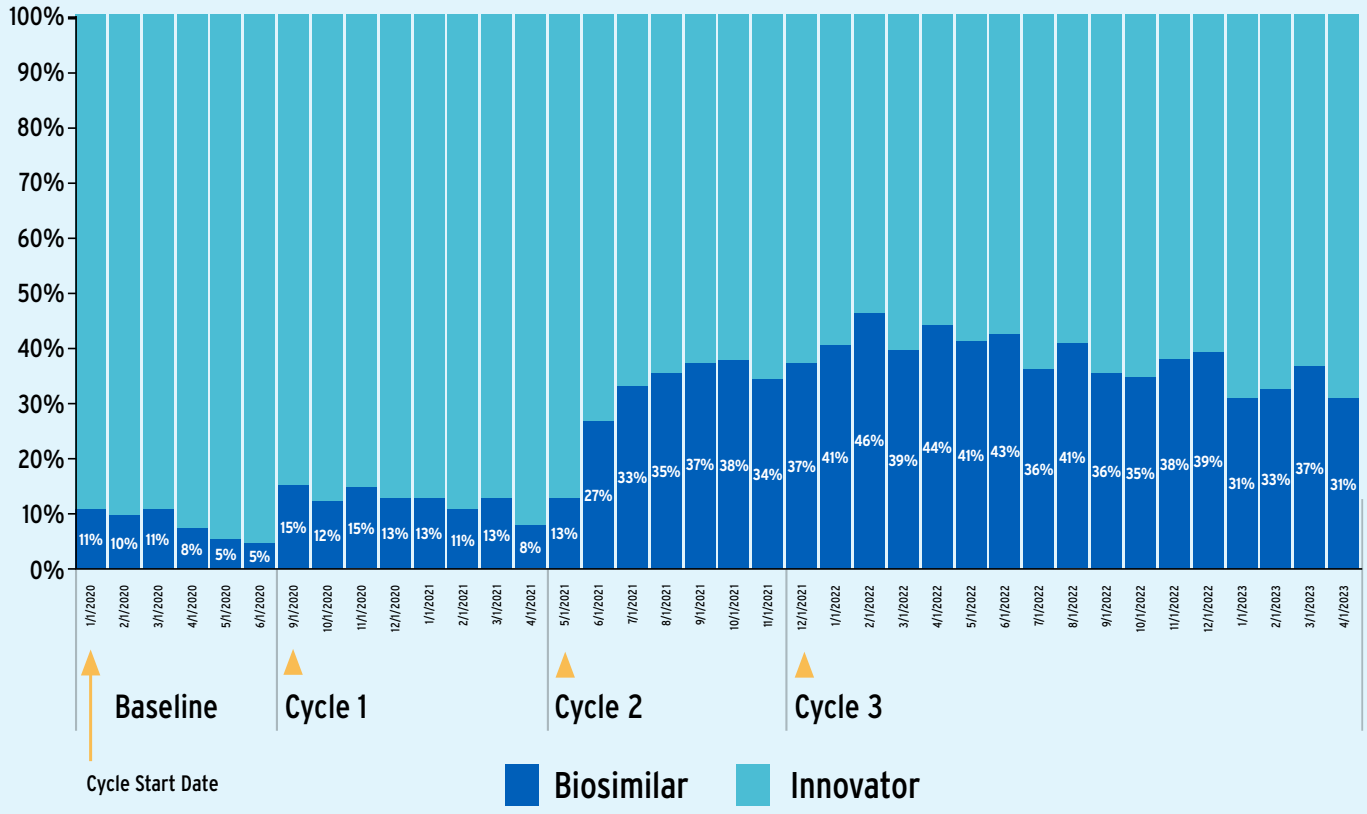
Efficiency is Driven by the Pharmacy

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.[6] (Figures 1 and 2)

A pharmacy-driven implementation is more efficient and effective than a physician-driven one. By introducing a thorough standardization of training by the pharmacy, the adoption of biosimilars was expedited while lowering clinic interruptions for physicians.[6]

Figure 2.

Physician-Driven Implementation



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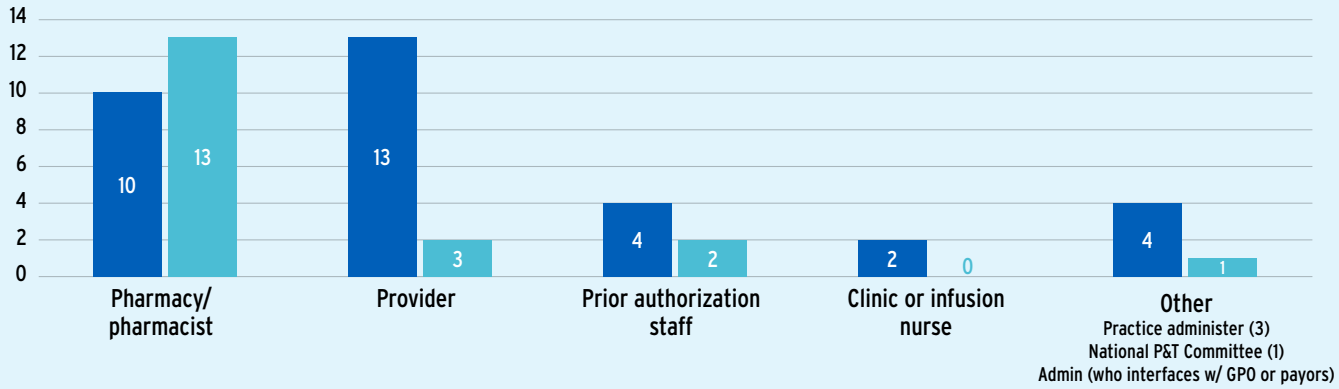
Institutional Differences Based on Size

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.

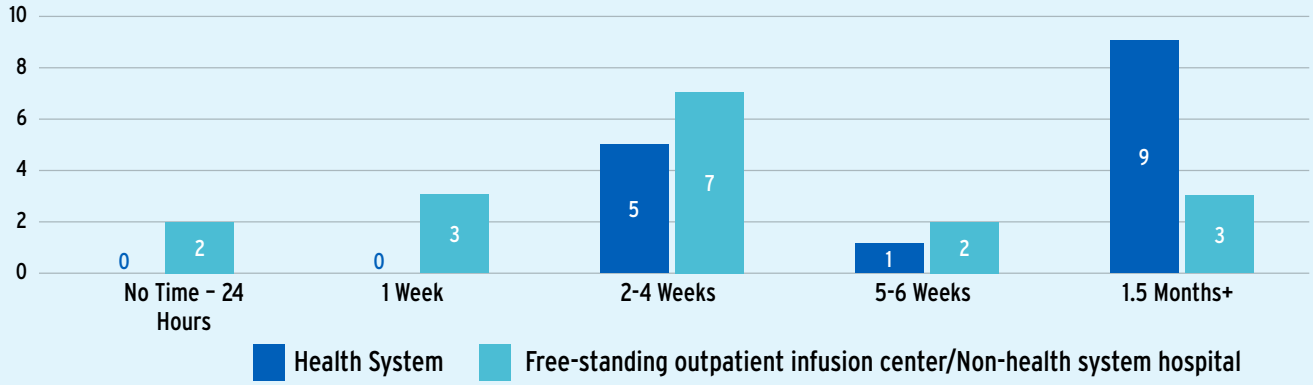
Results indicate that pharmacy-driven implementation is more common among smaller medical institutions, as provider staff may be smaller and limited. Smaller institutions may have fewer resources than larger ones and find that each staff member must perform their role optimally for the smooth flow of daily operations. (Figure 3)

Figure 3.

Which team member initiates adding a new biosimilar to formulary?



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?



Source: Source Data on File. Fresenius Kabi USA, LLC. 2022.[6]

On the other hand, larger health systems faced prolonged periods to integrate biosimilars into their formularies and should anticipate encountering additional barriers due to institutional size.[6]

Data also illustrates an inverse correlation between the size of an institution and its ability to capitalize on efficiency-improving strategies, with smaller establishments tending to lag behind.[6] (Figure 4)

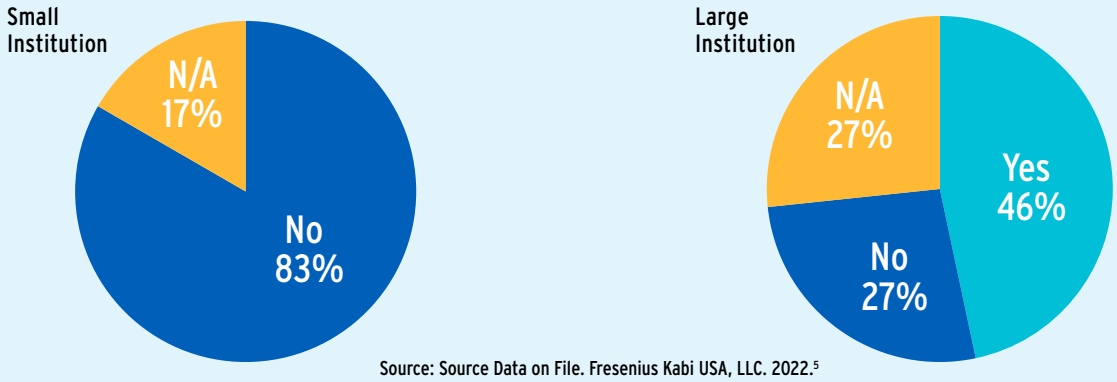
As such, smaller institutions may benefit significantly by evaluating current processes to find opportunities to improve review wait times.

Revisions to the implementation process that both large and small institutions can apply for greater efficiency:

- Creating an automatic 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.
- Instituting a shortened review timeframe to result in the quicker uptake of biosimilars as a full P&T review is not necessary for FDA-approved biosimilars.
- Forgoing re-consent for switching such as with pegfilgrastim molecules to 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.

Figure 4.

Have you revised your implementation process to shorten the time frame?



Source: Source Data on File. Fresenius Kabi USA, LLC. 2022.[5]

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 of the factors to consider for the evaluation include:

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

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

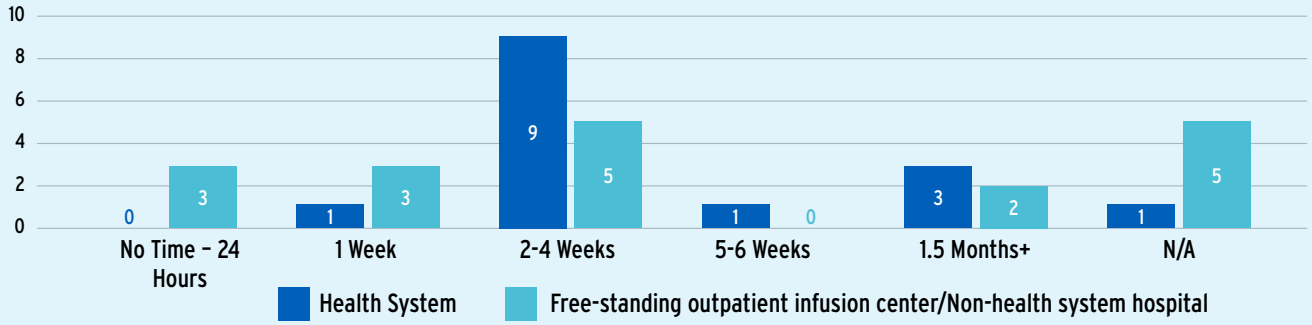
Critical challenges faced by the medical institutions that were shown to hinder the quick adoption of biosimilars included IT systems,

EHR/EMR integration, inventory management, and protocol formations. The research subsequently highlighted how healthcare providers could use best practices to overcome such issues.

Data shows that the majority of the demanding workload is within two to four weeks when it comes to both large and small institutions. This highlights how vital advance planning is for institutions to manage their operations within this timeframe effectively with the following best practice steps. (Figure 5.)

Figure 5.

How much time does Internal setup, including protocol revisions, inventory stocking, and EMR integration require?



Source: Source Data on File. Fresenius Kabi USA, LLC. 2022.[6]

Obstacle

The creating and updating of protocols requires a high level of awareness, time, and communication among staff.

Advice from Study Participant

Develop a system that allows for preferred biosimilar but ability to switch based on payer mandates easily.

Best Practice Steps to Take

1. Create a preferred biosimilar auto-substitution handled by the pharmacy to allow for easy switching basaed on payer mandates.
2. Establish SOPs that all staff can utilize to effectively communicate standardized practices. Allocate resources to ensure the SOPs are kept up to date.
3. If two or more biosimilar options are available, have the pharmacy create a template for physicians to sign off on.
4. Create a dedicated biosimilars build team who can update old protocols with new preferred biosimilars.

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 Participant

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

Best Practice Steps to Take

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 withing the protocol.
   - Ensure regular updates with biosimilar of choice.
3. Have software across various locations to support the aligned launch date.

Obstacle
Inventory management requires a high level of attention to ensure products are stocked and utilized properly.
Advice from Study Participant
Build direct therapeutic index for your system preferred biosimilars.
Best Practice Steps to Take
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 for the day of kickoff of conversion. – Have all staff education materials ready. 4. Ensure that EHR automation is built. – Orders are sets in place and ready to be used. – Set minimums and maximums. – Billing and coding information is in place.

Placing Emphasis on Education and Communication

Education and communication are some of the most crucial steps in implementation and should not be overlooked. All associated stakeholders, such as physicians, advance practice providers, pharmacists, treatment nurses, ad 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

Best practices for educating staff include:[6]

- 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 for patients and HCPs making the onboarding of biosimilars a smoother process.
- Locate information on manufacture's product or patient support websites.
- 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.

accordingly while avoiding unnecessary obstacles. Moreover, automatic authorization for preferred products or payer-required products can minimize the challenges of redundant processes.[6]

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

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

Key Takeaways

Three ways to improve the adoption process and ease implementation for Biosimilars according to a study participant:[6]

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

To learn more about implementing biosimilars into your institution fill out the contact form at stimufendhcp.com/register or call 1-888-391-6300 to speak with a Stimufend Key Account Manager.

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