

JOINT *Matters*

An Inflection Point for Arthritis Treatment

Biosimilars hold enormous promise to deliver cost-effective treatments indistinguishable from their reference biologics. With AbbVie's blockbuster drug [adalimumab \(Humira\)](#) losing its market exclusivity earlier this year, its biosimilars will have the opportunity to alter the treatment landscape for autoimmune arthritis after spending years in development, approvals and regulations.

The path to commercialization for a biosimilar is different from its reference product. Due to their close structural similarity to a reference biologic, biosimilars are allowed a contracted pathway for approval. Among other requirements, the [Food and Drug Administration \(FDA\)](#) necessitates studies showing "no clinically meaningful difference" in safety, purity and potency between the biosimilar and its reference biologic. In some cases, clinical switching studies are needed to show the [interchangeability](#) of the biosimilar with its reference product. This additional regulatory designation allows pharmacists to substitute the biosimilar for its reference product without additional approvals from the prescribing physician.

But despite an abbreviated approval process, biosimilars have been slow to make headway into U.S. health care markets, in part due to proprietary patents on reference biologics. Biotech companies spend billions of dollars on drug development and are accorded exclusive market share for a few years by the FDA. These companies often extend their exclusivity by filing multiple patents on their manufacturing processes, which can further delay biosimilars from entering markets.

Other [barriers](#) also stand in the way of biosimilars reaching consumers. Health care systems may continue to adhere to reference biologics to reap rebate benefits. Biosimilars must also fiercely compete with their reference biologics for patient preference and physician willingness to prescribe them over reference biologics. Consequently, unresolved provider or patient concerns about immunogenicity or interchangeability could be a significant setback.

There is, however, encouraging real-world evidence from Europe and other countries on biosimilars' long-term safety and efficacy, especially for rheumatoid arthritis treatment. For example, a recent [study](#) showed that a hospital-wide switch between adalimumab to its biosimilar (*Amgevita*) did not significantly affect patient treatment satisfaction. The study also reported no indication of increased side effects. Similar evidence also exists for the biosimilars for [rituximab \(MabThera\)](#) and [etanercept \(Enbrel\)](#).

To allay concerns and ease the adoption of biosimilars, the [Arthritis Foundation](#) stresses that switching from a reference biologic must be a joint decision between providers and patients. Further, the Foundation believes that health care stakeholders should be responsible for educating patients about biosimilars. As a recommendation to increase transparency, we assert that formulary changes involving biosimilars must be communicated to the patients promptly, and patients should see a reprieve in their out-of-pocket costs upon switching to biosimilars.

As many as [10 adalimumab biosimilars](#) await their launch into the U.S. market this year. Although the extent of hiccups of their assimilation into the U.S. health care system remains to be seen, the Arthritis Foundation believes that biosimilars have the potential to benefit every stakeholder in the health care system.

The Arthritis Foundation would like to thank Dr. Mark Box for his feedback on this article.



"Biosimilars will help drive down the costs of life-altering medications for autoimmune diseases. However, rheumatologists and their patients will have to adapt as insurers place restrictions on originator products by demanding biosimilar use initially or by imposing a switch from originator products. The hope will be for better access, but the insurance landscape post biosimilars introduction remains to be seen." — Mark Box, MD, Carondelet Rheumatology

Identifying Biomarkers to Better Guide Treatments

Close to half of all rheumatoid arthritis patients do not respond to targeted therapies using biologics. With the support of a [Rheumatoid Arthritis Research Program Award](#) from the Arthritis Foundation, Elaine Husni, MD, MPH, vice chair of the Cleveland Clinic's Department of Rheumatic and Immunologic Diseases, will be investigating if specific genetic markers can predict a refractory response to inhibitor drugs for tumor necrosis factor alpha (TNF- α), a cytokine implicated in inflammation.



“My translational research lab here at the...Lerner Research Institute has identified some genetic differences in the difference for of TNF receptors.” — Dr. Husni

Refractory rheumatoid arthritis is a disease state when drugs with different mechanisms of action have not successfully lowered the severity of the inflammatory symptoms or remission. Thus, understanding the basis of why rheumatoid arthritis refractory to TNF- α inhibitors represents an area of unmet clinical need.

“My translational research lab here at the (Cleveland Clinic) Lerner Research Institute has identified some genetic differences in the different forms of TNF receptors,” says Dr. Husni. “[One of] these genes involved in inflammation in rheumatoid arthritis may be responsible for, or influence, how somebody responds to a TNF inhibitor.”

The \$75,000 pilot award from the Arthritis Foundation will provide Dr. Husni with research funding for a year.

Closing Gaps in Care Through Inclusive Recruitment and Training

With a Diversity, Equity and Inclusion (DEI) Award from the Arthritis Foundation, Lisa Criscione-Schreiber, MD, professor of medicine and vice chair for education at Duke University School of Medicine, will be working to recruit and train rheumatologists from groups that are underrepresented in medicine.

The vast majority of rheumatologists in the U.S. are either White or Asian. This lack of diversity leads to communication gaps when moving across cultures, gender and economic backgrounds. Dr. Criscione-Schreiber's program at Duke University is structured to bridge this gap in rheumatology care by tackling the issue at two levels: 1) Recruiting medical students from underrepresented groups; and 2) Educating medical students and providers through podcasts, teaching and consultations about inclusive practices in rheumatology. In addition to bringing diversity to rheumatologist recruitment, Dr. Criscione-Schreiber will encourage physicians to protect their patients' health by addressing racial disparities at the root cause.

“When people have providers they can relate to, based on being the same sex, race or ethnic origin, their outcomes are better,” says Dr. Criscione-Schreiber.

The \$22,000 DEI Award from the Arthritis Foundation will provide Dr. Criscione-Schreiber with funding for a year.

ADVOCACY UPDATE

The Safe Step Act

Why it matters:

The Safe Step Act, an amendment to the Pharmacy Benefit Manager Reform Act, is a bipartisan bill that will put reasonable parameters around step therapy (where patients must try lower-cost prescription drugs before stepping up to similar acting, higher-cost alternatives). The act, supported by patients, providers and the Arthritis Foundation, will be considered by the Senate before being sent to the House Education and Workforce Committee for deliberation.

Arthritis Awareness Month Recognized

Why it matters:

Arthritis research and programs are underfunded relative to the disease burden. On May 11, 2023, the Arthritis Foundation co-hosted a congressional briefing with Angry@Arthritis in coordination with Reps. Gerry Connolly and Debbie Dingell. The Foundation highlighted the need for arthritis to be an urgent public health priority and featured researchers worldwide. During the briefing, Rep. Dingell introduced a [resolution](#) commemorating Arthritis Awareness Month and the Arthritis Foundation's 75th anniversary. Arthritis Foundation President and CEO Steven Taylor spoke about the importance of federal funding to support arthritis research. Dr. Blair Solow of UT Southwestern, Dr. Jennifer Elisseff of Johns Hopkins University and others presented the breadth of the need for new treatments for arthritis. Highlights from the briefing will be used to continue advancing the Foundation's legislative asks with appropriators and members of the Arthritis Caucus.



COMMUNITY IN ACTION

Make an impact! Join the Arthritis Foundation's signature events happening at a location near you.

Walk to Cure Arthritis is the largest arthritis gathering in the world, celebrating arthritis warriors while raising funds.

Jingle Bell Run is the most festive holiday run. Bring a team of friends, family members and co-workers to this festive holiday fundraiser, whether you run, walk or just cheer on everyone else from the sidelines.

California Coast Classic Bike Tour, presented by Amgen, is a scenic bike ride that takes place over eight days and covers 525 miles along the coast on Highway 1. The tour starts in the heart of San Francisco and ends on the iconic strand of Los Angeles.

To learn more about our events and participate, visit www.arthritis.org/events.

LET'S CONNECT!

To ensure you are receiving our most up-to-date communication from **Joint Matters**, please visit <https://www.arthritis.org/forms/hcp-e-newsletter> to confirm your subscription.

You can also email us at AFscience@arthritis.org.



Science Summit

The Arthritis Foundation's virtual Science Summit will bring together thought leaders and practitioners in clinical rheumatology, experts in curriculum development and DEI, fellows and people with arthritis to discuss strategies to encourage outreach and retention of underrepresented-in-medicine individuals in rheumatology training programs.

This virtual event will feature six currently funded Arthritis Foundation DEI grantees. They will be presenting on curriculum

development to address the lack of diversity of students in the medical training pipeline and health equity research in clinical rheumatology. Increasing the diversity of clinical rheumatologists improves the health outcomes of patients and increases health equity for people with arthritis across the U.S. This is an open invitation. Registration is coming soon. For questions, please email AFscience@arthritis.org.

