ADOPTING BIOSIMILARS WITH CONFIDENCE

For biosimilars to fulfill their potential to reduce the cost of biologic medicines, it will take the collective efforts of individual institutions and pharmacy directors leading the way through the adoption of biosimilars onto their formularies.

A **BIO**EVOLUTIONARY OPPORTUNITY

More biosimilars are being developed every year

Biosimilar Product Development Programs Registered With the FDA
(by fiscal year)[1,2]

References: 1. Jenkins J. Office of New Drugs, Center for Drug Evaluation and Research. Biosimilars in the US: Progress and Promise, DIA Biosimilars 2016. https://wayback.archive-it.org/7993/20170405202142/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM526935.pdf. Published October 27, 2016. Accessed May 19, 2020. **2.** US Department of Health and Human Services, Food and Drug Administration. Cumulative number of biosimilar development programs in the BPD Program in the month. https://accessdata-preprod.fda.gov/scripts/FDATrack/view/track.cfm?program=cder&id=CDER-RRDS-Number-of-biosimilar-dev-programs-in-BPD-Program. Accessed May 19, 2020.

BIOFUNDAMENTALS

Based on a foundation of science

Biosimilars are put through rigorous development and testing[1]

"All FDA-approved biological products, including reference products and biosimilar products, undergo a rigorous evaluation."[1] – FDA

Before applying to and receiving approval from the FDA, a biosimilar product must show that it has no clinically meaningful differences in safety, purity, and potency compared with the reference biologic. This is done through a step-wise approach:

Detailed Analytical Studies[1]

- **To identify and compare structural and functional characteristics** and to demonstrate the "highly similar" nature of a biosimilar product to the reference biologic

Comparative Clinical Studies (if necessary)[1]

- **To confirm biosimilarity of the product** in patients in at least one approved indication of the reference biologic

Reference: 1. US Department of Health and Human Services, Food and Drug Administration. Biosimilar development, review, and approval. https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval. Published October 20, 2017. Accessed May 6, 2019.

BIOLEADERSHIP

Spearheading institutional implementation

What to consider for biosimilar organizational adoption

Before adding any medicine onto formulary, nearly every organization relies on its pharmacy and therapeutics (P&T) committee to conduct a broad and detailed evaluation of the product, including biosimilars.

Key elements of biosimilar formulary review:

Clinical Parameters[1]

- Indications
- Clinical data
- Immunogenicity

Product Characteristics[1]

- Nomenclature
- Supply chain
- Packaging/Labeling

Institutional Considerations[1]

- Cost/Reimbursement
- Pharmacovigilance
- Patient/Provider education
- Tracking and information system implications

Reference: 1. Ventola CL. Evaluation of biosimilars for formulary inclusion: factors for consideration by P&T committees. *P&T*. 2015;40(10):680–689

THE POTENTIAL OF BIOSIMILARS

Biosimilars may offer health care system benefits[1,2]

- Increased competition
- Reduced cost for payers

References: 1. US Department of Health and Human Services, Food and Drug Administration. Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA's biosimilars action plan. https://wayback.archive-it.org/7993/20170405202142/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM526935.pdf. Published July 18, 2018. Accessed May 19, 2020. **2.** *Biosimilars Action Plan: Balancing Innovation and Competition.* US Food and Drug Administration: Silver Spring, MD; 2018. https://www.fda.gov/media/114574/download. Published July 18, 2018. Accessed May 14, 2019.