PrimO
Practical Recommendations in Immuno & Molecular Oncology

Seven Years of Biosimilar Experience in the U.S., Where Untapped Value Remains

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Learning Objectives

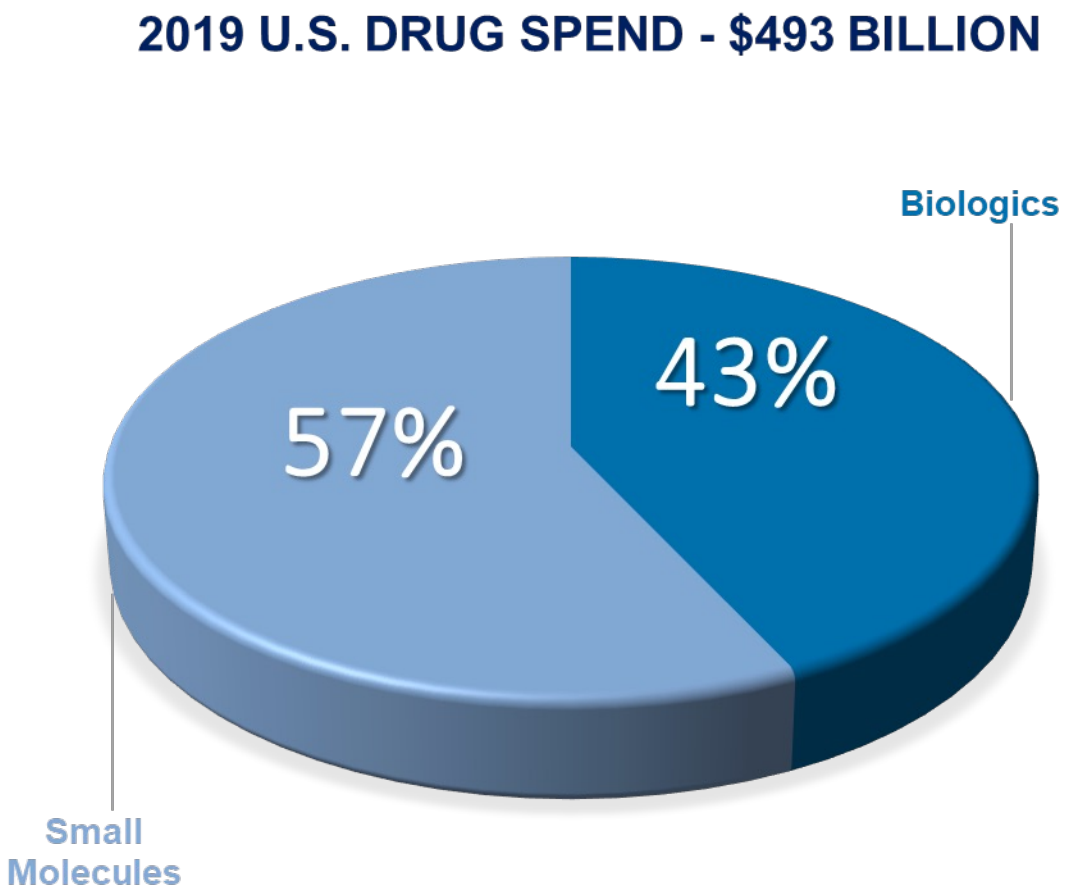
1) Identify cost trends in the biosimilar sector that impact therapy decisions

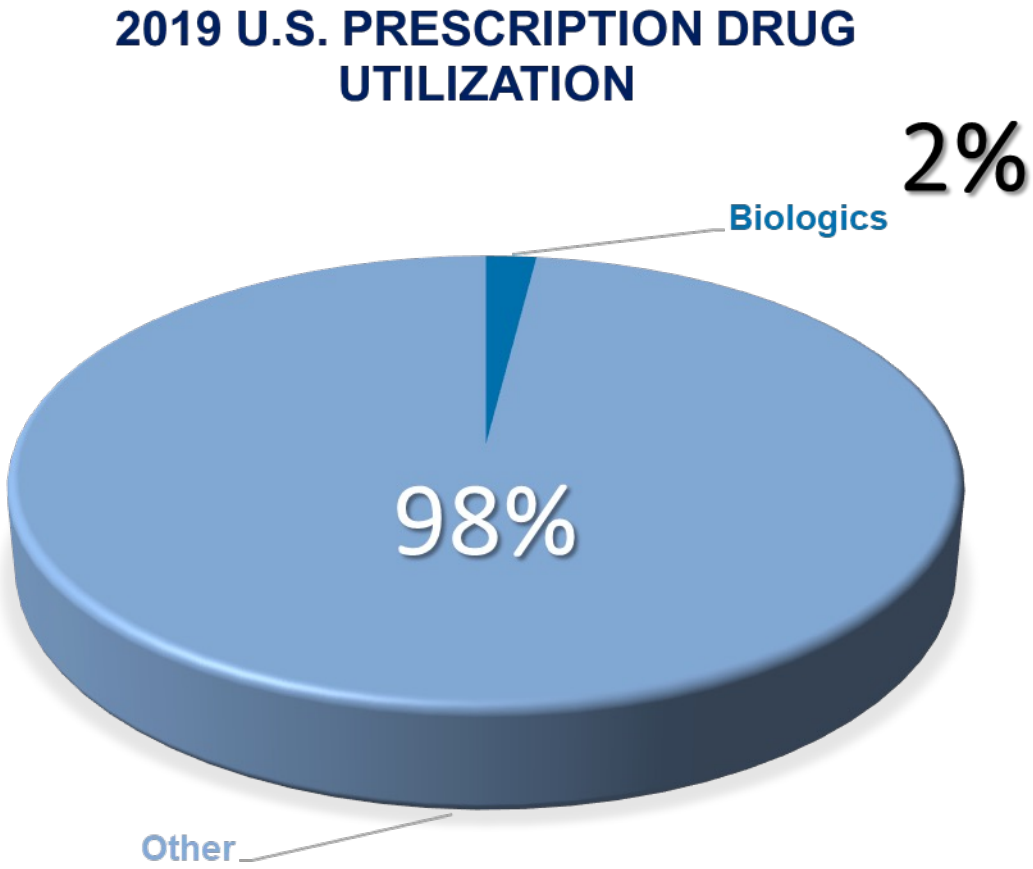
2) Discuss emerging biosimilar trends, challenges, and opportunities

3) Describe how having biosimilar strategies in place can be leveraged to provide additional value to your practice

Background

Cost of biologic pharmaceuticals have reached an all time high





1. Biosimilars in the United States 2020-2024. September 2020. https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024.Accessed October 6, 2021
2. Aggarwal, G., Nagpal, M., Sharma, A., Puri, V., Dhingra, G. *Upcoming Drifts in Biosimilars*. Current Reviews of Clinical and Experimental Pharmacology. (2021) 16, 39-51

Background

- Cancer drug cost increasing at twice the rate of general healthcare cost
- Median monthly cost of new U.S. cancer drugs surpassed the median monthly household income in year 2000 and more than doubled by 2014
- Oncology pipeline includes >700 drugs in clinical trials
  - Anticipated to grow
- Rising and unsustainable healthcare cost calls for cost containment strategies

1. *Unlocking the Potential of Biosimilars.* Cigna's Newsroom. Accessed October, 5, 2021
2. Medicine Use and Spending in the U.S. A Review of 2018 and Outlook to 2023. May 2019. IQVIA Institute for Human Data Science. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf?_=1602972025818. Accessed October 17, 2020.
3. Goll, G., Kvien, T. *An Opportunity Missed: Biosimilars in the United States.* American College of Theumatology. Vol 72, No. 7, July 2020, 1046-1048

Biosimilar Scientific Demonstration

Switching & Interchangeability

Switching

- The exchange of one medicine for another with the same therapeutic intent
- Presents no greater safety or efficacy risk than continuous treatment with the reference product
- Based on interchangeability designation
- One of the most contested biosimilar issues and inconsistently handled by approving agencies

1. Davio, K. *Biosimilar Beats Subcutaneous Rituximab on Cost Savings in NHL*. Centers for Biosimilars. December 5, 2018
2. Barbier, L., Mbuaki, A., Simoens, S., Declerck, P., Vulto, A., Huys, I. *Regulatory Information and Guidance on Biosimilars and Their Use Across Europe: A Call for Strengthened Once Voice Messaging*. Frontiers in medicine. Vol. 9 Article 820755. March 2022
3. Zinzani, P., Dreyling, M., Gradishar, W., Andre, M., Esteva, F., Boulos, S., Gonzalez, E., Curigliano. *Are Biosimilars the Future of Oncology and Hematology?* Drugs (2019) 79:1609-1624

FDA Interchangeability Guidance

FDA recognizes need to evaluate impact of repeated switches

Recommends at least 3 switches in study designs w/ 1 arm remaining unchanged

Primary endpoint to assess impact on

- PD & PK
- Immunogenicity
- Safety profile
- Efficacy (as supportive end point)

Sufficiently long to allow detection of clinically relevant differences

U.S. is the only country with a designated category for interchangeable biosimilars

1. Declerck, P., Bakalos, G., Zintzaras, E., Barton, B., Schreitmuller, T. *Monoclonal Antibody Biosimilars in Oncology: Critical Appraisal of Available Data on Switching*. Clinical Therapetuics. Vol. 40; Nov 5, 2018.
2. Nahleh, Z., Lyman, G., Schilsky, R., Peterson, D., Tagawa, S., Chavez-MacGregor, M., Rumble, B., Gupta, S. *Use of Biosimilar Medications in Oncology.* Journal of Clinical Oncology. Vol 18, Issue 3, 177-186. 2022

Approach to Switching

Expanding wealth of data, including blinded RCTs, provide increasing confidence that switching does not lead to loss of efficacy or increased adverse events:

- > 15 years
- > 16,000 immunogenicity publications
- Risk appears no greater than risk of switching between two different batches of a biologic
- Trending concern with nocebo effect
- Several observational studies reported less compliance with biosimilar etanercept compared to reference
- Medical community confidence needed to address nocebo effect

RCT = Randomized Clinical Trials

1. Afzali, A., Furtner, D., Melsheimer, R. *The Automatic Substitution of Biosimilars: Definitions of Interchangeability are not Interchangeable.* Adv Ther (2021) 38:2077-2093
2. Ebbers, H., Schellekens, H. *Are we Ready to Close the Discussion on the Interchangeability of Biosimilars*. Drug Discovery Today. Vol. 24 No. 10. October 2019

Approach to Switching

Interchangeability determined at federal level (FDA)

Substitution regulated at state level

- At least 45 states & Puerto Rico permit or require pharmacists to interchange allow
  - If biosimilar is considered interchangeable &
  - Covered under payer's pharmacy benefit

- Pharmacy & Therapeutics (P&T) Committee substation approval

- Health plans nonetheless treat biosimilars as "interchangeable"

- Interchangeability pursue expected to align with pharmacy benefit

1. Afzali, A., Furtner, D., Melsheimer, R. *The Automatic Substitution of Biosimilars: Definitions of Interchangeability are not Interchangeable.* Adv Ther (2021) 38:2077-2093
2. Declerck, P., Bakalos, G., Zintzaras, E., Barton, B., Schreitmuller, T. *Monoclonal Antibody Biosimilars in Oncology: Critical Appraisal of Available Data on Switching*. Clinical Therapetuics. Vol. 40; Nov 5, 2018.
3. Nabhan, C., Valley, A., Feinberg, B. *Barriers to Oncology Biosimilars Uptake in the United States*. The Oncologist. 2018;23:1261-1265
4. Lyman, G., Balaban, E., Diaz, M., Ferris, A., Tsao, A., Voest, E., Zon, R., Francisco, M., Green, S., Sherwood, S., Harvey, D., Schilsky, R. American Society of Clinical Oncology Statement: Biosimilars in Oncology. Journal of Clinical Oncology. Vol. 36 No. 12 April 2018.
5. Barbier, L., Mbuaki, A., Simoens, S., Declerck, P., Vulto, A., Huys, I. *Regulatory Information and Guidance on Biosimilars and Their Use Across Europe: A Call for Strengthened Once Voice Messaging*. Frontiers in medicine. Vol. 9 Article 820755. March 2022

Science for Biosimilarity Demonstration in Evolution

- Biosimilar approvals:
  2007 in Europe*
  2015 in U.S.
- Relevance of biosimilar animal studies under question
- Several not evaluated by FDA
- FDA & EMA have approved > 100 products, none of which have failed animal toxicity testing

* Eight years after approval of the first biosimilar, EU approved 15 products while US approved 39

1. Niazi, S. Biosimilars: *A Futuristic Fast-to-Market Advice to Developers*. Expert Opinion on Biologic Therapy. Vol. 22, No. 2, 149-155. Dec 27, 2021
2. Nahleh, Z., Lyman, G., Schilsky, R., Peterson, D., Tagawa, S., Chavez-MacGregor, M., Rumble, B., Gupta, S. *Use of Biosimilar Medications in Oncology*. Journal of Clinical Oncology. Vol 18, Issue 3, 177-186. 2022

Science for Biosimiliarity Demonstration

- Bioequivalence technology advances
  - Protein mass spectrometry (10 million-fold more sensitive than a decade ago)
  - In-process analytic controls producing higher batch-to-batch consistency

- FDA - “biosimilars may be approved based on PK and PD biomarker data without comparative clinical study with efficacy endpoint(s).”
  - shorter, less costly clinical studies
  - potential more sensitive testing vs clinical efficacy endpoints
  - filgrastim clinical analysis showing absolute neutrophil count more sensitive than duration of severe neutropenia

1. Niazi, S. Biosimilars: *A Futuristic Fast-to-Market Advice to Developers*. Expert Opinion on Biologic Therapy. Vol. 22, No. 2, 149-155. Dec 27, 2021
2. De Mora, F. *Biosimilars: A Value Proposition*. BioDrugs 33:353-356. 2019

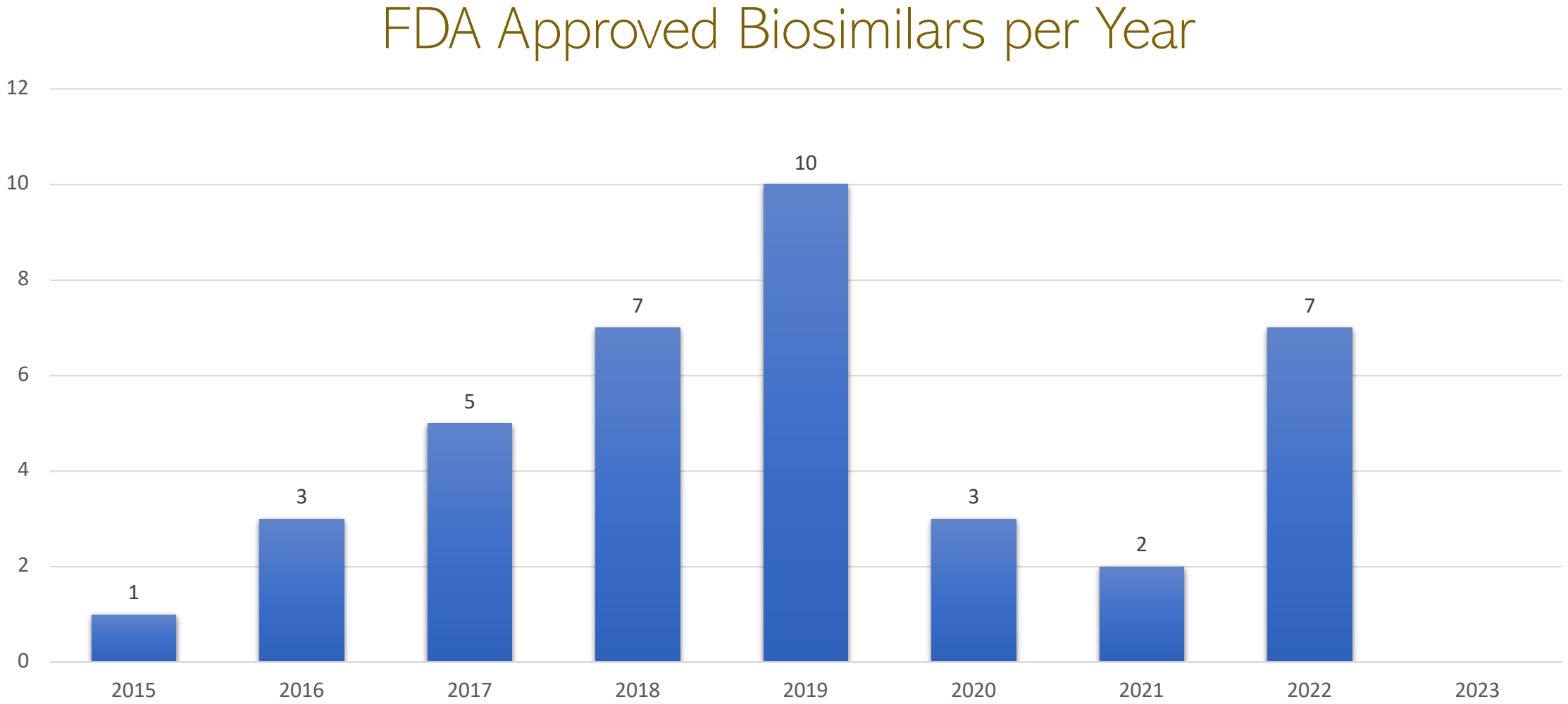
Science for Biosimiliarity Demonstration

- None of 100+ FDA/EMA approved biosimilars failed clinical efficacy testing if they met the analytics similarity and clinical pharmacology testing

- EMA has started to pilot clinical trial programs to advise how clinical testing can be reduced or avoided for biosimilars

1. Niazi, S. Biosimilars: *A Futuristic Fast-to-Market Advice to Developers*. Expert Opinion on Biologic Therapy. Vol. 22, No. 2, 149-155. Dec 27, 2021
2. De Mora, F. *Biosimilars: A Value Proposition*. BioDrugs 33:353-356. 2019

FDA-Approved Biosimilars



Purple Book: Reference to identify 351(k)-licensed products and respective biosimilarity and interchangeability status

FDA Approved Biosimilar Products. https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed Sept. 15, 2022

Other Biosimilar Emerging Trends

- Biosimilar use in clinical trials
  - Limited but expanding
  - Common practice with generics (e.g., cyclophosphamide, doxorubicin)
- Biosimilar misinformation
- Confusing terminology
- Claims not supported by referenced citations
- Misleading conclusion in the scientific literature
- Incorrect assertion that interchangeability is a higher quality standard than biosimilarity
- Varying global truths

Chen, J., Ngo, D., Yi, A. *Biosimilar Impact on oncology Clinical Trial Design and Operations*. Journal of Oncology Practice Editorials. Vol 18, Issue 3, 157-159
Cohen, H., McCobe, D. *The Importance of Countering Biosimilar Disparagement and Misinformation*. BioDrugs 34:407-414. 2020

Other Biosimilar Emerging Trends

- 2022 Biosimilar turning point
- Reaches broader patient populations
  - Diabetes
  - Ophthalmology

- 2023 Biosimilar turning point
- Adalimumab launch
- Beyond
- Expanded patient populations
  - Rheumatology
  - Immunology
  - E.g., ustekinumab & tocilizumab

1. Chen, J., Ngo, D., Yi, A. *Biosimilar Impact on oncology Clinical Trial Design and Operations*. Journal of Oncology Practice Editorials. Vol 18, Issue 3, 157-159
2. Cohen, H., McCobe, D. *The Importance of Countering Biosimilar Disparagement and Misinformation*. BioDrugs 34:407-414. 2020
3. Biosimilar Report: The U.S. Journey and Path Ahead. Cardinal Health. 2022.

Barriers to Market Entry

Biosimilar Marketplace Uncertainty

- No patent exclusivity
- Limited FDA-designated interchangeability
- Incomplete label indication (where applicable)
- Order of market entry uncertainty
- No guaranteed payer coverage
- No guaranteed market share
- No guaranteed sales

Patent Litigation “Patent Dance”

Biologics exclusivity by the Biologics Price Competition and Innovation Act

Several product patents

- Primary patent on molecule and manufacturing
- Formulations
- Delivery systems
- Absorption
- Others
- May extend exclusivity for years

Infringement litigation

Affecting most biosimilars; months to years of delays

1. Schwieterman, P. *A Strategic Review of Biosimilars in Oncology Practice*. Hematology/Oncology Pharmacy Association (HOPA) News. Volume 15, Issue 1 (2018)
2. *What if Biosimilars Never Arrive? Five Key Barriers Create Uncertainty for Biosimilars.* Optum.
3. Wechsler, J. *FDA Struggles to Advance Biosimilars*. PharmExec.com Commercial Insights for the C-Suite. Volume 38, Issue 9. Sept,01,2018

Barriers to Entry – Patent Litigation

Adalimumab Case; U.S. Experience

Risankizumab-rzaa

- Improved effectiveness in severe plaque psoriasis
- More favorable dosing schedule
- Expanding indications (e.g., Psoriatic Arthritis 1/21/22)

Upadacitinib

- Evidence of improved efficacy in RA
- 58 active clinical trials listed in ClinicalTrials.gov*

1. Upadacitinib Current Studies Listed in ClinicalTrials.Gov https://clinicaltrials.gov/ct2/results?cond=upadacitinib&term=&cntry=&state=&city=&dist= Accessed Sept. 15, 2022

Barriers to Entry - Adalimumab

Adalimumab Biosimilar Launches in the U.S. Market in January, 2023

- 8 FDA-approved biosimilars
- Fierce competition in race to capture market share for the top selling biologic in the world
- Most pursuing interchangeability status
- First launch expected in January 2023
- Expected to mark a turning point on biosimilar history in the U.S.
- Expected to achieve one of the most significant healthcare cost savings in recent history in the U.S.

1. Biosimilars Report: The U.S. Journey and Path Ahead. Cardinal Health. 2022.

Reimbursement

Medicare, Medicaid and commercial payers have all approached biosimilar reimbursement differently

CMS codes each biosimilar separately with:

- Unique HCPCS code
- ASP = (total net sales revenue / total product units)
- ASP + “administrative fee” % reference ASP
- CMS Pass-through benefit

Increasing the number of licensed biosimilars to increase market competition thereby reducing biosimilar/biologic drug cost.

ASP = Average Sales Price

DiGrande, S. *UnitedHealthcare Names 3 Biosimilars Preferred Treatment in 2019 MA Plans.* Centers for Biosimilars. October 17, 2018

CMS Biosimilar Reimbursement

Medicare Reimbursement

Reference	ASP + 6%
Biosimilar	Biosimilar WAC* + 3%
Biosimilar	Biosimilar ASP + 6% of Reference ASP

ASP = Average Selling Price WAC = Wholesaler Acquisition Cost

1. Part B Biosimilar Biological Product Payment and Required Modifiers. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment. Accessed October 19

Fee-For-Service Reimbursement

ASP-Dependent Reimbursement

- Significant ASP erosion
  - e.g., 46% in infliximab
- Impact on budgeting
- Impact on reimbursement
- Pressured provider market (e.g., site-of-care & white-bagging)

1. Cohen J. *Approval of First Interchangeable Biosimilar, Semglee, Is Sign of an Improving U.S. Biosimilars Market, Despite Challenges.* Forbes. August 1, 2021

Commercial Payer Cost Impact

ASP (unit of cost) x mark-up (4-6+ factor) = $Charge

Reimbursement = %$Charge

Product	Cost	Charge*	Reimbursement**
Reference	$10,000.00	$60,000.00	$30,000.00
Biosimilar	$6,500.00	$39,000.00	$19,500.00

* Based on standard 6x mark-up

** Based on payer reimbursement rate of 50% of charges

Payers hold the key to national biosimilar cost-savings potential

More Pharmacoeconomics Stable Biosimilar Market

Cigna Shared Savings Program

- Incentivizing enrollees for switching to biosimilars
- One time $500 debit card to cover health services or medications
- Positioning products as preferred status:
  - infliximab-axxq
  - infliximab-dyyb

- **Magellan Rx Management Oncology Biosimilar Solution**
- Biosimilars costing payers up to 40% less than reference
- Participating health plans experienced > 20% savings by
- switching to biosimilar
- $40 million in annualized savings

1. Cigna Continues Efforts to Lower Prescription Drug Costs by Promoting Biosimilars. Cigna Newsroom. Accessed October 5, 2021, https://newsroom.cigna.com/cigna-continues-efforts-to-lower-prescription-drug-cost
2. Magellan Rx Management Oncology Biosimilar Solution Delivers $40M+ in Annualized Savings for Early Adopter Health Plans. Magellan Health News Release. June 9, 2021. Accessed October 5, 2021, https://ir.magellanhealth.com/news-releases/news-release-details/magellan-rx-management-oncology-biosimilar-solution-delivers-40m

Case: Biosimilar Practice Model

Action	Previous	Current
Order	Specific Product	Generic order
Authorization Team Seeks Payer Certification	For specific product ordered	As follow in order of preference: 1- Facility-Preferred Product 2- If payer choice restricted, then tailor authorization to payer coverage
Payer Certification Documentation	Only visible in Business Office (BO) system	Documented on EHR and available to clinical teams
Product Selection	Back to provider if payer required a product different than originally ordered	Pharmacy selects authorized product prior to dispensation

Biosimilar-Focused Emerging Roles

Boston Medical Center

- Clinical Pharmacist + Pharmacy Technician
- New vs. existing infliximab patients transitioned to biosimilar based on pre-established clinical criteria

Miami Cancer Institute – Baptist Health South Florida

- Prospective monitoring:
  - Payer authorization for facility-preferred product
  - Product selection for dispensation
  - Conducted for every patient, prior to each infusion
- Pharmacy Technician with intervention escalation to pharmacist

Competition-Driven Innovation

New Delivery Systems
- Pegfilgrastim onbody device

New Formulations
- Rituximab hyaluronidase
- Trastuzumab hyaluronidase-oysk

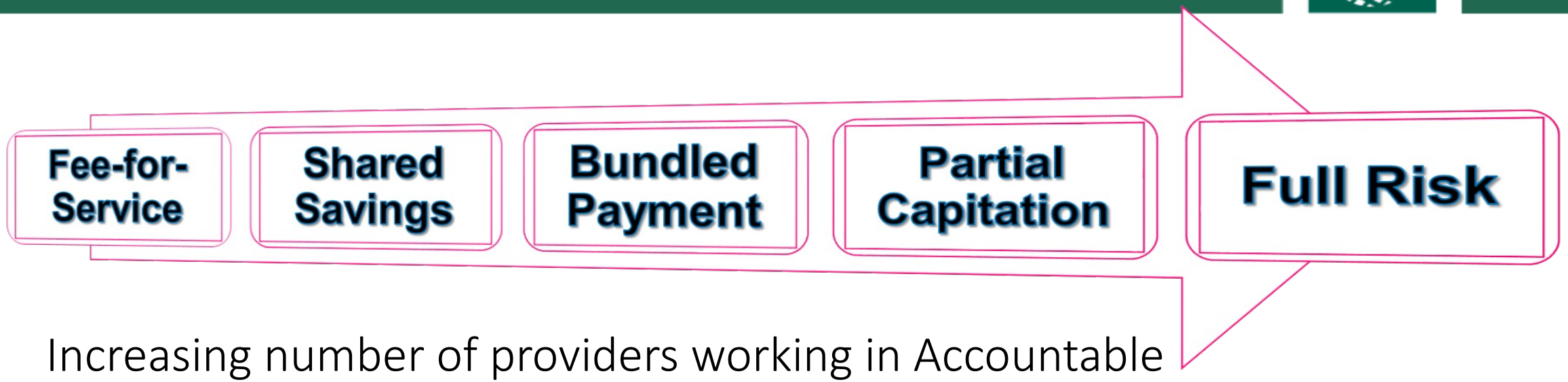
Value Considerations
- Infusion volume decongestion
- Transportation / access / adherence
- Revenue
- Site-of-care

- New efficacy and safety data supporting new indications
- Combination therapies
- Novel drugs
- Healthcare sustainability
- Global access

1. Wechsler, J. *FDA Struggles to Advance Biosimilars*. PharmExec.com Commercial Insights for the C-Suite. Volume 38, Issue 9. Sept,01,2018
2. Zalcberg, J. *Biosimilars are Coming: Ready or not*. Internal Medicine Journal. 48 (2018) 1027-1034
3. Zinzani, P., Dreyling, M., Gradishar, W., Andre, M., Esteva, F., Boulos, S., Gonzalez, E., Curigliano. *Are Biosimilars the Future of Oncology and Hematology?* Drugs (2019) 79:1609-1624
4. Simoens, S., Vulto, A. *A Health Economic Guide to Market Access of Biosimilars*. Expert Opinion on Biologic Therapy. Vol. 21, No. 1, 9-17. 2021

Economic Value

Payment Model Evolution



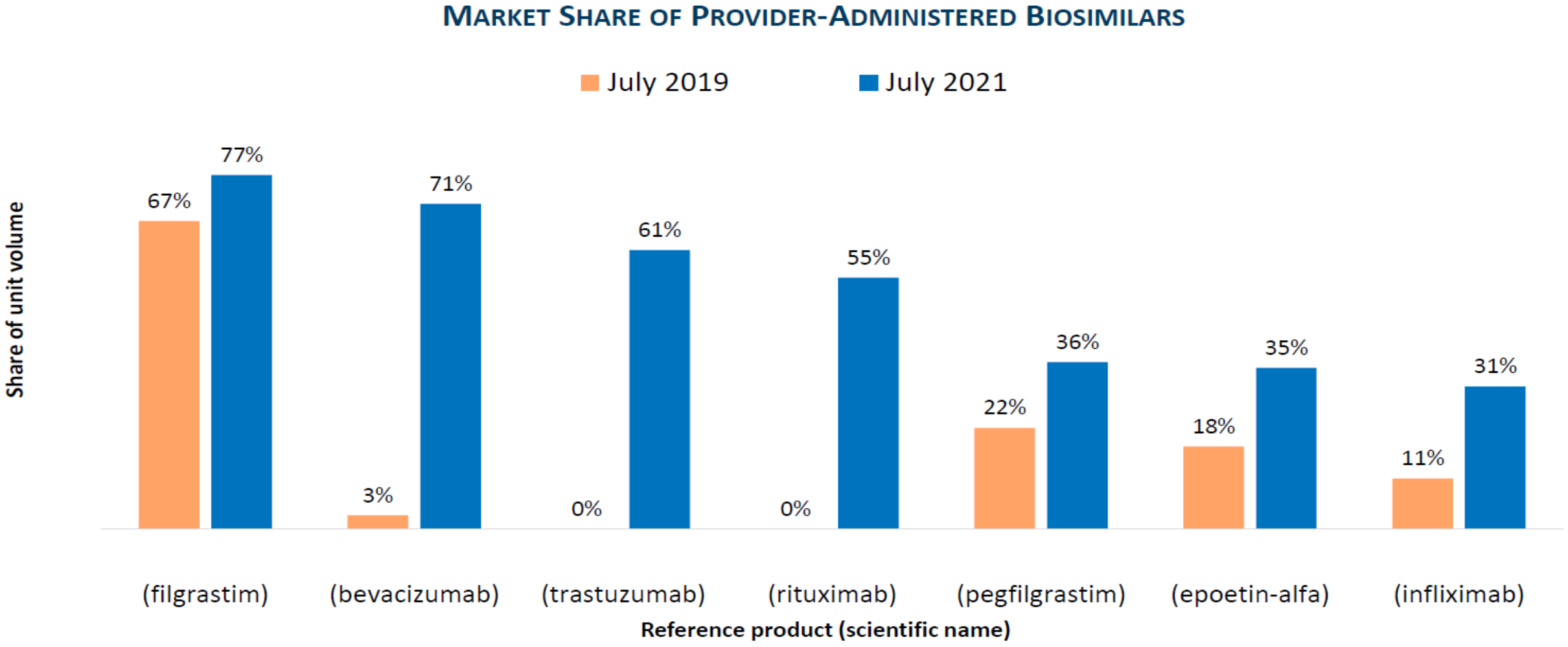
- Increasing number of providers working in Accountable Care Organizations (ACOs) and “narrow networks”
- University of Pittsburgh Medical Center (UPMC) / Highmark - Allegheny Health System
- Kaiser achieved 97% bevacizumab biosimilar 1 month after launch
- Self-insured Employee Health Plans

1. Kvien, T., Patel, K., Strand, V. *The Cost Savings of Biosimilars Can Help Increase Patient Access and Lift the Financial Burden of Health Care Systems.* Seminars in Arthritis and Rheumatism 52 (2002) 151939

Role of Employers in Value-Based Care

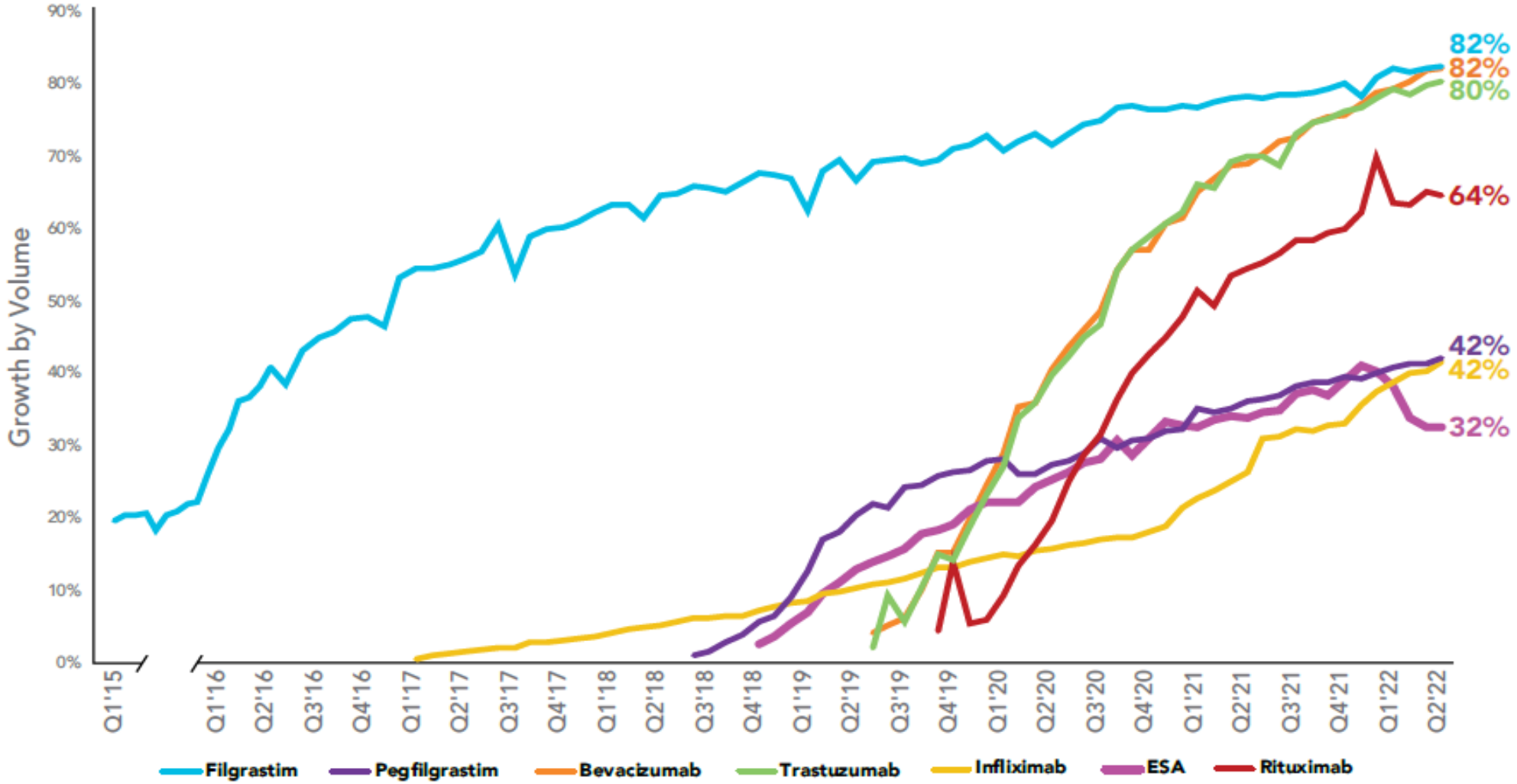
- Employers are the number one purchaser of health insurance
- Employers have a limited understanding of opportunities and risks
- Employers are in a position to influence benefit designs (e.g., biosimilar coverage) but need to understand obstacles
- Employers can align incentives at point of purchase
  - Getting system-owned specialty pharmacy in network
  - At-parity biosimilar coverage
- Payer rebate transparency

Market Share Journey



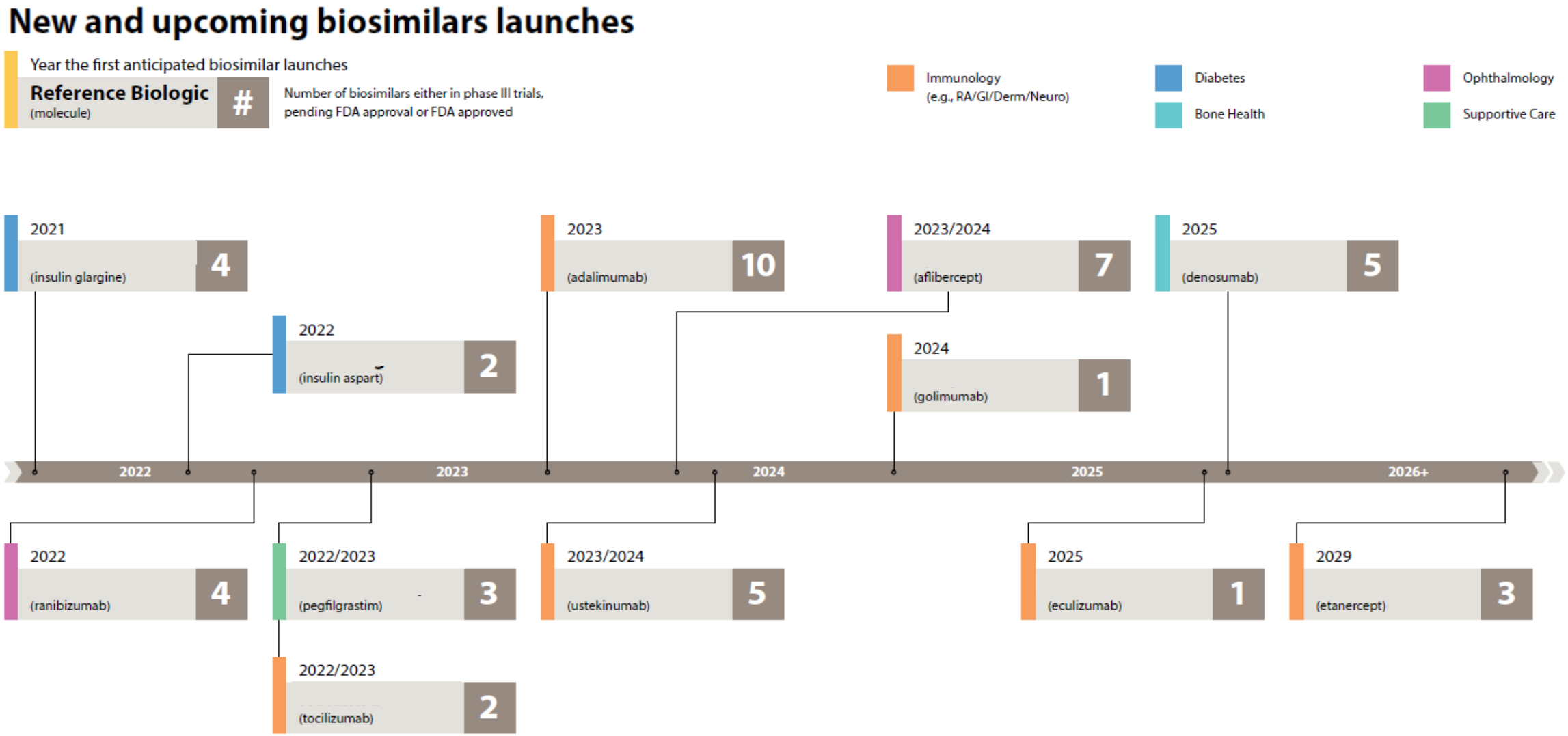
Source: *The 2021-22 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors*, Exhibit 112. Data show combined unit volume market share of biosimilars for named reference products. Volume share for Neupogen biosimilars includes Granix. Drug Channels Institute

Market Share Journey



Key: ESA – erythropoiesis-stimulating agent.
Source: OBU Customer Data Pack Weekly (IQVIA DDD + Chargeback).

Biosimilars-Projected Launches



Source: IPD Analytics. Market & Financial Insights. December 2021. https://www.ipdanalytics.com. Data reflects biosimilar pipeline information as of January 2022.

Biosimilar Report: The U.S. Journey and Path Ahead. Cardinal Health. 2022.

Biosimilars Policy

President Biden signs two bills in April 2022

- The Advancing Education on Biosimilars Act
  - Increasing utilization by stakeholder confidence and competition
- The Ensuring Innovation Act
  - Limit additional market exclusivity provided to reference products
- Close loopholes that delay competition and accessibility

FDA Biosimilar Action Plan

- Streamlining approval process
- Improving regulatory clarity
- Increasing educational efforts
- Collaborating with FTC to address anticompetitive behaviors

1. FTC = Federal Trade Commission
2. Biosimilar Report: The U.S. Journey and Path Ahead. Cardinal Health. 2022.
3. Zhai, M., Sarpatwari, A., Kesselheim, A. *Why Are Biosimilars Not Living up to Their Promise in the US?* AMA Journal of Ethics. Vol. 21. No. 8:E668-678. Aug 2019

Biosimilars Policy

- FDA additional rule-making
- FTC additional rule-making
- CMS expected maintain models that incentivize biosimilar use through both Part B and D benefits
- Bills NC SB 257, MO HB 2305
- Biologics Competition Act of 2022 (HR 8877)*

* Bill aiming to make interchangeable biosimilars more accessible

1. FTC = Federal Trade Commission
2. Biosimilar Report: The U.S. Journey and Path Ahead. Cardinal Health. 2022.

Connection With Purpose

Biosimilars Success Impact Beyond the Walls of the U.S.

The WHO estimates worldwide cancer cases to increase by 60%

- 18.1 million in 2018
- 29.5 million by 2040

Spending on all medicines used to treat cancer patients

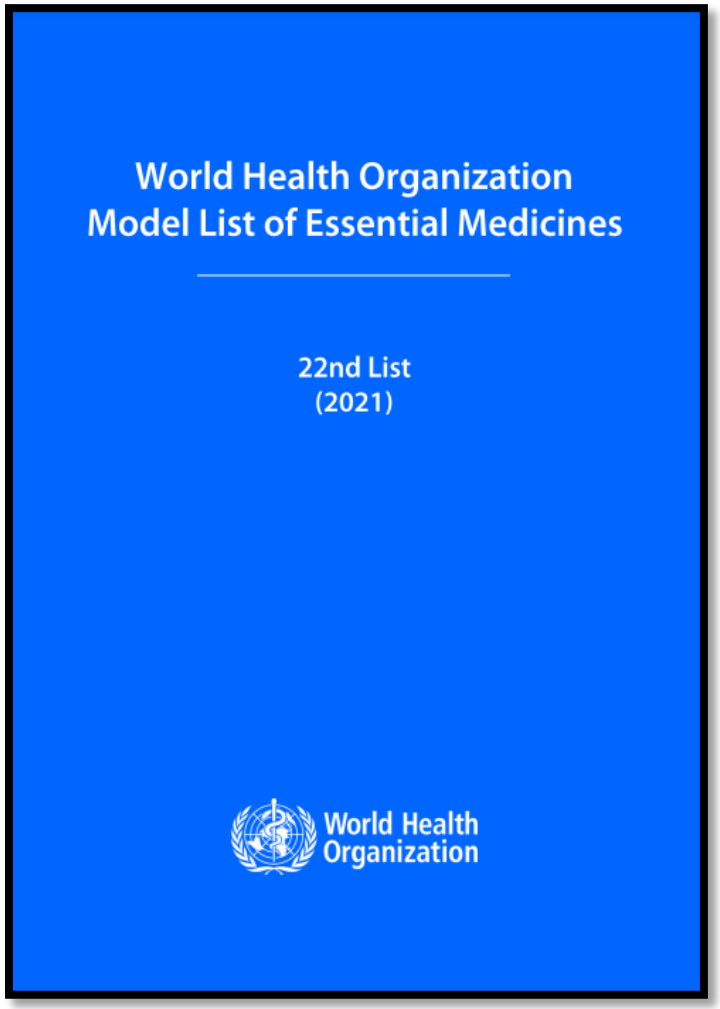
- $150 billion in 2018
- $240 billion by 2023

Cost and accessibility barriers

- Global uptake of biologics greatly limited by cost constrains
- Disparities in patient care and outcomes

1. Peeters, M., Planchard, D., Pegram, M., Goncalves, J., Bocquet, F. *Biosimilars in an Era of Rising Oncology Treatment Options. Future Oncology* (2021) 17(29), 3881-3892
2. Tariman, J. *Biosimilars; Exploring the history, science, and progress.* Clinical Journal of Oncology Nursing. Vol. 22 No. 5. October 2018

Biosimilars Success Impact Beyond the Walls of the U.S.



WHO Model List of Essential Medicines – 22nd List (2021)

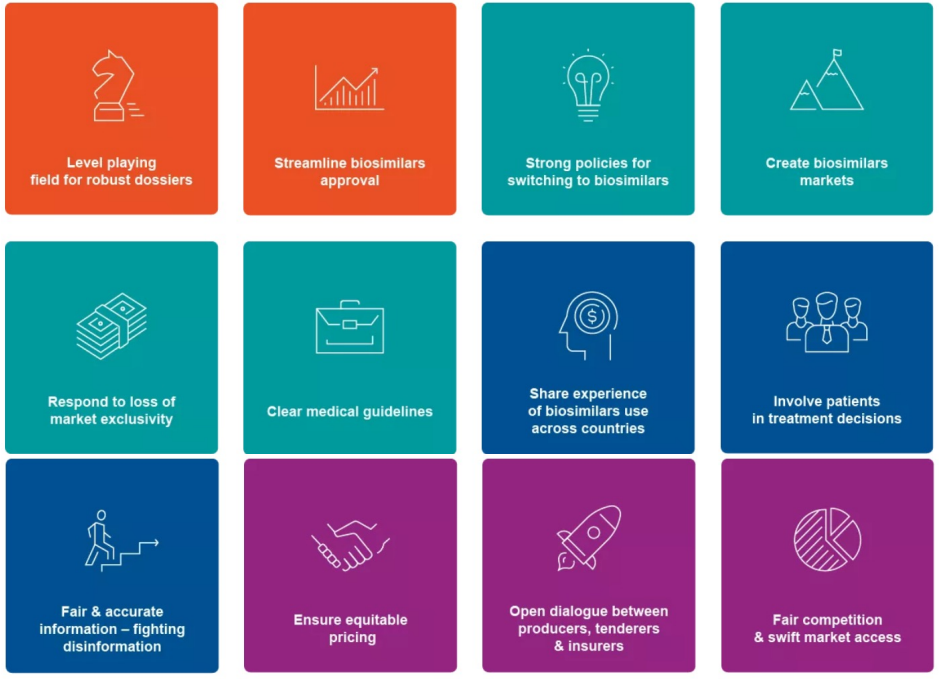
8.2.2 Targeted therapies	
Complementary List	
*rituximab** **including quality-assured biosimilars*	***Injection (intravenous):*** *100 mg/10 mL in 10 mL vial; 500 mg/50 mL in 50 mL vial.* – *Diffuse large B-cell lymphoma* – *Chronic lymphocytic leukaemia* – *Follicular lymphoma*
*trastuzumab** **including quality-assured biosimilars*	***Powder for injection:*** *60 mg; 150 mg; 440 mg in vial.* – *Early stage HER2 positive breast cancer* – *Metastatic HER2 positive breast cancer*

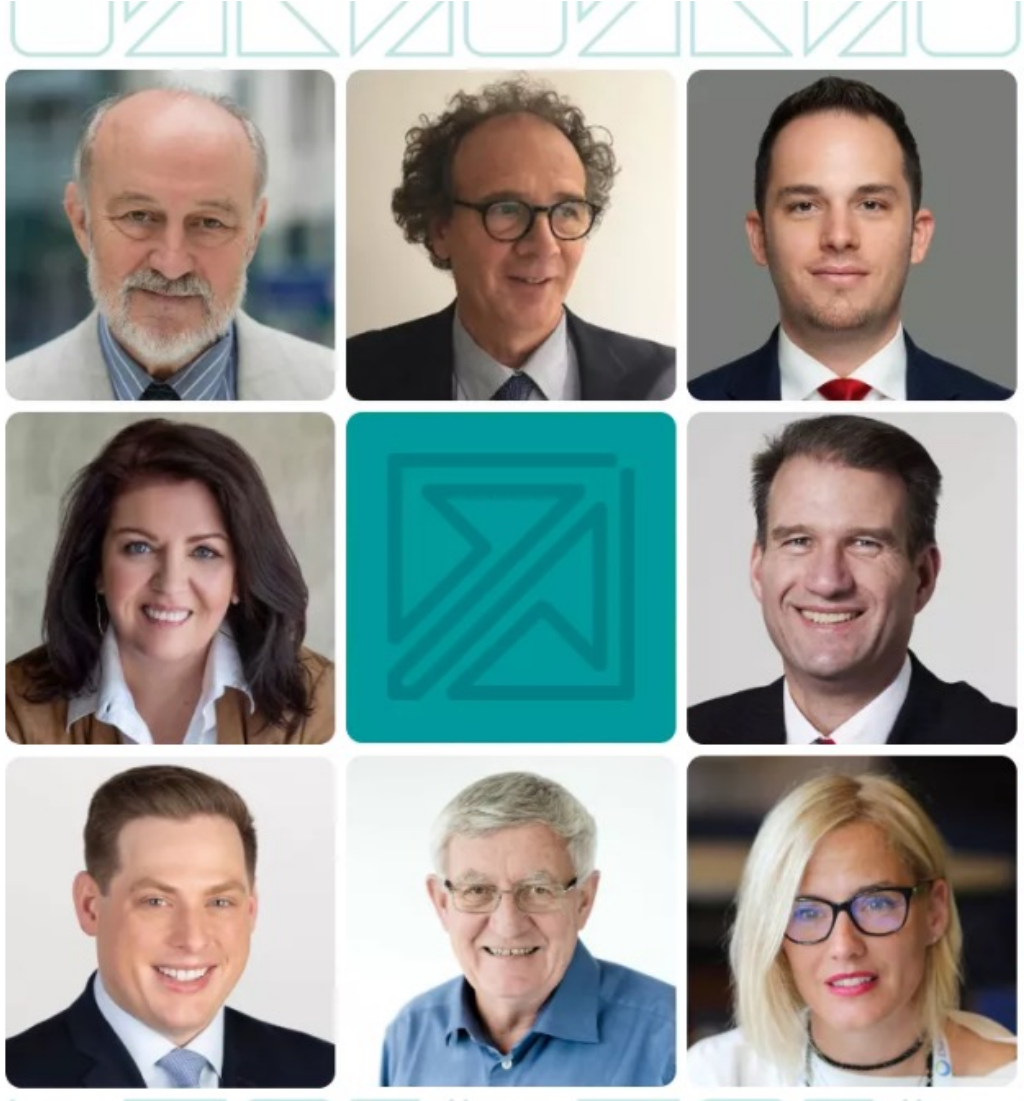
1. World Health Organization Model List of Essential medicines. file:///C:/Users/JOR05578/Downloads/WHO-MHP-HPS-EML-2021.02-eng.pdf Accessed Sept. 15, 2022

Act4Biosimilars Global Initiative

Act4Biosimilars Steering Committee

Act4Biosimilars is led by a multidisciplinary Steering Committee of patient advocacy leaders, healthcare professionals, biosimilar experts and industry leaders from around the world. It is supported by founding sponsor, Sandoz.





1. Act4Biosimilars Global Initiative. www.act4biosimilars.com Accessed Sept. 15, 2022.

Act4Biosimilars Global Initiative

Act4Biosimilars Steering Committee

Jorge J. García PharmD, MS, MHA, MBA, FACHE

Assistant Vice President

System Oncology Pharmacy Service Line

"My priority for A4B is… to relate economic and scientific evidence supporting the safe and effective use of biosimilars to increase global access of high-quality biologics at a fraction of the cost."

1. Act4Biosimilars Global Initiative. www.act4biosimilars.com Accessed Sept. 15, 2022.

Act4Biosimilars Vision and Mission

Act4Biosimilars Vision

A world in which patients have increased access to biologics by helping to accelerate biosimilar approvability, accessibility, acceptability and affordability.

Act4Biosimilars Mission

To increase the global adoption of biosimilars by at least 30% in 30+ countries by 2030.

1. Act4Biosimilars Global Initiative. www.act4biosimilars.com Accessed Sept. 15, 2022.

Summary & Key Takeaways

- Many pre- and post-marketing implementation barriers exist leading to slow adoption of biosimilar utilization in the U.S.
- Biosimilars are a tool at our disposal presenting one of the most important healthcare cost mitigation opportunities
- To reap the potential economic benefit biosimilars must be utilized
- Healthcare professionals uniquely positioned to promote the evaluation of the growing body of evidence and enable biosimilar utilization where there is evidence supporting safe and effective use.

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Practical Recommendations in Immuno & Molecular Oncology

Seven Years of Biosimilar Experience in the U.S., Where Untapped Value Remains

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Q & A