AMCP

PARTNERSHIP FORUM

No. 3 — 2020

Biosimilars: Policy, Practice, and Post Marketing Surveillance to Support Treatment and Coverage Decisions

Welcome

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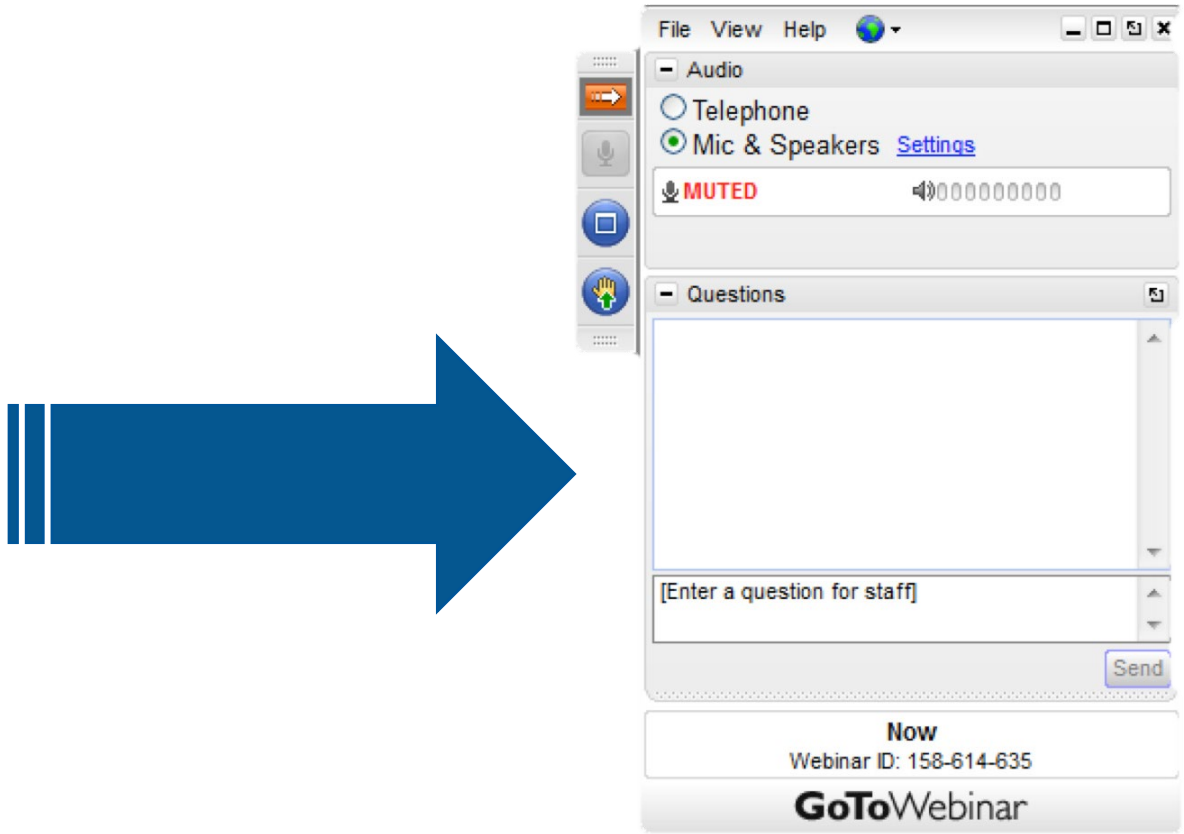

AMCP Partnership Forums
Collaboration for Optimization

The live, hands-on AMCP Partnership Forums bring key decision makers in managed care, integrated care, the pharmaceutical industry, and others together to discuss and collaborate on tactics and strategies to drive efficiencies and outcomes in integrated care and managed care.

Partnership Forums

2020

1. Helping Patients Anticipate and Manage Drug Costs
2. Preparing for and Managing Rare Diseases
3. Biosimilars: Policy, Practice, and Post Marketing Surveillance to Support Treatment and Coverage Decisions

2021

1. Racial Health Disparities: A Closer Look at Benefit Design
2. Digital Therapeutics
3. Addressing Evidence Gaps in the Expedited Approval Process: Payer Perspectives

Forum Objective

Identify key actions that can support the further development and use of biosimilars in the U.S. health care system. Provide consistent and accurate messages about the value of biosimilars.

Key Deliverables

1. Identify challenges with biosimilar adoption within the U.S. health care system.
2. Identify clear and unbiased scientific messaging to support broader acceptance of biologics as valid therapeutic options and to facilitate faster time to biosimilar adoption.
3. Discuss real-world evidence needs and opportunities help with biosimilar adoption.

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Our Faculty

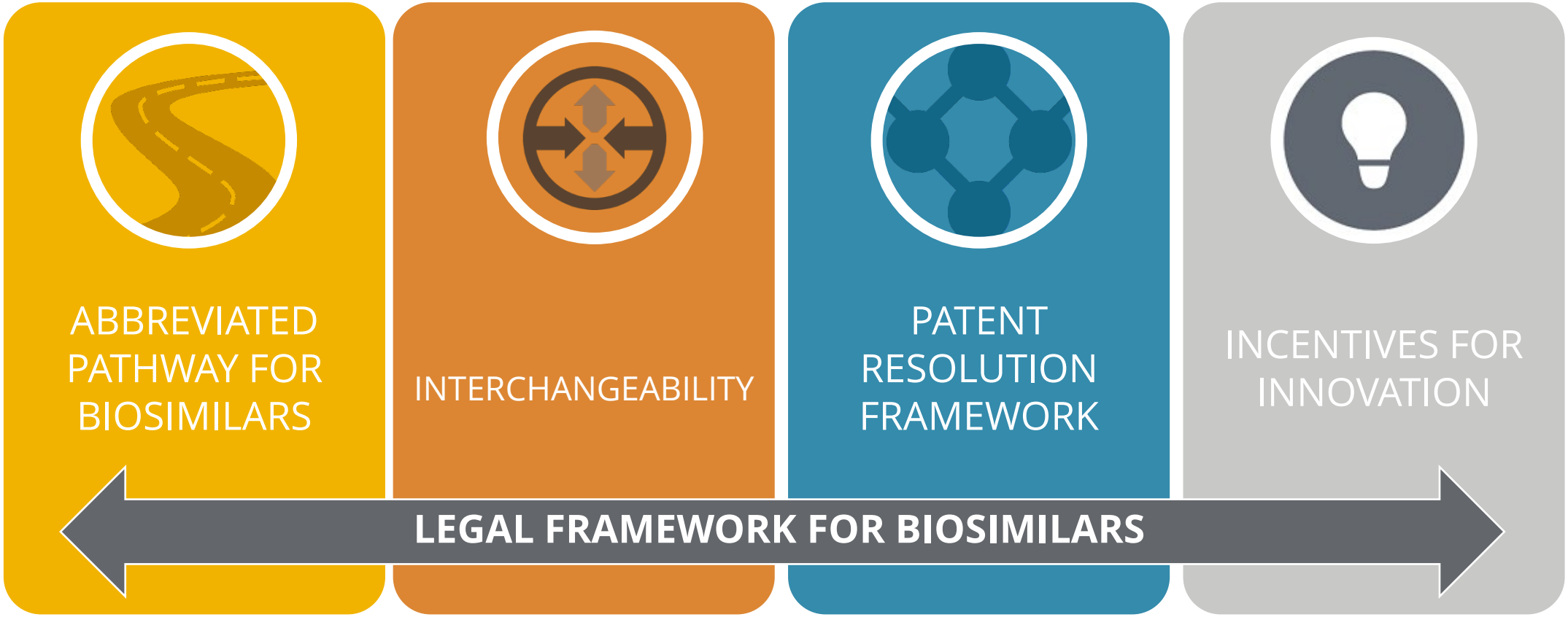
Sonia Oskouei, PharmD, BCMAS, DPLA
Vice President, Biosimilars
Cardinal Health

Carly Rodriguez, PharmD, FAMCP
Pharmacy Director, Clinical Innovation
Moda Health

Today's Agenda

- Perspectives on Biosimilars
- Forum findings and recommendations
- Q&A
- Next steps and action items

Biologics Price Competition and Innovation Act (BPCIA) created a legal framework for biosimilars



Biosimilars are approved under section 351(k) biologics license applications (BLAs).

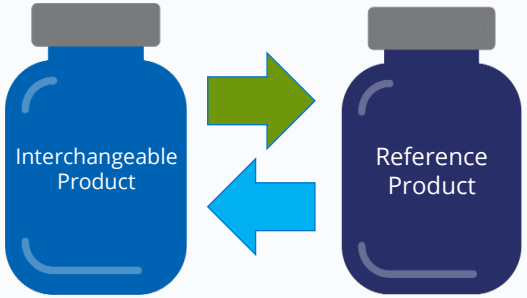
Key Definitions from the PHS Act

Reference Product

A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared

Biosimilar Product

A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product



Interchangeable Product

-Is a biosimilar

-Expected to produce the same clinical result as the reference product (RP) in any given patient

-Switching between the proposed product and the RP does not ↑safety risks or ↓effectiveness compared to using the RP without switching

29 FDA Approved Biosimilars, 20 Launched

Remicade (Janssen)		
Product	**Manufacturer**	**Launch Date**
Inflectra	Pfizer	Nov-16
Renflexis	Merck	Jul-17
Avsola	Amgen	Jul-20
Ixifi	Pfizer	No U.S. launch

Epogen/Procrit (Amgen/Janssen)		
Product	**Manufacturer**	**Launch Date**
Retacrit	Pfizer	Nov-18

Neupogen (Amgen)		
Product	**Manufacturer**	**Launch Date**
Granix*	Teva	Nov-13
Zarxio	Sandoz	Sep-15
Nivestym	Pfizer	Oct-18

Neulasta (Amgen)		
Product	**Manufacturer**	**Launch Date**
Fulphila	Viatris	Jul-18
Udencya	Coherus	Jan-19
Ziextenzo	Sandoz	Dec-19
Nyvepria	Pfizer	Dec- 20

*Granix approved prior to development of biosimilar regulatory approval pathway, therefore not a biosimilar

Avastin (Genentech)		
Product	**Manufacturer**	**Launch Date**
Zirabev	Pfizer	Jan-20
Mvasi	Amgen	Jul- 19

Herceptin (Genentech)		
Product	**Manufacturer**	**Launch Date**
Kanjinti	Amgen	Jul-19
Ogrivi	Viatris	Dec-19
Trazimera	Pfizer	Feb-20
Herzuma	Teva	Mar-20
Ontruzant	Merck	May-20

Rituxan (Genentech)		
Product	**Manufacturer**	**Launch Date**
Truxima	Teva	Nov-19
Ruxience	Pfizer	Feb-20
Riabni	Amgen	Jan-21

Humira (Abbvie)		
Product	**Manufacturer**	**Est. Launch Date**
Amjevita	*Amgen*	*2023*
Hadlima	*Merck*	*2023*
Cyltezo	*Boehringer ingelheim*	*2023*
Hulio	*Mylan*	*2023*
Hyrimoz	*Sandoz*	*2023*
Abrilada	*Pfizer*	*2023*

Enbrel (Amgen)		
Product	**Manufacturer**	**Est. Launch Date**
Eticovo	*Samsung Bioepis*	*TBD*
Erelzi	*Sandoz*	*Est. 2029*

Updated June 2021

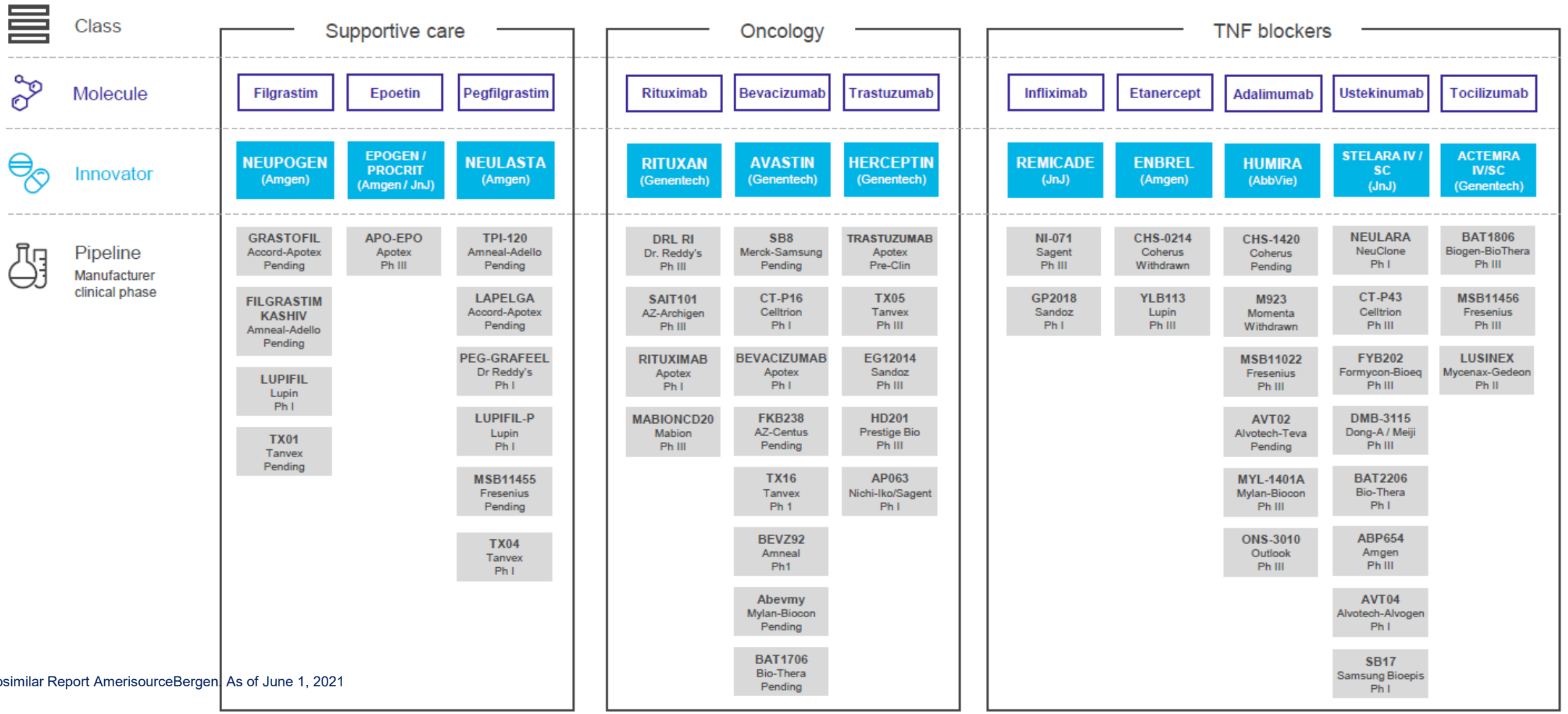
U.S. Biosimilars Market Share

Molecule	1st Biosimilar Launched	Appx. Biosimilars Market Share (units) as of 3/2021
Filgrastim	Sept 2015	90%*
Infliximab	Nov 2016	23%
Pegfilgrastim (Syr. only), (On-body + Syr.)	July 2018	74%, 35%
Epoetin Alfa	Nov 2018	49%
Bevacizumab	July 2019	65%
Trastuzumab	July 2019	51%
Rituximab	Nov 2019	56%
Adalimumab	Est. 2023	-
Etanercept	Est. 2029	-

Data source: IQVIA, accessed May 2021

U.S. biosimilar pipeline landscape

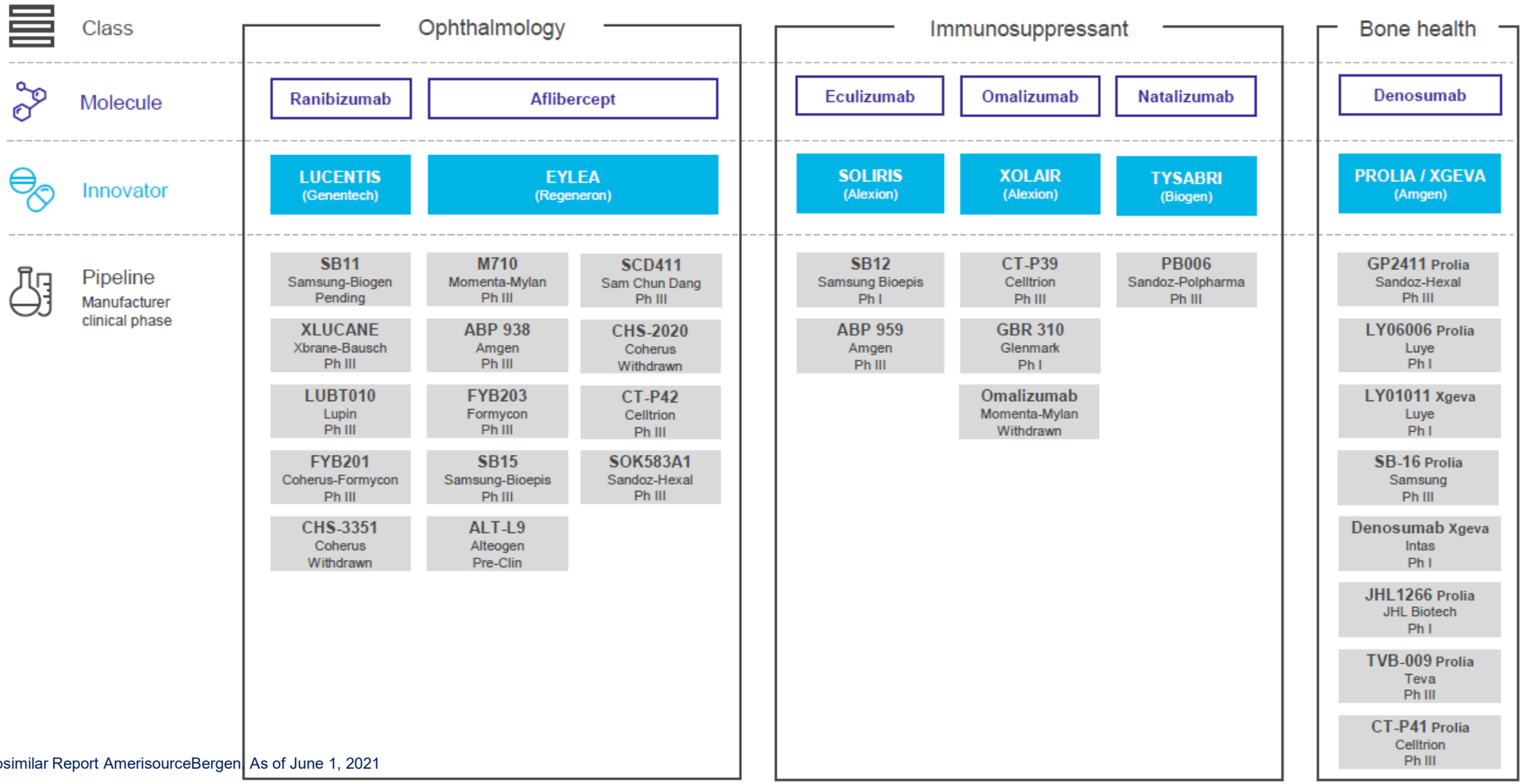
As of June 1, 2021



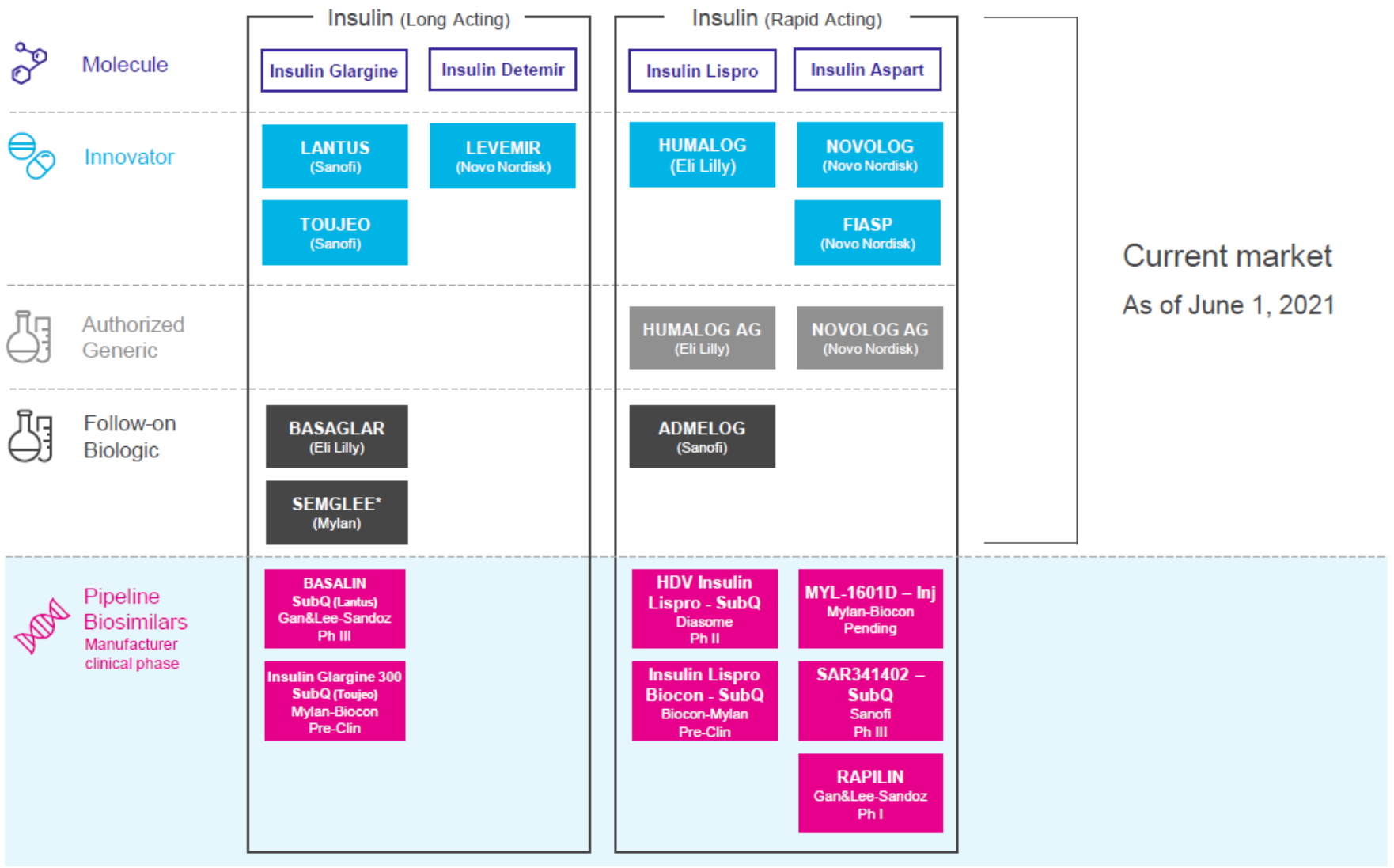
U.S. Biosimilar Report AmerisourceBergen. As of June 1, 2021

U.S. biosimilar pipeline landscape

As of June 1, 2021



U.S. insulin biosimilar market landscape & pipeline



*Semglee (Mylan) has filed 351(k) pathway for biosimilar approval, and interchangeability designation; through the FDA.

U.S. Biosimilar Report AmerisourceBergen. As of June 1, 2021

Biosimilar Impact

- U.S. uptake has been slow relative to the European market
- Largely adjudicated in the medical benefit (vs. pharmacy benefit)
- Increasingly leading to cost savings in the U.S. - with many reference products competing with multiple biosimilar versions

AMCP Foundation & PRIME Education Surveys

2020 vs. 2018

How have stakeholders' views on biosimilar adoption changed?

RESEARCH

Strategies for Overcoming Barriers to Adopting Biosimilars and Achieving Goals of the Biologics Price Competition and Innovation Act: A Survey of Managed Care and Specialty Pharmacy Professionals

Laurence Greene, PhD; Rubina M. Singh, PharmD, BCPS; Mary Jo Carden, RPh, JD; Caroline O. Pardo, PhD, CHCP, FACEHP; and Gary R. Lichtenstein, MD

ABSTRACT

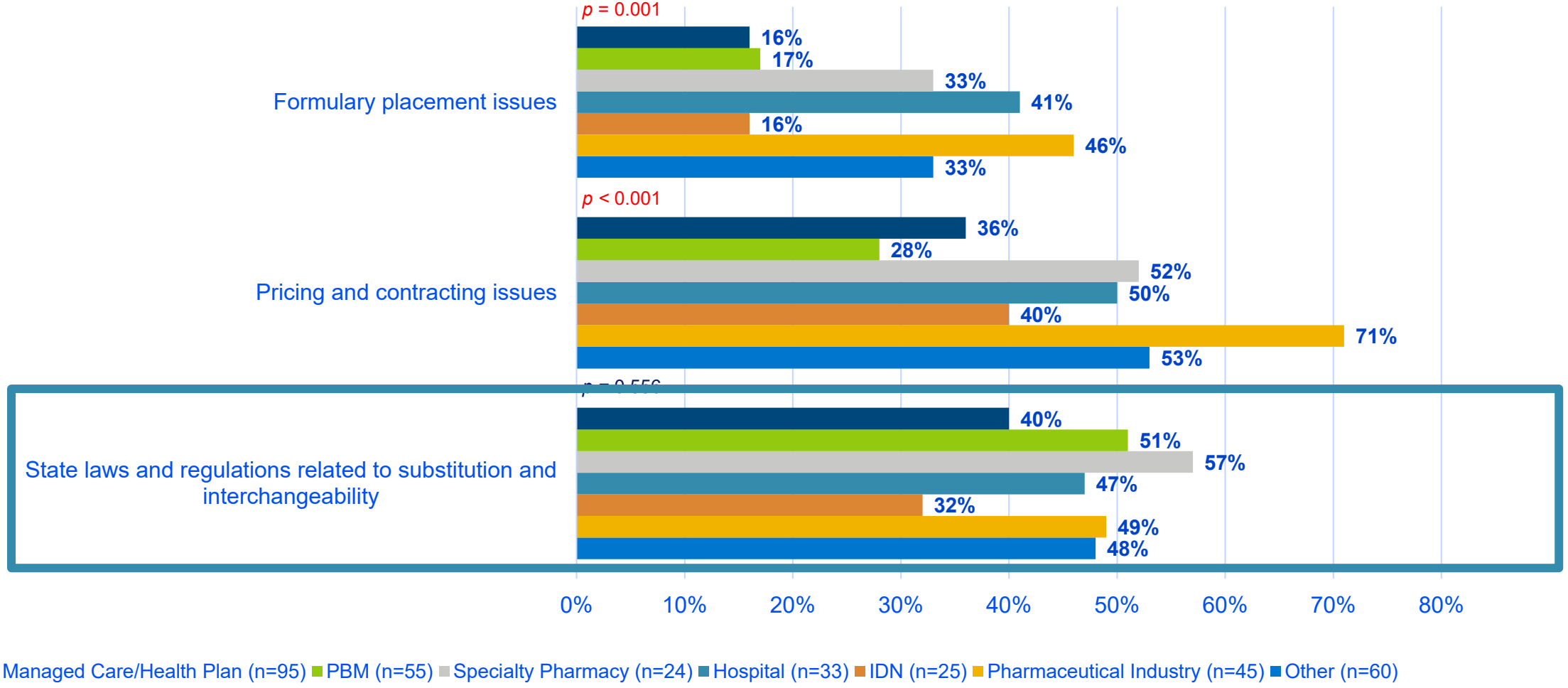
BACKGROUND: The Biologics Price Competition and Innovation Act (BPCIA) of 2009, which included pathways for FDA approval of biosimilar products, was designed to promote more affordable, expanded patient access to biologic therapies. Achieving these BPCIA goals depends on overcoming formidable barriers to biosimilar adoption. Managed care and specialty pharmacy professionals are uniquely qualified to inform initiatives to address these barriers.

CONCLUSIONS: Reflecting the unique knowledge, perspectives, and practices of managed care and specialty pharmacy professionals, the study findings are relevant to informing and advancing initiatives for achieving BPCIA goals.

J Manag Care Spec Pharm. 2019;25(8):904-12

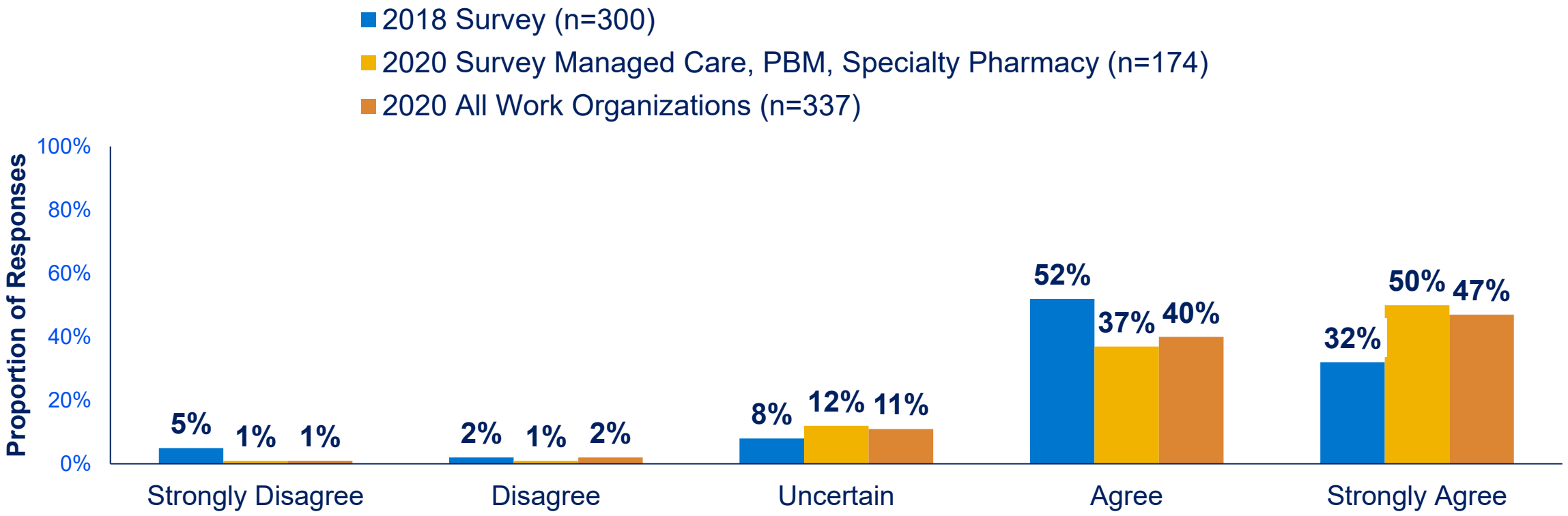
AMCP Foundation Survey: Key Barriers to Biosimilar Adoption 2020

% of all survey respondents who rated following barriers as difficult/extremely difficult to overcome:



AMCP Foundation Survey: Higher Levels of Agreement Switching to Biosimilars

Q: For patients whose conditions are treated on reference biologics, switching to a biosimilar product is safe and effective



Survey respondents in 2020 reported higher levels of agreement than survey respondents in 2018.

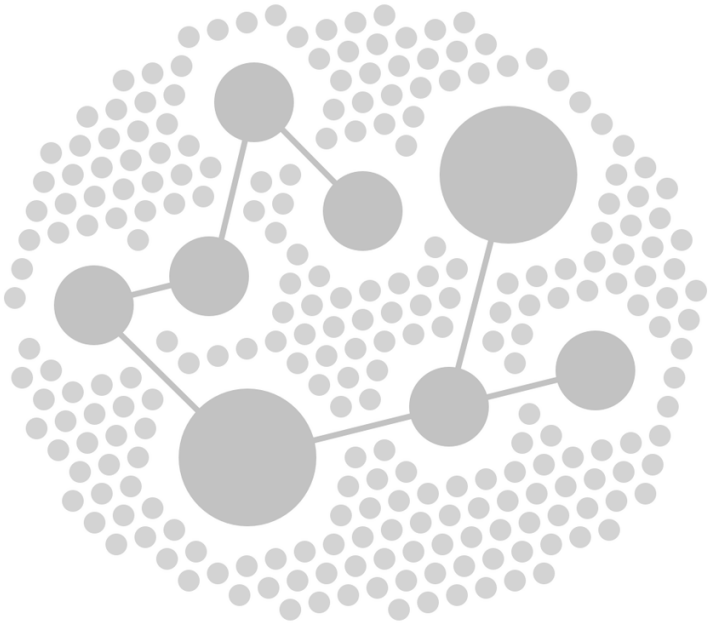
$U\ (n_{2018} = 300, n_{2020} = 174) = 22{,}601,\ p = 0.019$

$U\ (n_{2018} = 300, n_{2020} = 337) = 42{,}847,\ p = 0.001$

Participants Identified a Number of Challenges Associated with Biosimilar Adoption in the U.S.

High degree of complexity

- Different approval pathways & complexity of molecules
- Different benefit types & sites of care
- Different administration routes
- Complex electronic medical records
- Confusion around terminology
- Treatment naïve vs. established care



Participants Identified a Number of Challenges Associated with Biosimilar Adoption in the U.S.

- Clinical and administrative barriers
- Differences in specialty practice preferences & guidelines
- Health plan variations
- Contracting arrangements
- Patient support
- General scientific landscape

Participants Discussed and Highlighted Opportunities

- **Education** – Build positive, evidence based communication and education materials
- **Language** – Draw from best practices to clarify and simplify language around biosimilars
- **RWE** – Identify gaps in data that may require development of new resources and surveillance
- **Arrangements** - for providers and patients to help promote the use of biosimilars

Participants Discussed and Highlighted Opportunities

- **Benefit design –** review benefit design for access, especially as more biosimilars come to the pharmacy benefit
- **Legislation –** address attempts to unfairly delay competition
- **Confidence in science –** rebuild public confidence in science and regulatory agencies
- **Thought sharing –** disseminate best practices where biosimilar adoption has succeeded

Identify & Use Clear Unbiased Language

To support broader acceptance of biologics as valid therapeutic options and to facilitate faster time to biosimilar adoption

These statements could be adopted as a basis for commonalities in educational materials, and to help differentiate messaging by audience.

AMCP Partnership Forum Pre-Survey Rankings (n = 22 respondents)

Biosimilar Product Statements[1-11]	Ave. Strength	Audience				
		Patient	HCP	Payer	Manuf.	Policy
Biosimilars are as **safe and effective** as the original biologic; both are **rigorously and thoroughly evaluated** by the FDA before approval.	4.41	+++	**++++**	+++	+	+++
Biosimilars are approved after **rigorous scientific evaluation** by regulatory authorities.	4.27	++	**++++**	+++	+	+++
You can expect the same **safety and effectiveness** from a biosimilar over the course of treatment as you would from the reference product.	4.27	**++++**	++	++	+	+++
The same **quality manufacturing** standards that apply to the original biologic also apply to the biosimilar.	4.27	++	+++	++	++	+++
Supporting a **competitive** marketplace for biosimilars is essential for improving patient access to needed medications and reducing costs.	4.23	+	++	**++++**	+	**++++**
Biosimilars enhance **competition** among biological medicines, providing more treatment alternatives for patients and clinicians.	4.18	+	++	**++++**	+	++
Biosimilars have been used **safely** for many years.	4.05	**++++**	+++	++	+	+++
Biosimilars and generics are both versions of previously FDA approved medications and may offer more **affordable** treatment options to patients.	4.05	**++++**	++	++	+	++

Message Strength Scale: Excellent = 5, Good = 4, Fair = 3, Poor = 2, Very Poor = 1. Audience Scale % of Reponses: ++++ ≥ 90%, +++ 75-89%, ++ 50 – 74%, + <50%

Highlighted audience was identified by respondents as the most appropriate audience (>/= 90%) for the message.

Identify & Use Clear Unbiased Language

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AMCP Partnership Forum Pre-Survey Rankings (n = 22 respondents)

Biosimilar Product Statements[1-11]	Ave. Strength	Audience				
		Patient	HCP	Payer	Manuf.	Policy
An interchangeable biosimilar is expected to produce the same clinical result as the reference product in any given patient.	3.91	+	**++++**	++	+	++
As part of the assessment process, biosimilars must demonstrate that they are highly similar to an already approved originator biological medicine.	3.86	+	+++	+++	+	+++
Globally, regulators have confidence in the rigor of the scientific review and approval process for biosimilars.	3.82	+	++	+++	+	+++
The interchangeability designation is not superior to bio-similarity designation and all biosimilars approved by the FDA are safe and effective.	3.68	+	**++++**	**++++**	+	+++
Biosimilars are biological medicines of proven pharmaceutical quality.	3.55	**++++**	+++	++	+	+++
Biosimilars have been increasingly used in clinical practice in most countries.	3.55	++	+++	++	+	++
A full clinical development program is not necessary when extensive laboratory testing has demonstrated that the biosimilar is highly similar to the originator.	3.14	+	++	++	++	++

Message Strength Scale: Excellent = 5, Good = 4, Fair = 3, Poor = 2, Very Poor = 1. Audience Scale % of Reponses: ++++ ≥ 90%, +++ 75-89%, ++ 50 – 74%, + <50%

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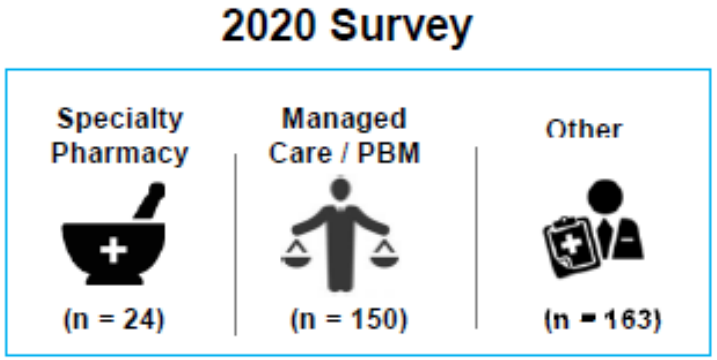
AMCP Foundation Survey:Top Strategies for Biosimilar Adoption
2020

2020 All Organizations

- **Prescriber education on switching studies**
- **Interchangeability studies**
- **Formulary policies for treatment-naive patients**
- **Prescriber education on real-world studies**
- **Reformed Medicare/Medicaid policies**
- **Active post-marketing evidence generation, including HC resource utilization and cost implications**



Other
- Hospital/Clinic (10%)
- Integrated Delivery Network (7%)
- Pharmaceutical Industry (13%)
- Other/Multiple Organization Types (18%)

337 Surveys Collected
(174 surveys from specialty pharmacy, managed care, or pharmacy benefits management)

AMCP Foundation Survey:Top Strategies for Biosimilar Adoption

2020 vs. 2018

2020 All Organizations

- **Prescriber education on switching studies**
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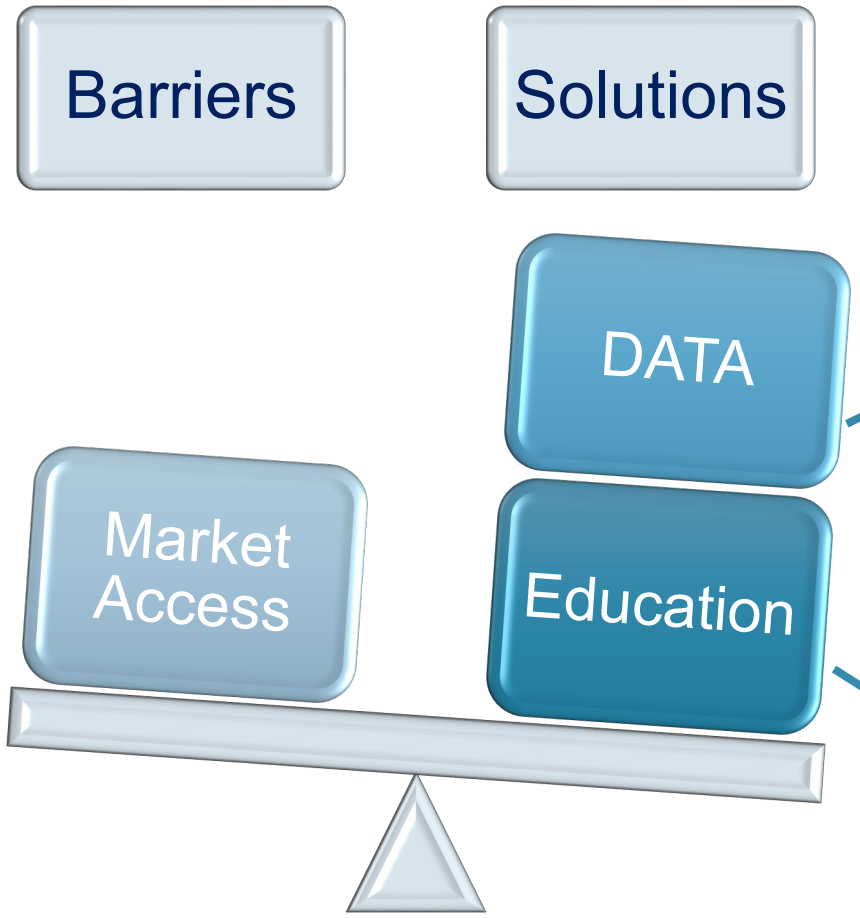
2020 & 2018 Managed Care, PBM, Specialty

- **Prescriber education on switching studies**
- Interchangeability studies
- **Formulary policies for treatment-naive patients**
- **Prescriber education on real-world studies**
- **Reformed Medicare/Medicaid policies**
- Active post-marketing evidence generation, including HC resource utilization and cost implications

Real World Evidence (RWE)

How Do We Solve these Biosimilar Challenges?



Support FDA Approval →Real-World Evidence

Business Arrangements → Data to inform FORMULARY decisions

Reimbursement → Real-world comparative safety and effectiveness

Patient and Provider Uncertainty → Real-World Evidence in “patients like me”

Information for education

AMCP Foundation Survey: Experiences & Expectations RWE

91%

Strongly agree or agree: Real-world evidence generation is very important in overcoming biosimilar adoption barriers

28%

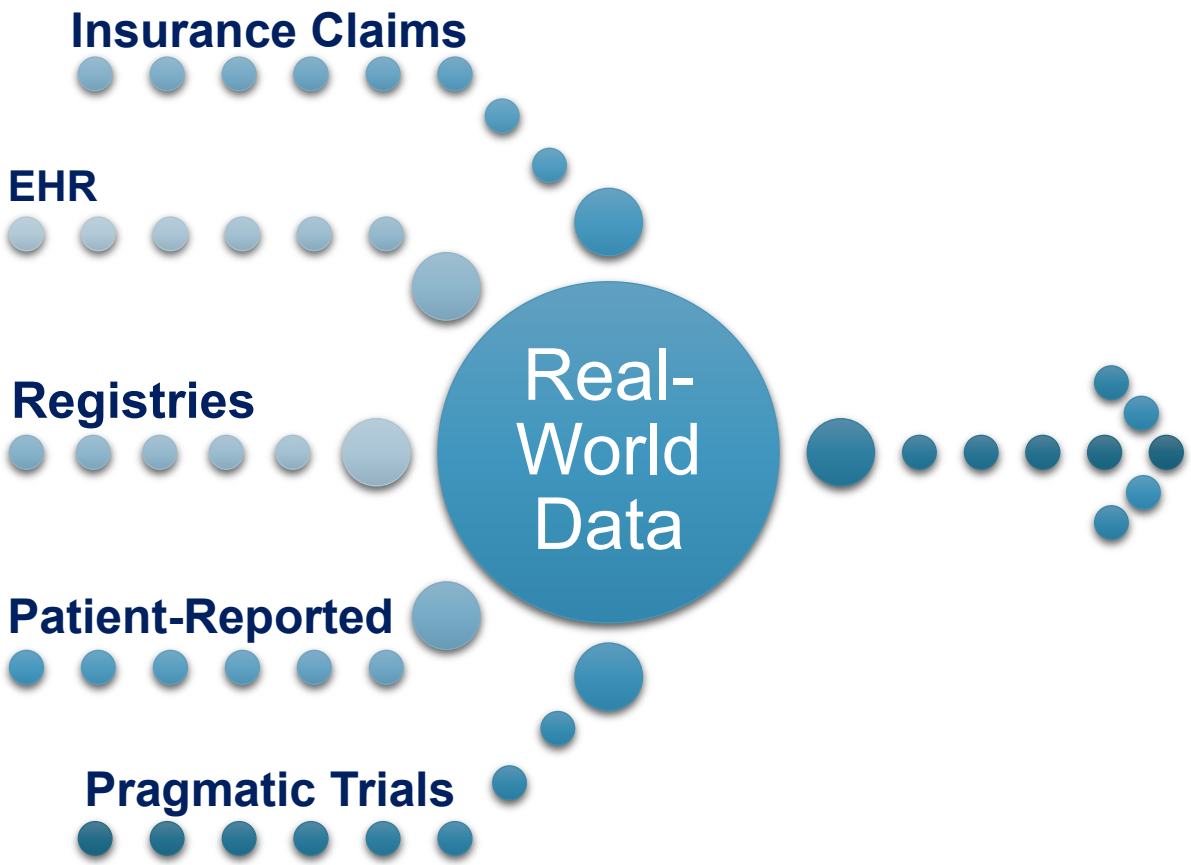
Currently work at organizations that are generating or tracking RWE to analyze biosimilar use

55%

Expect significant increase or slight increase: Change in organization's investments on RWE on biosimilars in next 2-3 years

RWE graphic: source CROS NT

Forum Participants Identified Challenges With RW Data



CHALLENGES

- Data collected for reasons *other than* research
- Data may not represent population of interest
- Need a large population to detect rare outcomes
- Complex and challenging to use data from more than one source
- Can be expensive to procure at scale
- Data quality and usefulness varies

Forum Participants Identified RWE Needs

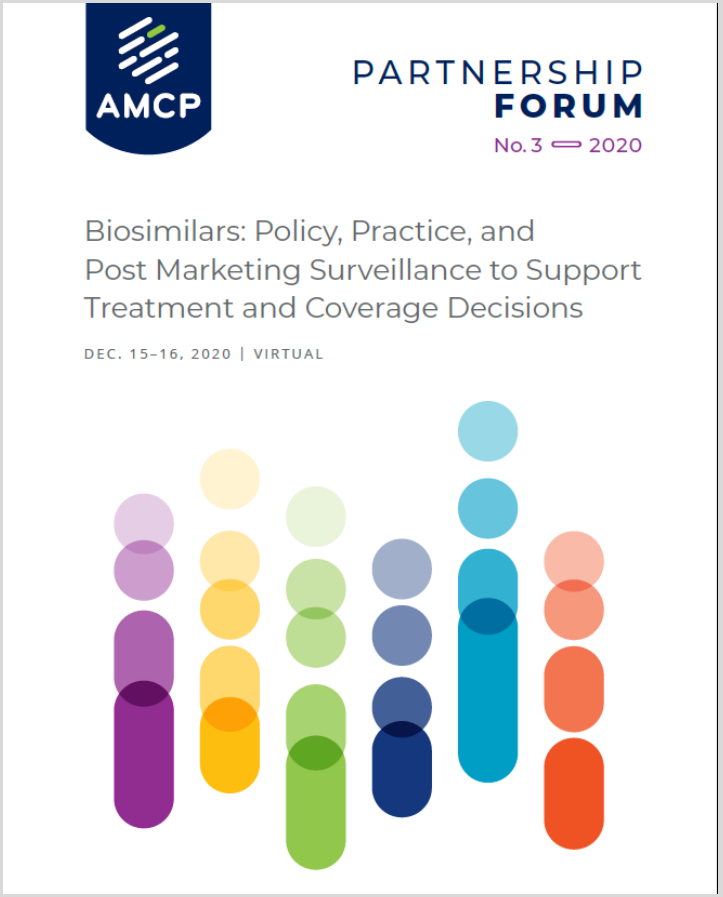
- Post-marketing surveillance data related to adverse events and side effects
- Switching data from reference products to biosimilars and from biosimilars to biosimilars
- Education materials could be differentiated by audience
  - Physicians may find more value in peer-to-peer reviews and sharing best practices
  - Patients may prefer stories from other similar patients with positive outcomes
  - Could further be differentiated by therapeutic area / disease state to engage audiences

Final Thoughts

Biosimilar adoption may be improved by:

- Providing more educational opportunities around the value of biosimilars, associated terminology, RWE, and other key topics of interest
- Supporting efforts to create incentives for providers and patients to help promote the use of biosimilars, particularly for treatment-naïve patients
- Continuing to seek strategic partners, including payers, patient advocates, physician groups, regulatory groups, and more, to help encourage creation of guiding principles around biosimilars

Next Steps



www.amcp.org/Resource-Center/meeting-proceedings-findings/biosimilars-policy-practice-and-post-marketing

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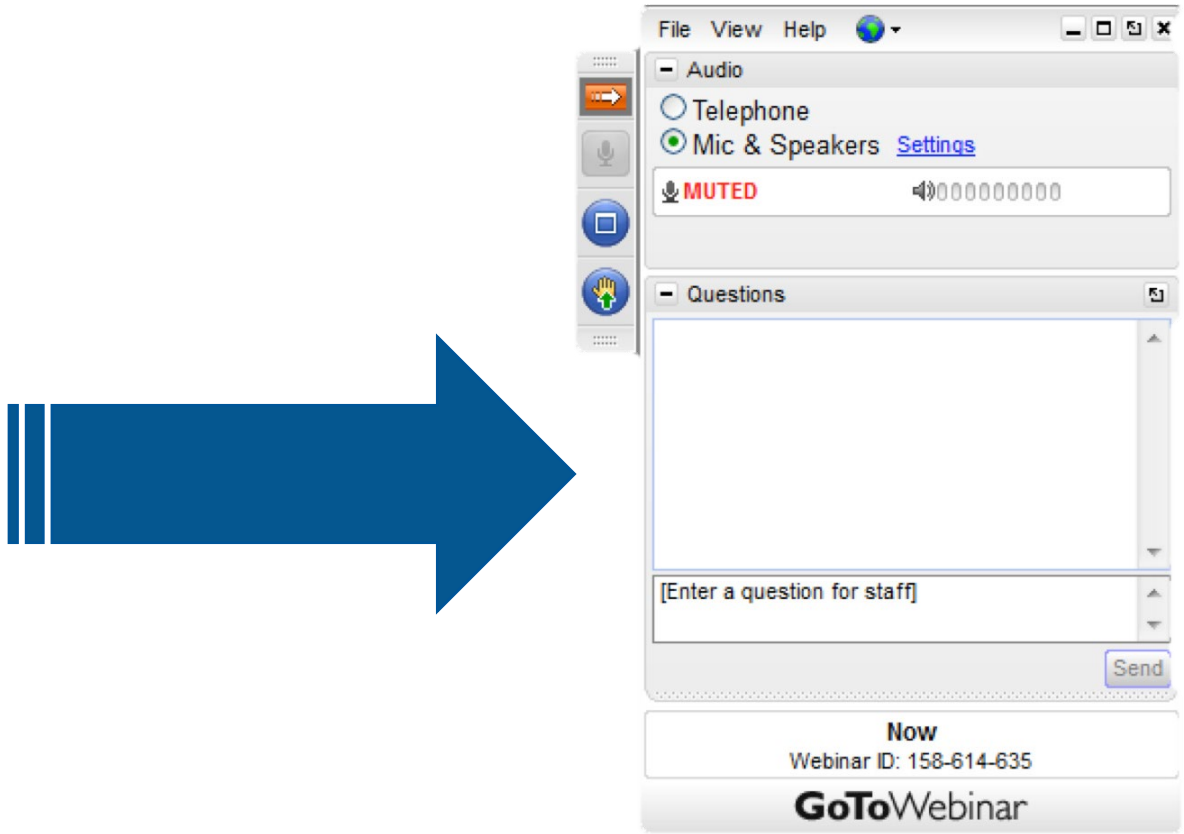

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Takeda

Biosimilar Product Statement References

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9. American Cancer Society-Cancer Action Network. Understanding biologic and biosimilar drugs. https://www.fightcancer.org/policy-resources/understanding-biologic-and-biosimilar-drugs.
10. Biosimilars Forum. Biosimilars: a new era in medicine. https://biosimilarsforum.org/
11. Biosimilars Council. Biosimilars 101. https://biosimilarscouncil.org/biosimilars-101/

Additional Resources

- www.fda.gov/biosimilars for access to all the education materials and information about biosimilar and interchangeable products.
- https://purplebooksearch.fda.gov/ **The Purple Book: Database of Licensed Biological Products** for information on biological products, including if products are biosimilar to a reference product.
- www.fda.gov/drugsatfda (**Drugs@FDA**) for information on all FDA approved drug products, including labeling and review information.
- https://www.fda.gov/advisory-committees/committees-and-meeting-materials/human-drug-advisory-committees for drug advisory committee meetings and materials related to biosimilars.

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