ASBM Study: US Physician Perspectives on Interchangeable Biosimilars

ISR Market Research
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Objective & Methodology

Objective

Understand US prescribers' attitudes and beliefs regarding the interchangeability of biosimilar medications with the originator biologics and the need for specific evaluation for the impact of switching on safety and efficacy.

Methodology

- On behalf of Alliance for Safe Biologic Medicines (ASBM), ISR Market Research conducted a web-based quantitative survey with 270 participants
- All participants practice medicine in the United States
    - 9 practice areas were included: Dermatology, Endocrinology, Gastrointestinal, Immunology, Nephrology, Neurology, Oncology, Ophthalmology, and Rheumatology
- A leading 3rd party physician panel was used to recruit research participants
- Research was conducted in August 2024
- ASBM was not identified as the sponsor of the research
- Participants were provided an honorarium for their time

Explanatory Text

- Respondents were shown the below explanatory text about biosimilars prior to receiving the survey questions.

"This survey will focus on the interchangeability of biosimilars. Please carefully read the description below to understand the latest legislation on this issue. The button to continue will appear after a few seconds.

BIOSIMILARS are copies of previously approved biologic medicines. Biologics, including biosimilars, are often used to treat serious and chronic conditions including rheumatoid arthritis, psoriasis, Crohn's disease, and cancer.

Biosimilars are safe and effective, however, unlike traditional chemical drugs, copies of biologics are highly similar but not identical to the medicines they copy because all biologics are made using living cells and the cell lines and the manufacturing process are proprietary.

Unlike generic drugs, biosimilars as a class may not be substituted at the pharmacy-level without involvement of the prescriber. However, all 50 states have passed laws permitting "INTERCHANGEABLE BIOSIMILARS" to be substituted at the pharmacy level.

In order for a biologic to be designated as "Interchangeable", additional data is submitted to the to FDA demonstrating that a patient who is switched from the reference product to the biosimilar will experience no loss of safety or efficacy, even over multiple switches, relative to a patient who was not switched, so as to ensure a patient's treatment stability is not jeopardized by a third-party non-medical switch. The FDA currently has broad flexibility to determine what data is required to demonstrate this; it may or may not require switching studies to be conducted prior to designation as interchangeable.

Congress is currently considering legislation which would require FDA to deem ALL biosimilars interchangeable (that is, make all biosimilars substitutable at the pharmacy level by a third-party insurer/PBM without physician involvement, like generics) and lower the approval standards by preventing the FDA from considering switching studies during approval. The FDA is also currently seeking comment on a proposal to eliminate its ability to consider switching studies when making a determination of interchangeability."

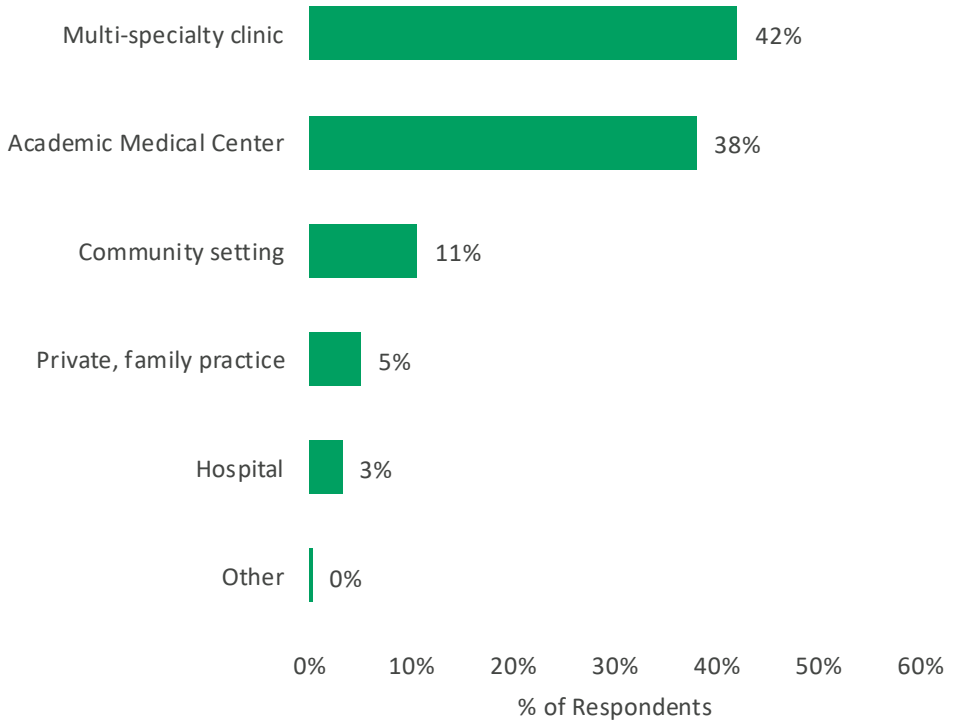
Respondent Profile

Respondent Profile

US State Representation

State	n	State	n	State	n	State	n
Alabama	1	Illinois	18	Montana	0	Rhode Island	1
Alaska	0	Indiana	8	Nebraska	1	South Carolina	4
Arizona	7	Iowa	2	Nevada	2	South Dakota	0
Arkansas	2	Kansas	2	New Hampshire	1	Tennessee	1
California	44	Kentucky	2	New Jersey	9	Texas	25
Colorado	3	Louisiana	3	New Mexico	2	Utah	1
Connecticut	2	Maine	0	New York	24	Vermont	0
Delaware	0	Maryland	5	North Carolina	6	Virginia	4
District of Columbia	1	Massachusetts	12	North Dakota	0	Washington	8
Florida	14	Michigan	4	Ohio	10	West Virginia	1
Georgia	9	Minnesota	4	Oklahoma	1	Wisconsin	2
Hawaii	2	Mississippi	1	Oregon	4	Wyoming	0
Idaho	0	Missouri	4	Pennsylvania	13		

Practice Type

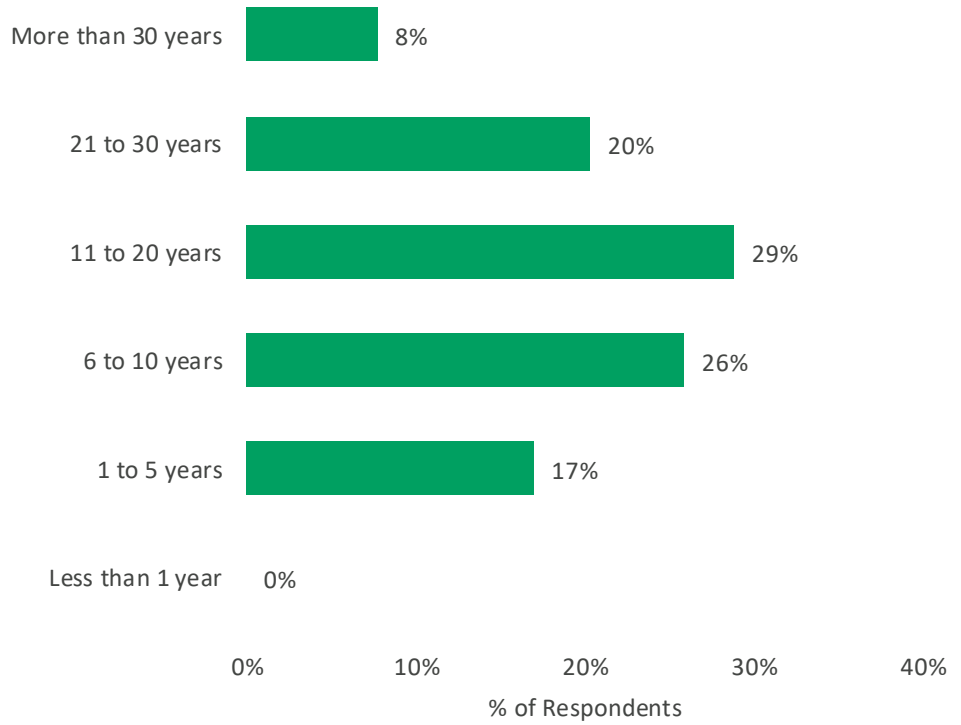


Respondent Profile

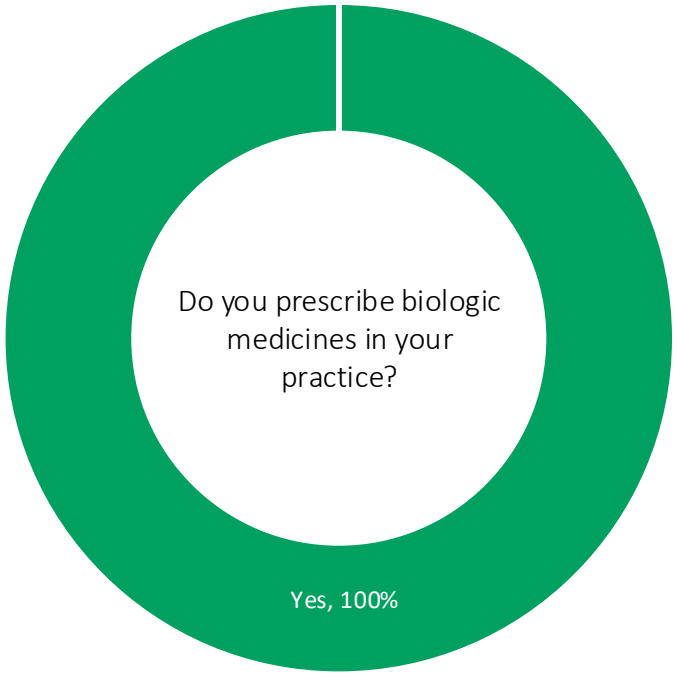
Therapeutic Specialty

Therapeutic Specialty	n
Dermatology	30
Endocrinology	30
Gastrointestinal	30
Immunology	30
Nephrology	30
Neurology	30
Oncology	30
Ophthalmology	30
Rheumatology	30

Physician Tenure



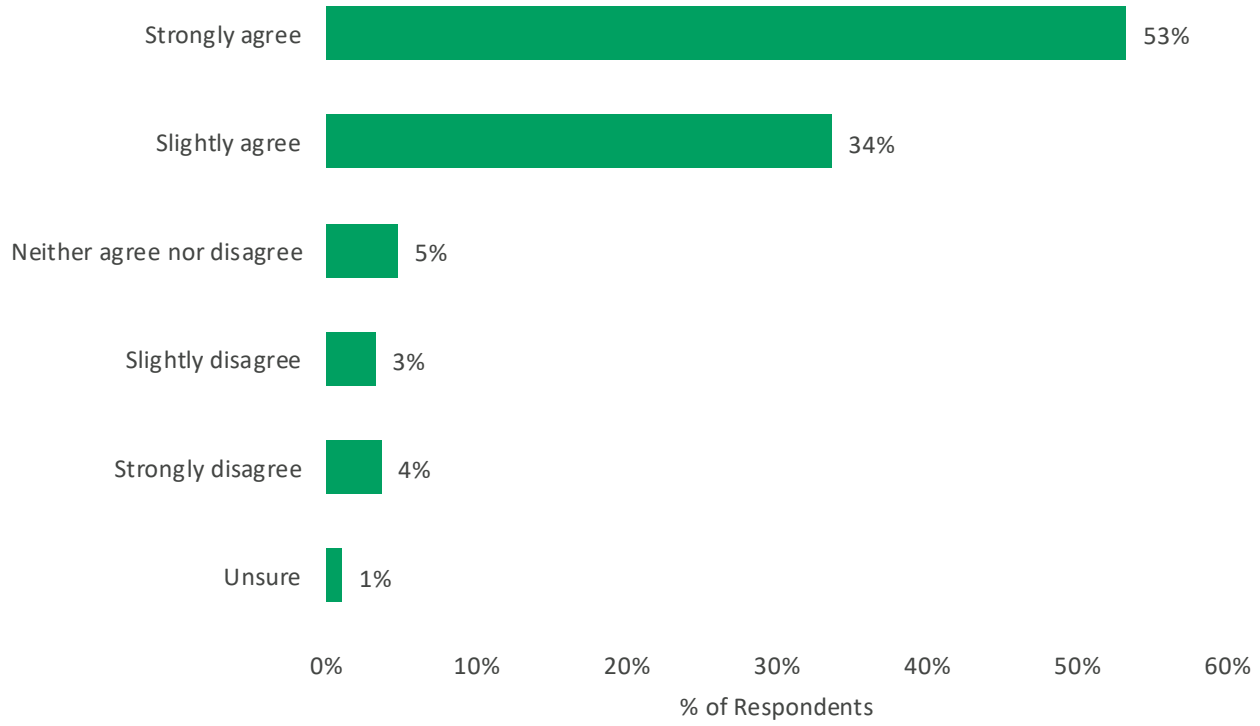
Respondent Profile



Findings

Comfort with Switching if Biosimilar Has Been Specifically Evaluated

Q1. To what extent do you agree with the following statement: "I am more comfortable switching a patient from an originator biologic to a biosimilar if that medicine has been specifically evaluated for the impact of switching on safety and efficacy." (n=270)



- 87% of respondents agreed that they are more comfortable switching a patient from an originator biologic to a biosimilar if that medicine has been specifically evaluated for the impact of switching on safety and efficacy.

Comfort with Switching if Biosimilar Has Been Specifically Evaluated – by Therapeutic Specialty

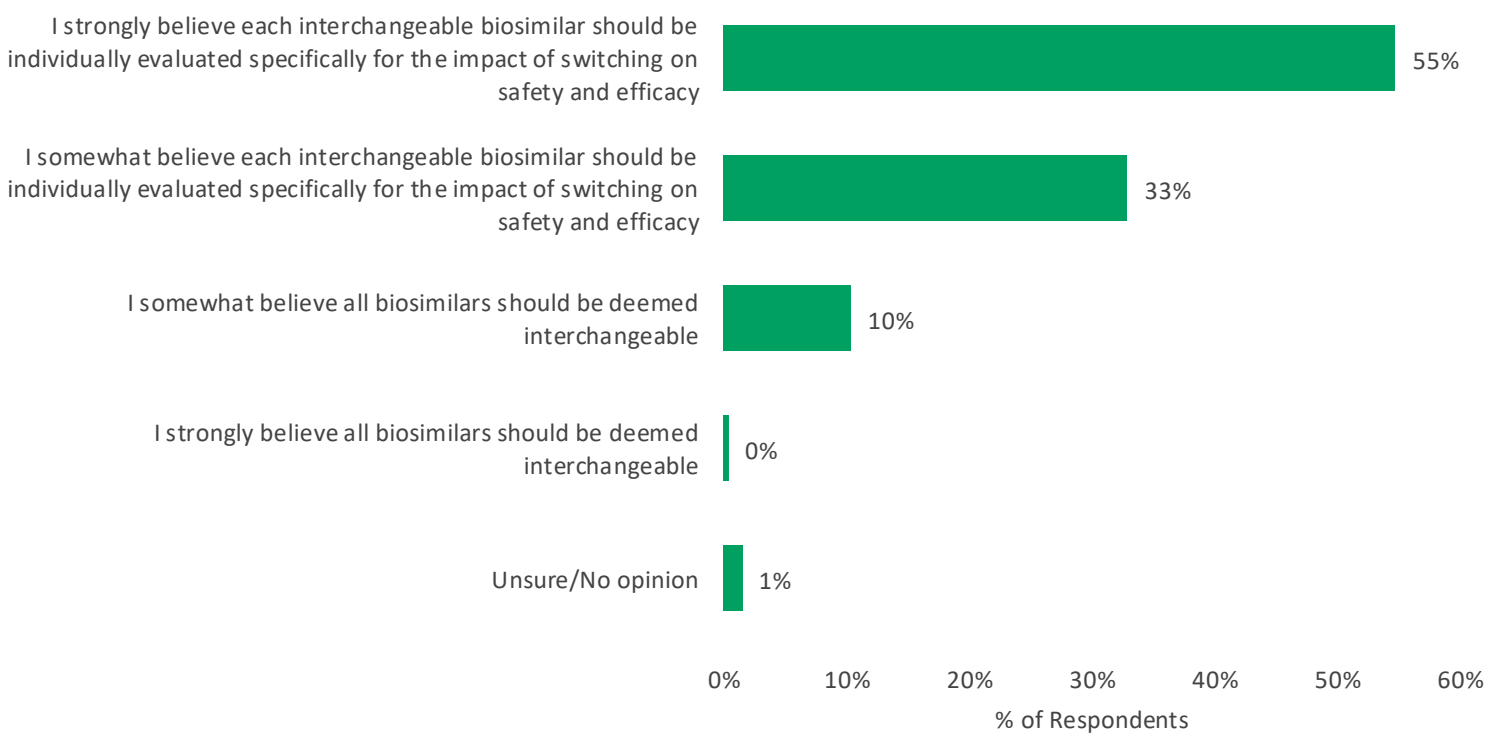
Q1. To what extent do you agree with the following statement: "I am more comfortable switching a patient from an originator biologic to a biosimilar if that medicine has been specifically evaluated for the impact of switching on safety and efficacy."

	Total	Dermatology	Endocrinology	Gastrointestinal	Immunology	Nephrology	Neurology	Oncology	Ophthalmology	Rheumatology
n-size	**270**	30	30	30	30	30	30	30	30	30
		A	B	C	D	E	F	G	H	I
Strongly agree	**53%**	40%	67% A, F	60%	57%	50%	37%	50%	67% A, F	53%
Slightly agree	**34%**	37%	30%	30%	17%	37%	53% D, H	47% D, H	20%	33%
Neither agree nor disagree	**5%**	3%	0%	10%	13% B, H	3%	7%	3%	0%	3%
Slightly disagree	**3%**	10%	3%	0%	0%	0%	3%	0%	3%	10%
Strongly disagree	**4%**	7%	0%	0%	13% B, C, F, G, I	7%	0%	0%	7%	0%
Unsure	**1%**	3%	0%	0%	0%	3%	0%	0%	3%	0%

Note: A capital letter under the % means that the number in that cell is significantly larger than the number in the cell indicated by the capital letter. For example, a significantly higher percentage of Endocrinology and Ophthalmology specialists (columns B and H) selected "Strongly agree" than Dermatology and Neurology Specialists (columns A and F).

Whether Interchangeable Biosimilars Should Be Individually Evaluated

Q2. "Which of the following statements best represents your opinion on deeming biosimilars as interchangeable with the original biologic product:" (n=270)



- 88% of respondents believe each interchangeable biosimilar should be individually evaluated specifically for the impact of switching on safety and efficacy.
- Only 11% believe all biosimilars should be deemed interchangeable.

Note: The words each and all were underlined in the response options when respondents took the survey.

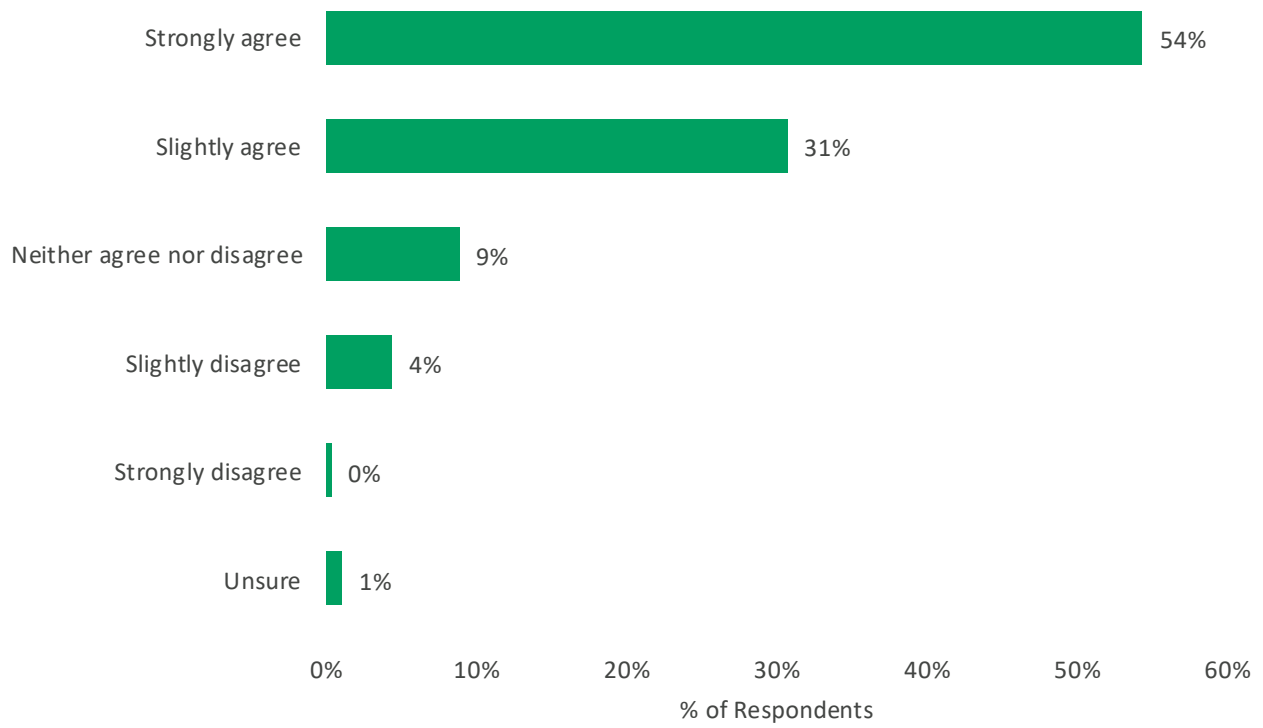
Whether Interchangeable Biosimilars Should Be Individually Evaluated – by Therapeutic Specialty

Q2. "Which of the following statements best represents your opinion on deeming biosimilars as interchangeable with the original biologic product:" (n=270)

	Total	Dermatology	Endocrinology	Gastrointestinal	Immunology	Nephrology	Neurology	Oncology	Ophthalmology	Rheumatology
n-size	270	30	30	30	30	30	30	30	30	30
		A	B	C	D	E	F	G	H	I
I strongly believe each interchangeable biosimilar should be individually evaluated specifically for the impact of switching on safety and efficacy	55%	53%	53%	57%	63% F	63% F	33%	50%	77% F, G, I	43%
I somewhat believe each interchangeable biosimilar should be individually evaluated specifically for the impact of switching on safety and efficacy	33%	40%	30%	30%	27%	30%	47%	33%	23%	37%
I somewhat believe all biosimilars should be deemed interchangeable	10%	3%	13% H	10%	10%	7%	17% H	17% H	0%	17% H
I strongly believe all biosimilars should be deemed interchangeable	0%	0%	3%	0%	0%	0%	0%	0%	0%	0%
Unsure/No opinion	1%	3%	0%	3%	0%	0%	3%	0%	0%	3%

Whether Only Individually Evaluated Biosimilars Should Be Deemed Interchangeable

Q3. To what extent do you agree with the following statement: "Only biosimilars that have been individually evaluated specifically for the impact of switching on safety and efficacy should be deemed interchangeable." (n=270)



- 85% of respondents agreed that only biosimilars that have been individually evaluated specifically for the impact of switching on safety and efficacy should be deemed interchangeable.

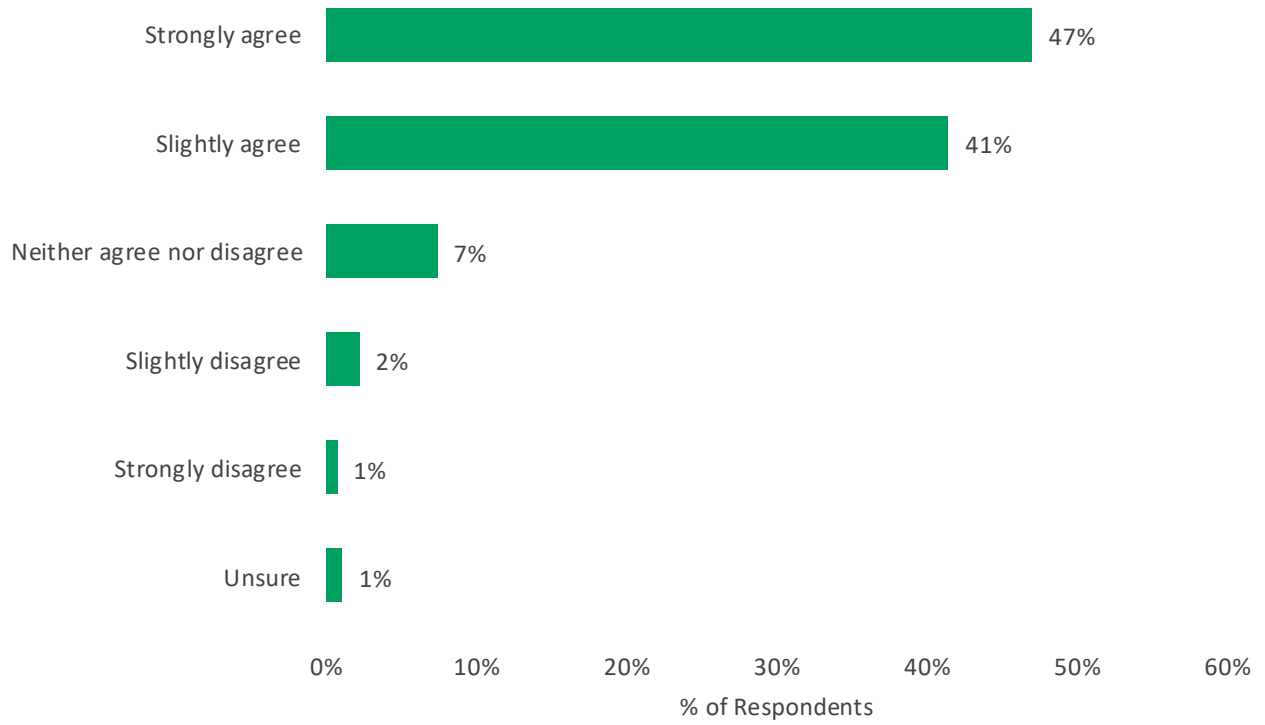
Whether Only Individually Evaluated Biosimilars Should Be Deemed Interchangeable – by Therapeutic Specialty

Q3. To what extent do you agree with the following statement: "Only biosimilars that have been individually evaluated specifically for the impact of switching on safety and efficacy should be deemed interchangeable." (n=270)

	Total	Dermatology	Endocrinology	Gastrointestinal	Immunology	Nephrology	Neurology	Oncology	Ophthalmology	Rheumatology
n-size	270	30	30	30	30	30	30	30	30	30
		A	B	C	D	E	F	G	H	I
Strongly agree	54%	57%	70% G	47%	57%	47%	50%	43%	60%	60%
Slightly agree	31%	30%	17%	33%	43% B	23%	27%	40% B	37%	27%
Neither agree nor disagree	9%	10%	7%	17% D, H	0%	13% D, H	13% D, H	10%	0%	10%
Slightly disagree	4%	0%	7%	0%	0%	10%	10%	7%	3%	3%
Strongly disagree	0%	0%	0%	0%	0%	3%	0%	0%	0%	0%
Unsure	1%	3%	0%	3%	0%	3%	0%	0%	0%	0%

Biosimilar Switching Studies' Effects on Confidence in Safety

*Q4. To what extent do you agree with the following statement: "Biologics are complex medicines that can cause unwanted immune responses in patients; biosimilar switching studies **increase my confidence** in the safety of moving my patients from an originator medicine to the biosimilar that has been studied and determined to be interchangeable with the originator." (n=270)*



- 88% of respondents agreed that biosimilar switching studies increase their confidence in the safety of moving their patients from an originator medicine to the biosimilar that has been studied and determined to be interchangeable with the originator.

Biosimilar Switching Studies' Effects on Confidence in Safety – by Therapeutic Specialty

*Q4. To what extent do you agree with the following statement: "Biologics are complex medicines that can cause unwanted immune responses in patients; biosimilar switching studies **increase my confidence** in the safety of moving my patients from an originator medicine to the biosimilar that has been studied and determined to be interchangeable with the originator." (n=270)*

	Total	Dermatology	Endocrinology	Gastrointestinal	Immunology	Nephrology	Neurology	Oncology	Ophthalmology	Rheumatology
n-size	270	30	30	30	30	30	30	30	30	30
		A	B	C	D	E	F	G	H	I
Strongly agree	47%	37%	50%	47%	57%	33%	40%	50%	70% A, E, F, I	40%
Slightly agree	41%	53% H	40%	37%	33%	47%	50%	33%	27%	53% H
Neither agree nor disagree	7%	7%	3%	17%	7%	10%	10%	7%	3%	3%
Slightly disagree	2%	0%	7%	0%	0%	7%	0%	7%	0%	0%
Strongly disagree	1%	0%	0%	0%	3%	0%	0%	0%	0%	3%
Unsure	1%	3%	0%	0%	0%	3%	0%	3%	0%	0%

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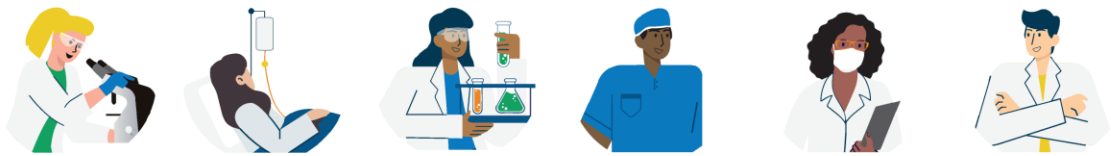

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