



Smarter questions • Smarter answers

ASBM US Prescribers Survey

Industry Standard Research

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Survey Methodology

- 202 Prescribers were recruited from specified practice areas in the United States
- 10 practice areas: Dermatology, Endocrinology, Gastrointestinal, Immunology, Nephrology, Neurology, Oncology, Ophthalmology, Rheumatology
- All N-size targets (country/practice area combinations) were reached
- 5 minute web-based survey
- Data were collected in May 2019

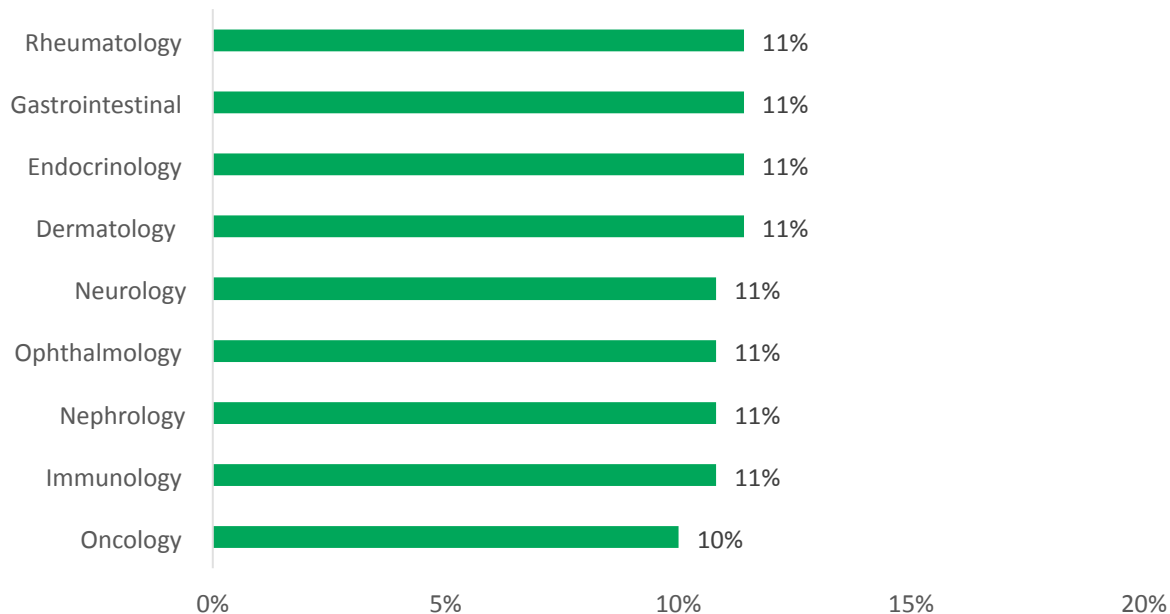


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DEMOGRAPHIC DATA/ SAMPLE CHARACTERISTICS

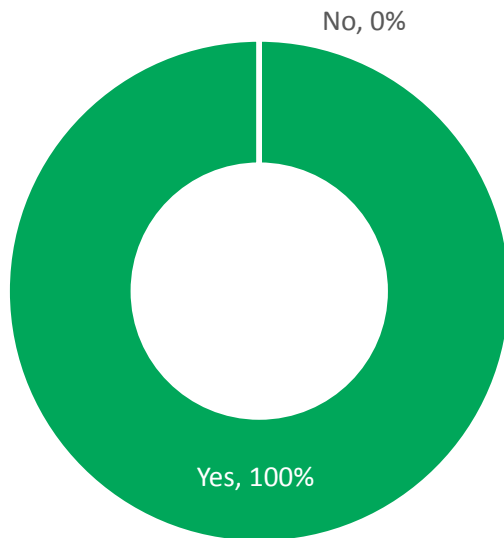
Primary Therapeutic Area

S1. Please indicate your primary practice area or therapeutic area in which you practice. (n=202)



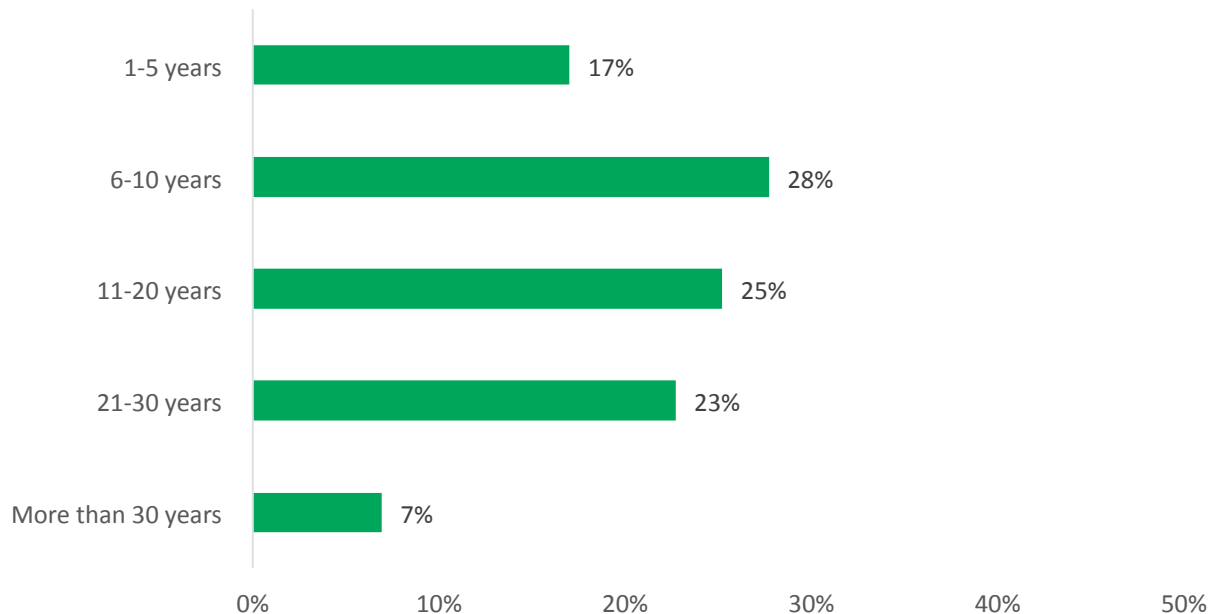
Biosimilar Approval Awareness

S2. Are you aware that a biosimilar may be approved for several or all indications of the reference product on the basis of clinical trials in only one of those indications? (n=202)



Length of Time Practicing Medicine

S3. For how many years post-residency have you been practicing medicine? (n=202)





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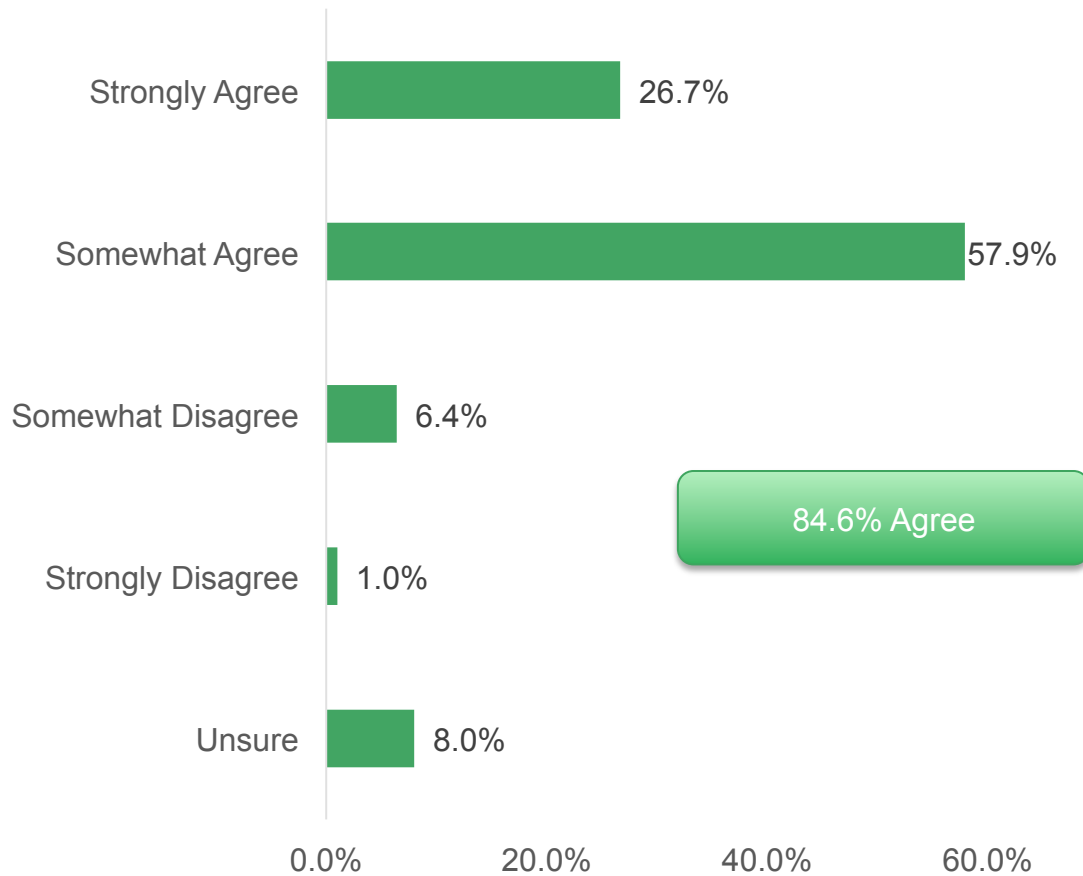
FINDINGS

Participant Introduction

- On March 8, FDA released updated draft guidance regarding their policy on the naming of biologic and biosimilar products:
Proposed Suffix for the Proper Name of a Biological Product (Docket No. FDA-2013-D-1543). The Draft Guidance is intended to reflect FDA's current thinking on nonproprietary names of certain biological products. According to the guidance:
 - Originator biologics previously approved without a suffix as part of the name would not be renamed to incorporate a suffix;
 - Biological products previously approved without a suffix under the Food, Drug and Cosmetic Act (e.g., insulin products, desirudin products, somatropin products) that will transition to be regulated under the Public Health Service Act in 2020, would not be renamed to incorporate a suffix
 - Biosimilars subsequently designated as interchangeable would not be renamed; each product would retain the unique suffix it was given at the time of biosimilar approval
 - Biologics approved as interchangeable would receive a unique 4 letter suffix, consistent with the naming practice for biosimilars and newly approved originator biologics

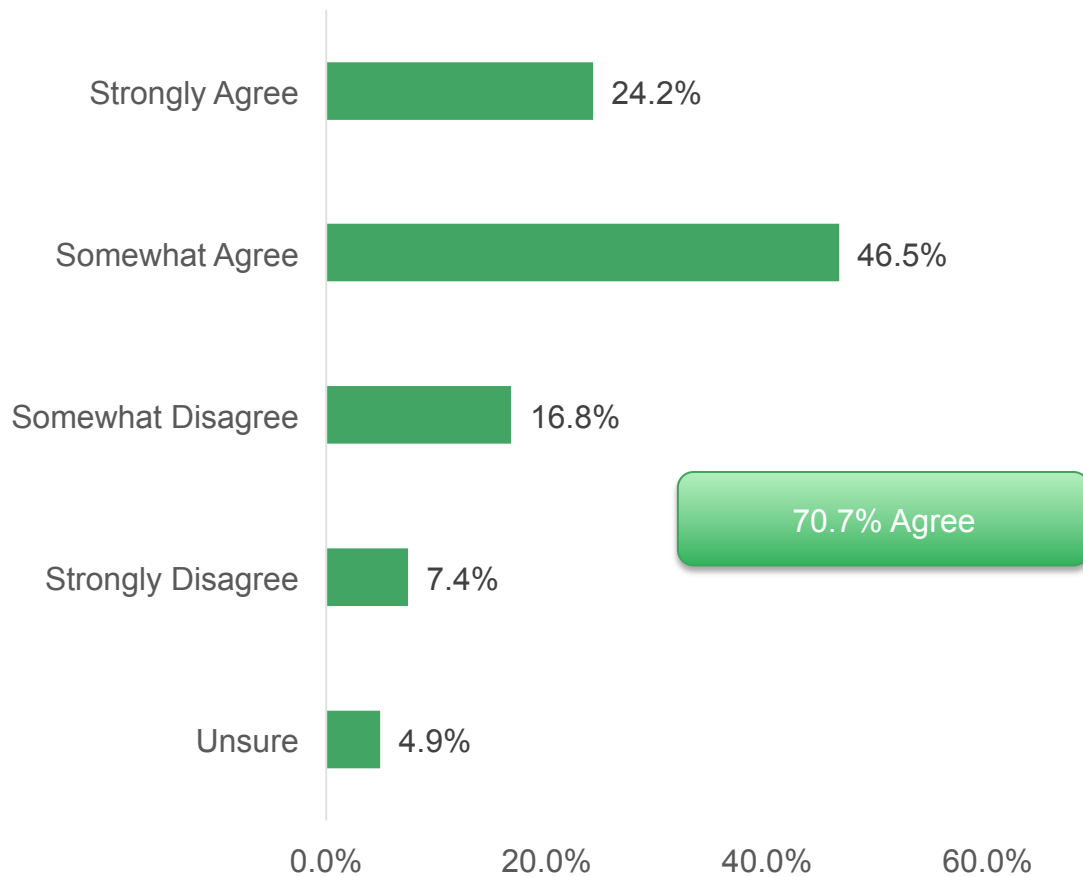
Use of Suffixes

Please rate your level of agreement with the FDA's decision to use 4-letter suffixes to clearly distinguish biosimilars from the originator product on which they are based, and from other biosimilars to that product? (n=202)



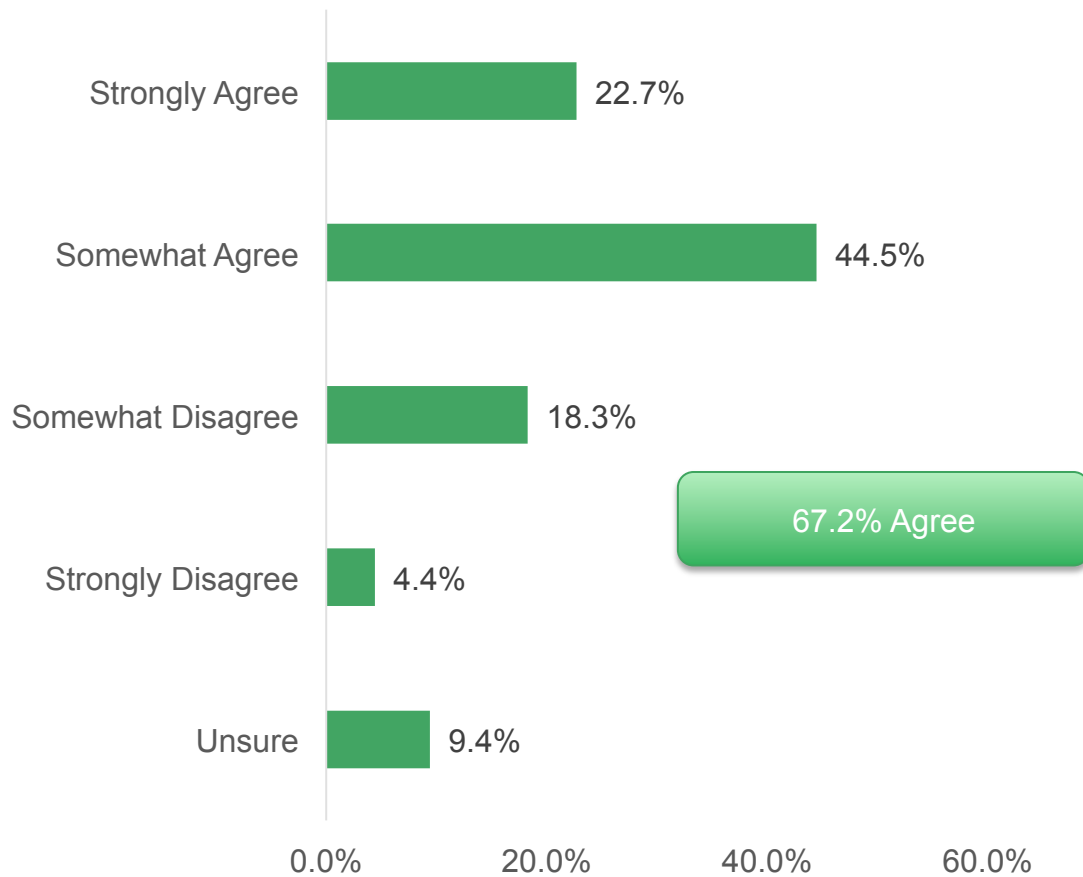
Retrospective Renaming

Please rate your level of agreement with FDA's decision not to rename previously approved biologics to incorporate a suffix?
(n=202)



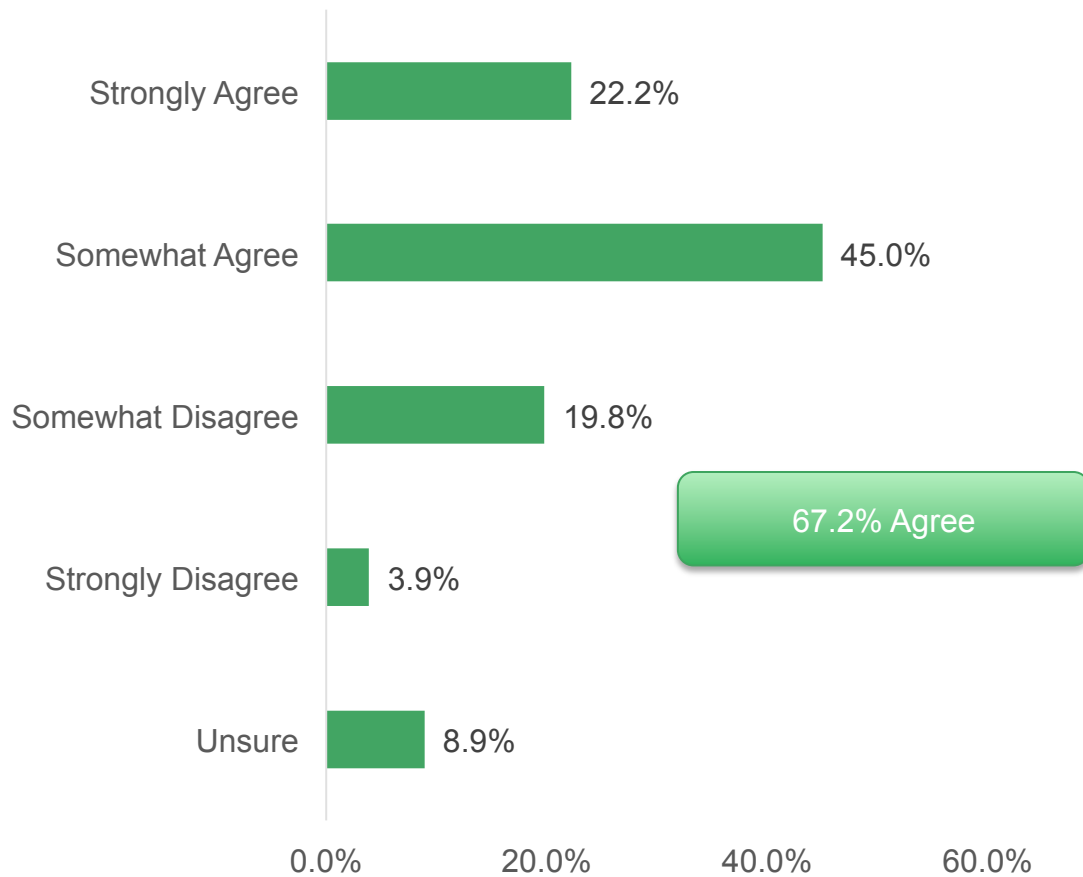
Retrospective Renaming

Please rate your level of agreement with FDA's decision not to rename biologics previously approved under the Food, Drug and Cosmetic Act (e.g., insulin products, desirudin products, somatropin products) that will transition to be regulated under the Public Health Service Act in 2020 to incorporate a suffix? (n=202)



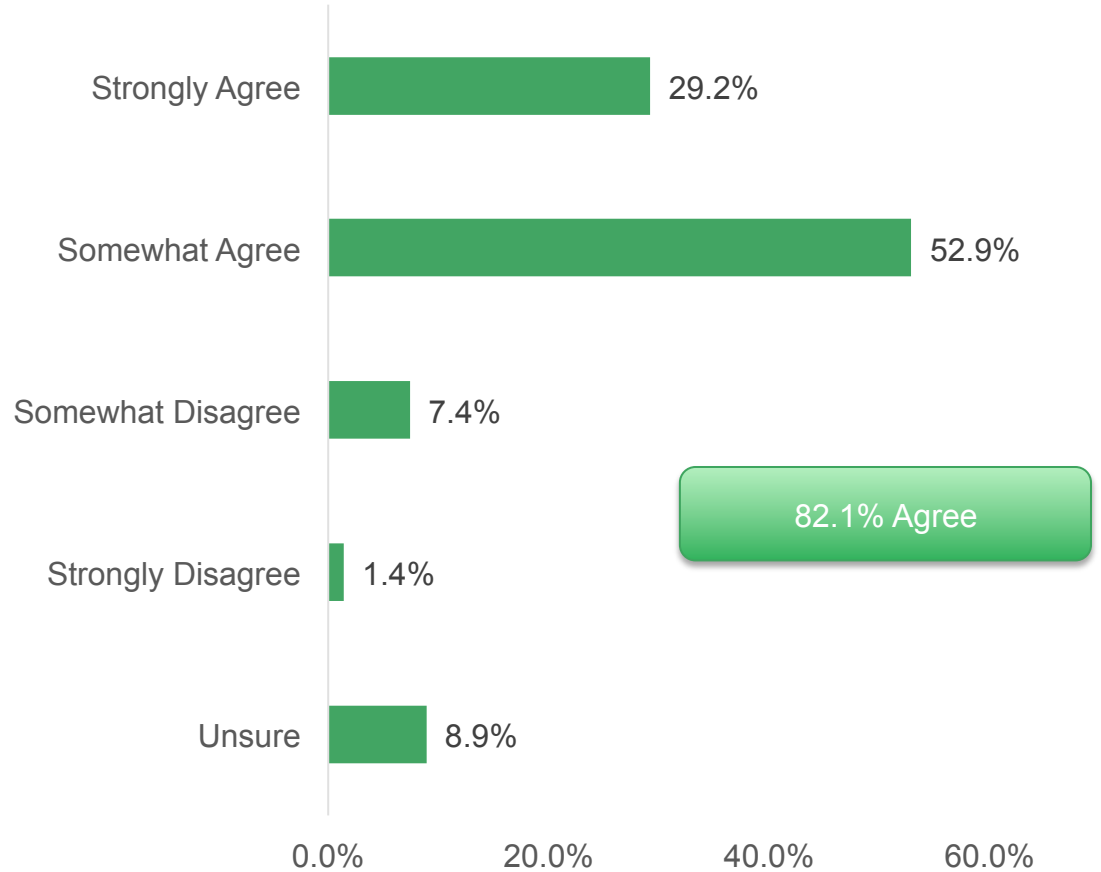
Renaming Post-Interchangeability Designation

Please rate your level of agreement with FDA's decision not to rename biosimilars subsequently designated as interchangeable; instead each product would retain the unique suffix it was given at the time of biosimilar approval?
(n=202)



Use of Suffixes

Please rate your level of agreement with FDA's decision to give a biologic approved as interchangeable a unique 4 letter suffix, as it does for biosimilars and newly approved originator products? (n=202)



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