ASBM Labeling Survey

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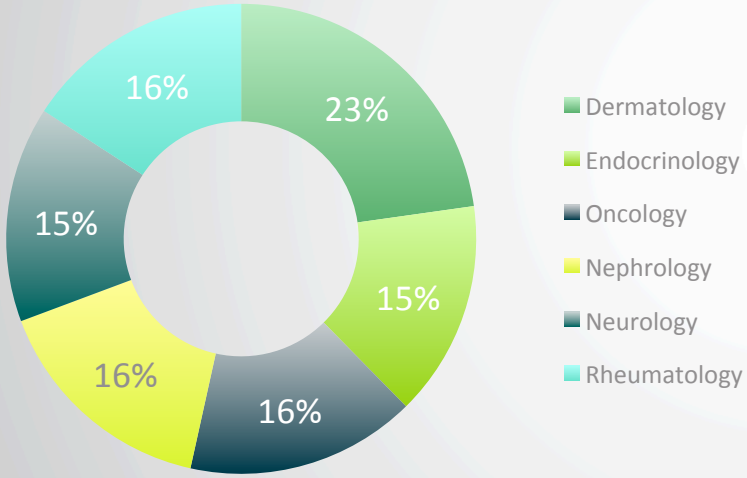
Methodology

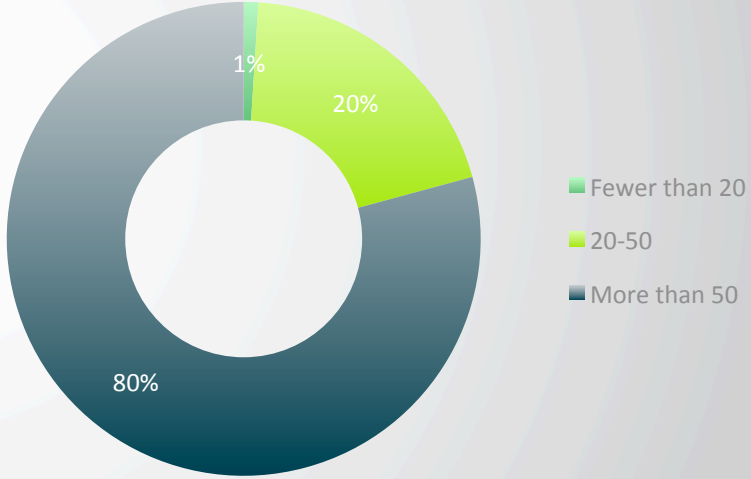
- 400 Web-based surveys
- All participants located in the U.S.
- Participants were recruited from a large, reputable panel of physicians
- Participants were screened for the following characteristics:
  - Board certified in one of 6 relevant specialties (Dermatology, Endocrinology, Oncology, Nephrology, Neurology, Rheumatology)
  - Must prescribe biologic medicines

Sample Characteristics

Distribution of Specialists

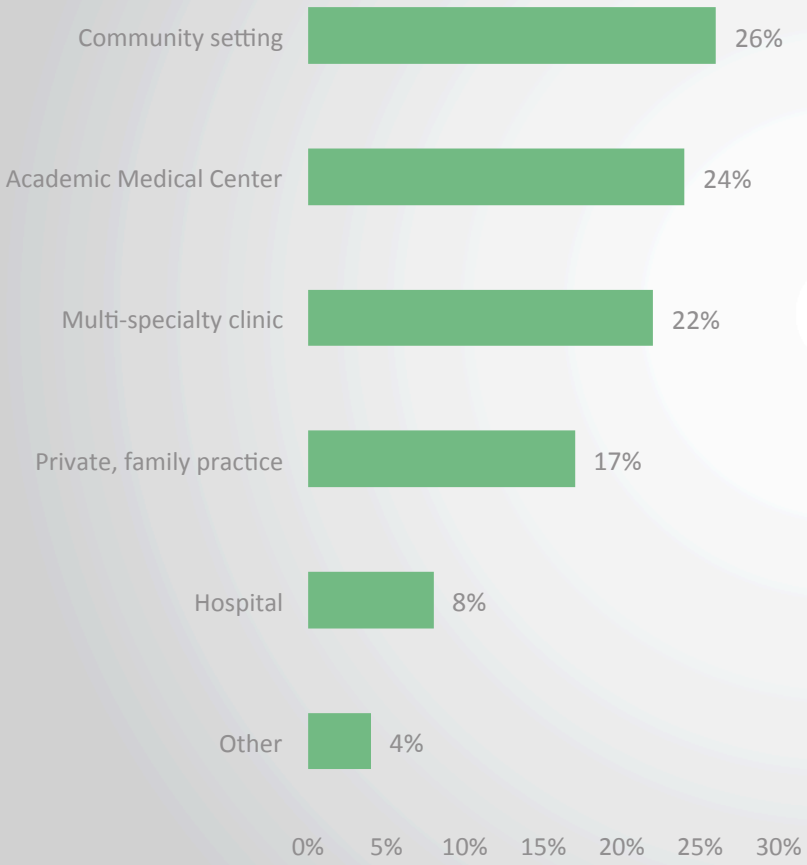


Patient Visits per Week



Sample Characteristics

Practice Type



Years in Healthcare

Executive Summary

- Generally speaking, all items tested were considered by prescribers to be very important for label inclusion.
  - On a 5 point scale, the lowest average importance rating was 4.1 (interchangeability) and the highest was 4.4 (indicating the drug is a biosimilar)
- Segment differences were examined for all items tested. Segments included specialty, time in the healthcare industry, and practice setting.
  - Very few specialty differences were noted and no differences for practice setting were noted.
  - In general, the longer a physician has been in the healthcare industry, the more important they believe it is to include these items on the biosimilar product label.

Survey Participant Context

All survey participants received the following introductory content, prior to answering questions:

In the United States, FDA can approve a biosimilar medicine as safe and effective for patients via one of two different pathways. The first, referred to as the full application, requires a full set of clinical trials to independently prove that the product is safe and effective for the proposed indications. The second, referred to as the biosimilar pathway, permits FDA to approve a product based on evidence that the product is highly similar to an already approved product. The sponsor does not prove that the biosimilar is safe and effective directly but by demonstrating that the biosimilar is highly similar to a product that was previously approved through the full pathway, referred to as the "reference product". Thus the biosimilar pathway can facilitate faster development and lower development costs by allowing approval without the conducting of full clinical trials.

Whereas generic drugs are identical copies of the active ingredient of a chemical drug, biosimilars will be highly similar but not identical because biologics are made in living cells. Therefore, biosimilars will have some nonclinical and clinical data to demonstrate the biosimilar is highly similar to the reference product.

The FDA has not yet indicated what a label for a biosimilar medicine will look like. Feedback from physicians who prescribe biologic medicines may help them determine what to include or leave out of biosimilar labels.

In the years to come, it is expected that there will be multiple biosimilar products for the significant biologic medicines that are no longer covered by patent protection. In choosing between reference product and multiple biosimilars by different manufacturers, what would you, as a prescriber of biologics, want to see in the product label that is the source of public data about the product?

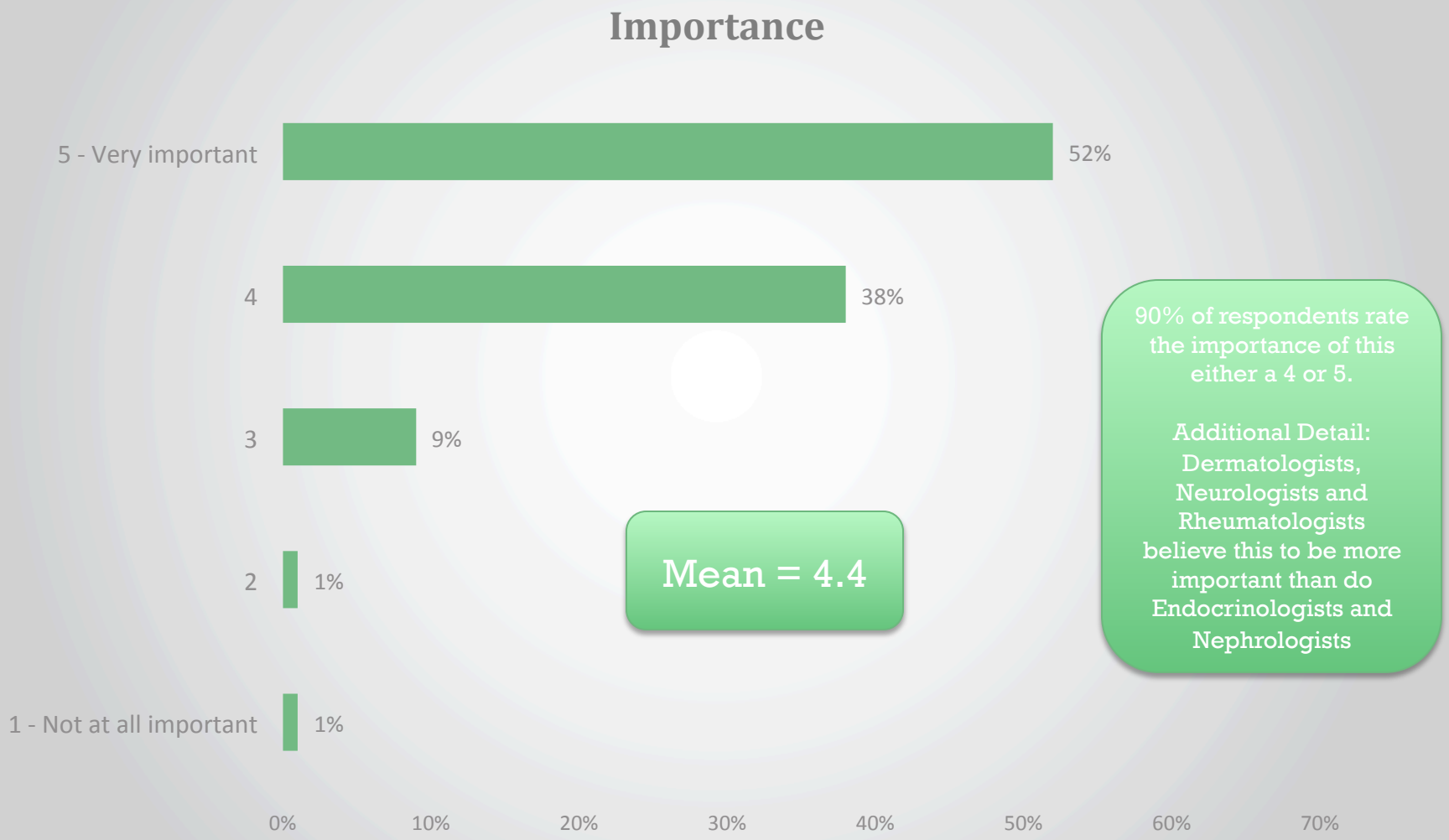
Study Questions

1. How important is it that a product label for a biosimilar clearly indicates that it is a biosimilar?
2. How important is it that a product label for a biosimilar defines what biosimiliarity means?
3. How important is it that the biosimilar label includes the analytical data developed by the biosimilar sponsor to demonstrate its analytical similarity to the reference product?
4. How important is it that the biosimilar label includes the clinical data, if any, submitted to FDA by the biosimilar sponsor to demonstrate that it is highly similar to the reference product?
5. How important is it that post marketing data related to the biosimilar be added to the biosimilar label?
6. How important is it that the label mentions the reference product by brand name so as to clarify the precise relationship between the originator product and the biosimilar product?
7. How important is it that the label explicitly states that specific indications or conditions of use that are approved for the originator product are NOT approved for the biosimilar product?
8. How important is it that the label clearly distinguishes those data generated by the biosimilar sponsor from those generated by the originator sponsor?
9. How important is it that the label includes all relevant clinical similarity data, including clinical immunogenicity findings, from the biosimilar product development?
10. How important is it that the label makes clear which indications were studied by the biosimilar sponsor and which indications were approved based on extrapolation from studies in other indications?
11. How important is it that a product label clearly indicates a biosimilar is or is not interchangeable, meaning it may be eligible for automatic substitution by a pharmacist depending on the state in which the prescription is written?

STUDY FINDINGS

# Indicates Biosimilar

1.How important is it that a product label for a biosimilar clearly indicates that it is a biosimilar?

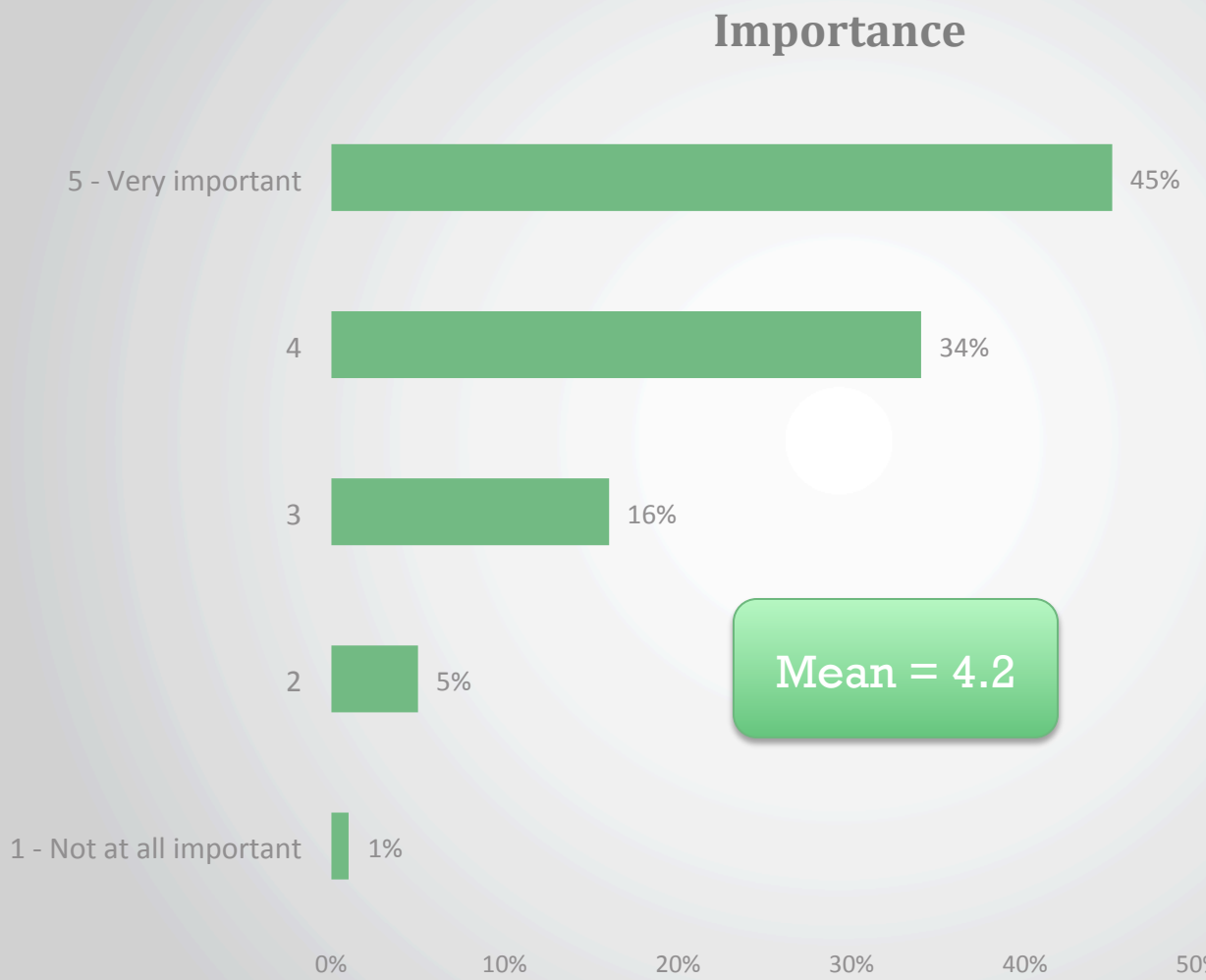


90% of respondents rate the importance of this either a 4 or 5.

Additional Detail: Dermatologists, Neurologists and Rheumatologists believe this to be more important than do Endocrinologists and Nephrologists

Defines Biosimilarity

2. How important is it that a product label for a biosimilar defines what biosimiliarity means?



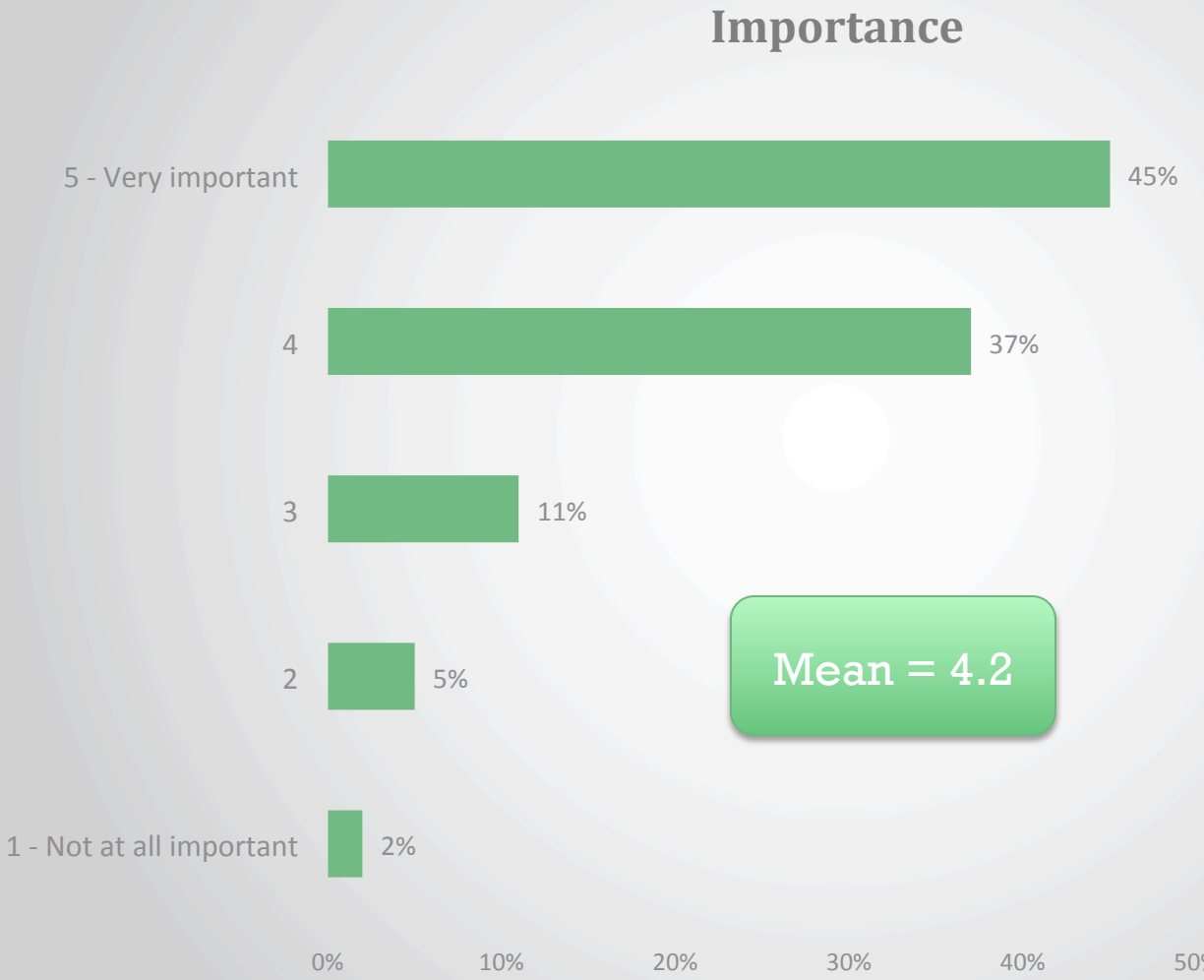
Mean = 4.2

79% of respondents rate the importance of this either a 4 or 5.

Additional Detail: Dermatologists, Endocrinologists, Neurologists, and Rheumatologists believe this to be more important than do Oncologists

Analytical Data

3. How important is it that the biosimilar label includes the analytical data developed by the biosimilar sponsor to demonstrate its analytical similarity to the reference product?



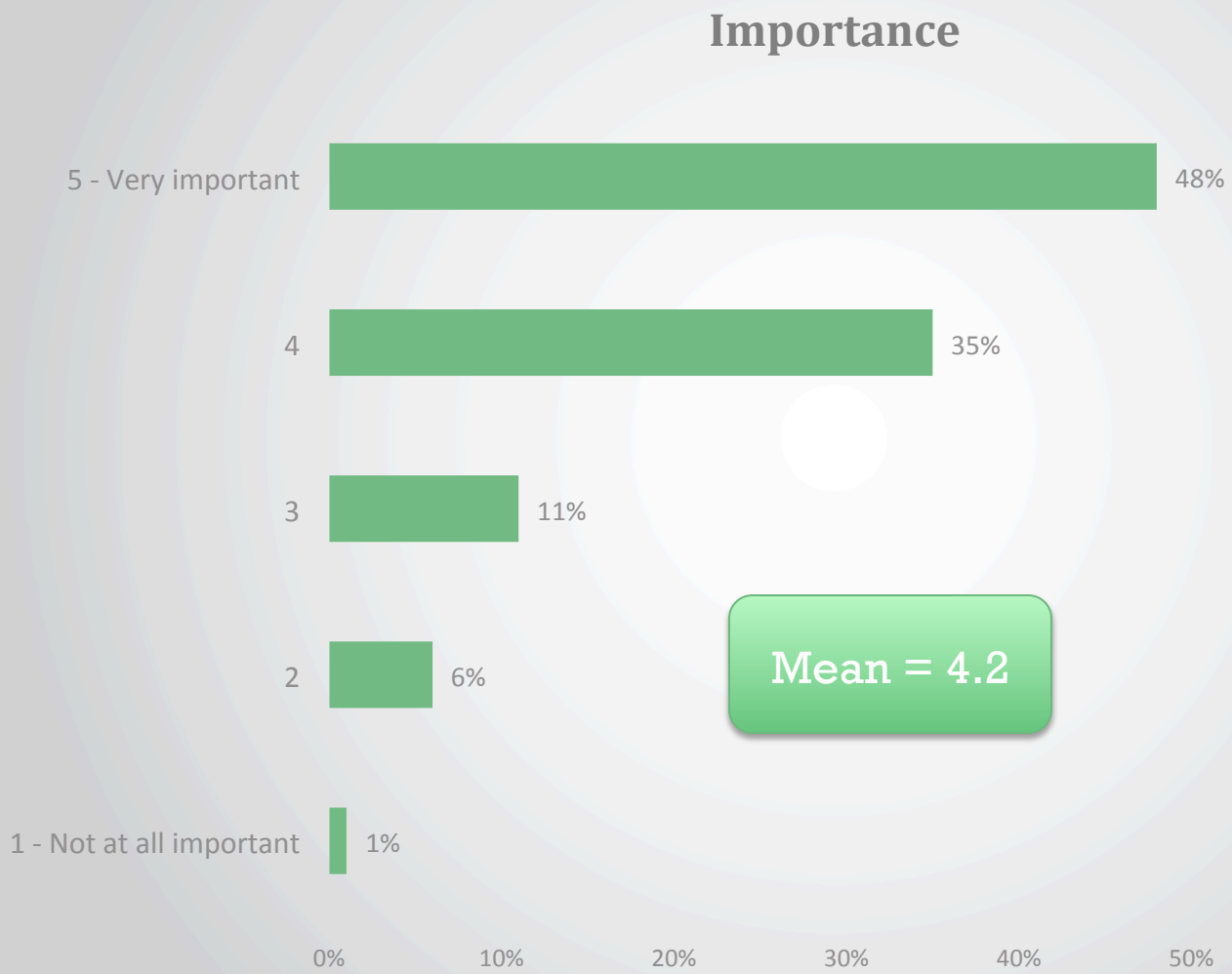
Mean = 4.2

82% of respondents rate the importance of this either a 4 or 5.

Additional Detail: No sub-segment differences were found.

Clinical Data

4. How important is it that the biosimilar label includes the clinical data, if any, submitted to FDA by the biosimilar sponsor to demonstrate that it is highly similar to the reference product?



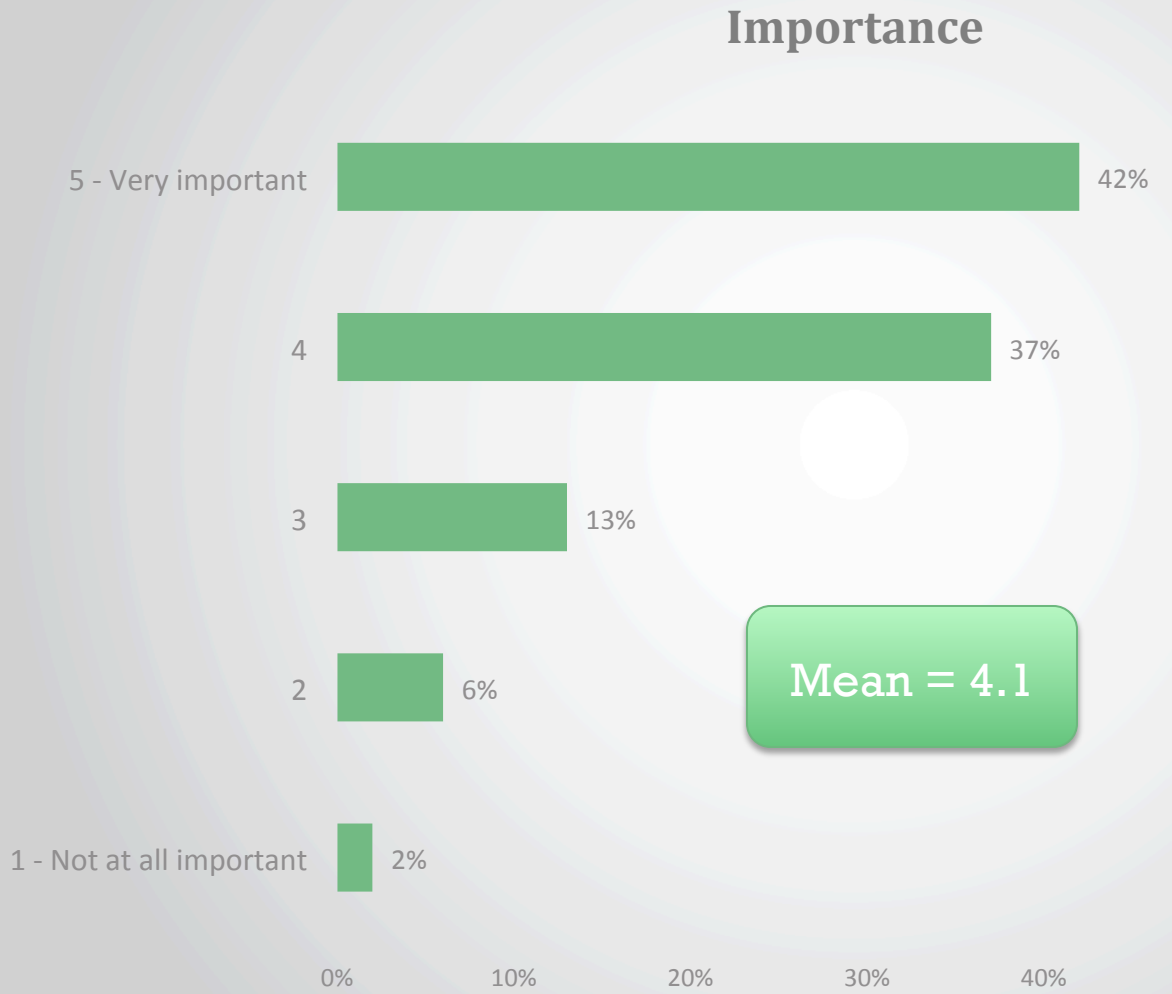
Mean = 4.2

83% of respondents rate the importance of this either a 4 or 5.

Additional Detail: No sub-segment differences were found.

Post Marketing Data

5. How important is it that post marketing data related to the biosimilar be added to the biosimilar label?



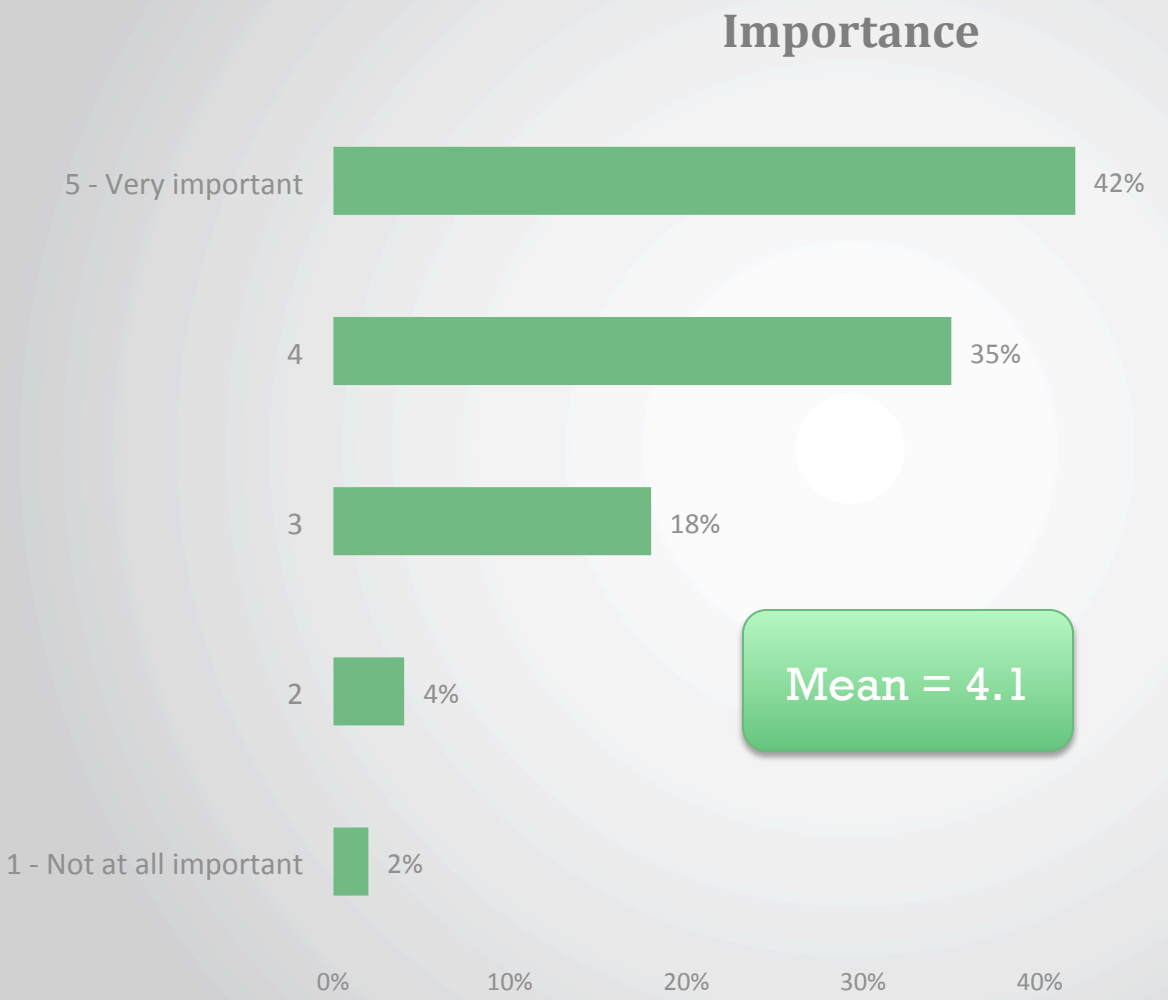
Mean = 4.1

79% of respondents rate the importance of this either a 4 or 5.

Additional Detail:
The longer a physician has been in the healthcare industry, the more important it is to them to include post marketing data.

Reference Brand Name

6. How important is it that the label mentions the reference product by brand name so as to clarify the precise relationship between the originator product and the biosimilar product?



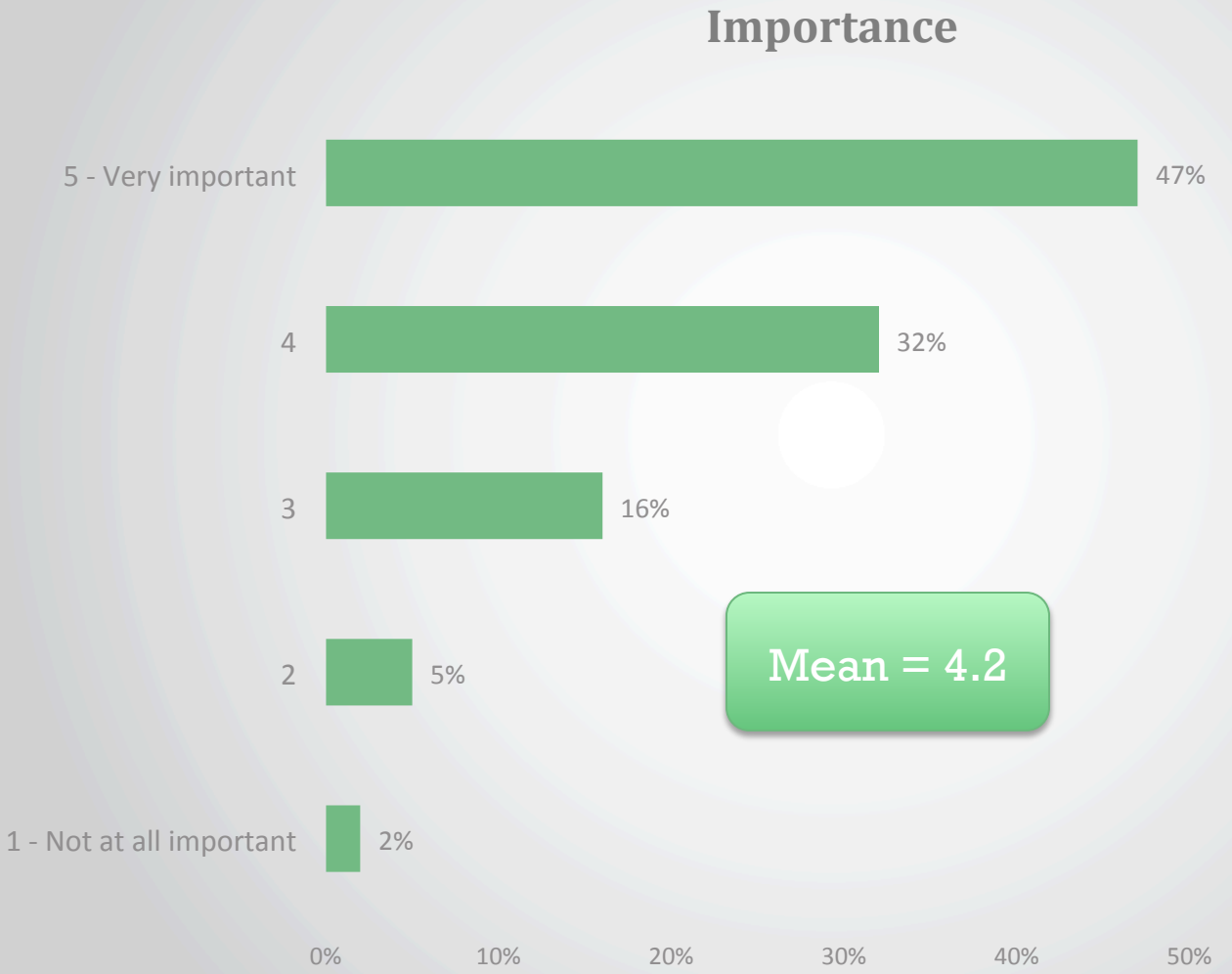
Mean = 4.1

77% of respondents rate the importance of this either a 4 or 5.

Additional Detail: No sub-segment differences were found.

Approved & Non-approved Indications

7. How important is it that the label explicitly states that specific indications or conditions of use that are approved for the originator product are NOT approved for the biosimilar product?

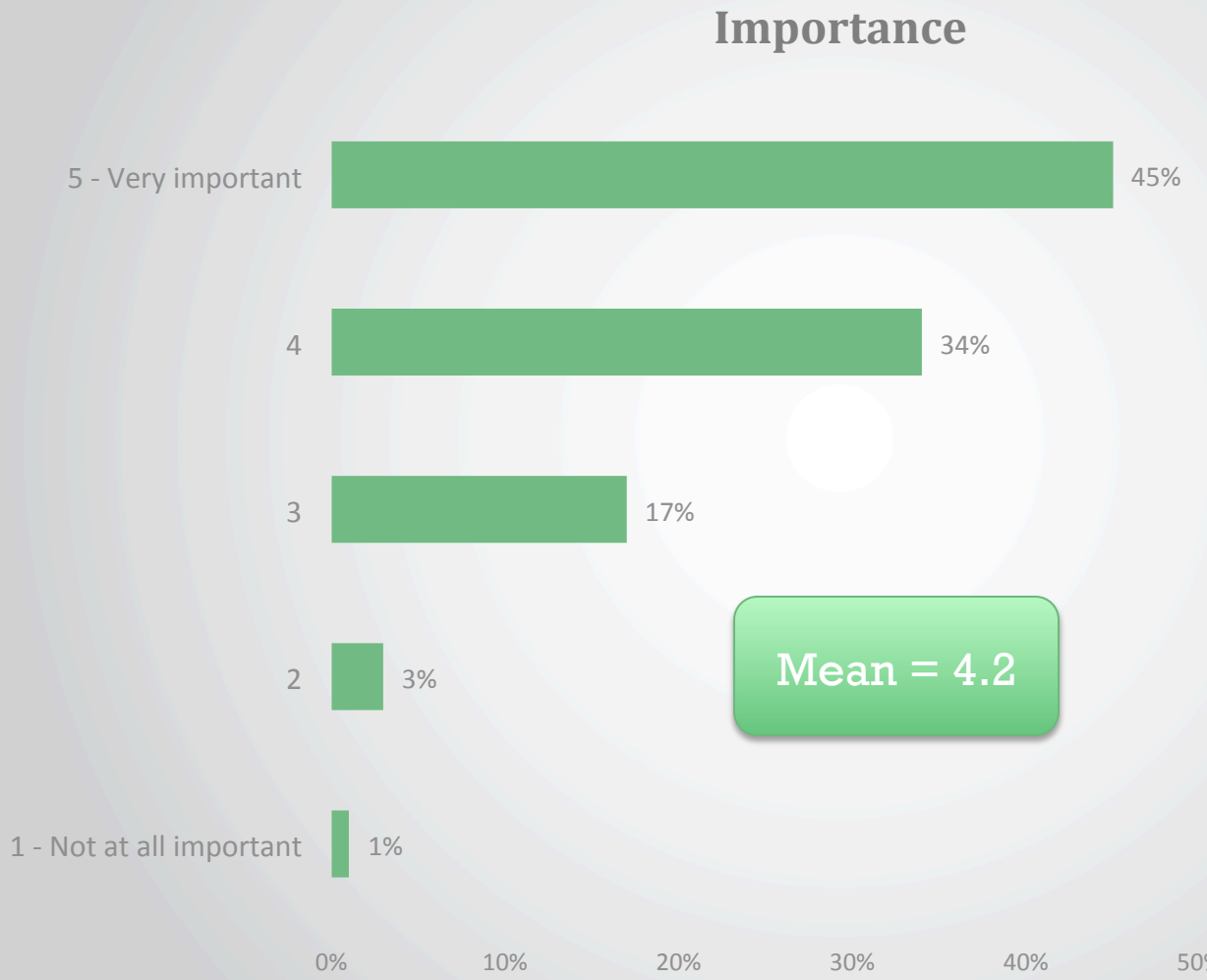


79% of respondents rate the importance of this either a 4 or 5.

Additional Detail: No sub-segment differences were found.

Originator vs. Biosimilar Data

8. How important is it that the label clearly distinguishes those data generated by the biosimilar sponsor from those generated by the originator sponsor?

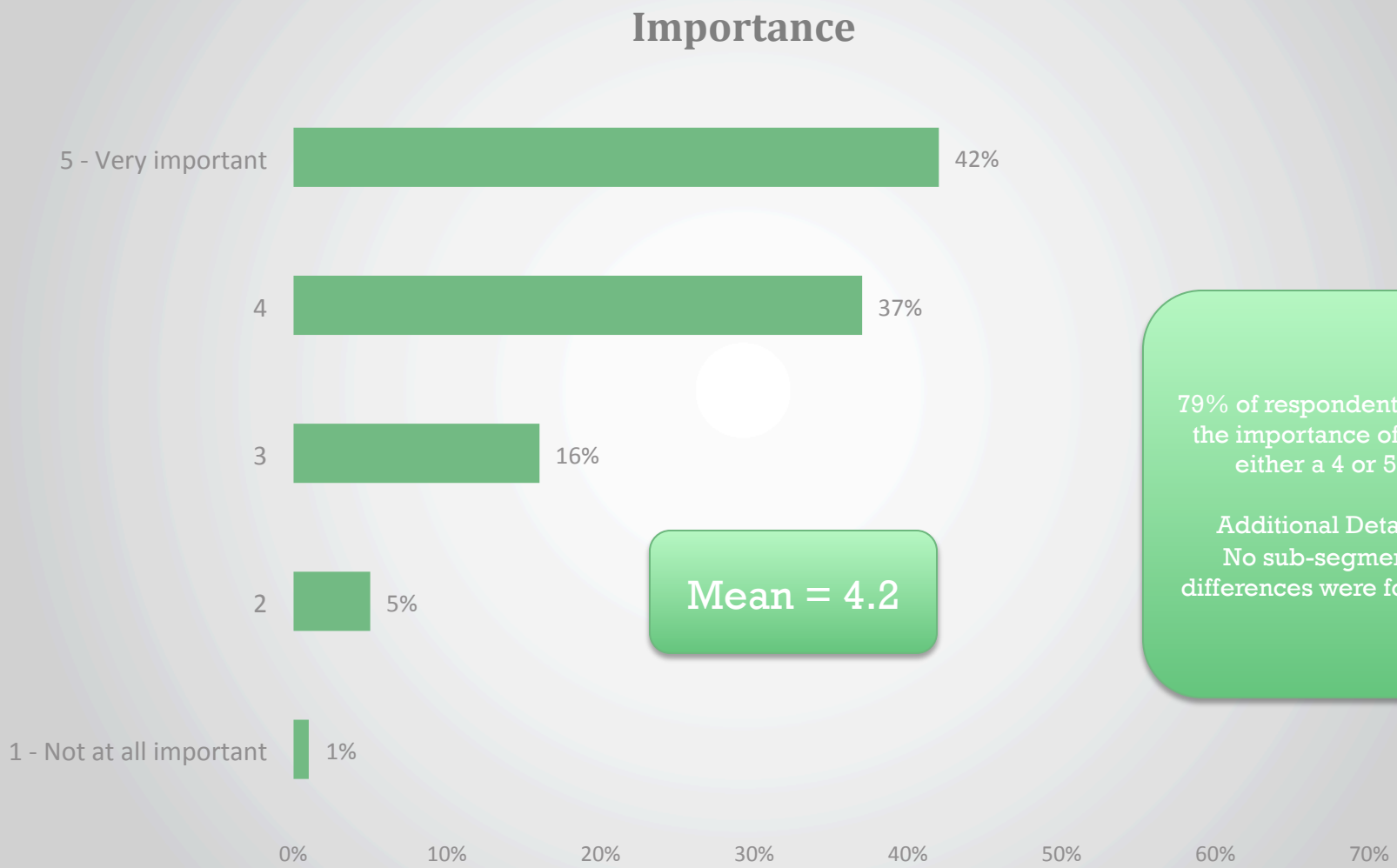


79% of respondents rate the importance of this either a 4 or 5.

Additional Detail: Physicians with 21-30 years in the industry perceive increased importance in this than those with between 6-20 years of experience.

Clinical Similarity

9. How important is it that the label includes all relevant clinical similarity data, including clinical immunogenicity findings, from the biosimilar product development?

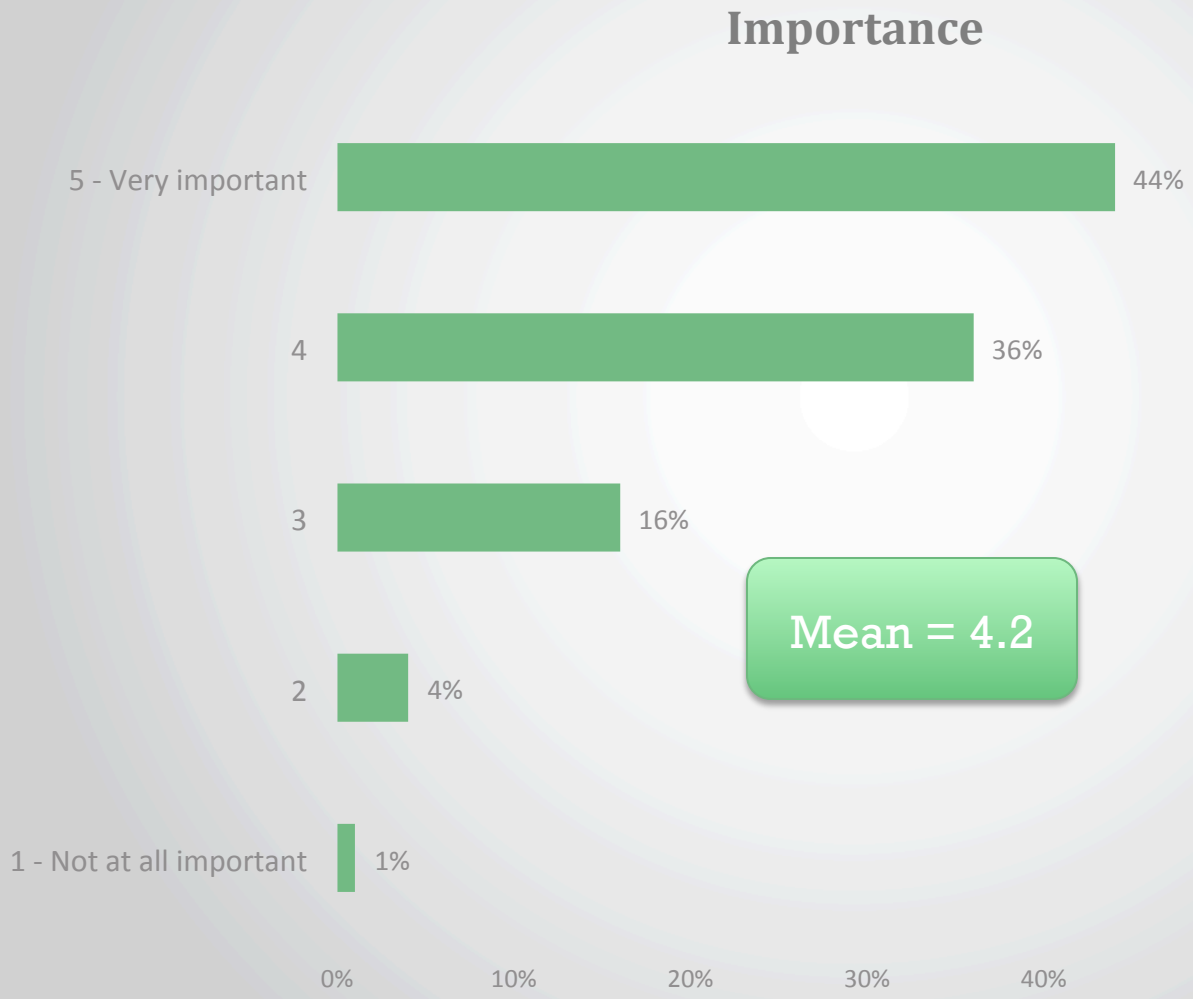


79% of respondents rate the importance of this either a 4 or 5.

Additional Detail:
No sub-segment differences were found.

Data Source

10. How important is it that the label makes clear which indications were studied by the biosimilar sponsor and which indications were approved based on extrapolation from studies in other indications?



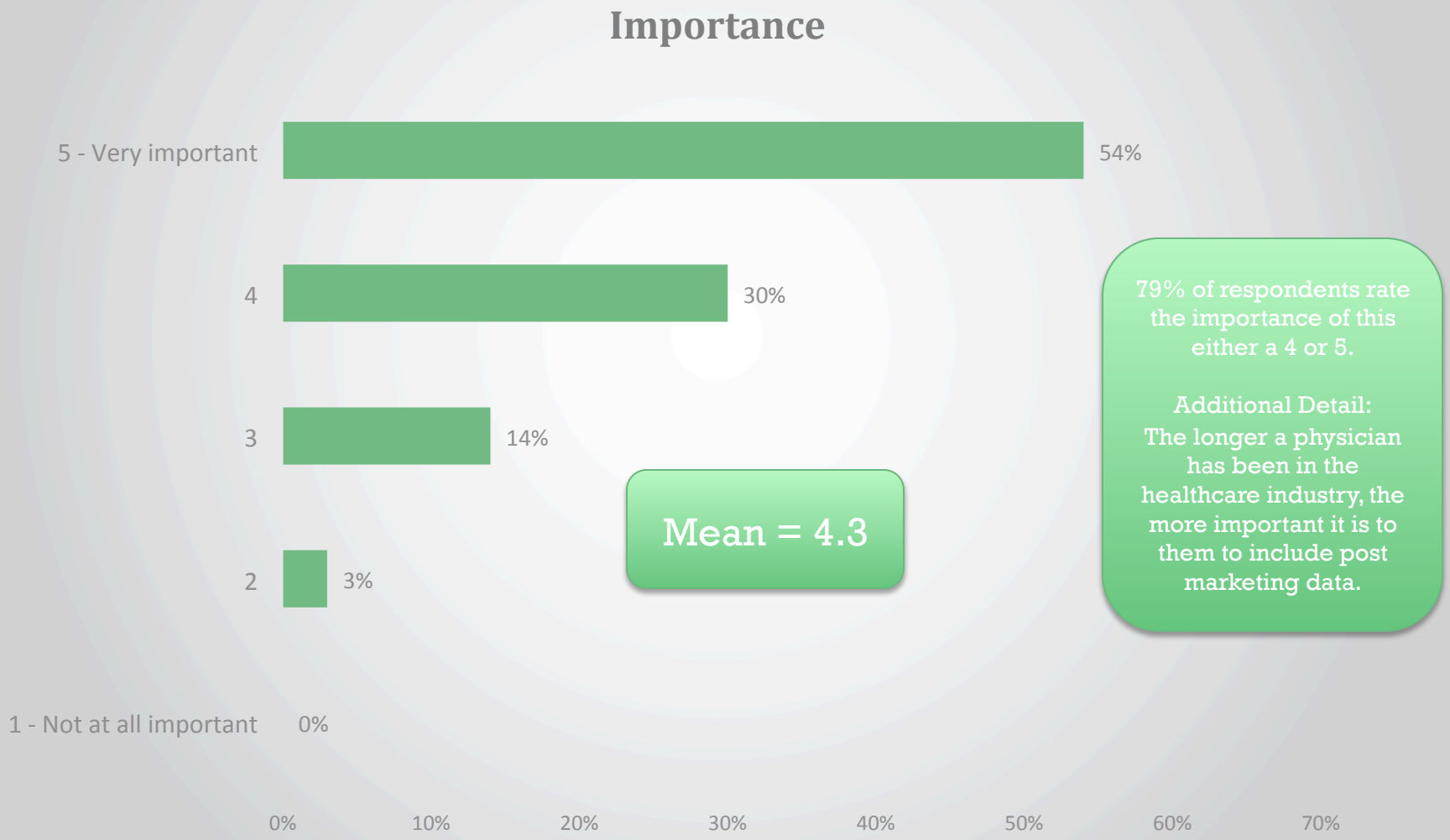
Mean = 4.2

80% of respondents rate the importance of this either a 4 or 5.

Additional Detail:
The longer a physician has been in the healthcare industry, the more important it is to them to include post marketing data.

Interchangeability / Substitution

11. How important is it that a product label clearly indicates a biosimilar is or is not interchangeable, meaning it may be eligible for automatic substitution by a pharmacist depending on the state in which the prescription is written?



Mean = 4.3

79% of respondents rate the importance of this either a 4 or 5.

Additional Detail:
The longer a physician has been in the healthcare industry, the more important it is to them to include post marketing data.