

Update for Projects using Umbrella Generic Clearance 0910-0847 (Data to Support Social and Behavioral Research as Used by FDA)

Project Title: Physician Knowledge of Drug Quality

The FDA Safe Use Initiative awarded a contract via the Broad Agency Announcement to investigate how U.S. physicians perceived drug quality and whether this perception varies by demographic subgroup and type of product (prescription branded, prescription generic, or over-the-counter (OTC) product).

What was the Problem to be Investigated?

Even among healthcare providers, what defines the concept of “quality” may differ. To one person, “quality” may refer to the shape and consistency of the pills, while another thinks about “quality” in terms of purity. In addition, physician trust of generic drug quality varies. Given this variation, it is important for FDA to understand how the concept is “quality” is viewed by physicians.

Medscape conducted an approximately 10-minute survey of its physician subscribers to measure their understanding of and attitudes toward drug product quality for prescription and OTC drugs. The survey addressed what drug quality means to physicians and whether they understand basic drug product manufacturing quality, the FDA’s role in drug quality regulation and drug approval, and how manufacturing quality can affect drug approval. This analysis improved FDA’s understanding of physicians’ views toward drug quality and how these views differ by demographics, prior knowledge of FDA quality processes, personal use of therapeutic drugs, and other factors.

Method used to Obtain the Sample

Survey invitations were emailed to a random sample of Medscape member healthcare providers. Respondents were required to be practicing U.S. physicians, aged 26 years and older, in practice for at least 5 years post-residency, spending at least 40% of their time to direct patient care, treating at least 20 patients per month, and have written any prescriptions in the past 30 days. Participating healthcare providers received an Amazon gift card (\$25 - \$50).

Total Burden

It is estimated that the survey took 10 minutes to complete. There were 650 participants. The total burden for this collection was estimated to be 108.3 hours (650 participants x 10 minutes).