FDA embraces real-world evidence in new final guidance

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On August 31, 2017, the U.S. Food and Drug Administration (FDA) finalized its guidance document entitled, "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices." The final guidance reiterates the principles outlined in the July 27, 2016, draft of the document. Both the draft and final guidance's are part of FDA's recent efforts to take creative approaches to the evidence required to support regulatory decision-making. FDA's willingness to consider the utility of real-world data in regulatory decision-making aligns with a general shift in the way these data are viewed by the larger scientific community, as well as a mandate in the FDA Reauthorization Act of 2017 (FDARA) to evaluate the utility of real-world evidence for such decision-making. Though success in use of real-world data has been mixed in practice, the messages emphasized in the Agency's final guidance will undoubtedly be well-received by the industry.

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Contacts

Michael Kasser

Director of Regulatory Sciences

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