

# FDA regulatory trends and challenges, and ACRP's role in the regulatory realm

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## **Abstract**

Drawing from a variety of independent sources, this article provides an overview of current regulatory trends and challenges related to the U.S. Food and Drug Administration's (FDA's) oversight of clinical trials at home and abroad. Considered herein are data and commentary on the activities of principal investigators, research sites, and institutional review boards; approvals of new drugs by FDA and other regulatory bodies; ramifications of the Open Payments (Formerly Sunshine) Act; and initiatives of the Association of Clinical Research Professionals (ACRP) in terms of monitoring and responding to relevant regulatory changes or proposals on behalf of its membership, with examples of such advocacy provided.

## **Key words**

regulatory affairs, research oversight, Sunshine Act, Open Payments Act, FDA, principal investigators

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