

Food and Drug Administration

EVALUATING THE APPROVAL PATH FOR SAFE AND EFFECTIVE NEW DRUGS AND BIOLOGICS

CASE STUDY

Booz Allen was asked to take a quantitative look at the impact of FDA's implementation of initiatives to enhance application review performance.



About Booz Allen

Booz Allen Hamilton has been at the forefront of management consulting for businesses and governments for more than 90 years. Providing consulting services in strategy, operations, organization and change, and information technology, Booz Allen is the one firm that helps clients solve their toughest problems, working by their side to help them achieve their missions. Booz Allen is committed to delivering results that endure.

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Client's Challenge

The Food and Drug Administration (FDA) is responsible for reviewing new products that are designed to treat human conditions or diseases for safety and effectiveness before they can be made available to consumers. The Prescription Drug User Fee Act (PDUFA) is a series of laws that allows the FDA to help fund the review of new drugs through fees paid by the companies that submit new drug applications. Industry provides the funding in exchange for an FDA agreement to not only meet drug-review performance goals, but also undertake specific initiatives to improve the effectiveness and efficiency of product reviews. Under PDUFA III, the agency was required to conduct an independent evaluation of the impact of recent initiatives on the review process.

What Booz Allen Did

Drawing on its deep experience in the public and private sectors of Life Sciences, Booz Allen Hamilton, a global strategy and technology consulting firm, is conducting a comprehensive four-phase study for the FDA. In Phase 1, we conducted an analysis of new drug applications submitted and approved between FY 2002 and FY 2004 to determine which factors contributed to or detracted from FDA's ability to make an approval decision in single versus multiple review cycles. We also examined the impact of FDA pilot programs that formalized early application submissions and increased FDA and manufacturer interactions activities during the application submission process. In the final phases of this far-reaching FDA project, we are extending the product review study through FY 2007 and examining the public health impact of post-market commitments that product sponsors and FDA agreed on to further define the safety, efficacy, or optimal use of a product after approval.

Results

Our analysis confirmed that effective communication between FDA and manufacturers resulted in higher first cycle approval rates. Fifty-two percent of companies that held a meeting with the FDA at the end of Phase 2 clinical trials received approval during the first review cycle, compared with 29 percent of those that did not. Our examination of the application submission pilot programs showed no significant increase in the first-cycle product approval rate over the programs, although the study identified several best practices for application review and submission. Based on our analysis and recommendations, FDA recommended that these programs would not be renewed for PDUFA IV.

As we continue the final phases of the FDA project, our unique perspective and understanding of FDA and pharmaceutical manufacturers has allowed us to identify tangible and actionable steps that FDA and private sector applicants can take to expedite application review and ensure medical products reach patients.

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