ICT fails to accelerate drug approvals

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Drug approvals are taking just as long as they ever did despite increased expenditure on new information technology at the Food and drug Administration. So says a statistical analysis of approval intervals from 1997 to 2006, published in the *International Journal of Electronic Healthcare*.

Since the middle of the 1990s, FDA review intervals have been an important topic of discussion for the boards of major pharmaceutical companies and among consumer groups desperate to see new, improved products on the market. The issue has been raised by economists and financiers and in Congress.

John Kros and Christopher Keller of the College of Business, at East Carolina University, in Greenville, North Carolina, explain that the implementation of new Information Technology (IT) at the FDA has been a persistent target for reducing the time taken between an application and final approval. They have analyzed data on three main categories of new drugs are studied: New Drug Application (NDA), the Supplemental New Drug Application (SNDA) and the Abbreviated New Drug Application (ANDA).

The team points out that under the 1992 Congressional Prescription Drug User Fee Act (PDUFA), drug companies agreed to pay fees to the FDA and in turn, the FDA agreed to time limits on the review process for new drug applications. Then, the FDA Modernization Act of 1997 new funds and user fees were authorized. Both changes coincided with a significant increase in the use of IT at the FDA.

However, significant increases in IT use do not seem to have translated into shorter interval times, according to the study by Kros and his team. They have found that the median review time (almost seven months) for an ANDA was significantly longer than that of an NDA and SDNA. In this study, which concludes the second part of a long-term analysis of the data, Kros and his colleagues saw no statistically significant reduction in review times.

Earlier research suggested that FDA review times decreased throughout the 1980s and into the 1990s, which was ascribed to greater resources and higher quality submissions as well as the PDUFA. However, increasing numbers of drug applications and increased concerns over drug safety, have to some extent negated the earlier gains in recent years.

"The FDA faces a balance between allocating resources between new drug reviews and the generic drug review process," the researchers say, "When more resources go to the new drugs, these new drugs can get to market faster and patients suffering from unsuccessfully treated diseases can benefit more quickly." Shorter drug review times can encourage new drug R&D, but more resources allocated to generic approvals can benefit the market and the consumer by offering more choice.

"The present research contributes a baseline for future comparison by which any future reductions in approval times which, do result from the implementation of information technology could be verified," the researchers conclude.

More information: "FDA drug approval intervals from 1997 to 2006: analysis and comparison during information technology implementation" in *International Journal of Electronic Healthcare*, 2009, 5, 164-176

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