U.S. Food and Drug Administration

News & Events

FDA NEWS RELEASE

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FDA issues final rule on safety information during clinical trials

The U.S. Food and Drug Administration today issued a final rule that clarifies what safety information must be reported during clinical trials of investigational drugs and biologics.

"This final rule will expedite FDA's review of critical safety information and help the agency monitor the safety of investigational drugs and biologics," said Rachel Behrman, M.D, associate director for medical policy in the FDA's Center for Drug Evaluation and Research. "These changes will better protect people who are enrolled in clinical trials."

The new rule requires that certain safety information that previously had not been required to be reported to FDA be reported within 15 days of becoming aware of an occurrence. These reports include:

- findings from clinical or epidemiological studies that suggest a significant risk to study participants
- serious suspected adverse reactions that occur at a rate higher than expected
- serious adverse events from bioavailability studies which determine what percentage and at what rate drug is absorbed by the bloodstream and bioequivalence studies which determine whether a generic drug has the same bioavailability as the brand name drug

The rule also provides examples of evidence that would suggest that an investigational product may be the cause of a safety problem. Under current regulations, drug sponsors often report all serious adverse events, even if there is little reason to believe the product caused the event. Such reporting complicates and delays the FDA's ability to detect a safety signal. The examples address when a single event should be reported or when there is need to wait for more thar one occurrence.

In addition, the rule revises definitions and reporting standards so that they are more consistent with two international organizations, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and the World Health Organization's Council for International Organizations of Medical Sciences. The changes are designed to help ensure harmonized reporting of globally conducted clinical trials.

Along with this final rule, the FDA also issued a draft guidance for industry and investigators that provides information and advice about the new requirements and other information.

For more information

Final Rule: Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalance Studies in Humans[1]

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1. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226358.htm