

WIPUS 0.2-2000

U.S. Department of Health & Human Services
Public Health Service
Office of the Assistant Secretary for Health

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On August 1, 2000, the Assistant Secretary for Health announced the expansion of the Clinical Trials.gov program to include all clinical trials conducted in the United States.

The expansion of Clinical Trials.gov is a key component of the Department's commitment to transparency and public access to clinical trial information.

The expansion of Clinical Trials.gov will provide the public with access to information about clinical trials that is currently only available to researchers and clinicians.

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Clinical trials.
longstanding

the agency's thinking to sponsors of clinical trials in the business community and the academic research community about their obligations under FDAAA. The bill, when finalized, will

ing on Chicago, Ill., gov. These factors illustrate the complexity of accurately measuring compliance.

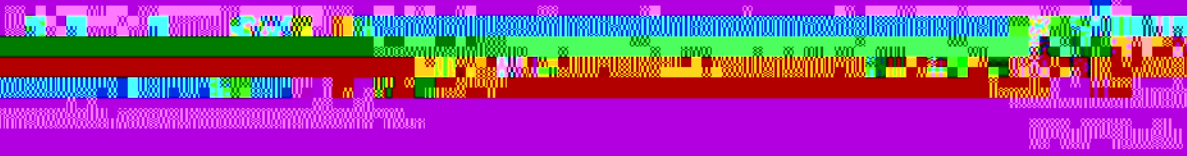
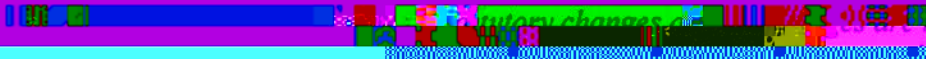
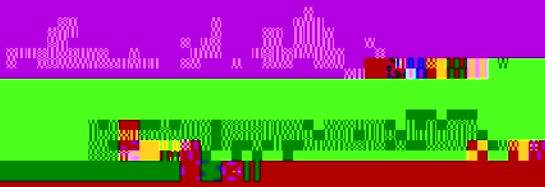


Figure 3: [unreadable]



agency's thinking to sponsors of clinical trials in the industry and the academic

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under FDAAA

Does NIH have sufficient resources and authority to implement the reporting requirements?

NIH has sufficient resources and authority to implement the reporting requirements.

3) Does NIH believe additional



Dear _____:

identical letter is being sent to _____

Enron

the agency's thinking, exposure of clinical trials in the business community and the academic research community about their obligations under FD-379. The FD-379, when finalized, will enhance our understanding of what the agency expects.

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Date:

2014/01/14

are necessary to address the issues of underreporting of clinical trials, data and non-compliance with reporting requirements in the Sector.

I would again like to thank you for your interest in the work of the Agency in the area of clinical trial compliance.

Sincerely yours,

[Signature]

[Name and Title]