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September 30, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Acurian's Comments on Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan
Docket No. 00D-1033, 65 Fed. Reg. 35798 (July 7, 2001)

Dear Sirs/Madams:

Acurian is respectfully submitting comments to the above-referenced draft guidance that was published in the July 9, 2001 issue of the *Federal Register*. We believe that the publication of clinical trial information on the Internet provides a valuable public health benefit and information service for consumers of health care information.

Acurian, Inc. is a private, for-profit company that has pioneered the use of the Internet and computerized databases to improve investigator and patient recruitment for clinical trials since its inception in 1998. We have recruited investigators and patients for over 40 biopharmaceutical companies, including the seven largest pharmaceutical companies in the world. Our services have been used to accelerate the launches of more than 60 studies, and we have helped thousands of patients learn about and participate in IRB-approved clinical research, including studies sponsored by the NIH and the NCI.

The potential benefits of the Data Bank to be established by the FDA include greater dissemination of information to health care consumers, and greater participation of patients in clinical research. As Acurian currently lists well over 40,000 clinical research study sites currently enrolling, we are firmly in agreement with this initiative. At the same time, it is important to permit the sponsors of clinical research to provide this information in a way that minimizes their administrative burden, while maximizing their ability to protect the disclosure of confidential or competitive information within the framework of disclosures necessary to enable the Data Bank.

Following are questions and concerns that Acurian would prefer to see addressed to assure that the final implementation plan guidance and overall Data Bank program

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sufficiently protects the confidentiality of information provided to the Data Bank that sponsors are not discouraged from participating.

Ability to Name a Proxy to Submit Study Information/Creation of Automated Data Entry Protocol.

Many pharmaceutical companies conduct hundreds, if not thousands, of clinical research studies at numerous investigative sites throughout the United States each year. The majority of these studies would seem to fall within the FDA's definition of "serious or life-threatening conditions" and would therefore be required to be entered in the Data Bank.

Given the number of studies, and the number of sites for each study, the administrative burden of entering information on each of the study sites for each of the clinical studies may be considerable. Furthermore, information on these studies will have to be updated on a regular basis, requiring constant work for the sponsors of clinical studies.

One way to reduce the administrative burden on the sponsors, and provide them with additional incentive to participate fully and freely in the Data Bank, is to permit them to outsource their data entry obligations to responsible third parties who could manage and maintain the Data Bank data entry obligations of the sponsors. Ideally, these third parties would serve as the PRS Administrators for the sponsors.

Ability to Name a Proxy as a Contact for Further Information and to Contact a Study Site.

In addition to the administrative burden imposed upon the sponsors of clinical research, the requirement of identification of the names and contact information of specific investigators conducting the studies creates numerous difficulties and concerns for sponsors.

First, the selection of investigators is closely guarded, confidential, and competitive information for sponsors. From the specific investigators selected, a knowledgeable reader can glean competitive intelligence about the protocol and the intentions of the study, among other information. Furthermore, in a heavily competitive investigator recruitment market, sponsors can gain competitive advantage by watching which investigators are selected to work on competitive drugs. Accordingly, the very selection of investigators is itself of competitive value.

Second, by publishing the direct contact information about selected investigators, the Data Bank enables thousands of patients surfing the Internet to declare their interest in a particular study, and contact the investigative sites directly. This creates the potential for a large burden on investigative sites, which typically operate with overworked staffs and use a very limited amount of resources to sift through large numbers of patients seeking to participate in the study.

Both of these difficulties can be minimized by permitting sponsors to name proxies, or agents, to receive and respond to public inquiries about study participation. Each sponsor's PRS administrator would include the name and contact information of the sponsor's agent in the Data Bank in lieu of the investigator's name and contact information. The agent could be a specific individual or a corporate entity that has contractually agreed to provide services necessary to support the goal articulated by FDAMA 113 of increasing awareness about clinical research studies and clinical research study participation. Individuals would be able to contact the agent through a telephone number or an Internet link from the Data Bank.

By implementing such a structure, sponsors could protect the confidentiality of investigator information, and individual investigator sites would have a reduced administrative burden.

* * * *

Acurian appreciates the chance to comment on the Data Bank implementation guidance. Acurian is available at your convenience to discuss the comments, and to provide any additional support and information that would be useful for completing the implementation of the FDAMA 113 Clinical Trial Data Bank.

Respectfully submitted,

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