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DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2012-N-0780]

Regulatory New Drug Review:
Solutions for Study Data Exchange
Standards; Notice of Meeting; Request
for Comments**AGENCY:** Food and Drug Administration, HHS**ACTION:** Announcement of meeting, request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting entitled “Regulatory New Drug Review: Solutions for Study Data Exchange Standards” the purpose of which is to solicit input from industry, technology vendors, and other members of the public regarding the advantages and disadvantages of current and emerging open, consensus-based standards for the exchange of regulated study data. FDA also seeks input from stakeholders and other members of the public on this topic and a set of premeeting questions discussed below.

DATES: The meeting will be held on November 5, 2012, from 10 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Office of Planning & Informatics, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1160, Silver Spring, MD 20993, 301-796-5333, FAX: 301-847-8443, email: CDERDataStandards@hhs.fda.gov.

SUPPLEMENTARY INFORMATION:

Comments: Regardless of attendance at the public workshop, interested

persons may submit either electronic or written comments regarding this document. Given that time will be limited at the public meeting, FDA encourages all interested persons to comment in writing to ensure that their comments are considered. The deadline for submitting responses regarding the premeeting questions is October 5, 2012.

Submit electronic responses to the premeeting questions to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

Registration: Registration is required in advance and participation will be limited. Send registration information (including name, title, firm name, country of citizenship, address, telephone and fax number, and email address) to Fatima Elnigoumi, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 1195, Silver Spring, MD 20993, 301-796-4863, email: CDERDataStandards@hhs.fda.gov. Registrations will be accepted in the order that they are received with a limit of 300. If you need special accommodations due to a disability, please contact Fatima Elnigoumi at least 7 days in advance.

I. Background

The current study data exchange format supported by FDA is the ASCII-based SAS Transport (XPORT) version 5 file format. Although XPORT has been an exchange format for many years, it is not an extensible modern technology. Moreover, it is not supported and maintained by an open, consensus-based standards development organization.

FDA would like to discuss the current and emerging open study data exchange standards that will support interoperability. Currently, the use of XPORT can be described as an example of the exchange of study data between two or more systems using a specified file format (e.g., XML, SQL, ASCII). However, the desired path forward is to achieve interoperability with other systems where the exchange of data between systems can be reviewed, analyzed, and reported with minimal need for data integration.

Based on feedback from this meeting and other information, an evaluation of the cost-benefit of a migration to a new study data exchange standard—on both FDA and regulated industry—will be

conducted to inform next steps, which will include an action plan.

II. Premeeeting Questions to Stakeholders

FDA seeks input from stakeholders and other members of the public on the following premeeting questions:

1. What are the most pressing challenges that industry faces with regard to study data management? Please address each of the following areas: (a) Study design/set-up, (b) capture, (c) integration, (d) analysis, (e) reporting, and (f) regulatory submission. What opportunities/solutions exist to meet *each* challenge?

2. How could FDA's regulatory requirements make the study data management process more efficient?

3. What does industry need to make clinical trials data management more effective and efficient? Please describe the tools, techniques, and processes that would help as well as the regulatory guidance documents that would be useful in this area.

4. What data standards are you currently using for the conduct of regulated research studies?

5. Would Health Level Seven v3¹ (e.g., messages, structured documents and Clinical Data Architecture) be a viable study data exchange standard? Please explain advantages and disadvantages. What would be the impact (e.g., financial, technical, or in terms of implementation or change in business processes)?

6. Would CDISC Operational Data Model² be a viable study data exchange standard? Please explain advantages and disadvantages. What would be the impact (e.g., financial, technical, or in terms of implementation or change in business processes)?

7. Are there other open data exchange standards that should be evaluated? Please explain advantages and disadvantages. What would be the impact (e.g., financial, technical, or in terms of implementation or change in business processes)?

8. What would be a reasonable phased implementation period for each recommended exchange standard? And should supporting multiple, concurrent study data exchange standards be evaluated (please explain advantages and disadvantages of this approach)? What can FDA do to help industry to be more prepared for, or reduce burden of, a migration to a new study data exchange standard?

9. FDA encourages sponsors to design study data collection systems so that

¹ See <http://www.hl7.org> for system description.

² See <http://www.cdsc.org> for system description.

relationships between data elements, as well as relationships across data domains, can be captured at the point of data entry. Describe the challenges, to and opportunities for, accomplishing this goal.

10. What other comments would you care to share with FDA concerning the general topic of data exchange standards?

Dated: August 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 563

[Docket No. NHTSA-2008-0004]

Event Data Recorders

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Denial of petition for rulemaking.

SUMMARY: On February 17, 2009, the Alliance of Automobile Manufacturers petitioned for NHTSA to initiate rulemaking to delay by one year the effective date of regulations establishing requirements related to event data recorders (EDRs) voluntarily installed on light vehicles. The petitioner suggested that the delay would enable vehicle manufacturers to retain current EDR functionality across all vehicle models and avoid disabling legacy EDR systems for a limited number of vehicle models. The agency is denying the petition since the implementation of the August 2006 final rule has already been delayed by two years and we have recently published a final rule responding to the remaining petitions for reconsideration. We believe these latest amendments alleviate the most significant areas of concern expressed by the Alliance and will not necessitate further delays in implementation.

FOR FURTHER INFORMATION CONTACT: For technical and policy issues, contact:

David Sutula, Office of

Crashworthiness Standards, NVS-112. Telephone: (202) 366-3273. Facsimile: (202) 366-7002.

For legal issues, contact:

Mr. David Jasinski, Office of the Chief Counsel, NCC-112. Telephone: (202) 366-4332. Facsimile: (202) 366-3820.

Both persons may be reached by mail at the following address:

National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., West Building, 4th Floor, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

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I. Background

In August 2006, NHTSA issued a final rule¹ amending 49 CFR Part 563 (Part 563) to establish uniform performance requirements for the accuracy, collection, storage, survivability and retrievability of onboard motor vehicle crash EDRs voluntarily installed in light passenger vehicles. Specifically, the regulation applies to passenger cars, multipurpose passenger vehicles, trucks and buses with a gross vehicle weight rating (GVWR) of 3,855 kg (8,500 pounds) or less and an unloaded vehicle weight of 2,495 kg (5,500 pounds) or less,² that are voluntarily equipped with an EDR. The final rule aimed to standardize the data obtained through EDRs so that such data would provide information to enhance the agency's understanding of crash events and safety system performance, thereby potentially contributing to safer vehicle designs and more effective safety regulations. The final rule was intended to be technology-neutral, so as to permit compliance with any available EDR technology that meets the specified performance requirements.

On January 14, 2008,³ the agency responded to petitions for reconsideration on the August 2006 final rule and the following amendments were made to Part 563:

- We clarified the event storage definitions to alleviate any uncertainties in multiple event crashes;
- Revised certain sensor ranges and accuracies to reflect current state of the art technologies;
- Clarified the recorded data reporting format;
- Specified vehicle storage conditions during compliance testing;
- Clarified the required data elements and scope of covered sensors; and
- Revised the effective date to provide sufficient time for manufacturers and suppliers to comply with the rule.

¹ 71 FR 50998.

² Walk-in van-type trucks or vehicles designed to be sold exclusively to the U.S. Postal Service are excluded.

³ 73 FR 2168.

The agency made these changes to encourage a broad application of EDR technologies in motor vehicles and maximize the usefulness of EDR data for vehicle designers, researchers and the medical community, without imposing unnecessary burdens or deterring future improvements to EDRs that have been voluntarily installed. The final rule also provided two additional years of lead time to provide manufacturers more time to implement the necessary changes to EDR architectures within their normal product development cycles.⁴

In response to the January 2008 final rule, the agency received three petitions for reconsideration from the Alliance of Automobile Manufacturers (Alliance), the Association of International Automobile Manufacturers, Inc., Technical Affairs Committee (AIAM)⁵ and Mr. Thomas Kowalick, a private citizen. The agency also received two requests for interpretation from the Automotive Occupant Restraints Council and Robert Bosch, LLC.

On August 5, 2011,⁶ the agency published a final rule responding to these petitions and made the following clarifications and amendments to Part 563:

- We removed the required standardization of the reporting requirements for all acceleration data requirements to address certification issues with data clipping, filtering and phase-shifting;
- Clarified the application of sensor tolerances to within the range of the applicable sensor;
- Clarified the event storage definition to alleviate uncertainties in multiple event crashes;
- Clarified our position regarding exclusion of peripheral sensors from the reporting requirements for EDRs;
- Revised requirements for the capture of event data in crashes that
 - Involve side or side curtain/tube air bags such that EDR data would only need to be locked if the vehicle also captures lateral delta-V data, and

⁴ NHTSA issued a **Federal Register** notice on February 8, 2008 (73 FR 8408) to correct the placement of decimal points for data in Table II of the final rule.

⁵ At the time of its submission, the AIAM Technical Affairs Committee members included: American Honda Motor Co., American Suzuki Motor Corp., Aston Martin Lagonda of North America, Inc., Ferrari North America, Inc., Hyundai Motor America, Isuzu Motors America LLC, Kia Motors America, Inc., Maserati North America, Inc., Nissan North America, Inc., Peugeot Motors of America, Subaru of America, ADVICS North America, Inc., Delphi Corporation, Denso International America, Inc., and Robert Bosch Corporation.

⁶ 76 FR 47478.