4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1450]

Electronic Submissions; Data Standards; Support for the International Institute of Electrical and Electronics Engineers Bioinformatics Computations and Analyses Standard for Bioinformatic Workflows

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing support for use in regulatory submissions the current version of the International Institute of Electrical and Electronics Engineers (IEEE) bioinformatics computations and analyses standard for bioinformatic workflows (BioCompute) and an update to include this standard in the FDA Data Standards Catalog for the submission of high-throughput sequencing (HTS) data in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) to the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Food Safety and Applied Nutrition (CFSAN).

DATES: Submit either electronic or written comments on the notice by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-N-1450 for "Electronic Submissions; Data Standards; Support for the International Institute of Electrical

and Electronics Engineers Bioinformatics Computations and Analyses Standard for Bioinformatic Workflows." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure laws. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket

number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; or Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993-0002, 301-796-0035; or Cindee Hogan, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2181.

SUPPLEMENTARY INFORMATION: FDA is announcing support for the use in regulatory submissions the current version of the IEEE BioCompute standard (available at https://standards.ieee.org/standard/) and an update to include this standard in the FDA Data Standards Catalog for the submission of HTS data in NDAs, ANDAs, BLAs, and INDs to CBER, CDER, and CFSAN.

Scientific workflows have emerged as a model for representing and managing complex scientific computations. The BioCompute standard facilitates the exchange of HTS bioinformatics workflows (i.e., computations and analyses) between various organizations by specifying the information needed to understand and organize bioinformatic analyses. Currently, the range of bioinformatics tools and associated parameters of those tools makes it difficult to describe, exchange, and assess the reproducibility of a complex analysis in a standardized format.

The BioCompute standard represents a distillation of the bioinformatics workflows, describing the mechanisms for each step on the pipeline. The pipeline steps are organized into groups of conceptually related information or domains, which provides the ability to describe the full extent of the analysis, the purpose of the experiment, and any other relevant information. BioCompute tracks the flow of data from the beginning to the end of the bioinformatics pipeline, making transformations apparent at each step. In this way, an analysis formatted according to the BioCompute standard provides the manifest (metadata) for the HTS data files.

Dated: July 16, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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