P2791

Submitter Email: c.carey@ieee.org
Type of Project: New IEEE Standard
PAR Request Date: 04-May-2018
PAR Approval Date: 14-Jun-2018
PAR Expiration Date: 31-Dec-2022
Status: PAR for a New IEEE Standard

1.1 Project Number: P2791
1.2 Type of Document: Standard
1.3 Life Cycle: Full Use

2.1 Title: Standard for Bioinformatics Computations and Analyses Generated by High-Throughput Sequencing (HTS) to Facilitate Communication

3.1 Working Group: BioCompute Working Group (EMB/Stds Com/BCOWG)
Contact Information for Working Group Chair
Name: Raja Mazumder
Email Address: keeneyjg@email.gwu.edu
Phone: 2029945004
Contact Information for Working Group Vice-Chair
None

3.2 Sponsoring Society and Committee: IEEE Engineering in Medicine and Biology Society/Standards Committee (EMB/Stds Com)
Contact Information for Sponsor Chair
Name: Carole Carey
Email Address: c.carey@ieee.org
Phone: 301-776-9882
Contact Information for Standards Representative
None

4.1 Type of Ballot: Individual
4.2 Expected Date of submission of draft to the IEEE-SA for Initial Sponsor Ballot: 09/2018
4.3 Projected Completion Date for Submittal to RevCom
Note: Usual minimum time between initial sponsor ballot and submission to Revcom is 6 months.: 12/2018

5.1 Approximate number of people expected to be actively involved in the development of this project: 20
5.2 Scope: This standard establishes accurate and secure communication of bioinformatics protocols in order to facilitate bioinformatic data analysis workflow related exchange and communication between regulatory agencies, pharmaceutical companies, bioinformatics platform providers and researchers. Accurate communication helps ensure responsibility, verify bioinformatics protocol, track provenance information and promote interoperability.

In addition, this standard also defines the assurance program for evaluating and certifying products against those requirements.

5.3 Is the completion of this standard dependent upon the completion of another standard: No
5.4 Purpose: The standard allows for the cross platform communications of complex bioinformatic data analysis from inception to manufacturing of medical products, resulting in decreased costs of drug discovery and accelerated delivery of treatment to patients.

5.5 Need for the Project: Computational biology algorithms are affected by a multiplicity of parameters much like a tangible physical, chemical, or biological experiment. This phenomenon is well documented, and is a result of the multitude of environmental and procedural factors. What is often systematically overlooked is that in silico experiments are no less volatile. The complexities of computational protocols and outcomes are only part of the challenge; there are also virtually no standardized and industry-accepted metadata schemas for reporting the computational pipelines and parameters together with their results. Thus, it is often impossible to reproduce the results of a previously performed computation due to missing information on parameters, versions, arguments, conditions, and procedures of application launch.

5.6 Stakeholders for the Standard: Government bodies and Regulatory Agencies; Medical product manufacturers and their suppliers; Laboratories developing clinical testing protocols; Bioinformatics tool and platform developers who wish to operate in a regulatory

environment, including cloud service (PaaS, IaaS, SaaS, FaaS) providers; Peer Reviewers for journals / scientific journal publishers; Public cloud companies operating in the Life Sciences sector including electronic health record (EHR) systems

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Intellectual Property
6.1.a. Is the Sponsor aware of any copyright permissions needed for this project?: Yes
If yes please explain: Please see the information in section 8.1 on this PAR.

6.1.b. Is the Sponsor aware of possible registration activity related to this project?: No

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7.1 Are there other standards or projects with a similar scope?: No
7.2 Joint Development
Is it the intent to develop this document jointly with another organization?: No

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8.1 Additional Explanatory Notes: 4.2: This potential standard has a foundational standard version to work from. The standard was developed by the BioCompute group (members from industry, academia and regulators). It is complete. The goal and next step is for the standard to be adopted and published as an IEEE standard. Thus, we are anticipating that an accelerated time for the IEEE standards development process would be possible.