P2802

Submitter Email: renhaiping@nifdc.org.cn
Type of Project: New IEEE Standard
PAR Request Date: 14-Oct-2018
PAR Approval Date: 05-Dec-2018
PAR Expiration Date: 31-Dec-2022
Status: PAR for a New IEEE Standard
Project Record: P2802

1.1 Project Number: P2802
1.2 Type of Document: Standard
1.3 Life Cycle: Full Use

2.1 Title: Standard for the Performance and Safety Evaluation of Artificial Intelligence Based Medical Device: Terminology

3.1 Working Group: Artificial Intelligence Medical Device Working Group (EMB/Stds Com/AIMDWG)
Contact Information for Working Group Chair
Name: Haiping REN
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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
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Phone: 301-776-9882
Contact Information for Standards Representative
None

4.1 Type of Ballot: Entity
4.2 Expected Date of submission of draft to the IEEE-SA for Initial Sponsor Ballot: 12/2020
4.3 Projected Completion Date for Submittal to RevCom
Note: Usual minimum time between initial sponsor ballot and submission to Revcom is 6 months.: 08/2021

5.1 Approximate number of entities expected to be actively involved in the development of this project: 8
5.2 Scope: The standard establishes terminology used in artificial intelligence medical device, including definitions of fundamental concepts and methodology that describe the safety, effectiveness, risks and quality management of artificial intelligence medical device.
The standard provides definitions using the following forms, such as but not limited to literal description, equations, tables, figures and legends.
The standard also establishes a vocabulary for the development of future standards for artificial intelligence medical device.

5.3 Is the completion of this standard dependent upon the completion of another standard: No
5.4 Purpose: The establishment of this consistent terminology promotes a more expansive and streamlined research, development, testing and quality control for the medical Artificial Intelligence (AI) industry.
The evaluation of AI will be based on concepts in this standard, which include, but are not limited, to performance metrics, safety hazards, cyber security, and software reliability. The standard also provides vocabulary for the development of future general or specific standards of AI medical device and help different parties clarify understanding of AI quality.

5.5 Need for the Project: The application of artificial intelligence in medical device is rising and shows potential to make an impact on healthcare. However, at present there is no standard to guide research, development, testing and quality control of AI-based medical devices. Industry, academia, medical community and government regulators may have different understanding of AI quality and generate discrepancy, inhibiting marketing and regulation of such medical devices. To address industry's (regulatory, academic, medical community, etc...) need, a common set of terminology and definition is required.

5.6 Stakeholders for the Standard: Medical device industry, regulators, medical community and academia

Intellectual Property

6.1.a. Is the Sponsor aware of any copyright permissions needed for this project?: No

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: