P2801

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: P2801

1.1 Project Number: P2801
1.2 Type of Document: Recommended Practice
1.3 Life Cycle: Full Use

2.1 Title: Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence

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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)
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Name: Carole Carey
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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 recommended practice identifies best practices for establishing a quality management system for datasets used for artificial intelligence medical device.
The recommended practice covers a full cycle of dataset management, including items such as but not limited to data collection, transfer, utilization, storage, maintenance and update.
The recommended practice recommends a list of critical factors that impact the quality of datasets, such as but not limited to data sources, data quality, annotation, privacy protection, personnel qualification/training/evaluation, tools, equipment, environment, process control and documentation.

5.3 Is the completion of this standard dependent upon the completion of another standard: No
5.4 Purpose: The purpose of this draft is to establish rules of quality management of datasets for medical Artificial Intelligence and improve the overall data quality.

5.5 Need for the Project: The success of medical artificial intelligence relies on the quality of datasets due to the nature of machine learning.However, spontaneous construction of datasets by different companies and institutions without a unified reference may bring in quality variation or problems, which further inhibits the research and development of medical AI products.
This recommended practice provides guidance for institutions that are building datasets for the training, verification, testing and validation of medical AI. It will help avoid risks during the construction of datasets and improve data quality. Discrepancies between different data providers may be diminished and increase the capacity of high-quality data sources.It can serve as a reference for medical device industry to evaluate external data providers. It also helps regulators with the inspection of quality management system in AI companies.

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

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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: