

November 4, 2015

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Pre-Submission Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Pre-Submission meeting to discuss the engineering model for a clinical study augmented with virtual patients

To Whom It May Concern:

This pre-submission provides FDA with an overview of the engineering model used to generate virtual patients for use as prior information in a clinical study. This work is part of the mock IDE submission project sponsored by the Medical Device Innovation Consortium (MDIC), and has been previously discussed as part of the informational meeting Q150804, held on July 14, 2015.

The virtual patient model incorporates in-vitro test data, in-vivo use condition measurements, and a statistical reliability projection methodology, to predict the survival of a hypothetical ICD lead, all of which are discussed in the pre-submission document.

The sponsor team requests feedback from FDA on the following two questions:

- 1) Is the approach documented in the pre-submission suitable for use as a virtual patient model for the particular failure mode of intracardiac lead fracture?
- 2) Is the proposed virtual patient model sufficiently credible for consideration as prior information in a clinical study design with a maximum percentage of virtual patients in the range of 30-50%, and a type I error in the range of 0.15-0.20?

The sponsor team recognizes that in order for FDA to provide a complete answer for question 2, it would be necessary to provide additional statistical data and analysis. The sponsor team plans to provide this information in an upcoming pre-submission that focuses on the clinical study. We request that the review team evaluate the current pre-submission information using the aforementioned ranges with the expectation that a detailed statistical analysis is forthcoming.

The sponsor team requests a one hour face-to-face meeting with FDA, and will work with FDA to schedule this meeting once the review team has been identified.

Sponsor Information:

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Two copies of this meeting request and pre-submission document are being submitted: one paper copy and one CD-ROM. The information being provided via CD-ROM is an exact copy of the paper copy.

If you have any questions, or if further information is required, please contact the undersigned.

Regards,

Adam Himes, on behalf of the MDIC working group on clinical trials informed by bench and simulation