

June 6, 2016

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 clinical study augmented with virtual patients**

To Whom It May Concern:

This pre-submission provides FDA with an overview of a hypothetical Bayesian clinical study using virtual patients as prior information. 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 and pre-submission meeting Q150804/S001, held on December 15, 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. The clinical study incorporates this virtual patient data as an informative prior, with a loss function that adjusts the weight of the prior based on agreement between the virtual and real patients.

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

1. Is the study design acceptable for the specific context of lead failure due to intracardiac conductor fractures, given the assumptions associated with this mock submission framework?
2. Is the virtual patient model discussed in Q150804/S001 suitable as an informative prior for the proposed study design?

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:**

**Name:** Medical Device Innovation Consortium  
1550 Utica Avenue South, Suite 740  
St. Louis Park, MN 55416  
952-314-1255  
mdic.org

**Primary Contact:** Adam Himes, M.S.  
Senior Principal Engineer  
Medtronic plc, Cardiac Rhythm and Heart Failure  
tel: 763-526-9414  
cell: 612-309-9971  
fax: 763-526-9414  
E-Mail: [adam.k.himes@medtronic.com](mailto:adam.k.himes@medtronic.com)

Two copies of this meeting request and pre-submission documents 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