405 The West Mall, Suite 900
Toronto, Ontario M9C 5J1
t: 416.620.1915
toll free: 1-866-586-3332
www.medtechcanada.org

Meeting Minutes

Meeting Title:	RAC Digital Health Sub-Committee	**Date:**	January 11, 2023
Place:	Microsoft Teams	**Time:**	10:00 to 11:00 am
Purpose:	Quarterly Meeting		

Present

Ugbaad Elmi, Chair	GE HealthCare
Martha Cunhamaluf-Burgman	Edwards Lifesciences
Jingxuan Cui	Boston Scientific
Jay Jadoo	Stryker
Nilanka Liyanage	Siemens Healthineers
Rishi Mehta	Medtronic
Roshanak Najafi	BD Canada
Charles Tam	Edwards Lifesciences
Nicole Zuk	Siemens Healthineers
Koen Cobbaert	Philips
Diane Johnson	Johnson & Johnson
Danna Zylka	Insulet
Stefan Feix	GE HealthCare
Wendy Holden	Baxter
Aniline Soco	Abbott
Mia Spiegelman	Medtech Canada
Debbie Gates	Medtech Canada

Committee Meeting Welcome

Ugbaad Elmi welcomed the committee members and read the competition policy statement: *"Medtech Canada members are encouraged to raise issues that have broad industry implications and are aimed at establishing a business environment that supports the medical device industry. However, participants will at no time engage in discussion or activities that might serve to lessen competition among its industry members, such as price adjustments, customer segmentation, or the sharing of confidential, proprietary information."*

Koen Cobbaert Update re IMDRF AI and SaMD Working Groups

Koen provided an overview of the two IMDRF groups on AI and SaMD. His presentation was shared with the committee following the presentation.

Members can contact Koen Cobbaert, koen.cobbaert@philips.com, if they have any questions.

Mia Spiegelman will investigate sharing the minutes of the IMDRF meetings.

ACTION: Mia Spiegelman and Debbie Gates will investigate how to share with members the DITTA updates on working groups.

Seek New Co-Chair

Diane Johnson from Johnson & Johnson has agreed to take on the co-chair role of this sub-committee.

Mia shared the committee chair/co-chair responsibilities.

Review Sub-Committee Scope

The scope of the digital Health sub-committee is to focus on regulator matters relating specifically to medical device software [both for software as a medical device (SaMD) and software in a medical device (SiMD)]. The sub-committee monitors, evaluates and comments on revised and emerging regulating and guidance that apply specifically to software, including classification of software, artificial intelligence, machine learning, remote monitoring solutions, virtual reality (VR) and augmented reality (AR), cybersecurity and 3D printing.

The scope will be shared with the sub-committee members for review and feedback.

Suggestion to consider adding remote monitoring solutions and VR/AR.

3D printing can also be added to Quality Assurance committee for discussion related to advanced manufacturing. Wait to see where this goes with Health Canada before determining what sub-committee should be handling.

Other Business

Identifying aspects of a cloud system that are specifically SaMD is a challenge for one company. Might be good to have expanded guidance on identifying specific aspects of cloud systems that qualify as SaMD. Seeking opportunity to discuss concerns further and make recommendations to Health Canada ?

Ugbaad will share the response from Colin Foster's team received in summer 2021 when clarification was sought.

Confirm Next Meeting Dates and Close

If you have any agenda items for the next meeting, please share with Ugbaad Elmi, Diane Johnson, or Debbie Gates.

Next meeting will be in second quarter of 2023.

The meeting adjourned at 11:02 am.