Design and Development

20 – 21 February 2023

WORKSHOP PROGRAMME

<u>Learning Outcomes</u>

At the end of this workshop, participants should be able to:

- List the key processes required for successful commercialization of In Vitro Diagnostics (IVD) and Software as a Medical Device (SaMD)

- Articulate the significance and contribution of the design and development stages to a successful production of IVD and SaMD

<u>Target Audience</u>

- Product developers, entrepreneurs and investors with interest in diagnostics, and Academia looking to understand how to take their ideas to a commercial IVD or SaMD

Design and Development

Academia, SGH Campus

20 – 21 February 2023

Day 1 (20th Feb 2023)

Time	Agenda	Speaker/Facilitator
8.00 am	**Registration**	
8.30 am	**Welcome Address and Workshop Briefing**	**CoRE**
8.40 am	**Workshop Overview**	**Dr Rahul Pandey** Outreach & Talent Development (DxDHub) **Dr John Thornback** Senior Advisor DxDHub
8.50 am	**Photo taking session**	
9.00 am	**Introduction to diagnostics**	**Ms Ho Yuan Lu** Vice President, Outreach & Talent Development DxDHub
9.30 am	**Total Product Lifecycle**	**Ms Chan Yang Sun** Quality Assurance & Regulatory Affairs DxDHub
10.15 am	**Tea Break**	
10.30 am	**Project Management**	**Dr John Thornback** DxDHub
11.15 am	**Introduction to Digital Diagnostics**	**Mr Lijoy George** Assistant Vice President, Digital Health DxDHub
11.45 am	**Initiating Product Design and Development**	**Dr John Thornback** DxDHub
12.15 pm	**Lunch**	
1.45 pm	**Target Product Profile (TPP)**	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
2.30pm	**Tea Break**	
3.00 pm	**Case Discussion 1** Applying TPP: Case studies using existing commercial products	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
5.00 pm	**Wrap Up and Lessons Learnt**	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
5.30 pm	**End of Day 1**	

*The Programme is accurate as of (17th Feb 2023) and may be subjected to further refinement if necessary before the actual workshop.

Day 2 (21st Feb 2023)

Time	Agenda	Speaker/Facilitator
8.00 am	**Registration**	
8.30 am	**Design Optimisation**	**Dr Lin You Bin** Senior Manager, Biomedical Project DxDHub **Mr Henry Johnson Susainathan** Senior Manager DxDHub
9.30 am	**Supplier Identification**	**Ms Tan Hwee Ee** Founder and Director DH RegSys Private Limited
10.00 am	**Tea Break**	
10.30 am	**Generating clinical evidence for IVD development**	**Dr Rahul Pandey** DxDHub
11.30 am	**Design Freeze**	**Dr John Thornback** DxDHub
12.30 pm	**Lunch**	
1.30 pm	<u>**Case Discussion 2**</u> Design Optimisation	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** DxDHub
2.20 pm	<u>**Case Studies**</u> Design Optimisation: Case studies using existing commercial products	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** DxDHub
3.15pm	**Tea Break**	
3:30 pm	<u>**Case Discussion 3**</u> TPP: Continuous Glucose Monitoring	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
4.30 pm	**Quiz**	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
5.00 pm	**Closing remarks with Lessons Learnt**	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
5.25 pm	**Workshop conclusion**	**CoRE**
5.30 pm	**End of Day 2**	

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