

# Design and Development

20 – 21 February 2024

## WORKSHOP PROGRAMME

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### Learning Outcomes

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

### Target Audience

- 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 2024

## Day 1 (20<sup>th</sup> Feb 2024)

Time	Agenda	Speaker/Facilitator
8.00 am	Registration	
8.30 am	Welcome Address	CoRE
8.40 am	Workshop Briefing	Dr Rahul Pandey Outreach & Talent Development DxDHub
8.50 am	Photo taking session	
9.00 am	Introduction to Diagnostics Development Hub	Ms Ho Yuan Lu Vice President Outreach & Talent Development DxDHub
9.30 am	Total Product Lifecycle and Introduction to Risk Management	Ms Chan Yang Sun Quality Assurance & Regulatory Affairs DxDHub
10.15 am	Tea Break	
10.30 am	Project Management	Ms Ho Yuan Lu 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 Lin You Bin Senior Manager Biomedical Project DxDHub
12.30 PM	Lunch	
1.45 pm	Target Product Profile (TPP)	Dr Rahul Pandey DxDHub
2.30pm	Tea Break	

\*The Programme is accurate as of (8<sup>th</sup> February 2024) and may be subjected to further refinement if necessary before the actual workshop.

3.00 pm	<b>Workshop</b> Target Product Profile	<b>Dr Rahul Pandey</b> <b>Dr Lin You Bin</b> DxDHub  <b>Mr Henry Johnson Susainathan</b> Principal Manager DxDHub  <b>Ms Janet Poh</b> Quality Assurance and Regulatory Affairs DxDHub  <b>Ms Tan Hwee Ee</b> Founder and Director DH RegSys Private Limited
5.00 pm	<b>Wrap Up and Lessons Learnt</b>	<b>Dr Rahul Pandey</b> DxDHub
5.30 pm	<b>End of Day 1</b>	

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## Day 2 (21<sup>st</sup> Feb 2024)

Time	Agenda	Speaker/Facilitator
8.00 am	<b>Registration</b>	
8.30 am	<b>Design Optimisation</b>	<b>Dr Lin You Bin</b> Senior Manager Biomedical Project DxDHub  <b>Mr Henry Johnson Susainathan</b> Principal Manager DxDHub
9.30 am	<b>Supplier Identification</b>	<b>Ms Tan Hwee Ee</b> Founder and Director DH RegSys Private Limited
<b>10.00 am</b>	<b>Tea Break</b>	
10.30 am	<b>Generating Clinical Evidence for IVD Development</b>	<b>Dr Rahul Pandey</b> DxDHub
11.30 am	<b>Design Freeze and Introduction to Pilot Manufacturing</b>	<b>Dr Ng Szu Shien</b> Quality Assurance and Regulatory Affairs DxDHub
<b>12.30 pm</b>	<b>Lunch</b>	
1.30 pm	<b>Workshop</b> Design Optimization	<b>Dr Lin You Bin</b> <b>Mr Henry Johnson Susainathan</b> DxDHub
2.20 pm	<b>Case Studies</b> Discussion on end-of-life and responsibilities of the product owner	<b>Dr Lin You Bin</b> <b>Mr Henry Johnson Susainathan</b> DxDHub  <b>Ms Tan Hwee Ee</b> DH RegSys Private Limited
<b>3.15pm</b>	<b>Tea Break</b>	
3:30pm	<b>Workshop</b> TPP for Continuous Glucose Monitoring	<b>Dr Rahul Pandey</b> <b>Dr Ng Szu Shien</b> <b>Ms Janet Poh</b> DxDHub  <b>Ms Tan Hwee Ee</b> DH RegSys Private Limited
4.30 pm	<b>Quiz</b>	<b>Dr Rahul Pandey</b> <b>Ms Janet Poh</b> DxDHub
5.00 pm	<b>Closing remarks with Lessons Learnt</b>	<b>Dr Rahul Pandey</b> DxDHub
<b>5.30 pm</b>	<b>End of Day 2</b>	

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