An Introduction to Diagnostics Development Hub (DxD Hub)

Diagnostics for Our Future

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ABOUT DXD HUB

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2014
Launched
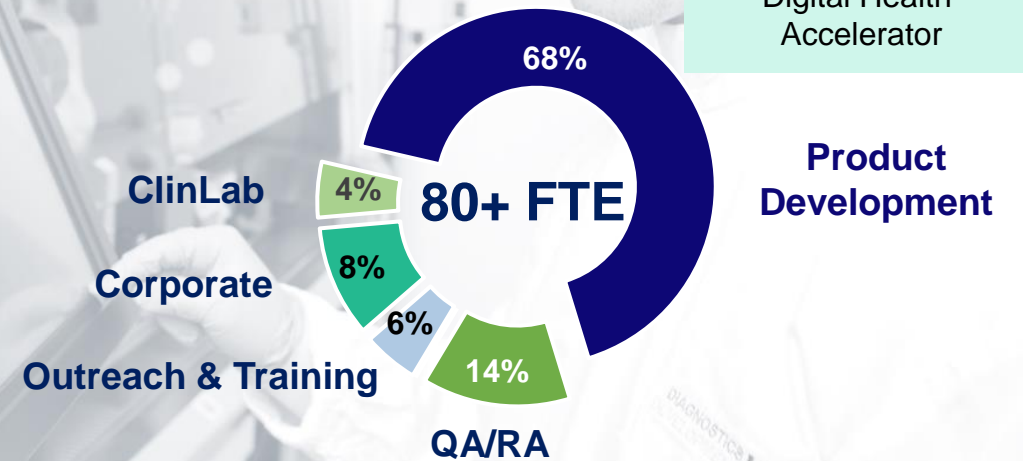
A Singapore National Platform with Dual Mission

Bridges the diagnostics **productization gap** in Singapore and brings translational research IPs to markets as validated registered diagnostics products

Catalyzes the **diagnostics medtech ecosystem** in Singapore by attracting research and private investment to Singapore
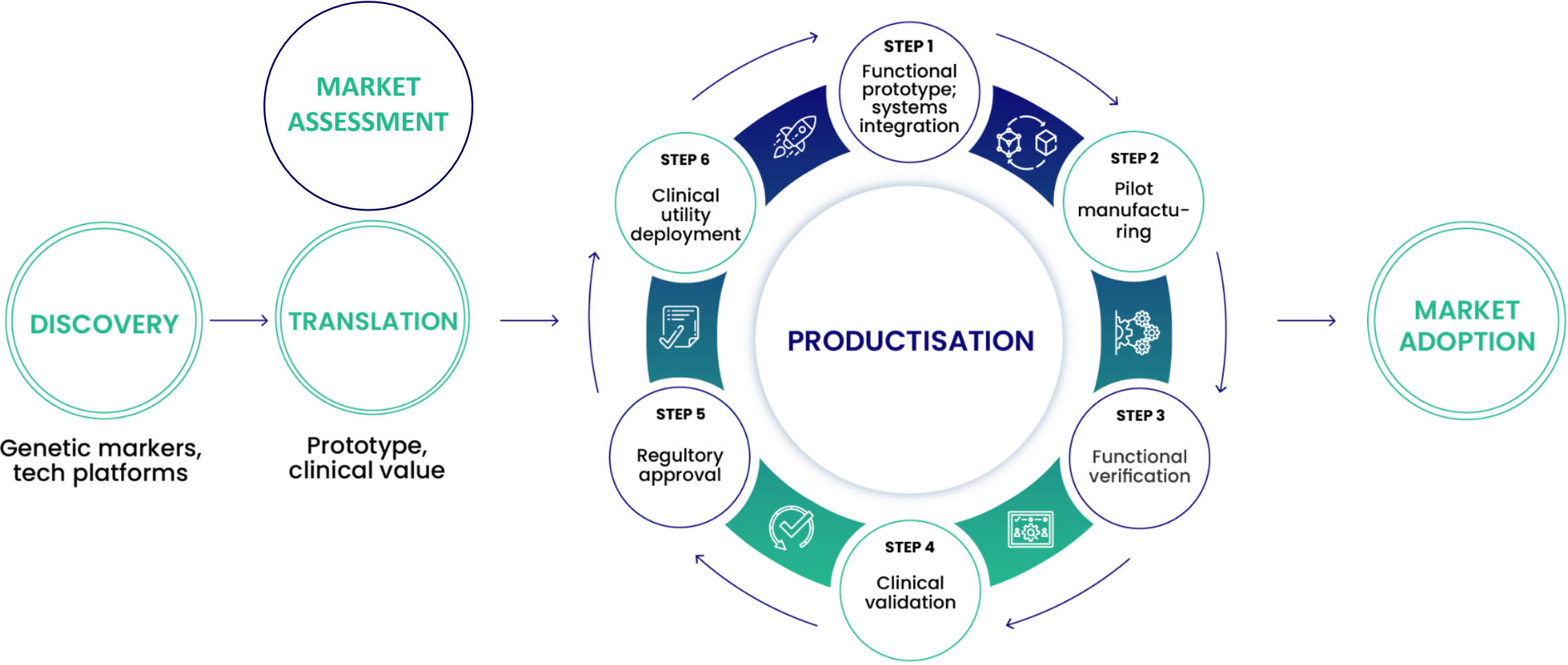
Our Multi-disciplinary Team

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Internal Multi-Disciplinary Skills Supporting Concept to Registration

Partnerships & Project Management	IVD Development	SaMD Development	IMT Development	Regulatory	Quality Management Systems	Adoption
Partnerships	Molecular Dx	Software Engineering	BioMedical Engineering	Regulatory Roadmap & Strategy	ISO 13485 (Medical Device)	Clinical Dx Lab
Product Dev & Project Management	Protein Dx	Interoperability Engineering	Design - ID, UI/UX		ISO 14971 (Risk Management)	Clinical Deployment
	Pathology	Data Science - Bioinformatics	Firmware Engineering		IEC62304 (Medical Software)	Commercial Lab Ops
	Pilot Manufacturing	UI/UX Designing	Mechanical Engineering			Digital Health Accelerator
		Systems Engineering	Design Engineering			

68%
ClinLab 4%
80+ FTE
Corporate 8%
6%
Outreach & Training
14%
QA/RA
Product Development

Focus on Diagnostics Productization

MARKET ASSESSMENT

DISCOVERY
Genetic markers, tech platforms

TRANSLATION
Prototype, clinical value

PRODUCTISATION

STEP 1
Functional prototype; systems integration

STEP 2
Pilot manufacturing

STEP 3
Functional verification

STEP 4
Clinical validation

STEP 5
Regultory approval

STEP 6
Clinical utility deployment

MARKET ADOPTION

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DxD Hub – Focus Areas

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Priority Areas:

- Precision Medicine

- Women's Health

- Infectious Diseases

Supported by DxD Hub capabilities in

- In Vitro Diagnostics (IVD)

- Digital Diagnostics (DDx)

- De-centralised Care

Nobody is safe, until everyone is safe

Nobody Is Safe, Until Everyone Is Safe

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ASEAN Dx Initiative is a platform endorsed by the ASEAN Committee of Science, Technology and Innovation.

- Co-chaired by Diagnostics Development Hub (DxD Hub) & Philippine Council for Health Research and Development (PCHRD)
- Mandate to build diagnostic capacity among ASEAN member countries.

TIMELY COMMITMENT BY ASEAN LEADERS in 2019

Capability Development: Delivering Dx Innovations by ASEAN for ASEAN

Capacity Building: Sharing of Best Practices Strengthening Bonds

ASEAN Dx INITIATIVE

ASEAN-NDI
ASEAN Network for Drugs, Diagnostics, Vaccines, and Traditional Medicines Innovation

Singapore To Catalyse ASEAN Medical Diagnostics Initiative And Deepen Regional Connectivity

The ASEAN Dx Initiative was conceptualized by COST-75 in 2018, and officially launched at by 18th ASEAN Ministerial Meeting in Oct 2019 for capability development and capacity building amongst ASEAN member states.

DxD Hub – A Diagnostic Pillar to Build Capabilities and Capacity for Pandemic Preparedness

DxD Hub leads the Diagnostics Cooperative

1. To accelerate the delivery of regulatory approved diagnostics with production capacity

2. To ensure supply chain readiness

3. To expedite speedy deployment of national testing

COVID-19 Diagnostics Solutions – Quick response to the unprecedented crisis

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Fortitude Series

- First "ready-made" COVID-19 hospital lab diagnostic test kit approved for clinical use in Singapore, launched within a month of the virus sequence's publication online
- The test range has since expanded to meet greater global needs in infectious disease testing
- **9M+ Fortitude test kits deployed to > 45 countries**

Fortitude 3.0

- Obtained Provisional Authorisation from HSA and has CE-mark

Fortitude Syndromic

- Beyond testing for COVID-19, this kit has additional PCR primers designed to detect Influenza A and B

RESOLUTE Series
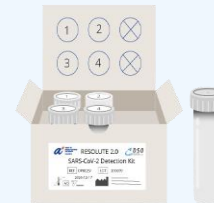
- World's first multiplex direct-PCR for SARS-CoV-2 detection test
- Utilised in Changi Airport's testing facility to support the reopening of the border
- Received the Defence Technology Prize (DTP) by MINDEF in 2021

- The latest iterations available are RESOLUTE 2.0 and **RESOLUTE 3.0**
- Obtained HSA Provisional Authorisation and CE-mark
- **3.5M+ RESOLUTE tests deployed**

Diagnostics Products & Services Co-Developed with Public and Private Partners

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GASTROClear

- First-in-the world miRNA-based liquid biopsy that can detect 87.5% of stage I gastric cancers and 89.5% of stage II gastric cancers
- Attained CE mark in 2017 and HSA clearance in 2019
- Set standard for microRNA-based diagnostics tests – used as an exemplar in the drafting of Singapore Standard 656
- Test deployed in >10 cities in China, Vietnam, Singapore

UNITED™ (Tissue500™)

- Pan-cancer assay to enable Asian-centric molecular characterisation of tumors based on next-generation sequencing technology
- Commercial launch in Sep 2021. Test is offered as a LDT by Lucence and service is provided by Lucence's CAP lab in SG, serving local and regional hospitals
- Showcased in Frontiers in Cancer Science Conference 2021 and USCAP 2022 annual meeting

FxMammo
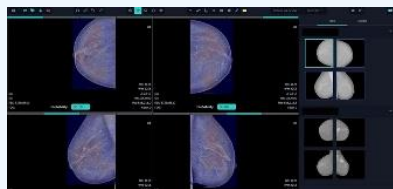
- In collaboration with NUS and NUHS
- An AI-powered diagnostics solution, which improves predictive accuracy of digital mammography – reduced false positive rates from 9% to 2% and reduced recall rates by 67%
- Attained SaMD HSA clearance in 2022

aiTriage™

- In collaboration with TIIM and SGH to refine and clinically validate the aiTriageTM system, an AI-powered diagnostic solution for rapid, real-time risk prediction for Major Adverse Cardiac Event (MACE)
- Shortens triage time significantly and enables better allocation of healthcare manpower for patient care
- HSA Class C Medical Device Registration

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In Digital Health…
A Chasm Exists Between Demand & Supply…

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Care Providers

Innovators

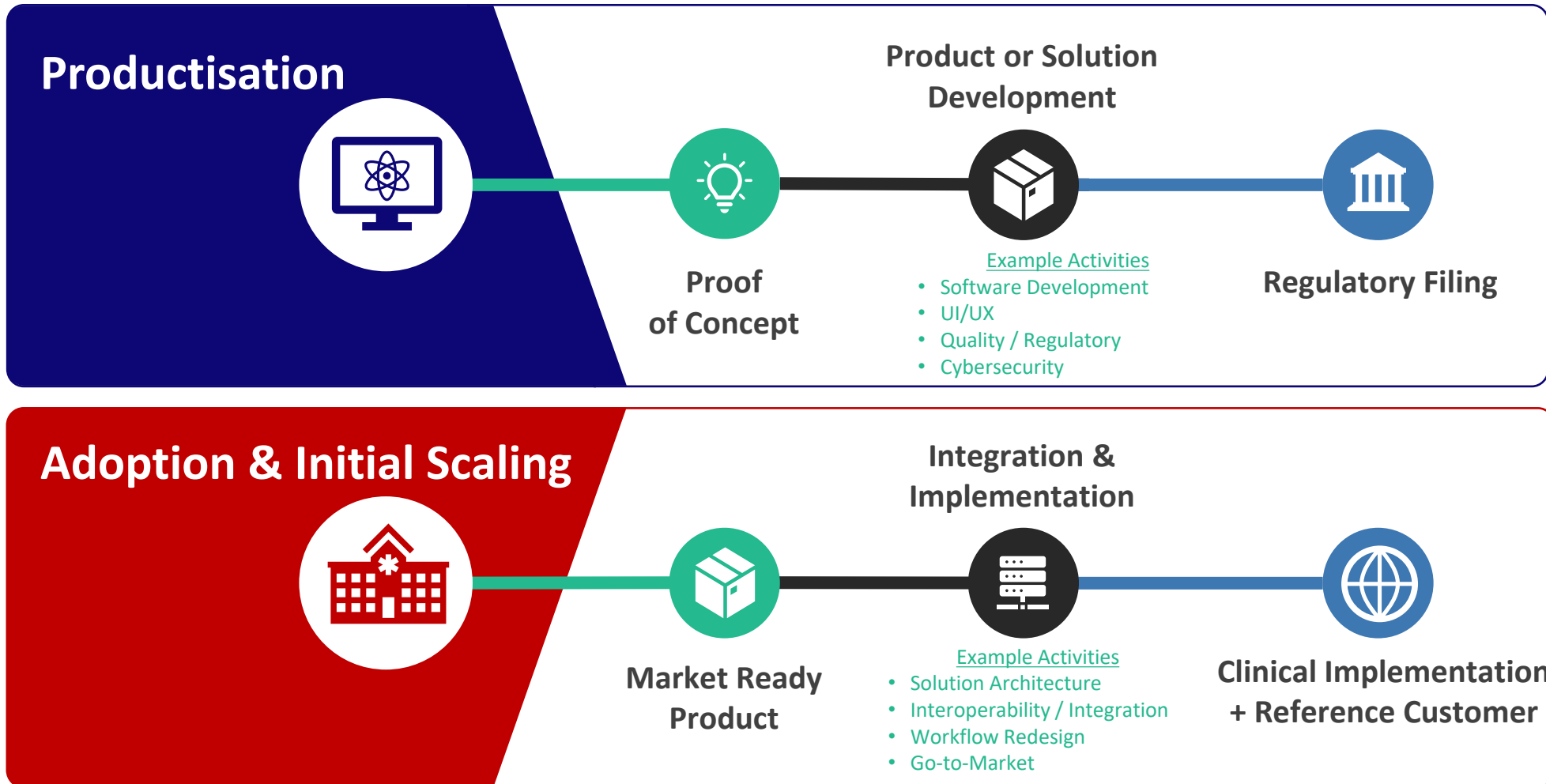**Productisation**

Adoption & Initial Scaling

I have a problem…

I have a solution…

Productisation	Adoption & Initial Scaling
UI/UX	Implementation
Interoperability	Integration
Regulatory Clearance	Cybersecurity
Quality Systems	Workflow Re-Engineering
Clinical Data Access	
Verification & Validation	

DHA Addresses Productisation and Commercialisation Challenges with Two Project Types

Project Scope and Approach Will be Customised based by DHA Project Managers based on Collaborator Needs

Productisation

Proof of Concept

Product or Solution Development

Example Activities
- Software Development
- UI/UX
- Quality / Regulatory
- Cybersecurity

Regulatory Filing

Adoption & Initial Scaling

Market Ready Product

Integration & Implementation

Example Activities
- Solution Architecture
- Interoperability / Integration
- Workflow Redesign
- Go-to-Market

Clinical Implementation + Reference Customer

DHA Projects Involve Contributions From All Parties

	Example Activities	Innovator	DHA	Health System
Productisation	QMS (ISO13485) Implementation	●	●	
	UI/UX, Workflow Design		●	
	AI Model Fine Tuning/Training		●	
	SW Dev, Documentation & Testing	●	●	
	Interoperability Engineering		●	●
	Clinical Validation	●	●	●
	Regulatory Submission Dossier	●	●	
Adoption & Initial Scaling	Baseline Performance		●	●
	Solution Validation	●	●	●
	Pilot Implementation	●	●	●
	Solutions Architecture (w/ Synapxe)		●	
	Integration Engineering	●	●	
	Process Re-Engineering		●	●
	Clinical Implementation	●	●	●
	Benefits Quantification	●	●	●

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Health Sciences Authority
- Regulations and guidance for digital health products

GUIDANCES ON DIGITAL HEALTH PRODUCTS & SERVICES

From HSA
Digital Health Products that are Medical Devices (www.hsa.gov.sg/medical-devices/digital-health)

From MOH – AI in Healthcare Guidelines (moh.gov.sg)

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DIAGNOSTICS DEVELOPMENT HUB

THANK YOU

For more information, visit

https://www.a-star.edu.sg/dxdhub

Celebrating 10 years of
Collaborative Excellence in Diagnostics

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