

FY2022 Annual Report

Diagnostics for Our Future

July 2023

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OPEN VERSION





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Introducing DxD Hub

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National Platform For Diagnostics Productisation



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2014

DxD Hub is an end-to-end productisation platform that bridges the diagnostics productisation gap in Singapore. By commercialising translated research IPs into clinically validated diagnostics, DxD Hub is dedicated to transforming the MedTech landscape in Singapore through innovative solutions from local and regional partners.

VISION

Global medical technology leader in transforming R&D output to medical diagnostics solutions to improve lives and livelihood

MISSION

Health Impact Economic Growth Pandemic Readiness



In 2022, DxD Hub began a new chapter under Singapore's Research Innovation and Enterprise (RIE) 2025 roadmap. DxD Hub 2.0 simultaneously returns us to our roots in Precision Medicine, Women's Health, and Infectious Diseases and pushes us into a future where valuebased care and Artificial Intelligence (AI) will play a stronger role.

This year's report covers the first year in this 4-year journey, and we are pleased to see the shoots of early success. Our accomplishments address key challenges in Singapore and the region, bringing innovation closer to the patient. Some examples from this report include:

- Development of AI models to support Antenatal Risk Stratification using both clinical and socioeconomic markers. This technology will be used as the basis of a Clinical Decision Support System co-developed by DxD Hub, Singapore's National University Hospital, and a commercial partner.
- Successful establishment of a thought leadership platform through the ASEAN Dx Initiative to consolidate regional diagnostics insights and build networks through projects such as the ASEAN SERO-Surveillance Study on COVID-19 vaccines.
- Development and delivery of Executive Certificate Workshops and in vitro diagnostics (IVD) online modules delivered via Duke-NUS Centre of Regulatory Excellence.
- The funding and launch of Singapore's Digital Health Accelerator with the Ministry of Health, public health clusters and the private sector, supporting the adoption and scaling of innovative digital health solutions

These achievements would not have been possible without investments made by DxD Hub in expanding its strength in IVD productisation and growing new strengths in areas like Digital Health.

On behalf of DxD Hub's Oversight Committee and the DxD Hub team, we would like to thank the National Research Foundation and our collaborators for the funding and support that made these investments and achievements possible.

Finally, during periods of transition, it is important to remember our previous successes and the foundation they were built on: our capabilities and people. This year's report highlights our multidisciplinary team, and we are confident that we will continue to play a valued role in supporting and growing Singapore's healthcare and diagnostics ecosystem.

DxD Hub's Oversight Committee Co-chairs





Mr John David Jeans

Dr Fidah Alsagoff

Acting CEO's Letter

Dear Friends of DxD Hub,

We're happy to report that DxD Hub continues to thrive post-COVID with Fiscal Year 2022 being a transformative year on multiple fronts. We worked through changes in three big areas: Funding, Focus, and Management, which we will share in more detail as part of this annual report.

2021 was the last year of our first wave of funding under the RIE 2020 Innovation & Enterprise Cluster Fund, including a Bridging tranche that funded our pandemic response efforts. As we end FY22, our work is now supported by the RIE 2025 Human Health and Potential (HHP) domain and Innovation & Enterprise (I&E) horizontal. Adding to this, we support additional strategic platforms such as the diagnostics arm of the PREPARE pandemic preparedness initiative, the Innovation Fellowship Program, and the Digital Health Accelerator. We thank our grantors for their confidence in us and will work to deliver impact for Singapore and Singaporeans.

During the COVID-19 pandemic, DxD Hub rapidly developed capacity and capabilities across multiple scientific and engineering disciplines including molecular diagnostics, protein diagnostics, pilot scale manufacturing, and commercial adoption and scaling. Our commercial ClinLab, for example, was accredited by the College of American Pathologists in 2022. This will allow us to support the adoption of innovative diagnostics across the region. As the pandemic recedes, we will take these capabilities and redeploy them to efforts in precision medicine and women's health while maintaining our world class infectious disease capabilities.



Sincerely, Irene Cheong Acting Chief Executive Officer Diagnostics Development Hub





Oversight Committee

The OC provides oversight of DxD Hub's resources and activities, including project pipeline and strategy.



Co-Chairs



Mr John Jeans Chairman of the Board, Digital Health and Care Innovation Centre, Scotland



Dr Fidah Alsagoff

Joint Head of Enterprise Development Group and Head of Life Sciences, Temasek Holdings



Prof Tan Sze Wee Assistant CEO, Innovation & Enterprise, A*STAR



Dr Vincent Ho Director, Human Health & Potential, National Research Foundation



Members

Prof Tan Say Beng Executive Director, National Medical Research Council



Dr Clarice Chen* Director, Healthcare & Biomedical, Enterprise Singapore



Mr Jean-Luc Butel (ex-officio) Chair, DxD HEC



Ms Irene Cheong Acting CEO, DxD Hub

* Ms Audrey Lok served on the OC for the full period of FY22. As of April 2023. Dr Clarice Chen stepped into the role of Director, Healthcare & Biomedical, Enterprise Singapore, and as a DxD Hub OC member.

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Hub Evaluation Committee



The HEC comprises members from varied backgrounds, such as the clinical community, biomedical/diagnostics and investment industries. They support the OC by providing independent review, evaluation and recommendation of major projects to be invested by DxD Hub (including licensing terms).



Mr Jean-Luc Butel (HEC Chair) (ex-officio) Chair, DxD HEC



Dr Rudi Pauwels Co-chair of the Diagnostics R&D Working Group of the Access to COVID-19 Tools (ACT)-Accelerator



Dr Bijan Dorri Advisor to A*STAR



Dr Tito Bacarese-Hamilton Former CEO, PredictImmune Limited



Mr Simranjit Singh CEO, Guardant Health AMEA



Dr Amit Kakar Senior Partner and Head, Novo Holdings Asia



Dr Wong Chiang Yin Former GCEO, Thomson Medical Group at Thomson Medical Center

Executive leadership

Dr Weng Ruifen Deputy Chief Executive Officer, Chief Technology Officer

Ms Ho Yuan Lu Vice-President, Outreach & Training

INGAPORE

Ms Irene Cheong Acting Chief Executive Officer, DxD Hub Ms Chan Yang Sun Assistant Vice-President, Quality Assurance & Regulatory Affairs

Mr David H Vu Chief Operating Officer

WEINE

Dr James Qu Director, Clinical Lab

THAT

dxdhub DIAGNOSTICS DEVELOPMENT HUB



DxD Hub in FY22

Year 1 / 4 of RIE2025

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FY22: Celebrating Success, Strengthening Teams, Building Networks





Overview of DxD Hub in FY22: Strengthen, Expand, Build





FY22 was a significant year of transition and growth for DxD Hub, marking the first year of DxD Hub 2.0 as we expanded our funding base from the initial Innovation & Enterprise focus, to add funding from the RIE Health and Human Potential Horizontal. We invested this funding into talent, equipment and laboratory space to build upon our base and operationalise the 2.0 Strategy to address rising demands in the future of healthcare delivery, supporting national health priorities, and the local MedTech ecosystem in building new local companies and products. Established under our Bridging tranche, FY22 saw our continued efforts in a multiyear effort to strengthen our multi-disciplinary team of scientists, engineers, quality & regulatory, and project management professionals. Between FY21 and FY22, we expanded our headcount by 15% and increased our project capacity by 20%, reflecting both the productivity and maturation of our team, as well as the need to do more in the face of market challenges in hiring technical staff. We also grew and delivered on our capabilities in Digital Diagnostics and Integrated MedTech. Such capabilities in project management, software engineering, and UI/UX were put to work by supporting collaborators across a wide spectrum of projects in Women's Health (e.g. FxMammo, Antenatal CDSS), Precision Medicine (e.g. Breast Cancer Risk Prediction), among many others.

DxD Hub aligned our resources to support the PREPARE Dx Initiative, which contributes to Singapore's national pandemic preparedness. Towards the end of the fiscal year, we were awarded funds to build Singapore's Digital Health Accelerator (DHA), which will focus on the adoption and scaling of digital health solutions. DHA was the culmination of a multi-year collaborative effort between A*STAR, MOH entities, and the private sector.

Talent development has been a key part of our ecosystem building efforts. In 2.0, DxD Hub was awarded funding under the Innovation Fellowship Programme (IFP) to develop both new and experienced talents for the MedTech industry. Our alumni continue to support the industry, with an estimated 75% continuing their journey in the healthcare industry or pursuing higher education.

Finally, DxD Hub also projects Singapore's influence in diagnostics abroad by building global networks and key partnerships. A key example of this is the ASEAN Dx Initiative, co-led by DxD Hub. Under ASEAN DxI, we now have 5 post-market clinical surveillance studies under way, funded by both DxD Hub and Temasek Foundation (TF).

Rebalancing Portfolio Mix to Meet Rising Demands in the Future Of Healthcare Delivery and National Health Priorities





The 3 thematic areas/pillars will be strongly supported by foundational DxD Hub capabilities in **In Vitro Diagnostics (IVD)**, **Digital Diagnostics (DDx)** and **De-centralised Care**.

FY22 saw a notable transition in our project portfolio mix. DxD Hub played a critical role in the fight against COVID-19 and received recognition and numerous accolades for developing critical products and services - including Fortitude 2.0, RESOLUTE 2.0, and cPass[™], as well as the validation of various lateral flow test kits for Singapore. As the world eases out of COVID-19, we are shifting the focus of our projects to balance between non-communicable diseases (NCDs) and infectious diseases.

In **Precision Medicine**, we are broadening our strategy to utilise our strength as a regional leader in diagnostics. While cancer is still an area of active interest—as exemplified by our development projects for breast cancer—we are further expanding our reach, by engaging in projects around Asian phenotype.

In **Women's Health**, we committed our resources to co-develop innovations centered on women's cancers, as well as pre-natal and early childhood development. Investment in this space is increasing exponentially, and national initiatives like GUSTO¹ ensure that there will be a continued supply of crucial data and IP assets for collaboration.

Finally, in **Infectious Diseases** (IDs), we will continue to build a portfolio of projects to contribute to pandemic readiness, as well as to combat other IDs relevant and prevalent in the Southeast Asian region.

¹ GUSTO Singapore (n.d.) *Growing Up in Singapore Towards Healthy Outcomes.* <u>https://www.gusto.sg/</u>

Key Trends Impacting Diagnostics Development



While we re-balance our portfolio, DxD Hub is cognisant of the pressure that healthcare systems across the globe are facing, to transform and diversify in order to tackle the increasing load of NCDs and chronic conditions with higher complexities. Health authorities around the world, including Singapore, are shifting from volume-based to value-based care models, of which the adoption of innovative diagnostics will be a key enabler¹.

Diagnostics are set to play a key role in the transition of healthcare delivery towards more personalised preventive care, to improve population health and reduce disease burden. This will augment the existing process that involves and begins with screening and detection. We anticipate our portfolio mix will evolve with the major national initiatives below:

- **HealthierSG**^{2,3} is a multi-year strategy to transform healthcare delivery and facilitate the shift into preventive care in primary care and community-based settings.
- **RIE2025 Human Health & Potential (HHP)** domain seeks to transform and protect health, by evolving health systems to become more datadriven and patient-centric to deliver value-based care, enabled by innovative use of technology and digital solutions at scale.
- The National Precision Medicine (NPM) research programme, coordinated by PRECISE⁴, aims to improve public health, enhance disease prevention, and deliver more targeted treatment for better outcomes.



DxD Hub's portfolio strategy is aligned and complementary with national initiatives. For FY23, DxD Hub anticipates critical discussions surrounding these areas, which will sharpen our selection of projects for better health and economic impact. We foresee more collaboration with existing and new industry and public sector partners to create innovations in digital health, and de-centralised care solutions.

¹ World Economic Forum. (2023, January 5). *The moment of truth for healthcare spending: How payment models can transform healthcare systems*. <u>https://www.weforum.org/reports/the-moment-of-truth-for-healthcare-spending-how-payment-models-can-transform-healthcare-systems</u>

² Healthier SG. (2022, September 21). *The White Paper on Healthier SG.* <u>https://www.healthiersg.gov.sg/resources/white-paper/</u>

³ Ministry of Health. (2022, March 9). Speech by Mr Ong Ye Kung, Minister for Health, at the Ministry of Health Committee of Supply Debate 2022. <u>https://www.moh.gov.sg/news-highlights/details/speech-by-mr-ong-ye-kung-minister-for-health-at-the-ministry-of-health-committee-of-supply-debate-2022</u>

⁴ PRECIsion Health Research, SingaporE (PRECISE) is the central entity coordinating whole-ofgovernment efforts to implement Singapore's national PM research strategy.

Project Highlights

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Antenatal Clinical Decision Support System for Pregnancy Risk Stratification

The Antenatal Clinical Decision Support System (CDSS) has been designed to improve patient outcomes by allowing for early detection of high-risk pregnancies and reducing the burden on healthcare systems by allowing for efficient healthcare resource utilisation. Pregnancy poses many risks, and about 15% of all pregnancies worldwide are at risk of developing potentially life-threatening complications¹. Studies have shown a disproportionate utilisation of antenatal care, with 26% of high-risk pregnancies going without the care required².

To address this issue, DxD Hub and Singapore's National University Hospital (NUH) have utilised artificial intelligence (AI) to improve the tools that practitioners use to triage pregnancies, thereby enhancing the quality of treatment that expecting mothers receive and resulting in favourable maternal, obstetric, and neonatal outcomes. Previous collaborations between DxD Hub and NUH have resulted in validated pregnancy risk prediction AI models. Healthcare providers were consulted and actively engaged in the prototype software development process, indicating a keen interest and demand for such a technology that would give practitioners a better perspective for making clinical decisions while enhancing the experience of pregnancy for mothers-to-be.

Following this, DxD Hub's next step is to further develop the CDSS for riskstratification, which will be deployed to clinical sites. With a commercial partner identified and established, DxD Hub is currently preparing the antenatal CDSS for HSA regulatory submission and commercialisation.

¹ Majella, M. G., Sarveswaran, G., Krishnamoorthy, Y., Sivaranjini, K., Arikrishnan, K., & Kumar, S. G. (2019). A longitudinal study on high risk pregnancy and its outcome among antenatal women attending rural primary health centre in Puducherry, South India. Journal of education and health promotion, 8, 12. <u>https://doi.org/10.4103/jehp.jehp_144_18</u>

² Yeoh, P. L., Hornetz, K., & Dahlui, M. (2016). Antenatal Care Utilisation and Content between Low-Risk and High-Risk Pregnant Women. PloS one, 11(3), e0152167. https://doi.org/10.1371/journal.pone.0152167





FxMammo Software as a Medical Device for Automated Breast Cancer





The original image shows a large mass at the center, which may be a lesion but achieving high diagnostic confidence is difficult for radiologists particularly with higher density breast tissue prevalent amongst Asian women. Using FxMammo, the regions of interest are automatically identified, and risk scores are predicted at a high accuracy; missed cancers and false-positives are then reduced.

¹ Elmore, J. G., Miglioretti, D. L., Reisch, L. M., Barton, M. B., Kreuter, W., Christiansen, C. L., & Fletcher, S. W. (2002). Screening mammograms by community radiologists: variability in false-positive rates. Journal of the National Cancer Institute, 94(18), 1373–1380. https://doi.org/10.1093/jnci/94.18.1373 FxMammo is software that automatically and accurately screens for breast cancer from digital mammogram images, before generating a diagnostic report. The currently available screening options are heavily reliant on human radiologists, who perform double-blind readings to diagnose breast cancer. Inevitably, this method has resulted in high variability in false-positive rates, ranging from 2.6% to 15.9%¹. This software also offers superior performance in comparison to other Computer-aided Detection (CAD) systems and has been trained with Asian datasets. As mammograms are currently the most reliable screening tool for breast cancer, enhancing this tool may contribute to patient outcomes via early detection, thus opening possibilities for fast intervention.

Developed by FathomX, a Digital Health AI spin-off company from the National University of Singapore and National University Health System, DxD Hub assisted in setting up a Quality Management System (QMS) for FxMammo in compliance with ISO 13485 — Medical Devices. In FY2022, FxMammo received HSA Class B registration and was one of six innovations to be awarded at the Healthcare InnoMatch 2022, organised by the Centre for Healthcare Innovation (CHI) and supported by the Ministry of Health (MOH) and Temasek Foundation (TF).

In bridging the gap between concept and market, DxD Hub's capabilities in validation, quality assurance, and regulatory affairs made FxMammo a reality; it filled a much-needed gap in breast cancer diagnostics that will better equip practitioners for breast cancer intervention. FxMammo is currently being piloted at NUH as part of Healthcare InnoMatch 2023.

Breast Cancer Risk Prediction for Asian Population Based on Next-Generation Sequencing – LDT and CDSS Development



Advancements in understanding the heritable component of breast cancer, coupled with the accessibility and progress in Next-Generation Sequencing (NGS) technologies, has paved the way for the development of risk prediction models based on genetic factors. These models aim to classify patients into different risk groups, allowing for personalised clinical management and improved patient outcomes.

In collaboration with Nalagenetics, DxD Hub is currently working on the development of an NGS workflow that enables low-coverage Whole Genome Sequencing (IcWGS) as a lab-developed test (LDT). The initial focus of this project is to create a reliable method for collecting high-quality NGS data, which will be essential for accurate interpretation and clinical decision-making. Concurrently, the development of a complementary clinical decision support software (CDSS) specifically for breast cancer risk prediction is underway. By combining clinical information with polygenic risk prediction scores, the software calculates the risk of breast cancer and generates comprehensive reports for healthcare practitioners. These reports not only inform practitioners about the risk level but also provide recommendations and steps for further follow-up.

This collaboration leverages DxD Hub's integrated diagnostic productisation capabilities, encompassing both In Vitro Diagnostics (IVD) and Software as a Medical Device (SaMD). This integration enables the development of end-to-end clinical decision support, facilitating the translation of research findings into practical solutions. The technology developed through this project holds the potential to benefit future risk prediction services, allowing for early-stage interventions that can improve patient outcomes not only in breast cancer but also in other conditions.





Nalagenetics is a Singapore-based biotech company dedicated to developing solutions for predictive genetic testing. They have received notable recognition for their efforts, having been honoured as one of the Top 3 Best Innovators at the 2022 Health Innovation Sprint Accelerator. Additionally, they represented Indonesia in the 2021 G20 Innovation League and won first place in the Healthcare category, showcasing their excellence in the field.

Capability Building Projects for Pandemic Resilience



Local Lateral Flow Development & Manufacturing Capabilities

Testing for SARS-CoV-2 infections remains key in the management of COVID-19 in Singapore. One essential screening tool is the SARS-CoV-2 antigen rapid test (ARTs), which utilises lateral flow technology to enable detection of SARS-CoV-2 proteins.

Given the current lack of locally-developed lateral flow tests in Singapore, DxD Hub has sought to develop an end-to-end lateral flow manufacturing process as internal product development and manufacturing capabilities. This project also seeks to future-proof the technology in face of potential supply disruptions, by reducing the reliance on overseas manufacturers. The technology and workflow generated from this project can potentially be generalised and expanded beyond COVID-19 applications, improving on DxD Hub's fundamental core capabilities in cooperation with current and future collaborators; as well as bolster national pandemic resilience for future outbreaks.

COVID-19 Flow Cytometry RUO Kit

With the SARS-CoV-2 virus constantly undergoing mutations, there is a need for less limiting serological assays that can accurately reflect the immune profile status of the clinical specimen tested.

In partnership with A*STAR Infectious Diseases Labs (ID Labs), DxD Hub aims to develop a RUO assay kit based on the spike protein flow-based assay (SFB), which utilises flow cytometry in detecting circulating antibodies in human plasma and serum against the full-length SARS-CoV-2 spike protein. This project aims to offer the scientific community a sensitive, multiplexed assay, capable of capturing isotype-independent SARS-CoV-2 antibodies. This hopes to help improve the accuracy of clinical assays that will enhance detection capabilities, thus bringing COVID-19 R&D to reach new heights and possibilities. With a strong, collaborative effort, DxD Hub's efforts will contribute to enhanced pandemic preparedness by better equipping the current toolkit with updated, and refined technology.

Strengthen

Our Team & Capabilities: An introduction to our Hubbers

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Strengthening Capabilities & Developing Talent to Support the Growing MedTech Ecosystem



DxD Hub is actively fostering a multi-disciplinary team, in line with our goal to deliver excellent products and cultivate talents for DxD Hub and the industry.

In FY22, we focused on investing in our headcount and manpower in order to support strategic activities, strengthening capabilities, and bolster strategic areas such as IMT and DDx. Improvements to our existing and potential headcount would allow us to ramp up collaborations and projects in both new and existing areas, and ultimately better serve Singapore's MedTech ecosystem.

Project Management & Business Development	In Vitro Diagnostics	Digital Diagnostics	Integrated Medtech				Clinical Lab				
Systems Integration	Molecular Dx	BioMedical Engineering					Clinica				
	Protein Dx	Design - ID, UI/UX					Comme				
	Pathology	Software Engr.	Firmware Engr.								
	Pilot Manufacturing	Interoperability Engr.	Mechanical Engr.								
		AI/ML Engr.	1								
Quality Assurance & Regulatory Affairs	Outreach & Training	Corporate	Special Projects								
ISO 13485 (Med Device)	Regional Business Dev.	Corporate Planning & Services]	otal Wo	orkforce	e (Full T	ime Emp	oloyees)	by Year
ISO 14971 (Risk Mgmt)	Training & Development	Business Planning & Analysis	2	2015	2016	2017	2018	2019	2020	End of FY 2021	End of FY 2022
IEC62304 (Med Software)			- 1	18	22	28	30	33	48	66	76

22

Business Development Team





From left to right: Ananth Chandrasekaran, Weng Ruifen, Belicia Choy, Sabrina Chua Absent from group photo: Hon Qi, Oscar Huang

Certain Who We Are

Our Business Development Team is dedicated to driving collaborations between industry and the public sector. By forging strategic partnerships, we aim to address clinical unmet needs not only within our local ecosystem but also on a regional level. Through our partnerships, we strive to foster innovation, accelerate the development of new technologies, and improve access to healthcare.



- ✓ Go-to-Market Strategy
- ✓ Due Diligence Analysis
- ✓ Ecosystem Connector
- ✓ Development Road mapping

In Vitro Diagnostics (IVD) Team





From left to right:

Top Row: Lin Youbin, Felicia Chang, Vincent Lim, Jaren Leng, Tang Yu Xuan, Damien Gee, Jiang Junxian, Steven Sim, Dominic Phua, Alan Wee

Bottom Row: Daniel Wu, Sui Lin, Eileen Ng, Felicia Heng, Janice Ngeow, Siti Zarina Zainul Rahim, Weng Ruifen, Ng Kai Ting, Janice Priya Dhanaraj, Geraldine Koh, Dai Mengqiao

Absent from group photo: Ou Chung-Pei, Sandy Lim, Anisah D/O Khalid, Lee Peishan, Lim Jian Heng, Claire Swa, Jillian Chan



At IVD, we are dedicated to developing innovative diagnostic devices for the medical sector, specialising in molecular and protein diagnostics including NGS, qPCR, LFA, ELISA, and cytology. We collaborate closely with a diverse range of stakeholders, such as companies. scientists. regulatory affairs experts, and healthcare professionals. Our throughout involvement the product development life cycle enables us to optimise, implement, and deliver high-quality diagnostic devices with improved accuracy, efficiency, and accessibility in healthcare settings.



- ✓ Molecular Diagnostics
- ✓ Protein Diagnostics
- ✓ Pathology
- ✓ Pilot Manufacturing

Digital Diagnostics Team





Who We Are

At Digital Diagnostics, we pride ourselves on being at the forefront of digital technology. Our versatile team comprises of project managers, software engineers, and data scientists who are dedicated in driving digital projects and supporting promising start-ups. With a diverse range of capabilities, we tackle multiple clinical applications and problem statements with agility and expertise. Our team stands ready to leverage the latest digital tools and techniques to deliver innovative solutions that help transform healthcare for the better.



- ✓ Image Processing
- ✓ Computer Vision
- Systems Integration
- Medical Software Development & Regulations
- ✓ Interoperability Engineering

From left to right:

Top Row: Zhang Jingxian, Liew Kai Shin, Tan Yuan Yu David, Weng Ruifen, Louis Chan, Harold Goh, Ponnusamy Sivaraj Ponvignesh **Bottom Row**: Susainathan Henry Johnson, Lijoy Kunnathu George **Absent from group photo:** Chai Wei Ming, Ramasamy Ganesh, U S Vaitesswar

Integrated Medical Technologies (IMT) Team





From left to right: Top Row: Sheng Chunlei, Desmond Soh, Lim Xian Sheng, Victor Oh Bottom Row: Relat Goberna Josep, Low Kean Wah, Lloyd Ah Qune

S Who We Are

At IMT, our team of skilled engineers and project managers specialise in the integration of medical devices to automate IVD assays. We were established in early-2021, and our team consists of experts in mechanical, electronic, and firmware engineering, as well as physics, physical chemistry, and bio-physics. As a bridge between hardware design, the engineering branch of product development, and IVD scientists with expertise in bio-assay development, we play a critical role in bringing together the technical and scientific aspects of IVD automation.



- ✓ Automation of Manual Bio-Assay
- ✓ Product and Process Engineering
- System Structuring & Integration (Hardware + Firmware)
- ✓ Sub-System Prototyping for V&V
- ✓ Design of Experiments
- ✓ Identify and Elucidate Critical Cause-Effect Relationships

ClinLab Team





From left to right: Top Row: Jina Cheu, Pragathi Arul Bottom Row: Amber Heng, Panneer Selvi Govindaraju, James Qu

Who We Are

At DxD ClinLab, we are committed to accelerating the development and deployment of cutting-edge diagnostics that have the potential to transform healthcare delivery and improve patient outcomes. We serve as a pilot deployment centre for innovative tests developed by DxD and its strategic partners in Singapore and the greater ASEAN region. We work closely with healthcare partners to ensure that innovative tests are made available nationwide, by bridging gaps in test accessibility until commercial labs are able to offer the tests.



What We Do / Capabilities

- **CAP** Guidelines \checkmark
- Healthcare Services Act (HCSA) \checkmark
- Molecular Diagnostics Assays \checkmark
- Immunology/Serology Assays \checkmark
- Cellular Pathology Assays \checkmark

Quality Assurance, Regulatory Affairs and Lab Operations Team



Who We Are

Our team plays a critical role in upholding the Quality Management System (QMS) at DxD Hub. As the champions of QMS, we are responsible for ensuring that all product design and development processes meet the highest safety and compliance standards. To achieve this, we work collaboratively with various departments across the organisation to ensure that all activities are aligned with the QMS framework. By facilitating cross-functional communication and knowledge sharing, our team helps to identify potential risks, and ensure that appropriate mitigation strategies are in place.

What We Do / Capabilities

- ✓ ISO 13485:2016
- ✓ Human Biomedical Research Act (HBRA)
- ✓ Personal Data Protection Act (PDPA)
- ✓ Export Control Regulations
- Workplace Safety, Health and Environment Regulations
- ✓ Audit



Top Row: Ngoh Xin Yi, Cheryl Soh, Wang Suk Mei, Joey Chu, Jayashree D/O Chandrasekaran, Ng Szu Shien, Nurul Zafirah D/O Shaik Dawood, Alicia Leong Bottom Row: Candy Liow, Janet Poh, Chan Yang Sun, Jessica Yap, Nur Shikin Binte Hussin OFFICIAL [OPEN]

Outreach & Talent Development Team



Who We Are

In the Outreach & Talent Development team, we are focused on building strong connection with industry partners, as well as effectively communicating the successes of DxD Hub. We believe that promoting our achievements is critical to establishing ourselves as a thoughtleader in the field of diagnostics. We are committed in fostering the personal and professional growth of individuals, which is essential to drive innovation and achieve our mission of improving healthcare through diagnostics. Through our outreach and talent development initiatives, we aim to engage with like-minded partners and individuals who share our vision and values, to build a thriving ecosystem that supports the growth and success of all involved.



- ✓ Outreach Programs
- ✓ Training
- ✓ Communications
- ✓ Talent Development
- ✓ Building Global Networks & Talents



From left to right: Rahul Pandey, Ho Yuan Lu, Rafiqin Razali, Alastair Chan

Corporate Team



Who We Are

Our Corporate Team seeks to improve operational efficiency, facilitate connections with the broader ecosystem, and support effective decision-making. Our team manages and collaborates with resource partners at A*STAR to provide critical support across key business functions, including Operations, Governance and Management Support, Resources, Finance, Human Legal, IT, Communications and Process Improvement. We are committed across all aspects of our operations, ensuring that our teams have the resources they need to achieve their goals, and maintaining strong connections with stakeholders across the ecosystem.



- ✓ Operations
- ✓ Governance
- ✓ Strategic Planning & Analysis
- ✓ Process Improvement
- ✓ HQ Linkage



From left to right: Top Row: Ho Shi Yun, Sherry Low, Vishnupriya D/O N Manivannan, Musrifah Musa Bottom Row: Denise Yeo, David Vu, Jacquelyn Chen

Special Projects Team



Who We Are

At our core, we are driven by a deep passion for developing assays with clinical value in detecting and managing emerging infections and cancer. Our ultimate goal is to create innovative MDx technology that not only furthers economic growth but also improves lives. Our product development initiatives are focused on addressing unmet medical needs and we strive to foster collaboration among clinicians, academia, and industry partners, both locally and internationally. Our vision is to become a global leader in MDx technology and open innovation, driving positive impact in healthcare and beyond.

What We Do / Capabilities

- ✓ Molecular assay design and development
- ✓ Assay validation and productisation
- Proof-of-concept testing for innovative molecular assays/ platforms



From left to right: Lee Feng Yi Karen, Masafumi Inoue, Goh Mei Ling

Expand

Our Toolkit: PREPARE, DHA

DxD Hub as the Diagnostic Pillar to Build Capabilities and Capacity for Pandemic Preparedness





DxD Hub is supporting PREPARE Diagnostics Co-op in its effort to :

PREPARE is a national programme initiated by the Ministry of Health (MOH) to bolster Singapore's key research capabilities, translational platforms and expertise. The program aims to develop tools, methods and products that can be tapped on to detect, respond to, and contain future infectious disease threats.

It was officially launched on the 3rd of November 2022 by Singapore Minister for Health Mr Ong Ye Kung, together with PREPARE Executive Director Professor Wang Linfa, and PREPARE Steering Committee Cochair and Chief Health Scientist (CHS) Professor Tan Chorh Chuan.



- 1. Establish an integrated and functional infectious disease diagnostic development co-operative with a diverse range of multidisciplinary R&D capabilities.
- 2. Strengthen linkages across the diagnostics development pathway, from research prototypes to product, to enable a swift and effective response to an expanded range of pathogens of interest.
- 3. Accelerate the development and delivery of regulatory-approved diagnostics with reliable production capacity.
- 4. Improve supply chain readiness and facilitate the expedited deployment of national testing.

Digital Health Accelerator Phase 1 Focuses On Accelerating the Adoption and Scaling of Clinically Deployable Digital Health Solutions



The Digital Health Accelerator (DHA) is led by A*STAR, Ministry of Health (MOH) Singapore, SingHealth, National Healthcare Group (NHG), and National University Health System (NUHS). DHA supports innovators in driving adoption and scaling of market ready or near-market ready digital health solutions. DHA operates by (i) sourcing innovative digital solutions from clinical entrepreneurs, universities, and companies (ii) rigorously assessing their clinical and operational utility and (iii) supporting Productisation and Commercialisation projects.

DHA Projects benefit from development expertise in software engineering, UI/UX, validation, optimisation and commercial expertise in deployment, change management, process re-engineering, and integration.





Solutions that successfully exit DHA will do so with a reference customer, demonstrated and quantified outcomes and opportunities for regional and global adoption and scaling. Singapore's health system benefits from access to digital innovation while mitigating the risk of being a technology "early adopter".

Global Networks and Talent: Outreach & Regional Efforts Talent Development

Build

Cedars-Sinai Accelerator: Innovation Week for SG Medtech Start Ups





In collaboration with the critically acclaimed CS Accelerator and Enterprise Singapore, nine MedTech startups from Singapore were invited to Innovation Week (16-20 May 2022) at Cedars-Sinai in Los Angeles, USA; an intensive immersion trip aimed to promote understanding of the US medical device market. These companies include: Aevice Health, Biobot Surgical, Biorithm, Crely Healthcare, Mesh Bio, Neurowyzr, Rocesco Technologies, Sunbird Bio; and Tetsuyu Healthcare.

During this trip, the startup founders were involved in a week of lectures, and one-on-one meetings with mentors—including Cedars-Sinai clinicians, regulatory consultants, and tech venture capitalists—matched with participants according to their respective needs.

Innovation Week concluded with a resounding success. For their efforts, Aevice Health was awarded \$100,000 in funding and mentorship, in their invitation to join CS Accelerator in August 2022. Cedars-Sinai also expressed interest in exploring tech venture activities in Singapore. The Singaporean participants found their interactions with their mentors productive and informative, with their experiences being customised and catered to best fit each company's needs.

Moving forward, Innovation Week is one of many partnership programmes to come. DxD Hub aims to continue fostering strong connections and relationships with overseas counterparts, focused on the growing potential in future collaborations and projects.

ASEAN Diagnostics Initiative: Diagnostics Ecosystem Builder for Our Region





The ASEAN Dx Initiative (ASEAN DxI) is an ASEAN COSTI-endorsed platform aimed at bridging knowledge gaps within the region by facilitating the co-development of healthcare diagnostic solutions that address the growing clinical needs within the ASEAN region. Co-chaired by the Philippine Council for Health Research and Development (PCHRD) and DxD Hub, ASEAN DxI intends to commercialise and increase the accessibility of locally developed diagnostic products by supporting capabilities building in ASEAN Member States (AMS) and closing the translational gap between collaborators to improve human health in the region. Through this collaborative initiative, DxD Hub expands its reach into MedTech ecosystems beyond Singapore, establishing collaborative partnerships in diagnostics to develop products created by ASEAN, for ASEAN.

To achieve these objectives, ASEAN DxI brings together experts and strategic stakeholders from the Programme Steering Committee (PSC) to advise and facilitate the development and delivery of diagnostic products within their respective AMS.

Key activities in FY22:

- Accelerating Diagnostics Access in ASEAN (ADAA) Regional Consultation (Feb 2022)
- Renewal of ASEAN DxI Governance Structure: Programme Steering Committee (Aug 2022)
- ASEAN Dxl Stakeholders Meeting (Nov 2022)
- PCHRD Innovation Mission to DxD Hub (Dec 2022)

ASEAN SERO-Surveillance Study on COVID-19 Vaccines (ASSeSS): Building Networks Through Regional Projects





ASSeSS aims to prepare the ASEAN region for quick response to potential pandemic outbreaks via diagnostics capacity building and network creation. Funded by the ASEAN Science Technology and Innovation Fund (ASTIF), Temasek Foundation (TF) and in-kind contributions from all collaborating PIs, the ASSeSS is joined by the ASEAN Member States (AMS), such as Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam.

Collaborating PIs are:

- Prof. Lin-Fa Wang, Duke-NUS, Singapore
- Dr Kristine Alvarado-Dela Cruz, Research Institute for Tropical Medicine, Philippines
- Dr Sidney Yee, Diagnostics Development Hub, Singapore
- Dr Weng Ruifen, Diagnostics Development Hub, Singapore
- Dr Barnaby Young, National Centre for Infectious Diseases, Singapore
- Dr Raghav Sundar, National University of Singapore, Singapore
- Prof Amin Soebandrio, University of Indonesia, Indonesia
- Dr Anak Agung Sagung Sawitri, Udayana University, Bali, Indonesia
- Dr I Nyoman Sutarsa, The Australian National University, Australia
- A/Prof. Yoke-Fun Chan, University of Malaya, Malaysia
- Dr Watsamon Jantarabenjakul, King Chulalongkorn Memorial Hospital, Thailand
- Dr Napaporn Chan, Chulalongkorn University, Thailand
- A/Prof. Le Van Tan, Oxford University Clinical Research Unit, Vietnam

In FY22, ASSeSS has:

- Harmonised the processes to sample collection, testing and results reporting in ASEAN.
- Performed the cPass[™] assay on more than 80% of 7500+ collected samples.
- Performed Roche S&N assays on more than 70% of 7500+ collected samples.
- Proposed a consortium amongst the ASEAN PIs at the 4th PI meeting, which is currently being discussed.
- Planned ASSeSS Phase 2, where all existing PIs have expressed keen desire to participate.

Temasek Foundation Pinnacle Series Lecture at 7th World One-Health Congress:



On November 10th, 2022, DxD Hub was invited by the One Health Congress (OHC) to organise and host a workshop, as part of the Pandemic Preparedness and Health System Resilience track of the Temasek Foundation Pinnacle Series. Coinciding with the 7th World One Health Congress, DxD Hub's Transformational Innovation for Preparedness and Resilience workshop was hosted at the Sands Convention Centre, attracting over 250 participants across the world, and more than 120 in-person attendees.

One of the first post-pandemic workshops to be held in person, the session showcased a distinguished line-up of speakers from Indonesia, Philippines, Thailand, and Singapore's Agency for Science, Technology, and Research (A*STAR), including Dr. Jaime Montoya, Professor Andy Hor, and Professor Amin Soebandrio. Topics that were shared during the workshop revolved around pandemic responses and actions going forward, innovative approaches for pandemic preparedness and strategies to enhance ASEAN's resilience against future pandemics, as well as discussions about the challenges ASEAN countries face in dealing with outbreaks and emerging infections. The session ended with lunch, allowing the audience to network and build relationships for regional impact.

Overall, the event was lauded with praise from both participants and organisers, having achieved its intended outcomes and provided a platform of discussion for speakers and audience alike.

Innovation & Enterprise Fellowship Programme (IFP): Medtech Talent Development



The DxD Hub IFP is a new development talent programme funded by NRF to train and expand the pool of deep-tech talents who can take on diagnostics and medical devices translation, productisation and commercialisation activities in Singapore.

The programme is designed to provide the fellows structured learning and on-the-job training on DxD Hub's product development and productisation capabilities which closely aligned with the requirements in ISO13485 and FDA's Total Product Life Cycle framework.

The programme is scheduled to be launched in FY23. Upon completion of the programme, the fellows will be competent to explore relevant roles in DxD Hub, A*STAR or the private sector.

Enabling the Ecosystem

Talent Development based on Medical Device Regulatory Requirements





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