



Diagnostics Development Hub

FY2023 Annual Report

Diagnostics for Our Future

July 2024

OPEN VERSION

dxdhub
DIAGNOSTICS DEVELOPMENT HUB

a[★] Agency for
Science, Technology
and Research
SINGAPORE

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Diagnostics for Our Future

DxD Hub is an end-to-end product development to deployment 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

Creating Health Impact, Economic Growth and enabling Pandemic Readiness.

Message from our Governance Board (OC Co-Chairs)

This year DxD Hub will mark a decade of innovation and impact to the diagnostics industry, to Singapore and for Singaporeans. Although it is a good time to take stock and celebrate the accomplishments, we are aware that the Hub's work is far from over. The challenges facing healthcare globally continue to intensify, and the need for innovative solutions in the focus areas of Precision Medicine, Women's Health and Infectious Diseases, are as pressing as ever.

This year's report focuses on collaborations and the exciting products that have, or will, yield significant benefits. However, of equal significance is the work being undertaken to activate new platforms and initiatives that support the Research Innovation and Enterprise 2025 roadmap and position the Hub for emerging priorities in preparedness for RIE 2030.

Some examples in the pages that follow:

- This year, DxD Hub announced an exciting partnership with PRECISE, the implementation entity for Singapore's National Precision Medicine programme. Under the terms of the MOU with PRECISE, DxD Hub will serve as a strategic product development partner yielding new opportunities for clinical and economic impact.
- Digital Health Accelerator is a national platform hosted by DxD Hub that focuses on Development, Adoption and Scaling of Digital Health solutions used in care delivery. DHA kicked-off in FY 2023, and the team tirelessly worked to activate the program, built a new project evaluation committee, processes, team and capabilities. DxD Hub is pleased to report that the first two DHA projects have been awarded with a robust pipeline to follow.
- The PREPARE Diagnostics Co-Op, now in its second year under DxD Hub, seeks to bolster Singapore's capability to respond rapidly to future pandemics. In FY 2023, the Hub was awarded Phase 2 core funding, led an open grant call, and kicked-off multiple pandemic related projects supported by PREPARE.
- The on-boarding of new staff under the Innovation and Enterprise Fellowship Program funded by NRF. The programme aims to bring talents from other industries into the diagnostics and digital health sector.

Each of the above initiatives has opportunities to act synergistically with DxD Hub's HHP Core and I&E Translation funding initiatives and represents a vote of confidence from funders. On behalf of DxD Hub's Oversight Committee, the Hub Evaluation Committee, the Hub Evaluation Committee (Digital Health) and the DxD Hub team, we would like to thank the National Research Foundation, PREPARE, and MTI for their far sighted and continued commitment to funding DxD Hub's important, and evolving, mission.

DxD Hub's Oversight Committee Co-Chairs



Mr John Jeans



Dr Fidah Alsagoff

Message from Acting CEO

Dear Friends of DxD Hub,

The end of FY 2023 officially marks the half-way mark of our four-year funding runway under RIE 2025. It also marks the approach of the 10th anniversary of our founding – an occasion we will celebrate this September.

These milestones are a good time to pause and reflect, and we're pleased to report that 10 years on, DxD Hub is more relevant than ever, and we continue to invest and deliver on our mission to support the development of products, companies and people.

Collaboration is the way we work at DxD Hub. We have initiated 26 new collaboration projects this year, of which this report highlights numerous examples of our work that put our collaborators at the center of what we do. DxD Hub also secured 6 commercial licences for technologies and products developed with our partners this year, confirming the continued value our partners see in working alongside us.

Digital Solutions are becoming a larger part of our portfolio mix and we're working on exciting new projects as well as progressing existing ones. Last year, for example, we reported on our breakthrough development of an Antenatal Clinical Decision Support System for pregnancy risk stratification. This year, with NRF support, we launched DHA, Singapore's Digital Health Accelerator, focused on Adoption and Scaling of new-to-market digital solutions.

Infectious Disease will always be a bedrock capability of DxD Hub. In FY 2023, we launched an important collaboration with Shimadzu to develop a point-of-care PCR test for Dengue and Chikungunya viruses. DxD Hub also actively contributes to the diagnostic Co-Op of the PREPARE initiative that will enable Singapore to develop and deploy a diagnostic test for future pandemics in less than 100 days.

I'd like to thank our Oversight Committee, Hub Evaluation Committee, our Collaborators and our Hubbers for everything they do. Here's to the next 10 years!

Sincerely,

Irene Cheong | Acting Chief Executive Officer



DxD Hub's Governing Committees

The **Oversight Committee** 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

Members



Prof Tan Size Wee

Assistant Chief Executive
BMRC, Senior Advisor
(I&E and National
Platforms), A*STAR



**Ms Amanda Ang
Tian Wei**

Director, Human Health
& Potential, National
Research Foundation



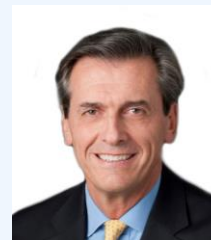
Prof Tan Say Beng

Executive Director,
National Medical
Research Council



Dr Clarice Chen

Director, Healthcare &
Biomedical, Enterprise
Singapore



Mr Jean-Luc Butel

(ex-officio) Chair, DxD
HEC



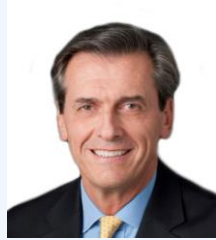
Ms Irene Cheong

Acting CEO, DxD Hub

DxD Hub's Governing Committees

The **Hub Evaluation Committee** 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).

Members



**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 Centre

Dream Team



Ms Chan Yang Sun
Assistant Vice-President,
Quality Assurance & Regulatory
Affairs

Ms Ho Yuan Lu
Vice-President,
Outreach & Training

Ms Irene Cheong
Acting Chief Executive Officer

Dr James Qu
Director, Clinical Lab

Mr David H Vu
Chief Operating Officer

Dr Weng Ruifen
Deputy Chief Executive Officer,
Chief Technology Officer

DxD Hub in FY23

Over the past year, DxD Hub has been leveraging our productisation capabilities in molecular, protein, point-of-care and digital health diagnostics to deliver on our commitments with precision and impact. We are thrilled to share our highlights and developments in FY23 in delivering these solutions through quality product design, operational excellence in execution, and successful collaborations with strategic partners.

One of our key success drivers has been our collaborative approach. By working closely with industry leaders, national programmes, healthcare providers, research institutions, and other public sector enablers we have been able to harness collective expertise and resources, leading to innovative solutions that improve health outcomes. These successful partnerships have further solidified our position as the leader in diagnostics design and development in Singapore and amplified our ability to create lasting health and economic impact beyond traditional metrics.



DxD Hub in 2023

- Co-organization of READI Workshop with PREPARE SG



- Kick-off of Digital Health Accelerator (DHA) Phase 1 Funding Initiative.



- Renewed commitment to accelerating ASEAN's access to quality diagnostics at the 84th ASEAN Committee on Science, Technology & Innovation (COSTI) Meetings.
- Launched PREPARE Diagnostics Co-op Commissioned Projects Awarded and Open Grant Call

- Establishing DxD Hub as strategic product development partner with PRECISE - MOU Signing
- Launched 2nd run of the Duke-NUS Core Executive Certificate Workshops



APR

MAY

JUN

JUL

SEP

OCT

NOV

DEC

JAN

FEB

MAR

- Signed MOU with Korea Health Industry Development Institute (KHIDI)
- Awarded RIE2025 Innovation & Enterprise Fellowship Programme (IFP) FI
- Successful execution of DxD Hub Duke-NUS CoRE Executive Certificate Workshop for Design Development (Feb), Verification and Validation (Mar), QMS and Manufacturing of IVDs and SaMD (Apr) with 60 attendees from the field of diagnostics and academia.



- Addition of new Protein Assay and Integrated Medtech lab space at Helios L3



- Raising awareness on Rapid Test Manufacturing through the Lateral Flow Assay (LFA) Workshop by DxD Hub and Global Life Sciences Solutions Singapore Pte Ltd [Cytiva]



- Creating collaboration opportunities in Arbovirus Diagnostics through ASEAN Pandemic Readiness Webinar – with PREPARE & APEIR



- Awarded the first 2 DHA projects– First 2 Projects Endorsed by Project Selection Committee (HEC-DH)



Building our Portfolio Mix



In FY2023, DxHub continued to emphasise on three thematic areas: **Precision Medicine, Women's Health, and Infectious Diseases**. These areas were identified as critical in meeting the rising demands of the future healthcare landscape and aligning with national health priorities.

Stage 1: Introductory Engagements

Discovering TRL Level, Commercial Partner & Fit to DxHub

132
Prospective Collaborations

Stage 2: High Potential Pipeline

Initial project scopes that align well with the high-level criteria for the product, commercial partner, and strategic fit to DxHub

83
High Potential Pipeline

Stage 3: Approved & Kicked-off Projects

21
Approved & Signed RCA

We strategically sourced and evaluated our pipeline based on criteria such as strategic fit, technical feasibility, and market potential. This process culminated in the curation of a portfolio comprising impactful projects with the potential to address pressing national health challenges and scale commercially.

In the following section of this report, we aim to showcase key projects executed in FY23.



Precision Medicine

The global Precision Medicine (PM) market reached USD 71.29 billion in 2022, with an expected compound annual growth rate (CAGR) of 10.7% from 2023 to 2030. Factors driving this growth include notable rise in conditions like cancer, chronic diseases, and rare diseases that drive demand for personalized healthcare solutions. The rise of targeted cancer therapies requiring companion diagnostics has further fueled this expansion. Technological advancements, particularly in genomics and molecular diagnostics such as Next Generation Sequencing (NGS), have revolutionised PM, offering deeper insights into patient profiles for tailored treatments.

With new insights made available through PM, patients may receive more accurate diagnoses, customised treatments and reduced health care costs. Such benefits to patients, healthcare providers and governments have prompted rising demands and are exemplified by initiatives like Singapore's HealthierSG program.

Despite Asia making up 60% of world's population, many Asian ancestries are underrepresented in large-scale genomic databases. This poses challenges for developing precise diagnostics and treatments tailored to Asians, such as misdiagnoses or missed opportunities for early interventions. In response, Singapore initiated the National Precision Medicine (NPM) programme, a whole-of-government approach, exploring the optimal deployment of PM to drive research insights, clinical innovation, economic growth and improved health outcomes for Singaporeans and the greater Asian populations.

In line with this development, DxD Hub has been keeping abreast by building state-of-the-art genomics and molecular diagnostics capabilities internally, while forging strategic partnerships with key players in the ecosystem.

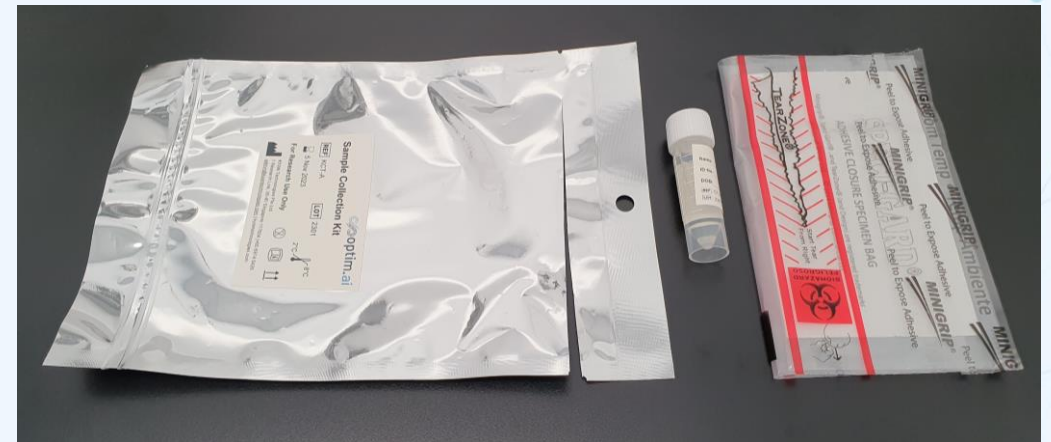
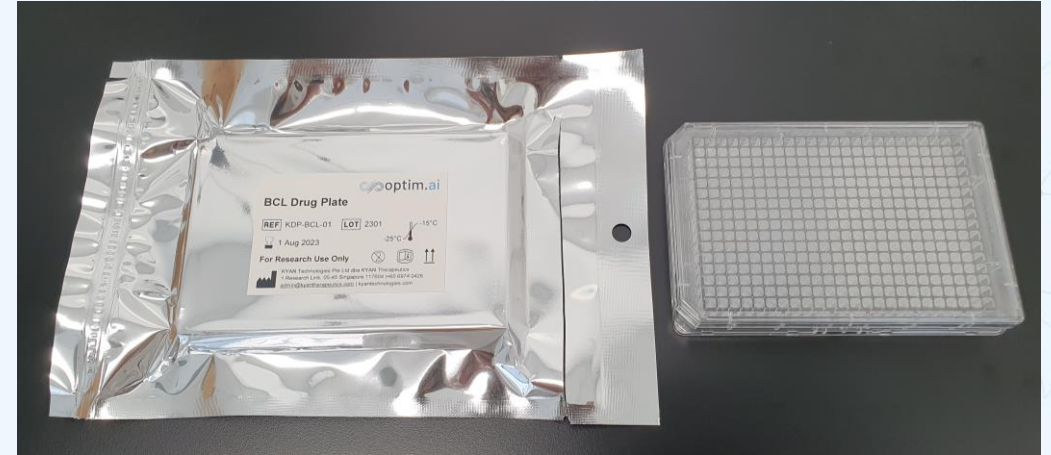
Kyan Clinical Workflow Development and Deployment

With approximately 20 million cancer cases globally¹, many patients face ineffective treatments, requiring multiple lines of therapy. For certain types of cancer, response rates drop significantly by the third line of treatment. Clinicians encounter significant challenge in identifying subsequent lines of treatment due to factors like evolving genetic mutational background, limited therapeutic options and drug resistance.

KYAN Technologies Pte Ltd (KYAN) has developed Optim.AI®, a functional precision medicine platform that uses experimental biology and computational analysis to identify the most effective drug combinations from the interrogated search space. DxD Hub and KYAN collaborated and jointly developed Product Manufacturing SOPs for proprietary plates containing drug combinations for ex vivo testing and tissue sample collection device as RUO kits, supporting KYAN's laboratory-developed Test (LDT) clinical workflow development in Singapore and the US. This approach facilitates the identification of individualised combination therapies, addressing the clinical need for personalized cancer treatment.

KYAN Technologies is a clinical-stage company transforming patient treatment and therapy development with its Optim.AI® platform. KYAN's platform is a phenotypic response system which is taking out the guesswork from combination therapy design. Its proprietary platform combines Small Data AI with Biological Experiments to analyze the functional response of drug-dose combinations across different biological models.

Optim.AI® is very efficient and provides best-in-class solutions to advance functional precision medicine for cancer patients and support research teams during their drug development efforts. KYAN is a venture-backed start-up and an academic spin off from technology developed from the National University of Singapore (NUS) and UCLA. KYAN has approval from Singapore's Ministry of Health for clinical services and has already been expanding its footprint across several other markets.



Women's Health

The diagnostics industry is increasingly focused on the unique healthcare needs of women. The market for women's health diagnostics is estimated at USD 17.8 billion in 2022, projected to grow at a compound annual growth rate (CAGR) of 7.3% from 2023 to 2030. This growth is propelled by increased focus on precision medicine, advancements in digital health solutions, emphasis on reproductive health and preventive screening.

Precision medicine techniques like advanced genetic testing, biomarker analysis, and molecular diagnostics, enable tailored treatments to individuals' genetic profiles, optimising efficacy and minimising adverse effects. This is especially advantageous in reproductive health, covering fertility testing, antenatal screening, and gynecological analysis. Advanced genetic testing allows for comprehensive carrier screening, aiding couples in family planning decisions. DxHub is a key player in enabling precision medicine with significant investments in this area.

The integration of digital health technologies, such as telemedicine, wearable devices, and AI-powered analytics, also improves the efficiency and accessibility of women's health diagnostics. Women are empowered to take charge of their health outcomes through personalised solutions offered by remote monitoring, predictive analytics, and health management platforms.

Furthermore, preventive screening is increasingly vital as chronic diseases become more prevalent in women. Advances in diagnostic modalities like molecular profiling, liquid biopsy, and targeted imaging such as digital mammography and 3D breast imaging significantly improve early detection rates and accuracy. These advancements prioritize patient comfort and convenience, encouraging routine screenings and timely interventions.

Acknowledging these trends and evolving healthcare needs, DxHub has been leveraging its expertise to deliver impactful solutions in women's health diagnostics.



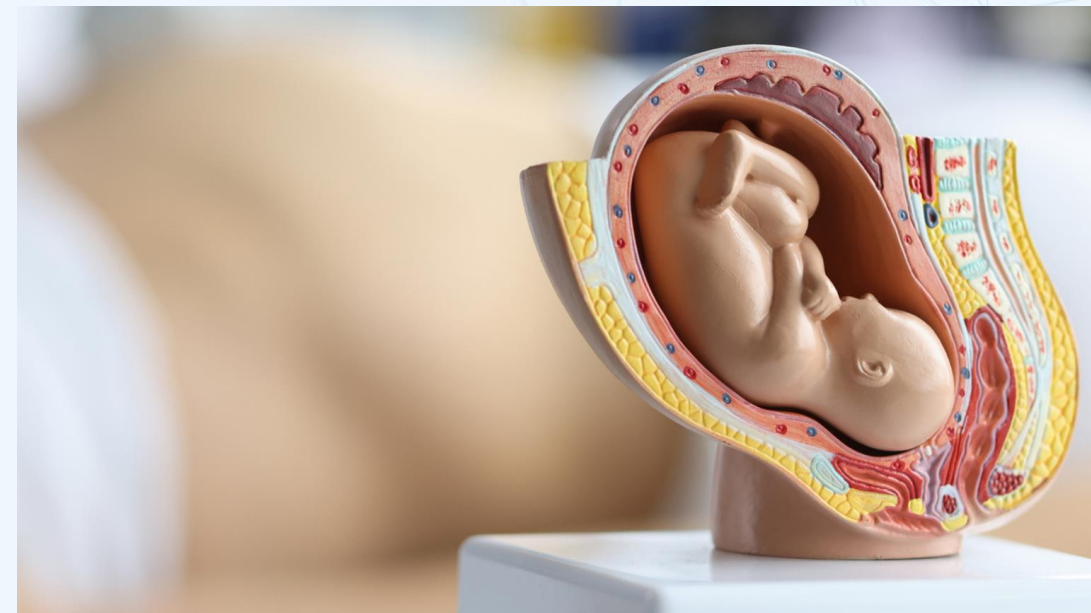
INEX NUH Antenatal AI CDSS for Pregnancy Risk Stratification

The Antenatal Clinical Decision Support System (CDSS), developed collaboratively by DxHub and Singapore's National University Hospital (NUH), aims to enhance patient outcomes and optimise healthcare resource utilization. This advanced AI system aids in the early detection of high-risk pregnancies, improving care for expectant mothers and resulting in favourable maternal, obstetric, and neonatal outcomes. Previous successful collaborations between DxHub and NUH have led to validated pregnancy risk prediction AI models, laying the foundation for this transformative project. Healthcare providers actively contributed to its development, demonstrating the demand for technology-driven solutions that enhance clinical decision-making and patient experiences during pregnancy.

Since the FY22 Annual Report update, the project has been progressing with a target to get the Antenatal CDSS HSA submission in Q1 2025, and the licensing discussions for the IPs generated for the Antenatal CDSS are ongoing. These project milestones enable the transition of the Antenatal CDSS from a conceptual framework to a tangible solution ready for real-world implementation, benefiting healthcare providers and patients alike.

Additionally, the data required for the clinical validation of the Antenatal CDSS is being collected through a prospective data collection study from Singapore. The ongoing prospective study at NUH aims to gather data from 6,500 pregnant women by the end of 2025, with 2,500 patient data points successfully collected. Furthermore, a 20 million patient retrospective dataset from the USA is being utilized to develop an AI model for the US market.

Additionally, ongoing discussions among INEX, Universidad de los Andes (UANDES), and DxHub involve developing a prototype CDSS system tailored for the Spanish market. This initiative extends the impact of the innovative technology to a broader international audience. The success of the Antenatal CDSS project underscores the importance of collaboration, technology integration, and user-centric design in improving healthcare outcomes and driving positive change in maternal and neonatal care.



INEX Innovate, Asia's leading healthcare technology company, specialises in Molecular Diagnostics tailored to address unmet needs in women's and fetal health. Founded as a spin-out from National University of Singapore (NUS), the company seeks to make advanced diagnostic technologies globally accessible, empowering women in their healthcare decisions, through strategic partnerships and exclusive licenses for Next Generation Sequencing Technology and Non-Invasive Prenatal Testing.



Infectious Diseases

The Infectious Disease Diagnostics Market is projected to reach USD 31.5 billion by 2028, growing at an 8.0% Compound Annual Growth Rate (CAGR) from USD 21.4 billion in 2023. The COVID-19 pandemic has accelerated focus on pandemic preparedness, leading to investments and innovations in diagnostic solutions, therapeutics, and preventive measures. Additionally, challenges posed by other infectious diseases in the region, dengue fever, malaria, tuberculosis, and emerging pathogens, underline the need for robust infectious disease management strategies.

One key trend shaping the market is the demand for rapid and accurate diagnostic solutions, driven by the advent of Point-Of-Care Testing Systems towards better enablement of decentralized cares.

Moreover, connectivity, data analytics, and integration capabilities are crucial for infectious disease management systems. They facilitate seamless results aggregation and trend analysis, empowering healthcare providers and policymakers with valuable insights for effective disease surveillance, outbreak monitoring, and intervention planning.

DxD Hub's established capabilities and co-development projects exemplify our dedication to innovating diagnostic solutions for infectious disease management. We actively contribute to regional and national platforms such as ASEAN Dxl and the PREPARE Diagnostics Co-Op, advancing infectious disease diagnostics and preparedness in the Southeast Asian and beyond. Our leadership and expertise in infectious disease diagnostics affirms our position as a trusted partner and leader in driving impactful solutions to improve healthcare outcomes amid evolving infectious disease challenges.

https://www.marketsandmarkets.com/Market-Reports/infectious-disease-diagnostics-market-116764589.html?gad_source=1&qclid=Cj0KCQjwIZixBhCoARIsAIC745DSTJC4JAoQcQRX_07QQ807M2_iIJPd1ChwtoDDX8sah2xVA9onWKcaAgvREALw_wcB

Shimadzu Direct Detection of Chikungunya and Dengue Pathogens from Blood

Vector-borne diseases like Chikungunya and Dengue are serious public health concerns worldwide. However, current diagnostic methods are often costly, require specialised equipment and trained personnel, and take too long for results, limiting access in smaller healthcare facilities and resource-limited areas.

To address this challenge, DxH Hub collaborated with Shimadzu (Asia Pacific) Pte Ltd (Shimadzu) to develop an accurate and sensitive RT-PCR multiplex assay for use with Shimadzu's point-of-care diagnostic device. The device, Shimadzu AutoAmp, employs real-time PCR technology with their proprietary direct PCR reagent, AmpDirect to detect Chikungunya and Dengue viruses through a fully automated workflow, delivering quick results. It's designed for non-specialized healthcare personnel, provides results rapidly, and aids in prompt clinical decisions and outbreak control measures.

This project aims to enhance disease management by enabling early detection, timely treatment, and effective outbreak containment. Its portable design extends diagnostic capabilities to resource-limited areas, while its versatility allows for the detection of various infectious diseases across diverse healthcare settings.

Shimadzu (Asia Pacific) Pte Ltd is a renowned leader in analytical instrumentation across the Asia Pacific region, boasting over 140 years of innovation and reliability. Their diverse range of cutting-edge products serves industries such as pharmaceuticals, healthcare, environmental sciences, food and beverages, and materials science. As a subsidiary of Shimadzu Corporation in Kyoto, Japan, they uphold a legacy of excellence, offering top-notch solutions, technical support, and training programs for customers. Shimadzu (Asia Pacific) is widely respected for its innovation, reliability, and technological advancements in analytical instrumentation.



In Vitro Diagnostics (IVD)

DxD Hub strategically invests in key capabilities in In Vitro Diagnostics (IVD), spanning molecular and protein diagnostics, next-generation sequencing (NGS), quantitative PCR (qPCR), lateral flow assays (LFA), enzyme-linked immunosorbent assays (ELISA), cytology, and lyophilisation. These empower us to develop and optimize diagnostic tests for detecting genetic aberrations, proteins, or antibodies associated with diseases.

Specifically, our investments in NGS and lyophilisation, are critical for the future of healthcare delivery and precision medicine. NGS enables high-throughput genetic sequencing, providing vital insights for personalized treatment strategies and targeted therapies. It advances precision medicine, enabling informed clinical decisions and improved patient care outcomes. Additionally, our expertise in lyophilisation ensures the stability. This is a key capability that supports and facilitates pilot manufacturing and enable point-of-care testing.



Nano-ChIPSeq RUO Kit for Epigenomic Profiling

Studying the epigenetic landscape in human diseases is instrumental in unlocking valuable insights that can significantly impact health outcomes. A collaborative effort between DxD Hub and the Genome Institute of Singapore (GIS) focused on developing and verifying Formalin-Fixed Paraffin-Embedded (FFPE) biological samples as a specimen type for inclusion into the Nano-ChIPSeq (Chromatin Immunoprecipitation-Sequencing) RUO tool kit for epigenomic profiling. This endeavor, coupled with an ISO 9001-certified Nano-ChIPSeq service workflow, aimed to revolutionize epigenomic research by enabling a wide range of applications for discovering, validating, and screening genome-wide histone modifications efficiently.

The core technology of this project revolves around a Nano-ChIPSeq strategy utilizing antibodies against different variants of histone proteins. Nano-ChIPSeq is a specialized application of ChIP-Seq that leverages NGS technology to achieve comprehensive and high-resolution analysis of protein-DNA interactions, making it a valuable tool in epigenomic research and precision medicine efforts. By expanding the sample type to include FFPE, researchers gained the ability to identify epigenetic biomarkers in a larger cohort of samples, facilitating a deeper understanding of the epigenomic landscapes associated with various human diseases. This advancement is pivotal in developing biomarkers for early disease diagnosis and drug discovery, with downstream applications extending to large-scale epigenomic profiling, for oncology research.

As a testament to the project's success, two technology disclosures have been licensed to the commercial partner Auristone Pte Ltd, a Epigenomic Medtech spin-off from GIS. Their service, Signomax™, offers a sample-to-report ChIP-Seq and RNA-Seq service, empowering clinical researchers in their epigenomic research endeavors and ultimately contributing to advancements in healthcare through enhanced understanding and targeted interventions based on epigenetic insights.



Auristone Pte Ltd, a spin-off from A*STAR's Genome Institute of Singapore (GIS), is a leading player in the realm of epigenomic research and innovation for clinical application. Leveraging its roots in GIS, Auristone is dedicated to harnessing the power of epigenomic insights to propel the field of precision medicine forward. The company's focus on developing cutting-edge diagnostics and therapeutic solutions underscores its commitment to prioritizing patient care. Through offerings like EPI-CALL™, Signomax™, and EPI-Tome™, Auristone actively engages with clinical partners to deliver transformative healthcare solutions that cater to the evolving needs of patients globally.

Seeding Capabilities in Nucleic Acid Quantitative Technologies (NuQuant) – Lyophilisation Manufacturing

NuQuant is a collaboration between GIS, BII, IMCB, BTI, SIMTech, NTU, NUH, and DxHub. NuQuant, an IAF-PP initiative, aims to enhance accessibility and cost-effectiveness of nucleic acid diagnostic solutions, making them viable for routine clinical practice and benefiting a wider population segment. This involves building automation, lyophilisation, enzyme engineering, and device prototyping platform capabilities to develop more cost-effective diagnostic products.

DxHub's pivotal role in this project includes developing lyophilised reagents for a diagnostic platform that enables room temperature setup, eliminating the need for cold storage. The project encompasses creating formulations and lyophilised bead for various assays like qRT-PCR. Additionally, a pilot facility for lyophilisation service will be established in DxHub to facilitate collaboration with SME or larger enterprise partners for initial development before scaling up, with potential for the manufacturing protocols to be licensed out and scaled by commercial partners.

The project's progress and outcomes are significant, as it ensures Singapore acquires core know-how in lyophilisation formulations, reducing reliance on overseas vendors and bolstering local manufacturing capabilities.

Collaboration with DxHub ensures the project meets local capability-building needs, improving time-to-market for locally developed solutions, fostering valuable IP creation, and positioning Singapore competitively on the global stage. These efforts will lead to new spinoffs, strengthen local companies, establish a robust local supply chain, and mitigate disruptions from large-scale market events like pandemics on local product development and deployment.

Collaborating organisations:



DxD Hub strategically allocates resources to establishing a specialised Digital Diagnostics team. This team is equipped with a comprehensive set of capabilities essential for productizing digital diagnostics software as medical devices. This expertise spans software development, regulatory compliance, data security, and privacy protocols, ensuring the development of robust and compliant digital diagnostic solutions. Additionally, the team is proficient in Artificial Intelligence technologies, facilitating the integration of advanced algorithms for data analysis, pattern recognition, and decision support.

Furthermore, DxD Hub's Digital Diagnostics team excels in UI/UX (User Interface/User Experience) design, creating intuitive interfaces that enhance the usability and adoption of digital diagnostic tools among healthcare professionals. Specializing in process re-engineering, solution architecture, and simulations, the team optimizes diagnostic workflows, seamlessly integrates with existing healthcare systems, and develops scalable digital diagnostic solutions. Overall, DxD Hub's investment in this multidisciplinary Digital Diagnostics team underscores its commitment to driving innovation in healthcare through cutting-edge digital solutions.

Digital Diagnostics (DDx)



CareCam AI-powered Digital Screening Tool For Fall Risks Assessment

Falls are a leading cause of injuries and disability-related deaths worldwide. Current clinical practices often neglect routine fall risk assessments until after a patient experiences their first fall, missing critical opportunities for prevention. Gait changes are often too subtle to be detected through clinical observation alone, while lab-based gait analysis is space-consuming, time-consuming, and costly. To address this gap, DxHub has collaborated with CareCam to develop a mobile app-based system that can identify individuals at higher risk of falls within a regular clinical setting.

This innovative solution leverages AI and background technologies developed in partnership with the Institute for Infocomm Research (I²R). Using simple video recordings from iOS mobile devices, the system quantifies 2D and 3D measurements of key body points to assess gait and detect clinically significant biomarkers like hip and knee flexion, stride length, and velocity. DxHub's capabilities in ISO 13485 QMS implementation, application server development (front-end for clinicians' dashboard, back-end system for user & data management), cybersecurity assessment, regulatory support, and project management play a crucial role in supporting this project's development and regulatory compliance.

The AI-powered digital screening tool is envisioned in two phases: Gen 1 as a triaging tool for identifying fall risk during routine health visits and Gen 2 with kinematic trackers to assess gait disorders and guide treatment plans. This initiative also aligns with DxHub's RIE2025 focus on precision medicine, aiming to enable early detection of fall risks in the elderly, reduce hospital utilization due to falls, and alleviate the socio-economic burden on caregivers. The project's strategic alignment with DxHub's digital diagnostics strategy and potential adoption by public health institutions through the Digital Health Accelerator highlights its significance in addressing critical healthcare challenges and advancing patient care.

CareCam revolutionizes patient care through innovative digital solutions. By leveraging advanced AI and computer vision technologies, CareCam develops cutting-edge tools to address critical healthcare challenges, such as fall risk assessment and gait analysis. Their mobile app-based systems empower healthcare professionals with efficient and accurate screening tools, enabling early detection of health risks and guiding personalized treatment plans. Through strategic collaborations and a commitment to technological excellence, CareCam is at the forefront of transforming healthcare delivery and improving patient outcomes.





De-centralised Care

DxD Hub invests in de-centralised care to improve healthcare accessibility, efficiency, and quality, aligning with our strategic focus. Notably, significant resources are directed towards Point-of-Care Testing (POCT) capabilities like lateral flow assays, enabling swift diagnostic testing near patients. Leveraging digital technologies, automation, workflow optimization, and process re-engineering, DxD Hub supports healthcare providers in delivering timely and effective care across diverse settings.

POCT is foundational in decentralised care, complementing preventive care initiatives like HealthierSG. It encourages proactive health management and early intervention through self-administered testing. Moreover, POCT extends care through e-health services, reducing clinic visits and travel burdens, particularly for remote areas. This shift streamlines diagnostics, enhances personalized care delivery, and ultimately improves preventive care, health management, and patient outcomes. DxD Hub's investments in IVD automation supports decentralised care by increasing accessibility, efficiency, and accuracy in diagnostic testing beyond traditional laboratory settings. Automated IVD systems expedite processes, reduce reliance on centralized laboratories, streamline workflows, and contribute to faster diagnoses, aligning with DxD Hub's overarching goal of advancing healthcare accessibility and quality.

Capability Building for Quantitative Electrochemical POCT Platform

DxD Hub has strategically invested in expanding its core capabilities in quantitative electrochemical Point-Of-Care Testing (POCT) and establishing in-house pilot manufacturing capabilities that adhere to industrial standards. The quantitative electrochemical POCT platform is crucial for various applications, offering precise and multiplex measurements essential for precision medicine. Similar technologies are used in devices for both self-administered and professional applications, such as continuous glucose monitoring (CGM) systems and Abbott's hand-held blood analyser (I-STAT).

To achieve this, DxD Hub works with partners to develop comprehensive manufacturing protocols and creates dossiers for the bio-functionalization and assembly of electrode strips from raw materials. Additionally, DxD Hub will establish critical-to-quality evaluation criteria for these electrodes and develop a reader plug-and-play platform, which can be adopted to new assays rapidly.. This expertise will significantly reduce the commercialization risks associated with design and development. It will also offer small-quantity contract manufacturing services and process optimization compatible with downstream scaled manufacturing. These capabilities will enable new assays to be commercialized within Singapore's local ecosystem, supporting both self-administered and professional POCT formats.

The anticipated outcomes of this initiative include expanding DxD Hub's core technological capabilities for the quantitative electrochemical POCT platform. This development could foster new partnerships and accelerate the commercialization of quantitative assays, enhancing Singapore's diagnostic ecosystem. Additionally, establishing an in-house pilot manufacturing capability compatible with scaled industrial processes will synergize with DxD Hub's lyophilisation capabilities. This integrated approach provides a complete end-to-end solution for electrochemical sensors and other biosensor products at a single site, streamlining processes and ensuring efficient product development.

Development of Multi-Respiratory Pathogen Lateral Flow Assay with MP Biomedicals

This collaboration brings together DxD Hub and MP Biomedicals Asia Pacific Pte Ltd (MP Bio) to address the pressing need for rapid and efficient diagnostic tools for respiratory illnesses. The primary objective is to develop a self-administering multiplex rapid lateral flow test capable of detecting four prevalent respiratory pathogens: influenza A, influenza B, respiratory syncytial virus (RSV), and SARS-CoV-2. By focusing on these pathogens, the project aims to facilitate early detection and timely intervention, which are crucial for preventing widespread outbreaks and improving clinical outcomes.

The innovative lateral flow test will empower individuals to conduct self-assessments, enabling quicker responses to potential outbreaks. Early identification of these pathogens can lead to better allocation of medical resources, and overall enhanced public health safety. This initiative is particularly significant in the context of ongoing and future pandemics, as it supports the need for robust diagnostic infrastructure. Moreover, this project aligns with Singapore's national healthcare transformation initiatives, such as HealthierSG. By promoting decentralized care and the use of e-health services, the project contributes to a more resilient and sustainable healthcare system. The ability to conduct tests outside traditional healthcare settings supports the vision of a more connected and proactive healthcare approach, enhancing the nation's preparedness for future health crises.

The partnership capitalizes on the unique strengths of each collaborator. MP Biomedicals brings its advanced manufacturing capabilities to the table, ensuring that the test kits can be produced locally at scale, which is crucial for rapid deployment during health emergencies. DxD Hub, facilitates end-to-end product development.

In collaboration with DxD Hub, MP Biomedicals has played a pivotal role in several impactful projects, showcasing their expertise in contract development and manufacturing. Notably, they served as the CDMO for a Pancreatic ductal adenocarcinoma (PDAC) kit, demonstrating their proficiency in developing specialized diagnostic solutions. Additionally, MP Bio was a co-development partner and licensee for the ASSURE SARS Cov-2 IgG/IgM Test, highlighting their contributions to combating the COVID-19 pandemic through rapid and accurate diagnostic tools. Furthermore, their role as the manufacturer for the GenScript cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit underscores their commitment to supporting efforts in infectious disease management and immunology research.

Quality & Regulatory Assurance

DxD Hub key capability in Quality & Regulatory Assurance supports our collaborators through, product design and development documentation, product validation requirements, and the establishment of Quality Management Systems (QMS).

Our commitment to quality is demonstrated by our maintenance of ISO certifications. We recently achieved re-certification of ISO 13485:2016, which encompasses the design and development of In Vitro Diagnostic (IVD) and Software as a Medical Device (SaMD) products, as well as contract manufacturing for IVDs. This certification validates our ability to support and facilitate productisation, ensuring that all processes and outputs align with international quality and safety standards.

Beyond operational expertise, DxD Hub is actively involved in thought leadership within the medical device field. We serve as trainers in the Duke-NUS Core EC Workshop, where we educate participants on the total product life cycle of medical devices. Additionally, we are members of the Technical Committee on Medical Devices and Quality Management Systems of the Biomedical and Health Standards Committee under the Singapore Standards Council. These roles enable us to influence industry best practices and stay updated on the latest advancements and regulatory requirements in the medical device sector.



Platforms & Initiatives

Beyond our core competencies in diagnostic productisation, DxD Hub has established various platforms and initiatives that form the foundation of our expanding ecosystem. These platforms are dedicated to clinical testing, promoting and scaling digital health solutions, nationwide and regional outreach, and talent development. Together, these efforts enable DxD Hub to operate comprehensively, supporting companies and driving healthcare innovation. By fostering networks for sharing knowledge and expertise across borders, DxD Hub not only enhances healthcare standards but also collective preparedness against emerging health threats. This positions DxD Hub as a key player in shaping the future of healthcare in the region.





Digital Health Accelerator (DHA) operates with a downstream emphasis on fostering the Adoption and Scaling of Digital Health solutions, aiding collaborators and innovators in navigating the challenging journey through two critical phases in MedTech innovation:

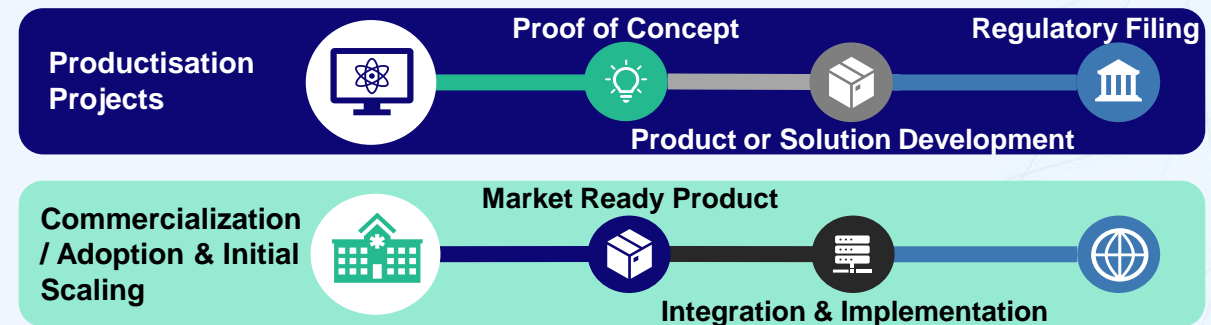
- Facilitating the transition from proof-of-concept (POC) to a market-ready product, which includes addressing crucial aspects such as the acquisition of curated data for model development and potential regulatory approval processes.
- Supporting clinical implementation of the solution to demonstrate real-world evidence that will result in a reference customer and quantified outcomes.

DHA leverages on collaborative efforts with key stakeholders in the healthcare ecosystem, such as A*STAR/DxD Hub, SingHealth, NHG, NUHS, and Synapxe, to foster the development, integration, and implementation of digital health solutions across care delivery organizations.

DHA works closely with Public Healthcare Institutions (PHIs) to curate solutions ready for adoption following key steps:

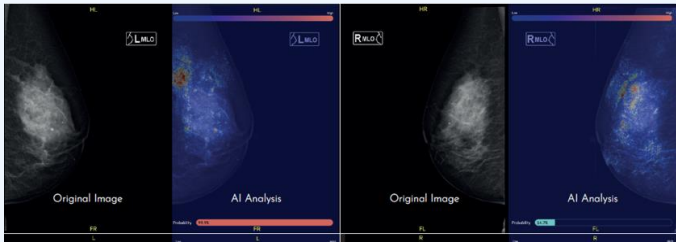
- 1. Needs Identification and Prioritization:** Clinical and operational needs are sourced from PHIs and gathered through established initiatives and agencies such as NHIC and MHI. These needs are then prioritized based on factors including clinical significance, global market potential, common hospital requirements, and alignment with Synapxe standards.
- 2. Pipeline Development:** Projects are sourced from publicly funded initiatives and companies (including SMEs and startups) with potential for regional or global deployment. Various criteria, such as technology readiness level, regulatory clearance, and business leadership, inform the prioritization process within the DHA project pipeline.
- 3. Assessment:** Prior to implementation, all projects undergo rigorous evaluation by the Hub Evaluation Committee – Digital Health (HEC-DH), comprising experts from PHIs, Synapxe, and technical/market domains. Evaluation criteria encompass product viability, technical implementation, commercial feasibility, and strategic alignment with DHA objectives

Identified innovations under DHA would typically progress through two main stages:



FxMammo by FathomX

Supported by:



DHA played an integral role in implementing the FxMammo solution at NUH and TTSH hospitals, through both productisation and commercialization. Developed by NUS spin-off FathomX, FxMammo utilizes AI to enhance breast cancer screening accuracy from digital mammography images through automated analysis. This innovative solution is expected to improve predictive accuracy and productivity by automating image reading and reporting processes.

AiTriage by TIIM Healthcare

Supported by:



AiTriage is an AI-driven chest pain triaging SaMD (Software as a Medical Device) developed to aid ED and primary care physicians to quickly analyse and stratify chest pain presentations into low, medium, or high-risk categories for a Major Adverse Cardiac Event (MACE). This solution aims to reduce diagnostic uncertainty and dependence on biomarker testing, which can reduce turnaround time for chest pain triaging, ED resource utilisation, and hospital admissions.

DHA's Role in FxMammo & AiTriage

Productisation Stage

- Quality Management System (QMS) Compliance
- ISO13485 Certification
- Software Design Control documentation
- Clinical Validation with Radiologists
- HSA Regulatory Submission
- Commercial Strategy Consultancy

Adoption & Initial Scaling Stage

- Validate clinical needs and solutions
- Re-engineer processes
- Facilitate implementation and integration
- Scale commercially
- Workflow integration
- Secure initial adoption by stakeholders (e.g. NUH, TTSH, SingHealth)

Through such collaborations, DHA is committed to supporting innovators in adopting and scaling digital health technologies, while mitigating implementation risks for early adopters in healthcare clusters.

DxD Hub ClinLab supports the entry of new diagnostics tests into the market by providing an accredited clinical laboratory that can offer tests that have not yet been adopted by commercial laboratories.

Our onboarding process thrives on collaborative communication and teamwork. We meticulously evaluate products to gauge market needs and potential healthcare benefits. Upon successful assessment, we initiate steps to integrate the test into our platform. Tech-transfer ensues post-agreement, followed by rigorous evaluation tests to validate performance. The resultant report instills confidence in the local Singapore population and commercial laboratories regarding the test's efficacy and commercial viability.

DxD Hub ClinLab offers validation and deployment services to collaborators. While we do not directly interact with patients, our role is pivotal in ensuring the reliability and effectiveness of diagnostic tests. In addition to deployment services, we extend support for clinical validation of assays under development. This includes designing validation plans, executing procedures, and providing milestone reviews, bolstering the robustness of diagnostic innovations.

In FY2023, we conducted method and clinical validation for X-ZELL, a groundbreaking blood-based circulating tumor cell isolation and identification test. Leveraging our HCSA license and CAP accreditation, along with skilled operators, we conducted experiments and generated reports, demonstrating our commitment to advancing diagnostic capabilities. Beyond our core functions, DxD Hub ClinLab offers its services for projects encompassing clinical research or national/ASEAN surveillance procedures. Notably, our involvement in sero-surveillance projects enabled the evaluation of S and N protein antibodies, as well as COVID neutralizing antibodies using the cPass test, across populations in Singapore and Thailand. This underscores our versatility and dedication to addressing emerging healthcare challenges.



Nation-wide Pandemic Effort

DxD Hub is actively supporting the Programme for Research in Epidemic Preparedness and REsponse (PREPARE) by curating, facilitating, and executing projects and building platforms with end-to-end capabilities to develop and deploy diagnostic solutions within 100 days of the onset of the next pandemic. The PREPARE initiative seeks to address bottlenecks encountered during the COVID-19 pandemic by focusing on three key areas: strengthening linkages across the diagnostics development pathway, from research prototypes to products, to ensure an expeditious response to an expanded range of pathogens of interest; accelerating the delivery of regulatory-approved diagnostics with sufficient production capacity; and ensuring supply chain readiness to expedite deployment for national testing. These efforts aim to create a more robust and agile response framework for future pandemics.

To address these challenges, DxD Hub has initiated commissioned projects intended to build product master plans for diagnostics that address critical use cases during a pandemic. These include the development of Automated End-To-End Systems, which streamline the entire diagnostic process from sample collection to result interpretation, thus enhancing efficiency and accuracy. Additionally, the projects focus on creating POCT Platforms that allow for rapid, decentralized testing, which is crucial for early detection and management of infectious diseases. Another key area is the development of Immune Profiling Research Tools, essential for understanding immune responses to new pathogens and informing vaccine and therapeutic development. By focusing on these critical use cases, DxD Hub is building robust capabilities that will ensure rapid and effective responses to future pandemics, ultimately enhancing Singapore's epidemic preparedness and response framework.

Outreach & Regional Efforts

ASEAN DxI is dedicated to advancing diagnostics capacity within ASEAN through two primary focus areas.

- To bolster diagnostics capacity, ensuring accurate and efficient diagnoses of various health conditions. This entails enhancing capabilities and essential infrastructure across healthcare facilities by deploying state-of-the-art technologies, nurturing skilled professionals, and promoting widespread access to diagnostic services.
- Establish a robust network of shared knowledge, expertise, and resources. Through fostering collaboration among ASEAN Member States (AMS), we facilitate cooperative projects and initiatives, thereby promoting regional well-being through collective effort and innovation. This collaborative approach enhances healthcare outcomes against prevalent diseases and fortifies the region's resilience against future outbreaks.

PREPARE-READI Workshop (15-19 May)

The workshop series, a component of the PREPARE program sponsored by the Temasek Foundation, featured four thematic workshops. Organized jointly by PREPARE Diagnostics Co-op (DxD Hub) and the ASEAN Diagnostics Initiative, it focused on "Peacetime Research on Biological and Physical Detection Technologies for Surveillance and Diagnostics."

The workshops aimed to establish a robust network of scientists and institutes across ASEAN committed to conducting research aimed at preparing for Disease X. Moreover, the workshops sought to develop a comprehensive portfolio of domains and projects of interest, fostering regional research collaboration.

The program included presentations by esteemed speakers from Singaporean institutions and ASEAN research teams, followed by discussions on key topics. Additionally, participants could embark on site visits to prominent Singaporean institutions such as DxD Hub, EHI, SCELSE, GIS, SigN, and NCID/MOH.

This workshop promoted collaboration, knowledge exchange, and research in the critical areas of surveillance and diagnostics. By fostering regional cooperation, it enhanced preparedness for emerging infectious diseases within ASEAN and beyond.



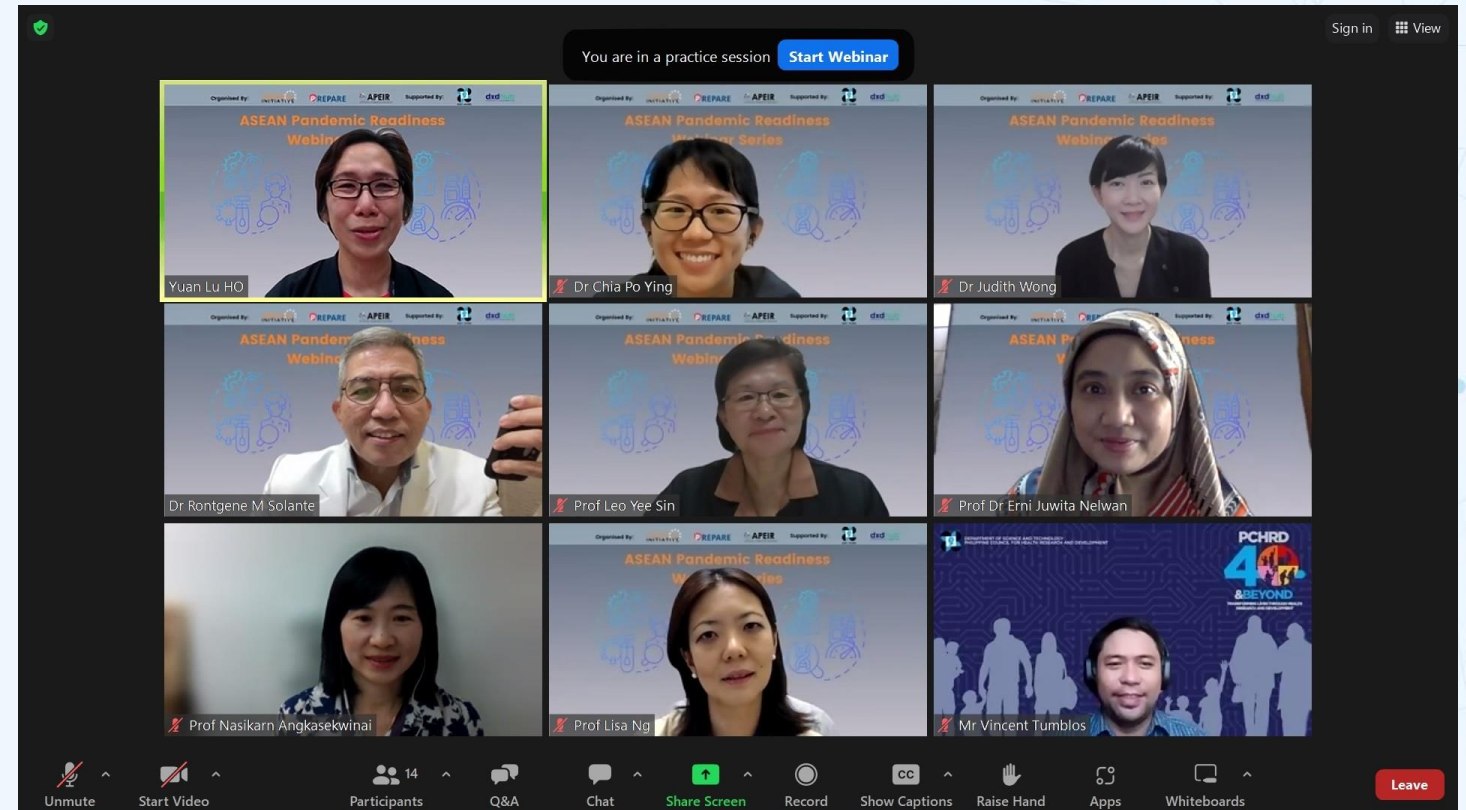
Outreach & Regional Efforts

ASEAN Pandemic Readiness Webinar Series

The webinar series fosters the exchange of best practices on emerging infectious diseases and pandemic preparedness, fostering collaborative ideas within the region and synergistic efforts to combat health challenges. It also aims to expand and fortify networks within the region, specifically on diagnostics development. Through these multifaceted initiatives, the series contributes significantly to regional healthcare.

The webinar, *The Emerging Threat of Arboviruses: What can ASEAN do to prepare for this epidemic?*, brings together field experts who will share their insights into these challenges. Arbovirus infections such as Dengue, Chikungunya and Zika viruses continue to challenge public health globally. Recognizing the gravity of this, the World Health Organization (WHO) launched the Global Arbovirus Initiative in 2022 to raise awareness and convene partners to strengthen coordination, communication, capacity-building, research, preparedness, and response to mitigate the growing risk of epidemics.

Epidemics caused by arboviruses are focal points in ASEAN regional pandemic preparedness. Through discussions, the webinar seeks to stimulate regional collaborations to address the impact of arbovirus infections in the ASEAN community.



Talent Development

The DxH Hub IFP is a talent development initiative funded by NRF aimed at training and enlarging/enhance the pool of deep-tech professionals who can take on diagnostics and medical devices translation, productisation and commercialisation activities in Singapore.

This programme provides fellows with structured learning and on-the-job training on DxH Hub's product development and productisation capabilities, which closely aligns with the requirements in ISO13485 and FDA's Total Product Life Cycle framework. Upon completion of the programme, fellows will be equipped with the necessary skills to take on relevant roles in the DxH Hub, A*STAR or the private sector.

Can you describe your overall experience in the Innovation and Enterprise Fellowship Programme at DxH Hub?

“My overall experience with the I&E Fellowship Programme in DxH Hub has been a challenging but memorable one. The programme has given me a chance to observe the stringent business framework and processes in managing a successful productisation engine for the Singapore MedTech ecosystem.”

Mr Oscar Huang
Project Management Associate, Partnerships

“My experience in the Innovation and Enterprise Fellowship Programme at DxH Hub has been incredibly enriching, thanks to the supportive community and the collaborative learning environment with fellow IFP participants. The O&T team has provided numerous learning opportunities, and my colleagues' willingness to share their knowledge has greatly accelerated my growth. The freedom to choose what I want to learn has made the experience even more engaging and beneficial.”

Ms Kellie Chin
Junior Engineer, Digital Diagnostics

““The Innovation and Enterprise Fellowship Programme at DxH Hub has provided me with an enriching experience, offering invaluable opportunities for growth and professional development.”

Ms Toh Yu Lin
Associate, Quality Assurance and Regulatory Affairs

What has been the most rewarding aspect of your experience in the fellowship so far?

“One of the most rewarding experiences as an PMO Associate in this programme is the unique opportunity to learn & work with colleagues of different areas of expertise. From technical to non-technical, I thoroughly enjoyed learning about the Total Product Life Cycle, various professional principles and applying them to create software solutions for the business’s growth.”

Mr Oscar Huang
Project Management Associate, Partnerships

“The most rewarding part of the fellowship has been applying what I've learned to solve real-world problems. For example, while developing AI models, I picked up on using metrics common in the medical field. This not only helped me communicate the model's performance more effectively to doctors but also made the tool itself more valuable and practical.”

Ms Kellie Chin
Junior Engineer, Digital Diagnostics

“The most rewarding aspect of my fellowship experience thus far has been the opportunity to collaborate with individuals from different backgrounds, cultivating personal and professional growth.”

Ms Toh Yu Lin
Associate, Quality Assurance and Regulatory Affairs

How has the on-the-job training during your time here, contributed to your professional growth?

“The on-the-job training has significantly boosted my understanding of the MedTech industry and improved my technical skills in data science. Exposure to various types of data and solving different problems has strengthened my problem-solving and communication skills, making me more confident in my work overall.”

Ms Kellie Chin
Junior Engineer, Digital Diagnostics

“The on-the-job training has significantly contributed to my professional growth by providing hands-on experience. As a QA associate, I am required to be involved in various aspects of QMS, such as reviewing SOPs and providing support in the implementation of QMS for startups, which I have been able to do here in DxD Hub.”

Ms Toh Yu Lin
Associate, Quality Assurance and Regulatory Affairs

How has the fellowship prepared you for your future career goals?

“Amongst many things, the role has given me a clearer idea of what specialization I enjoy in the industry. The programme has given me the inspiration to continue pursuing my knowledge in project management and business analytics.”

Mr Oscar Huang
Project Management Associate, Partnerships

“The fellowship has prepared me for my future career goals by equipping me with practical skills, industry knowledge, and a professional network that will be invaluable as I pursue my aspirations.”

Ms Toh Yu Lin
Associate, Quality Assurance and Regulatory Affairs

Feedback from Reporting Officers

“Recruiting Yu Lin as IFP has been a win-win situation for QARA; it gave us the opportunity to train and mentor a fresh grad ready for QA role and benefit from fruits of our labour. QA has faced manpower challenge of providing QA support for our collaborator; Yu Lin fills this role which gave her the OJT experience so that she will continue to grow in her competency as a QA support in Digital Health product development.”

Ms Chan Yang Sun
AVP, QARA

“Having Kellie on the team has provided opportunities for seniors to mentor her while also receiving positive challenges. Before Kellie joined the team, we faced significant challenges in data processing and cleaning. Her data science expertise effectively addressed these gaps, leading to smoother operations within the data science group. In our various projects, Kellie has developed and trained machine learning models which significantly advanced our capabilities in this area. She also played a crucial role in creating semantic segmentation models alongside other data scientists. Her proactive problem-solving skills and innovative approaches has helped us overcome several technical hurdles, improving overall team productivity.

Overall, this program not only benefitted recipients by providing exposure to SaMD development, but also hones the team’s mentoring skills, ensuring a resource-ready approach for projects.”

Mr Lijoy George
AVP, Digital Diagnostics

Diagnostics Development Hub

10 Biopolis Road, 03-01, Chromos, 138670

enquiry@dxdhub.sg

www.a-star.edu.sg/dxdhub