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FY2021 Annual Report

Diagnostics for Our Future

07 June 2022

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Diagnosics for Our Future

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Table of Contents

Co-Chairs' Foreword	4
CEO's Letter	6
Introduction	7
Bridging to DxD Hub 2.0	12
Diagnostics Solutions, Our Innovations	13
Highlighted Diagnostics Solutions	18
Regional and International Efforts to Advocate Diagnostics	27
Building Local Talent Pool, Talent Development	29
Recognition, Our Accolades	31
DxD Hub 2.0: Strengthen, Expand, Build	34
Partnership Models	37
Strategic Projects and Partnerships	39
Contact Information	45



Co-Chairs' Foreword

The completion of fiscal year 2021 marks the end of Diagnostics Development Hub's (DxD Hub) Bridging Fund, a 2-year period of transition funding into Research, Innovation and Enterprise 2025 (RIE2025).

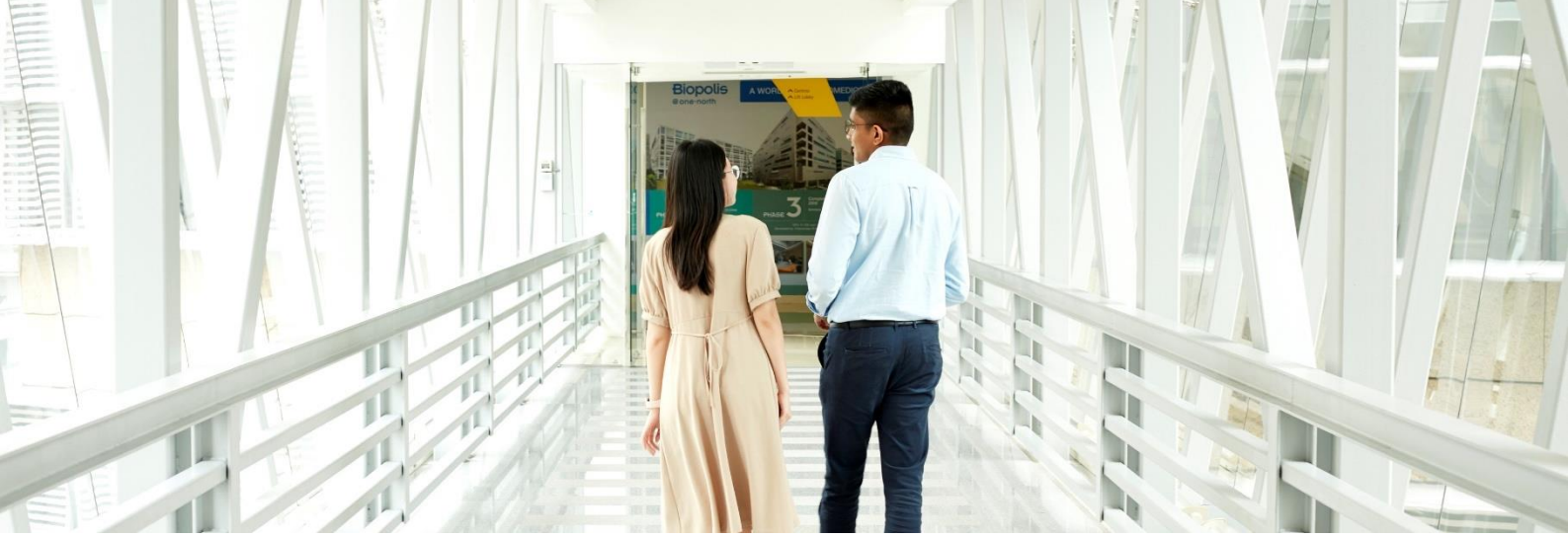
This year's report covers the Hub's progress in the second half of the transition, but we feel it is also worth looking at the totality of the transition period. Indeed, FY2020 to FY2021 marked a period of transformation well beyond what anyone could have anticipated when the Bridging Fund was approved.

If 2020 was about rising to the COVID-19 challenge by creating new solutions, 2021 could accurately be described as a year of scaling and adoption to seed the development of a robust Business Engine in the next phase of DxD Hub's development.

Examples of success abound in this report:

- ❑ A continued focus to incentivise adoption of COVID-19 testing solutions with end-to-end innovations such as deep throat saliva testing, improved automation, and AI enabled batch-reading
- ❑ DxD Hub's Clinical Laboratory (ClinLab), an accredited clinical laboratory that was instrumental in catalysing the adoption of the cPass™ neutralising antibody test for COVID-19, which is now offered by multiple commercial labs in Singapore
- ❑ In Digital Diagnostics, an area of intense investment by DxD Hub, the team led the formation of a 17-member consortium and was selected by the Ministry of Health (MOH) to lead its Digital Health Accelerator (DHA) and is working to launch a Proof-of-Concept program focused on adoption of digital solutions.

(Continued...)



At the time of writing, DxD Hub has secured National Research Foundation (NRF) funding for the next four years, seeing it through RIE2025. We expect with its expanded capabilities and funding that DxD Hub will continue its significant contributions to Singapore’s MedTech ambitions. We are grateful to the NRF for its continued support of DxD Hub and its exceptional team.

Finally, in a symbolic but meaningful gesture, DxD Hub launched its new tagline this year: “Diagnostics for Our Future”. It is a fitting end to this second chapter for DxD Hub and a new start for its future.

DxD Hub's Oversight Committee Co-chairs



Dr Fidah Alsagoff



Mr John David Jeans

CEO's Letter

Dear Oversight Committee Co-Chairs, Members, Colleagues and Friends,

When we started DxD Hub in 2014, we began with a simple idea: drive the adoption of diagnostics intellectual property by bridging the gap in productisation. We believed that if we could develop a set of capabilities in diagnostics product development, we would accelerate the pathway to achieving ready-to-register products with effective go-to-market strategies. This in turn would have a catalytic effect on the local diagnostics ecosystem.

The result is what we now call the DxD Hub Productisation Engine. A set of people, processes, and infrastructure that allow us to systemically evaluate, productise and launch diagnostics products. Equally important is our network of relationships across the region, public and private sectors, that make our engine sustainable. This Productisation Engine was put to the test in 2020, allowing DxD Hub and our collaborators to bring important COVID-19 assays to the market.

As part of our work, we learned that driving the adoption of transformative products and services at scale would require changes to clinical practice and established workflows. This is true regardless of the technology, be it IVD, device, or digital. This know-how is our Business Engine.

The results described in the enclosed report represent what we are capable of with these two engines – combined with our collaborators, our A*STAR hosts and your support – working in concert. With this, we look forward to another four years of service to Singapore's MedTech vision.

Sincerely,
Dr Sidney Yee
Founding Chief Executive Officer
Diagnostics Development Hub



Introduction

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The Diagnostics Development Hub (DxD Hub) is a national platform funded by the National Research Foundation (NRF) under its Innovation & Enterprise Cluster Fund (IECF) from 2014 to 2021. This period included the first phase funding of DxD Hub (or DxD Hub 1.0), and a Bridging Fund to transition DxD Hub into its second phase (or DxD Hub 2.0) (Figure 1).

In DxD Hub 1.0, DxD Hub demonstrated its capabilities in the co-development of diagnostics products with both local and international enterprises by bridging the gap in productisation expertise in Singapore.

The Bridging Fund has allowed DxD Hub to continue to both deliver and expand – delivering products to bolster testing capacity for Singapore in the uncertain climate of COVID-19 and expanding its capacity and capabilities to remain contemporary in the post-COVID-19 future.

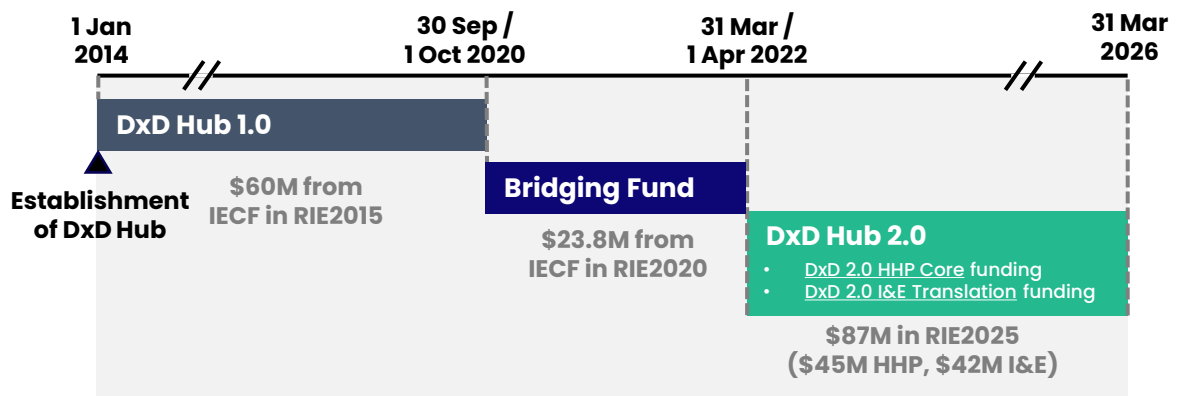


Figure 1: Timeline illustrating the various funding phases of DxD Hub

Deliver

This is the third fiscal year in which DxD Hub has played a pivotal role in Singapore’s COVID-19 response. During this time, DxD Hub worked with public sector partners to rapidly develop a suite of diagnostics products and services for Singapore to respond to this unprecedented crisis.

In FY2021, DxD Hub continued to focus on refining its existing repertoire of COVID-19 directed testing strategies. The DxD Hub Team (i) launched complementary innovations, such as deep throat saliva testing, improved automation, artificial intelligence (AI) error-proofing; (ii) introduced new test platforms (e.g. LAMP) and test iterations; and (iii) assisted public sector agencies to plan for testing capacity of various key use cases.

DxD Hub delivered Health Science Authority (HSA) approved diagnostic Software as a Medical Device (SaMD) with the launch and deployment of INSPECTA. Co-developed by DxD Hub and I²R, INSPECTA uses a Machine Learning algorithm developed by DxD Hub data scientists to reduce the time required to interpret quantitative polymerase chain reaction (qPCR) results in high-volume laboratory workflows.

In addition, work has resumed on the pre-pandemic portfolio of projects. One such product is Lucence's UNITED™ (Tissue500™), a pan-cancer assay to enable Asian-centric molecular characterisation of tumours based on next-generation sequencing technology. Another product is TIIM Healthcare's aiTriage™, a machine learning based diagnostics solution, which accelerates the triage process of chest pain patients.

Throughout the development process, DxD Hub teams have forged tight and efficient working relationships, becoming trusted partners throughout Singapore and internationally. For example, DxD Hub worked closely with the Ministry of Health (MOH) to evaluate protein and nucleic acid-based COVID-19 detection assays for the national COVID-19 effort. Leveraging DxD Hub's quality and productisation expertise, a standardised measurement methodology was developed to support MOH where 38 products were evaluated, leading to the successful commercial launch of 8 products.

With significant growth in terms of the products developed and talents recruited, DxD Hub is determined to become a regional key opinion leader (KOL) for diagnostics in RIE2025. The ASEAN Diagnostics Initiative (ASEAN DxI), co-founded by DxD Hub, has been an important platform in this regard. In FY2021, DxD Hub led a series of ASEAN Dx Pandemic Preparedness webinars to generate awareness about diagnostics technologies and trends in the fight against the COVID-19 crisis. This includes direct PCR, genomic surveillance of variants of concerns and surrogate viral neutralisation tests on population immunity from COVID-19 vaccines. The 4 webinars were attended by a combined total of over 2600 attendees from the ASEAN region and beyond.

DxD Hub recognises the importance of nurturing talents in Singapore to build a robust and competitive knowledge-based economy as emphasised in RIE2025. An apprenticeship programme was launched to groom the new generation of talents in the diagnostics productisation field. Over the Bridging Tranche, 25 interns and 16 apprentices were trained in various aspects of the medical device industry. Graduates of the apprenticeship programme are “industry-ready” and have filled roles at DxD Hub and in the broader diagnostics or MedTech ecosystem.

Expand

Expanding its core competencies and capabilities in in vitro diagnostics (IVD) product development, DxD Hub has built into Integrated MedTech (IMT) and Digital Diagnostics (DDx). These efforts have already begun fostering the growth of local SMEs.

In the area of DDx, DxD Hub continues to build its diagnostics capabilities to create health-related SaMD for clinical adoption. As of the end of FY2021, DxD Hub and its collaborators have launched 3 SaMD products. Driven in part by the apprenticeship programme, DxD Hub grew a team of software engineers, software Quality Assurance and Regulatory Affairs (QA/RA) specialists, app designers, data scientists and project managers.

IMT capabilities focus on building end-to-end sample-to-result instrumentation as well as point-of-care (POC) devices. These will enhance DxD Hub's diagnostics strategy from point solutions to integrated platforms that are better aligned with market dynamics.

As Singapore enters the COVID-19 endemic phase, DxD Hub has been positioning itself to support an NCID-led national pandemic readiness initiative called Programme for Research in Epidemic Preparedness and REsponse (PREPARE). Specifically, DxD Hub will serve as the Diagnostics Incubator under the PREPARE Dx Co-Operative. This partnership will focus on building just-in-time assembly of robust diagnostic prototypes in the event of a disease outbreak.

In a vote of confidence from the Singapore ecosystem, a 17-member consortium, led by DxD Hub, A*STAR, SingHealth, National University Health System (NUHS), and National Healthcare Group (NHG), was selected by MOH to host a Digital Health Accelerator (DHA) Proof-of-Concept proposal. This was an evolution of the Digital Satellite concept, described in last year's annual report. It brings together clinicians, developers, and investors to accelerate the adoption of digital health (DH) solutions in Singapore and beyond.



Bridging to DxD Hub 2.0

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Diagnostics Solutions, Our Innovations

FY2021 concludes DxD Hub's Bridging Tranche (01 Oct 2020 to 31 Mar 2022), where funding was approved to support the transition to DxD Hub 2.0 in RIE2025. This has proved to be helpful in light of the COVID-19 pandemic, allowing DxD Hub to scale up and position itself for the COVID-19 endemic future while tackling the ongoing development of products.

DxD Hub is a critical enabler in the development of diagnostics products and services. The COVID-19 pandemic has exemplified DxD Hub's role in Singapore's response to this unprecedented crisis. Other than COVID-19, work on a pre-pandemic portfolio of projects also resumed to provide diagnostics solutions in disease areas such as oncology and cardiovascular diseases. Over the Bridging Tranche, DxD Hub has delivered 10 diagnostic products as summarised in the following pages.

Fortitude Series



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

Fortitude 3.0

- Obtained Provisional Authorisation from HSA and has CE-mark

Fortitude Syndromic

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



cPass™



- Following HSA Provisional Authorisation in 2020, cPass™ has obtained full IVD approval
- Offered as an innovative test through DxD Hub’s ClinLab, which led to clinical adoption by Innoquest, Raffles Medical and Parkway Laboratories in FY2021

- Utilised in population immunity study conducted across 6 ASEAN countries in the ASSeSS study
- **5M+ tests administered**



abTES COVID-19 LAMP-CD Test Kit



- Co-developed with Genome Institute of Singapore (GIS), this kit is based on loop-mediated isothermal amplification (LAMP) technology, which enables rapid amplification and detection of COVID-19
- Since licensing to AITBiotech, it has been commercialised and received CE IVD certification



RESOLUTE Series



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

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



INSPECTA



- Automated Reverse Transcription Polymerase Chain Reaction (RT-PCR) Curve Analysis and Test Interpretation system to be used with RESOLUTE 2.0 Direct PCR Test Kit for SARS-CoV-2 Detection
- Received HSA approval as Class A SaMD
- Brought to market under a licensing agreement with Alliance Biomed and deployed at a local commercial laboratory

INSPECTA CFX

- Validated with Bio-Rad's CFX qPCR system
- Co-developed with I²R

INSPECTA QS5

- Validated with Applied Biosystems QuantStudio 5 System



REDAPT



- Sample collection kit with proprietary chemistry to enable deep throat saliva (DTS) specimen collection for RESOLUTE 2.0
- Only test kit approved for use with the RESOLUTE 2.0 test kit by HSA



UNITED™ (Tissue500™)

- Pan-cancer assay to enable Asian-centric molecular characterisation of tumors based on next-generation sequencing technology
- Commercial launch in Sep 2021
- Showcased in Frontiers in Cancer Science Conference 2021 and USCAP 2022 annual meeting
- Current clinical uptake by KKH Women's and Children's Hospital

LUCENCE



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aiTriage™



- In collaboration with TIIM and SingHealth
- An AI-powered diagnostics solution, which accelerates the triage process of chest pain patients
- Submitted for SaMD HSA approval in 2022



NHIC National Health Innovation Centre



dxdhub



Highlighted Diagnostics Solutions

RESOLUTE Series



The strategic partnership between DSO and A*STAR resulted in the co-development of the direct PCR SARS-CoV-2 detection kits RESOLUTE 1.0, and subsequently, RESOLUTE 2.0, which have proved pivotal in the early COVID-19 pandemic response.

Since receiving HSA provisional authorisation for clinical use in 2020, RESOLUTE 2.0 has been licensed to Advanced MedTech (AMT), a local MedTech company, and proceeded to obtain HSA full-IVD approval in 2021. AMT also took the product global, obtaining full registration in Australia (TGA) and Europe (CE-IVD mark), as well as provisional authorization in Malaysia (MDA), Indonesia (FDA) and Philippines (FDA).



Figure 2: Illustration of RESOLUTE kit

Currently, RESOLUTE 2.0 is used by DSO, MINDEF Forward Deployment Laboratories (FDL) and local private testing laboratories to assist in national testing capacity. It was one of the key tests allowing border re-opening thanks to its rapid turnaround time. Besides local users, RESOLUTE 2.0 has also been utilised by overseas users such as Cedars-Sinai Medical Centre in the United States. To date, more than 3.5 million RESOLUTE 2.0 tests have been sold by AMT globally.

DxD Hub and its collaborators have continued to improve RESOLUTE. RESOLUTE 3.0 allows (i) more resilient testing of SARS-CoV-2, including variants, (ii) reduced supply chain reliance on overseas producers by considering the local supply of key reagents, and (iii) reduced chances of sample error in low positive samples with increased sample volumes to the test reaction.

For their contributions towards enhancing the defence capabilities of Singapore, the RESOLUTE team was awarded the Ministry of Defence's Award for Defence Technology Prize (DTP) last year.

What Collaborators are Saying...



Partnership with DxD Hub was instrumental in the productisation of “RESOLUTE” – the direct-PCR diagnostic kit for COVID-19.

Building on DSO’s proprietary formulation and development of the assay to detect COVID-19, DxD Hub was able to provide their expertise to quickly translate this into a portable kit within just 3 months. Sidney’s team was very enthusiastic and responded swiftly to our queries. Their domain expertise on productisation and manufacturing also contributed to improved versions of the RESOLUTE kit, which continues to be used widely today.”

Dr Tan Boon Huan
Distinguished Scientist, DSO

Clinical Laboratory



Figure 3: Ms Paneer Selvi in ClinLab

Newly developed diagnostics entering the market face significant adoption challenges. This includes the difficulty in gaining commercial laboratory interest due to the uncertain demand for a new assay and lack of awareness among clinicians. Commercial labs would carefully consider the opportunity cost of running a new assay compared to the benefits of running a more popular diagnostic test.

DxD Hub Clinical Lab (ClinLab) was set up in 2019 as a tool to overcome this challenge of clinical adoption. ClinLab offers laboratory diagnostics for innovative tests that are new to the market. Clinicians can offer diagnostic tests done by ClinLab to patients, which would help to generate awareness and assess initial market demand for the tests.

What Hubbers are Saying...



Working in DxD Hub and especially in a clinical lab in Diagnostic Development environment is a new and exciting experience. We act as the first testing centre for newly developed diagnostic tests! And contribute to the market-readiness of the diagnostics, which would impact many lives.”

Ms Paneer Selvi
Senior Laboratory Manager of ClinLab

Clinical Laboratory

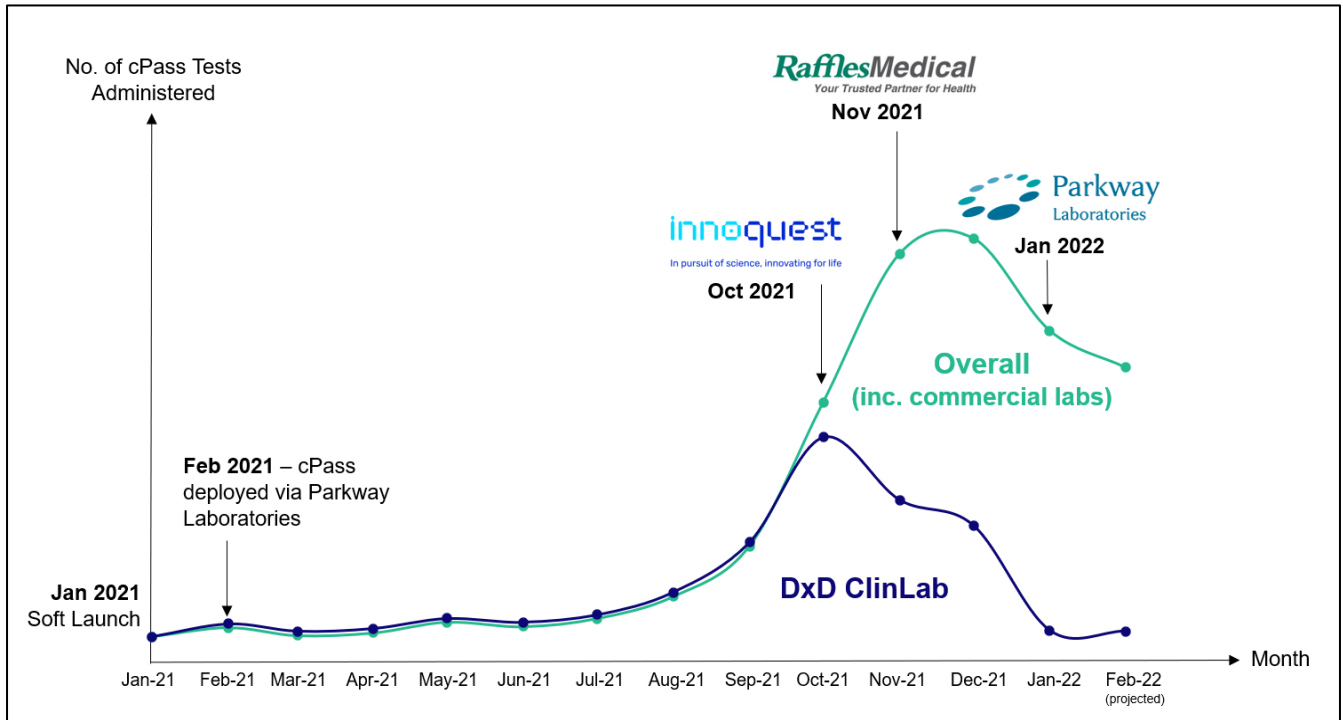


Figure 4: Graph illustrating cPass™ uptake through DxD Hub's ClinLab

Last year, DxD Hub's investment in ClinLab proved its value with the successful launch of cPass™, a neutralising antibody test developed through a collaboration between DxD Hub, Duke-NUS, and GenScript. In Jan 2021, ClinLab commenced the administration of cPass™ tests. One month after, cPass™ was offered to patients as a "send-out" test via Parkway Laboratories. Over the subsequent months, there was an exponential increase in the number of tests ordered and performed by ClinLab.

This demonstrated the commercial viability and attractiveness of cPass™, which led to its uptake by commercial clinical laboratories such as Innoquest in Oct 2021 and Raffles Medical in Nov 2021, creating a virtuous adoption cycle. The full takeover by commercial laboratories was completed with the adoption by Parkway Laboratories in Jan 2022.

Moving forward, ClinLab is well poised to run and bring other innovative tests such as X-Zell Rare Cell Detection System to the market.

Asians contribute to 58.3% of global cancer-related deaths. In 2020 alone, GLOBOCAN reported an estimated 10 million cancer-related deaths worldwide [1]. The ability to identify the right therapy is critical for patients, especially for those who are not responding well to current standard-of-care treatments. Current cancer diagnostics assays tend to be Caucasian-centric and underrepresent markers and mutations that are typical for Asians. There is therefore an unmet need for molecular diagnostics tests addressing Asian ethnicities' needs.

In 2019, DxD Hub entered a public-private partnership with Lucence Diagnostics Pte Ltd, National Cancer Centre of Singapore and Singapore General Hospital to co-develop a pan-cancer assay to enable Asian-centric molecular characterisation of tumours based on next-generation sequencing technology. The multi-disciplinary team comprising oncologists, pathologists, product development scientists and bioinformaticians worked together to design, develop and validate the test which covers more than 10 cancer types prevalent in Asia such as lung, hepatobiliary and stomach cancers etc.

The outcome of this collaboration is the successful commercial launch in Sep 2021 of Lucence UNITED™ assay, designed with more than 500 carefully curated Asian-centric cancer biomarkers and known driver mutations, as well as more than 70 fusion genes. This work had been showcased at both local and regional conferences such as Frontier in Cancer Science 2021 in Singapore and at the United States & Canadian Academy of Pathology (USCAP) 2022 Annual Meeting. There has also been assay uptake by local clinical community such as KK Women's and Children's Hospital within the short span of time since launch late 2021. This collaboration is a testament to the importance of public-private partnerships to achieve sustainable and impactful innovation that can potentially benefit cancer patients and help advance precision medicine locally and globally.

[1] <https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21660>

What Collaborators are Saying...



Lucence's partnership with A*STAR's DxD Hub has been one of excellence, dedication and mutual respect.

Lucence's partnership with A*STAR's DxD Hub has been one of excellence, dedication and mutual respect. While Lucence's mission is to bring clarity to cancer care through precision diagnostics, DxD Hub is committed to advancing MedTech innovation through effective partnerships. With similar goals in mind, Lucence and DxD Hub, together with National Cancer Centre Singapore and Singapore General Hospital, collaborated on bringing a pan-cancer genetic test all the way from bench to bedside to help cancer patients choose the right treatment. The finalised product, UNITED™ (Tissue500™), was commercialized through Lucence in September 2021. UNITED™ (Tissue500™) has since gone on to help more than 100 cancer patients across Singapore and South-East Asia obtain personalized and timely cancer treatment.

Throughout our 2-year collaborative journey, we are grateful to have leveraged on DxD Hub's strong technological expertise and product development capabilities. DxD Hub's team of Scientists, Research Officers and Bioinformaticians also provided great support in realising our shared product vision.

We certainly look forward to future exciting opportunities to partner with DxD Hub again for the benefit of cancer patients all around the world."

Chest pain triage workflows are inefficient and resource intensive. Physicians need to differentiate high and low risk chest pain patients quickly using complex workflows, yet up to 75% of these cases are not cardiac emergencies. This leads to wasted physician resources and overcrowding of the Emergency Department (ED), while also resulting in a negative patient experience.

aiTriage™ is a robust new way to help doctors triage chest pain patients objectively and efficiently - that is non-invasive, automated, and fast. aiTriage™ accelerates chest pain triage by generating an objective risk stratification score (0-100) using a patient's heart rate variability (HRV) and heart rate n-variability (HRnV) parameters derived from a continuous 5-minute ECG and other readily available patient information, without needing any cardiac biomarker tests. The data is processed with a novel AI-based technology in real time, allowing doctors to quickly identify high-risk patients for timely care, and low-risk patients for management, while reducing excessive investigation and monitoring.

TIIM Healthcare has designed aiTriage™ for large-scale deployment across healthcare facilities, such as EDs, General Practitioners (GPs), community clinics and nursing homes. When paired with telemedicine technology, aiTriage™ may effectively operate in rural areas to offer high quality chest pain triage where clinical resources are extremely limited, allowing doctors to distinguish between chest pain patients who require urgent attention and those who do not have life-threatening conditions. This means high-risk patients can be timely intervened and unnecessary visits to tertiary hospitals can be avoided for low-risk patients.

TIIM Healthcare has filed aiTriage™ for HSA approval ahead of a commercial launch.

What Collaborators are Saying...



DxD Hub provided the fuel to drive our entire journey of the development and refinement of aiTriage

The decision to partner with DxD Hub was an easy one, hailing from a lean MedTech start-up.

DxD Hub provided the fuel to drive our entire journey of the development and refinement of aiTriage™, bringing years of practical experience in productisation, design processes, clinical validation as well as regulatory support.

Throughout our collaboration, the team at DxD Hub has shown an incredible level of devotion to our project, especially nurturing our technical team with extensive process knowledge and often aiming to provide a new perspective on the problems we've been working on.

To highlight the efforts that went into the clinical validation of aiTriage™, DxD Hub has played an integral role in securing a 3-way collaboration with SingHealth to support our clinical study which accelerated our productisation. Their dedicated hands-on approach, and in-depth experience, is imprinted in the success of our product, and we are ready to hit the ground running to bring it to market."

Mr Michael Cheng
COO of TIIM Healthcare

Regional and International Efforts to Advocate Diagnostics

ASEAN Diagnostics Initiative (ASEAN Dxi)

The COVID-19 Pandemic remained a regional priority in FY2021. It led to the development of three key activities contributing to diagnostics capacity building across ASEAN.

Firstly, the ASEAN Dxi Preparedness Webinar series took center stage as an outreach platform to diagnostics innovators, practitioners and policy makers involved in COVID-19 diagnostics. Four webinars were organised last year: (i) *“Introducing the Novel Direct PCR as an Efficient Way to Scale PCR Testing for COVID”*, (ii) *“Genomic Surveillance Used in Tracking the Emergence of New Variants of Concern”*, (iii) *“The Use of Surrogate Viral Neutralisation Test to Measure the Effectiveness of Vaccination”* and (iv) *“Vaccination Approaches Achieving Herd Immunity and Combating Omicron”*. The attendance of the webinars grew from a handful of ASEAN Member States (AMS) to all ten member countries, and participation grew from around 400 to over 1200 per webinar by the end of FY2021.

Another major contribution of the ASEAN Dxi was the initiation of the first ASEAN wide collaborative study “ASEAN Sero-Surveillance Study on COVID-19 Vaccines” (ASSESS) to investigate the seroconversion and longevity of vaccine-induced protection from different vaccines used across ASEAN. The study was endorsed by the 79th ASEAN Committee on Science, Technology and Innovation (COSTI) Meeting and approved by the 11th Informal ASEAN Ministerial Meeting on Science, Technology and Innovation (IAMMSTI). The study was also supported by lead institutes across the ASEAN Region including Singapore’s Duke-NUS School of Medicine and DxD Hub, Philippine’s Research Institute in Tropical Medicine (RITM), Indonesia’s Udayana University and University of Indonesia, Malaysia’s Universiti Malaya Faculty of Medicine, Thailand’s King Chulalongkorn Children Hospital and Vietnam’s Oxford University Clinical Research Unit (OUCRU).

In addition, the study received a grant from the ASEAN Technology Innovation Fund which attracted further support from Temasek Foundation and in-kind support from MNCs providing test assays.

FY2021 ended with a regional roundtable to advance discussions to provide better access to diagnostics. The Accelerating Diagnostics Access in ASEAN (ADAA) regional consultation was held by ASEAN DxI and the London School of Hygiene and Tropical Medicine's (LSHTM). More than 40 representatives from medical device regulators, science and technology institutions, public health, and industry observers across 8 AMS joined the consultation event and shared learnings and best practices in overcoming the diagnostics hurdles during the COVID-19 pandemic. Four focus areas were identified to develop solutions to accelerate regional diagnostics access: (i) diagnostics regulatory approval, (ii) product quality and quality assurance, (iii) regional diagnostics capacity building and (iv) public health and policy.



Figure 5: Screenshot of the ADAA regional consultation

Building Local Talent Pool, Talent Development

The MedTech talent shortage has been consistently raised as a strategic focal point by industry members. This was echoed during an industry engagement town-hall hosted by DxD Hub with the Minister of Trade and Industry (Min T&I) in Nov 2021. As the national platform for diagnostics development, DxD Hub has taken up the remit to expand the talent pool and contribute to the vibrancy of this sector.

With the aim of developing skilled talents to support the growing MedTech sector, DxD Hub launched an apprenticeship programme in 2020. The programme's intention was to groom local talents for the medical diagnostics industry through on-the-job-training. This one-year programme attracted fresh graduates to DxD Hub and has since trained 16 apprentices in various aspects of the medical device industry including IVD, DDx, QA/RA, Outreach and Talent Development and Corporate Planning.

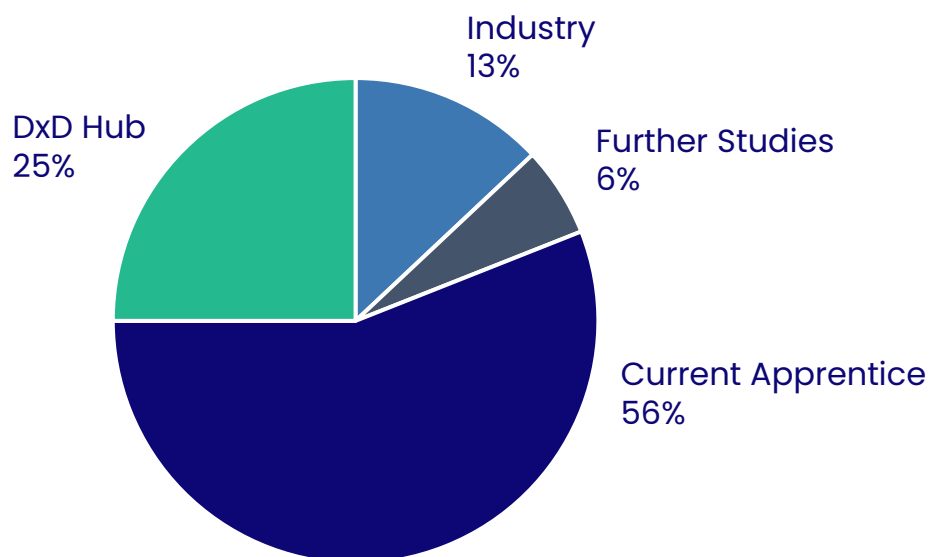


Figure 6: The distribution of DxD Hub's apprentices

Upon completing the apprenticeship programme, most of the talents have remained in the MedTech industry (Figure 6). Following the success of the apprenticeship programme, DxD Hub is working with Manpower NRF to pilot a fellowship programme.

What Hubbers are Saying...



DxD Hub is analogous to an institution; it nurtures and supports people to grow to their success. Being part of the Quality Assurance Team, I am grateful for the training and opportunities provided to enhance myself in this field. It has indeed aided me to ensure that our products and results are of quality and are compliant with the established standards. In DxD Hub, we not only deliver quality outcomes but also produce them with confidence.”

Ms Nurul Zafirah

Apprentice in 2020, Quality Assurance Associate

In addition to the apprenticeship programme, DxD Hub also provides experiential internships to prepare talent for the ecosystem. During the Bridging Tranche, 25 interns were exposed to the MedTech industry and developed their technical skillsets and knowledge.

DxD Hub is also active in advocating MedTech as a career option for new scientists, engineers, and innovators. In FY2021, DxD Hub participated in the following events:

- ❑ Collaboration with Centre for Healthcare Innovation (CHI) Fellowship. DxD Hub shared experiences in diagnostics solutions development and deployment and journey in supporting COVID-19 efforts.
- ❑ NUS Career Fest 2022. DxD Hub’s virtual career booth attracted more than 20 students. Students were interested to learn more about DxD Hub, and the internships and career opportunities offered.
- ❑ Immersive Learning Programme for pre-university students. Pre-university students learnt about the diagnostics field through lectures, hands-on experience and guest speaker sessions in DxD Hub facilities.

Recognition, Our Accolades

The health impact of diagnostics is DxD Hub's core motivation in fulfilling our purpose as the national platform for diagnostics development. The COVID-19 pandemic has undoubtedly highlighted the importance of DxD Hub as a critical enabler of the healthcare and biomedical industry.

As the founding CEO of DxD Hub, Dr Sidney Yee led DxD Hub in leveraging its capabilities to develop and deploy several nationally and internationally significant COVID-19 diagnostics products within a short span of time. These products include Fortitude, cPass™, and RESOLUTE. Dr Yee's efforts have led to her winning the Ministry of Trade and Industry (MTI) 2021 Exemplary Firefly Award (Gold), an award for individuals who inject innovation and champion the spirit of collaboration and perseverance in their work.

What Hubbers are Saying...



The award was unexpected because I view my work as my responsibility. But above all, I'm humbled, honoured and grateful for the recognition. The people, culture, values and relationships we cultivated at DxD Hub made it possible for us to work through the last 18 months of pandemic."

Dr Sidney Yee
Founding CEO of DxD Hub

The development of RESOLUTE has gained recognition from the Ministry of Defence. Developed within three months after the first reported COVID-19 case in Singapore, RESOLUTE overcame the global shortage of testing materials, enabled the scaling of testing capacity and simplified the diagnostic workflow. RESOLUTE reduces COVID-19 exposure to lab operators and requires only basic laboratory equipment to conduct the test.

The RESOLUTE team, comprising members from DxD Hub (Figure 7), DSO National Laboratories and HQ Medical Corps from Singapore Armed Forces (SAF), received the DTP for their outstanding achievements and contributions to the development of RESOLUTE.



Figure 7: DxD Hub's development team for RESOLUTE

DxD Hub's accomplishments are attributed to the efforts and commitment of talented individuals. Two DxD Hub staff received the 2020 National Day Awards from President Halimah Yacob on 4 Apr 2021. Dr Inoue Masafumi (Principal Scientist, DxD Hub) was awarded The Public Administration Medal (Bronze) while Dr Weng Ruifen (Chief Technology Officer/ Deputy Chief Executive Officer) was awarded The National Commendation Medal. These awards provide recognition and commemorate DxD Hub's journey thus far.

Public sector stakeholders have also expressed support for DxD Hub's continued efforts during various engagements and visits, such as:

- ❑ **The Head of Civil Service visit to A*STAR.** Fortitude and RESOLUTE were highlighted as success stories of A*STAR's collective efforts against COVID-19.
- ❑ **The Public Service Commission members visit to A*STAR.** The lessons learnt during COVID-19 were shared and cPass™ and aiTriage™ were showcased in two live demonstrations.
- ❑ **Minister of Trade and Industry (Min T&I), Mr Gan Kim Yong's, visit to DxD Hub.** Mr Gan was given insights on DxD Hub's role in productisation, successful partnership models and products developed (Figure 8). Topics on garnering support for made-in-Singapore diagnostics and creating and capturing value for DxD Hub were deliberated. An industry engagement discussion between Mr Gan and DxD Hub's collaborators was held, where access to talents and enhancing research translation for the Biomedical sector were discussed.

With these key achievements and recognition, DxD Hub confidently transitions into DxD Hub 2.0 to strengthen, expand, and build our capabilities.



Figure 8: Min T&I, Mr Gan Kim Yong's visit to DxD Hub

An aerial photograph of a modern city street, likely in Singapore, showing a wide road with yellow lane markings, sidewalks, and lush green trees. Tall, modern buildings with glass and metal facades line the street. The sky is blue with scattered white clouds. A large teal overlay covers the left side of the image, containing white text.

DxD Hub 2.0: Strengthen, Expand, Build

DxD Hub will strengthen existing productisation processes, expand into new areas, and build new capabilities. The plans for RIE2025 (Figure 9), were reviewed and supported by DxD Hub’s Oversight Committee (OC) during its 2nd OC meeting held in March 2022.

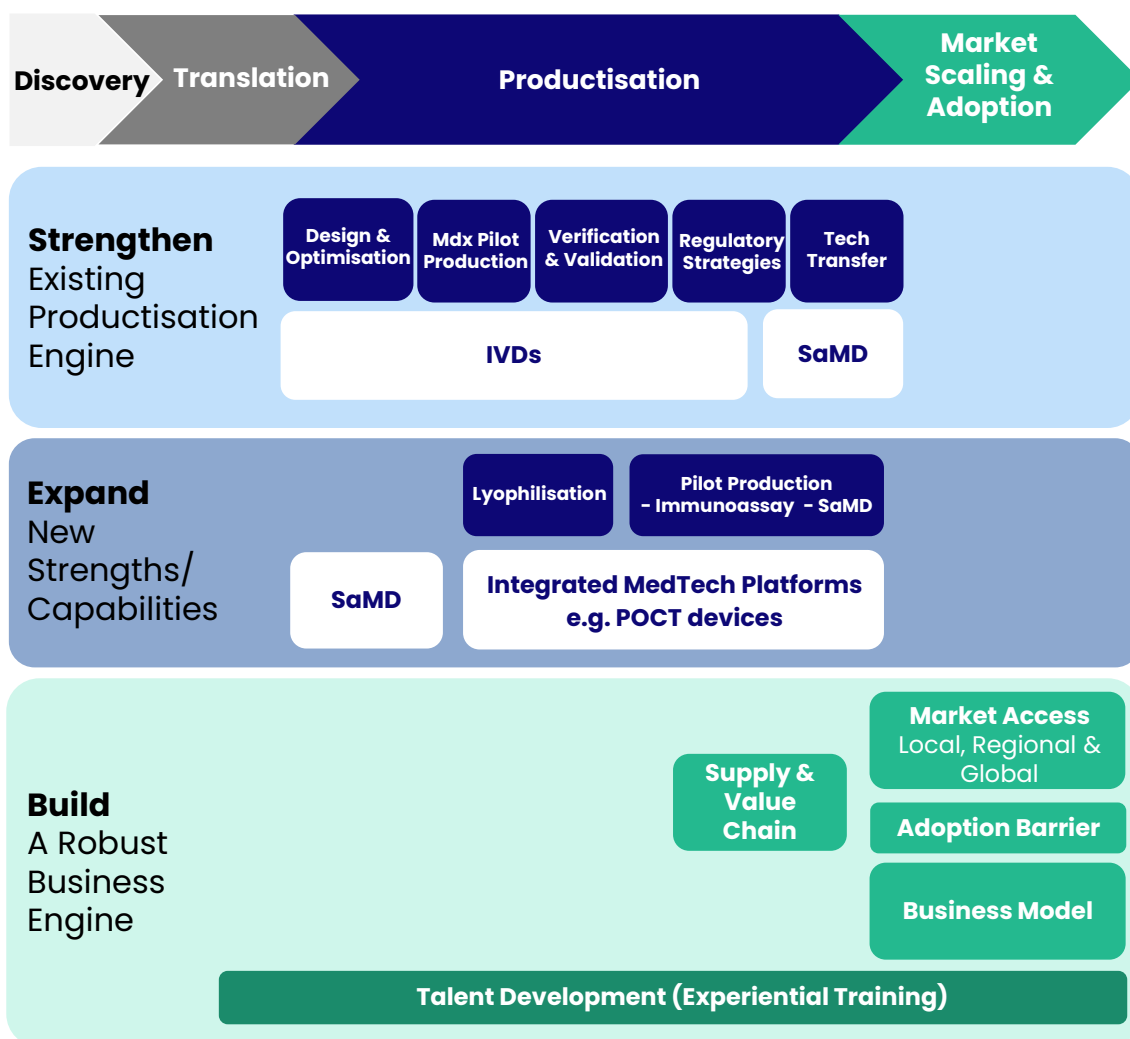


Figure 9: Graphic illustrating DxD Hub's strategic plans for RIE2025

Strengthen Existing Productisation Engine

DxD Hub has built up a rigorous and high throughput productisation engine, with capabilities in design and optimisation, pilot production, verification and validation, regulatory strategies, and technology transfer. These processes have enabled us to take product ideas from Proof-of-Concept to regulatory clearance and launch as described in the sections above. DxD Hub will continue to build up the team and skills through process improvements and trainings.

Expand into New Strengths/Capabilities

DxD Hub envisions the future of healthcare delivery to be person-centric, delivers care everywhere and is digitally connected. Therefore, DxD Hub aims to expand and diversify capabilities across different domains in diagnostics, such as SaMD and integrated platforms focusing on point-of-care-testing (POCT) devices. In tandem, DxD Hub will expand its pilot manufacturing capabilities from Molecular Diagnostics to Immunodiagnosics and SaMD. As a result, pilot production capacity will be increased to engage more local supply chain players. To accommodate the need to be more accessible to users in terms of logistics and cost-effectiveness, it is necessary to incorporate lyophilisation in the product development life cycle. Capabilities in lyophilisation will be one of the key focus areas. This will be critical in accelerating product development and building resilience for Singapore [2].

Build a Robust Business Engine

DxD Hub is building a robust Business Engine that considers market components and addresses the need for talent to empower its partnering enterprises.

The development of future business strategies is founded on scaling and adoption. These strategies will take into consideration market dynamics such as supply and value chains, market access, adoption barriers and business models in an iterative way throughout the project and product life cycles. DxD Hub will leverage engagements with venture builders to provide support for product and enterprise development.

The continuing effort in training talents through the apprenticeship programme, as well as strengthening regional and global networks will contribute to the building of a robust Business Engine.

[2] Alliance for Action on MedTech identified lyophilisation capabilities for IVD design and development lacking in Singapore, resulting in the need for long TAT between prototyping and productisation, hence delaying speed-to-market and the ability to effectively scale up the process development from pilot to full manufacturing.

Partnership Models

Public Partnerships

As a national platform for diagnostics development, DxD Hub has been well connected with other public partners, tapping into complementary capabilities and resources to deliver products and services.

Three main types of public partnerships have been identified as strategic priorities moving forward:

Upstream Research Groups

This would involve IP originators from groups such as hospital clusters, or pre-feasibility projects based on use cases. Such groups would provide a steady flow of high-quality pipeline projects and allow value capture through the productisation of such IP.

Clinical Users and Payers

Early engagement of clinical clusters and clinicians would ensure better alignment with healthcare policies, provide clinical sponsors and champions and demonstrate proof-of-value for diagnostic products. This would better facilitate market adoption through local healthcare impact.

Ecosystem Enablers

Aligned with DxD Hub's mission to enable local enterprise, partnerships with government agencies and other national platforms will provide synergistic support for collaborators, giving them an edge as they enter the market. Such partnerships would also allow the expansion of regional and global networks. This would develop channels to KOLs and enhance international market reach for local start-ups.

Private Partnerships

To engage the private sector, DxD Hub will employ a key account management approach on three main types of companies:

Local Key Bets

To grow high-value local companies, DxD Hub will align and collaborate on partners' top priority developments and focus on demonstrating proof-of-value and building reference users.

MNCs, SMEs and VCs

DxD Hub will collaborate with ESG and EDB in identifying companies to build MedTech value and supply chains. This would involve efforts such as localising raw materials manufacturing, addressing clinical productisation gaps, engaging supply chain SMEs and developing a wide investor and VC network.

High Potential Overseas Companies

To generate critical mass and demand, DxD Hub will partner with companies that demonstrate high potential through promising innovative platforms and robust business models. These would prove valuable in enriching the local diagnostic ecosystem, allowing access to global innovative platforms, and sustaining local supply chain companies.

Strategic Projects and Partnerships

PREPARE

Singapore, as an international travel hub, is particularly vulnerable to imported and local transmissions of novel infectious diseases (IDs) and re-emergence of existing IDs. COVID-19 has strongly demonstrated the severe health, economic and societal impact of such pandemics on Singapore. Other historical examples of ID outbreaks, such as SARS (2003), the influenza pandemic (2009) and Zika (2016), show that COVID-19 will not be the last pandemic to hit Singapore. Thus, it is a national priority in peacetime to support and strengthen essential research capabilities, translational platforms and expertise that could be harnessed to prevent, prepare, and respond to future ID threats.

As one of the five Co-Operatives in PREPARE, the Diagnostics Co-Operative (Dx Co-Op) programme aims to aid pandemic response through accelerated delivery of regulatory approved diagnostics solutions with production ease, supply chain readiness and expedited deployment of national testing in times of crisis.

The Dx Co-Op leverages a use-case guided approach to call for innovative technologies in the ecosystem that would fill current diagnostic gaps. With core capabilities in product design, optimisation and systems integration, DxD Hub serves as Dx Co-Op Incubator to support the translation of IPs from public and private sectors into minimal viable products.

DxD Hub will continue to leverage its productisation expertise to develop end-to-end clinical and deployment workflows, as well as product master plans in the process of developing products and platforms. The first platforms to be developed and validated are whole system automated lab-based instruments and POC devices, which are aligned with DxD Hub's core expertise and focus for DxD Hub's 2.0 plans.



Figure 10: 5 co-operative programmes of PREPARE

Digital Health Accelerator

Multiple forces have been driving the adoption of DH solutions over the past two decades. These include (i) macroeconomic factors (e.g. ageing population, emerging markets), (ii) clinician shortages, (iii) decentralized care delivery and a shift to value-based funding models, and (iv) reduced development and deployment costs due to technical advancements (e.g. cloud, microservices). This has been further accelerated by the COVID-19 pandemic. Despite this, significant global barriers remain to clinical adoption that Singapore can address, such as systems-level assessment, curated data for model assessment, productisation and solution adoption, and scaling.

In late 2021, MOH proposed the creation of a Digital Health Accelerator (DHA) and subsequently accepted a proposal put forward by A*STAR (DxD Hub), the public health clusters, and a broad spectrum of public and private sector agencies and firms. A Proof-of-Concept programme then emerged that would select the most promising DH innovations and drive their productisation and clinical adoption. Participating companies would benefit from accelerated adoption

and quantified evidence to support their claims and regulatory filings. This programme would focus on project deliverables such as (i) Procurement process support, (ii) Baseline Performance Assessment, (iii) Process Re-Engineering, (iv) Integration, (v) implementation and (vi) Return on Investment Calculation (Figure 11).

DxD Hub has committed a portion of its Innovation and Enterprise (I&E) funding to address the objectives of the DHA Proof-of-Concept. DxD Hub and MOH will work together to seek additional funding to support the Proof-of-Concept.

Digital Health Accelerator

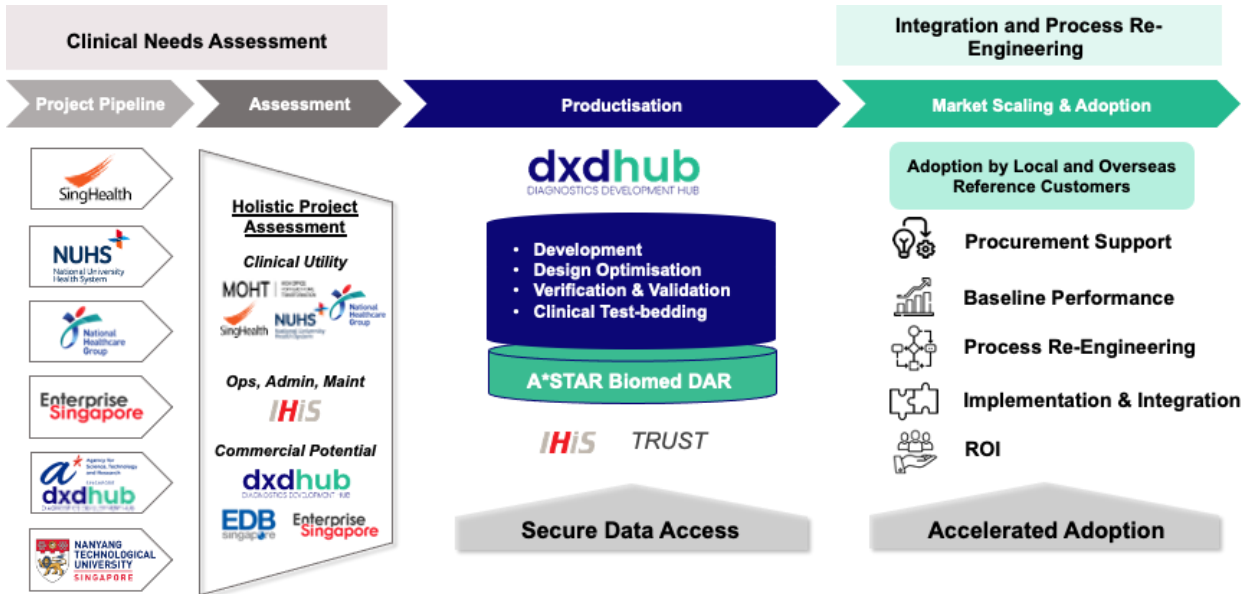


Figure 11: Demonstrating DxD Hub's role in DHA

GenScript BioTech



Figure 12: Virtual signing of MoU between GenScript and DxD Hub

The effective partnership established between DxD Hub and GenScript Biotech for cPass™ led to the signing of a Memorandum of Understanding (MoU), bringing the partnership to the next level. This was witnessed by Mr Alvin Tan, the Minister of State for Trade and Industry, and Culture, Community and Youth, during the opening ceremony of GenScript's manufacturing facility on 10 February 2022. This marked a momentous milestone in the collaborative relationship between the two parties.

The new GenScript manufacturing facility will build capability and capacity

for high throughput protein and gene synthesis. Additionally, the facility will ensure continuity in the molecular and protein-based reagents supply chain to the scientific community in the Asia Pacific (APAC) region. The MoU also seeks to explore strategies for addressing the growing needs of the medical diagnostics industry, such as expanding the local talent pool and joint product development. This joint programme between DxD Hub and GenScript will enrich both the life sciences R&D and MedTech supply chain, strengthening Singapore's resilience in future pandemic responses.

GenScript BioTech

What Collaborators are Saying...



The team provided excellent guidance and expertise in both the regulatory and productisation areas which has enabled us to deploy our product to the market in a very short timeframe.

We established our partnership with DxD Hub during the start of the COVID-19 pandemic. DxD Hub was our key partner in bringing our test kit from design verification and validation to successful regulatory approval. The team provided excellent guidance and expertise in both the regulatory and productisation areas which has enabled us to deploy our product to the market in a very short timeframe. We are delighted to have DxD Hub as our strategic partner to accelerate the commercialization of our diagnostic kits and look forward to more collaborations in the coming years. We are proud our first collaboration cPass™ SARS-CoV-2 neutralisation antibody detection is serving most clinics in Singapore and 63 other nations."

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