



Unlocking the Value of Quality Next-Generation Sequencing in APAC Paper Launch

December 2022



AGENDA

Topic		Presenter
5'	Opening remarks & intro	Cindy Pelou APACMed
20'	NGS Whitepaper summary	Stephen Sunderland L.E.K Consulting
30'	Panel discussion and Q&A	<u>Panelists</u> Richard Vines , Rare Cancers Australia Sayyidi Hamzi , Pantai Premier Pathology Dr Amol Zimur , Illumina Dr Suyog Jain , Guardant Health <u>Moderation</u> Stephen Sunderland
5'	Next steps & closing	Cindy Pelou APACMed



Opening remarks

Cindy Pelou
Manager, APACMed

About APACMed

01 WHO

APACMed represents manufacturers and suppliers of **medical equipment, devices and in-vitro diagnostics**, industry associations and other key stakeholders in the medical technology industry in Asia Pacific.

02 WHAT

We aim to improve the **standards of care** for patients through innovative **collaborations** among stakeholders to jointly shape the future of healthcare in the Asia Pacific region.

03 WHY

We provide a **unifying voice** for the medical devices, in-vitro diagnostics and digital health industry in Asia Pacific, and strive to **promote innovation** and impact policy that advances healthcare access for patients.

04 HOW

Our functional committees include:

- Regulatory Affairs
- Government Affairs & Market Access
- Legal, Ethics & Compliance
- Digital Health
- Start-ups & SMEs



NGS Whitepaper summary

Stephen Sunderland
Partner, L.E.K Consulting

Unlocking the Value of Quality Next- Generation Sequencing in APAC

These materials are intended to supplement a discussion with L.E.K. Consulting. These perspectives will, therefore, only be meaningful to those in attendance. The contents of the materials are confidential and subject to obligations of non-disclosure. Your attention is drawn to the full disclaimer contained in this document.



APACMed's NGS working group asked L.E.K. to help jump start an advocacy agenda in APAC with a white paper to anchor the value of quality NGS, and what is needed to achieve that



Context

- In 2022 APACMed formed a working group dedicated to next generation sequencing (NGS)
- There are a wide range of NGS tests and testing providers available in the APAC market, operating to a range of standards with regards to science, clinical evidence, operating procedures, clarity of reporting, etc.
- Need to establish and reinforce the value of quality NGS in a diverse range of audiences: patients, HCPs, providers, payors and policy makers

NGS Working group members:



The goal of the white paper was to establish and reinforce the value of quality NGS among a diverse range of audiences in APAC

Overall goal



To establish effective and market-appropriate national policy influence strategies, with a focus on reinforcing the value of quality NGS



Publication objectives



Articulate the value of quality NGS through highlighting benefits of quality NGS and cautionary tales when there is lack of quality NGS



Provide guidance on setting quality standards across the NGS workflow



Illustrate how standard for quality NGS can be concretely set and implemented in different resource settings in APAC for a diverse group of stakeholders

Two roundtable sessions hosting 22 regional and international NGS experts were held to discuss the value and need for quality NGS in APAC

Roundtable #1 – May 19th

Objective



- To **articulate the value of quality NGS** in the *(the 'why')*
 - Clear understanding of why we need quality NGS would **facilitate** roundtable #2 discussion **on defining guidelines to set standards for quality NGS**



Attendee composition (N = 10)

- 4 medical oncologists
- 2 patient group representatives
- 2 industry representatives
- 1 policymaker
- 1 global expert on NGS-related policy issues

Roundtable #2 – May 23rd

Objective



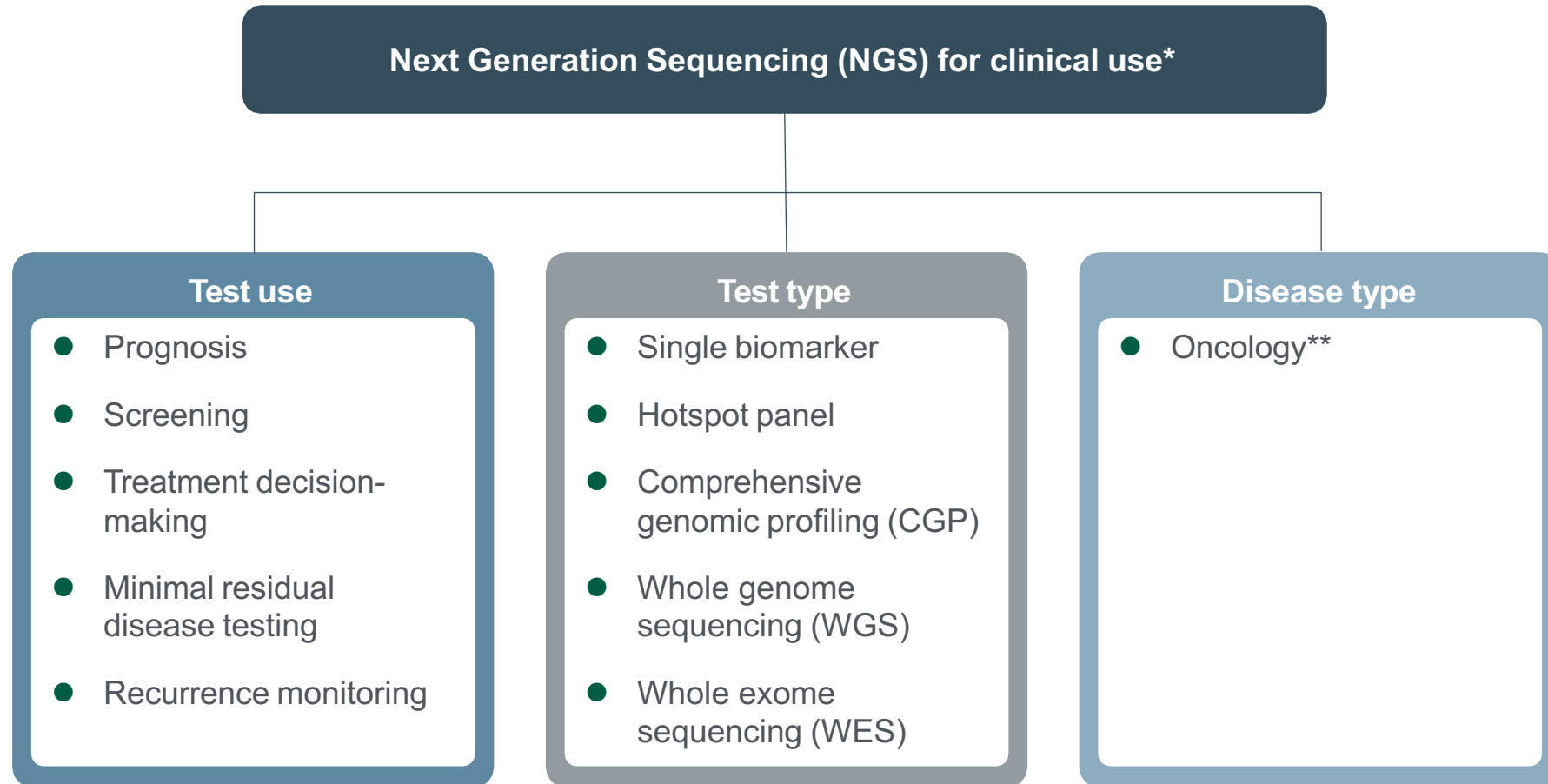
- To **define guidelines for setting quality NGS standards** across the workflow *(the 'what')*
 - Including NGS tests, laboratories performing NGS, data analysis, interpretation and reporting, and clinical usage
- To illustrate **how quality NGS can be concretely implemented** in different resource settings within APAC *(the 'how')*



Attendee composition (N = 12)

- 4 pathologists and geneticists
- 8 industry representatives

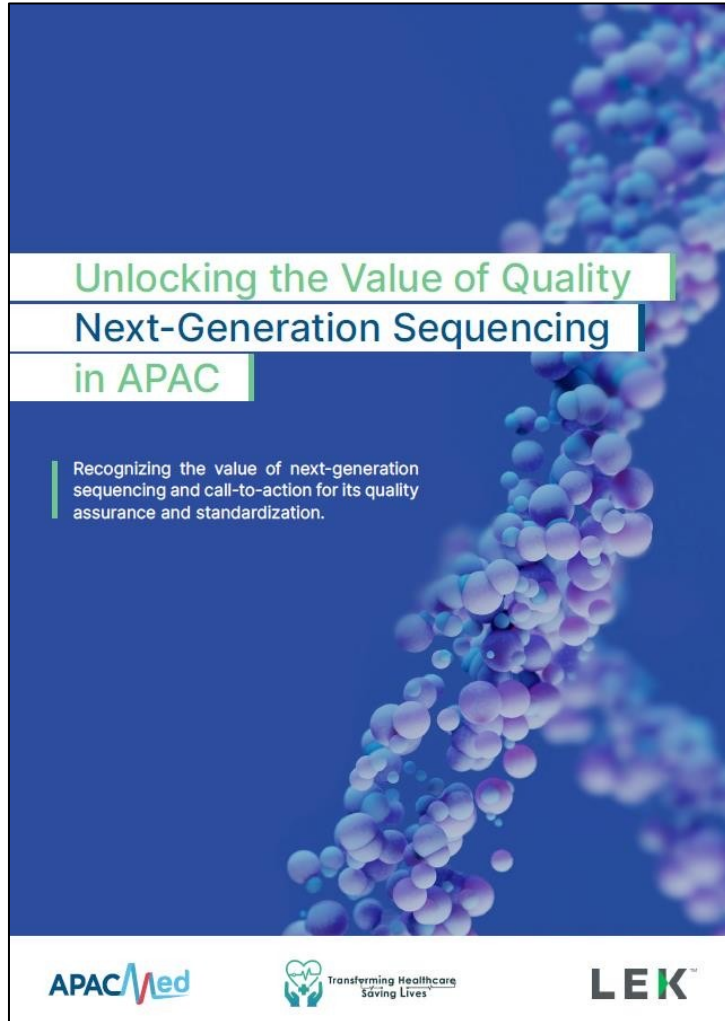
The focus of the roundtable discussions and white paper is the full range of NGS tests for oncology



Note: * This encompasses both solid and liquid samples and involves all providers for the whole NGS process including in-house testing labs and overseas labs;

** Specifically for tumor

The white paper covers 5 main topics



Core agenda

- The Value of Next-Generation Sequencing
- Best practice guidelines and reference for quality Next-Generation Sequencing
- Challenges and recommendations
- Quality considerations for Next-Generation Sequencing
- Initiatives for quality Next-Generation Sequencing

The paper details 5 areas of best practice in NGS, with examples drawn from around the world, to inform recommendations relevant for APAC

To ensure accuracy, reproducibility, and repeatability of the test	 Quality guidelines for NGS tests
To support consistent and reliable analysis and interpretation of data	 Quality guidelines for NGS test data analysis and interpretation
To ensure patients and HCPs have necessary and accurate information to make informed decisions	 Data reporting standards for NGS data generated
To ascertain that clinical utility of the NGS test has been proven, and test results can inform appropriate treatment and patients management	 Clinical guidelines for NGS usage
To provide assurance of standardized testing, reliability and quality control for HCPs and patients	 Quality guidelines for laboratories

- Analytical validity (accuracy, precision, LOD)
- Clinical validity
- Clinical utility
- Process validation
- Trained and qualified professionals
- Software validation
- Reporting
- Approach
- Variants detected / not detected
- Limitations
- Relevance for different cancer types and stages
- Test / instrument selection
- Sample collection
- Test interpretation
- CLIA / CLEP / ISO15189 / NPAAC etc.

A range of APAC-specific concerns were considered in relation to how to apply best practice in the region (1)



Differences between markets

- Within APAC, there are large differences between the markets in terms of **regulatory**, **accessibility** and **quality** of NGS tests
- NGS tests are **reimbursed** in some mature APAC markets, and out-of-pocket in most markets



NGS tests IVD vs. LDTs

- **IVDs are largely regulated** in all markets; experts are assured of quality of IVD tests
- However, **regulations of LDTs differ between markets**, some have no formalized regulation of LDTs, raising concerns on quality
- Experts noted **high usage of LDTs** in the region (at the lab level)

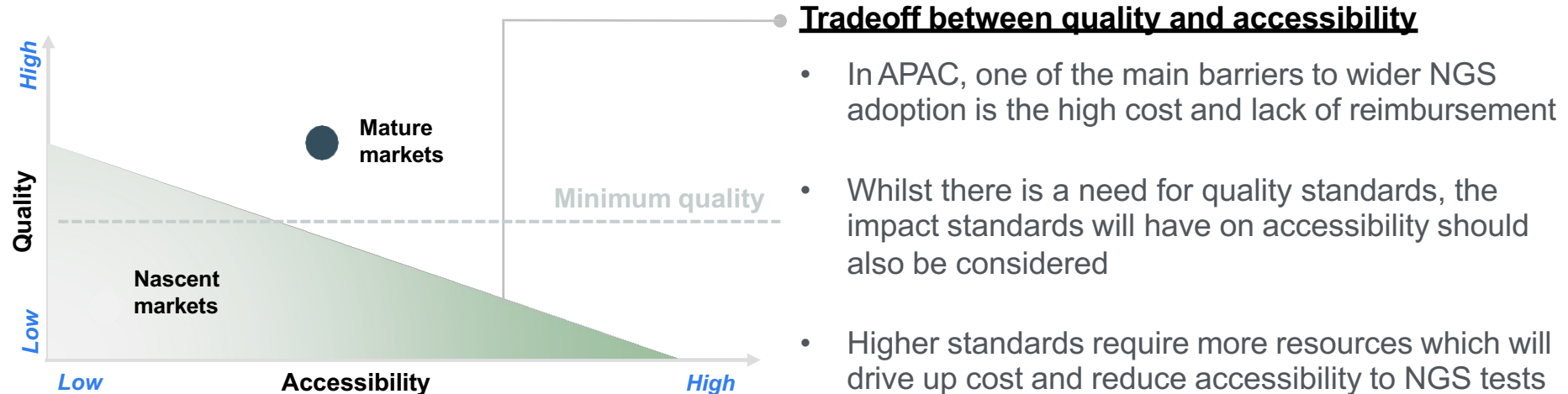


Laboratories performing NGS-based tests

- In some markets, there are **no regulations** of labs performing NGS-based tests, labs are left to self-regulate
- Variations in outcome have been observed between labs, given the same sample, raising **concerns on lab capabilities** and **user's confidence in outcomes**

A range of APAC-specific concerns were considered in relation to how to apply best practice in the region (2)

Correlation between quality and accessibility



It was agreed that there should be standards to ensure **minimum** quality which is achievable by all markets, as a first step to elevate the quality of NGS

- Panellists agreed that a holistic approach was needed for APAC region
- Given the heterogeneity, the initial minimum quality standard should be at a level that is feasibly achievable by all markets
"Given the heterogeneity within APAC... guidelines set should follow a minimum common denominator, achievable across all markets..."

The white paper makes 3 'tier one' recommendations to deliver consistent, better patient outcomes and cost efficiency that are applicable across APAC's heterogeneous markets

1

Publication of guidelines ensuring standardisation and quality NGS across the entire workflow

2

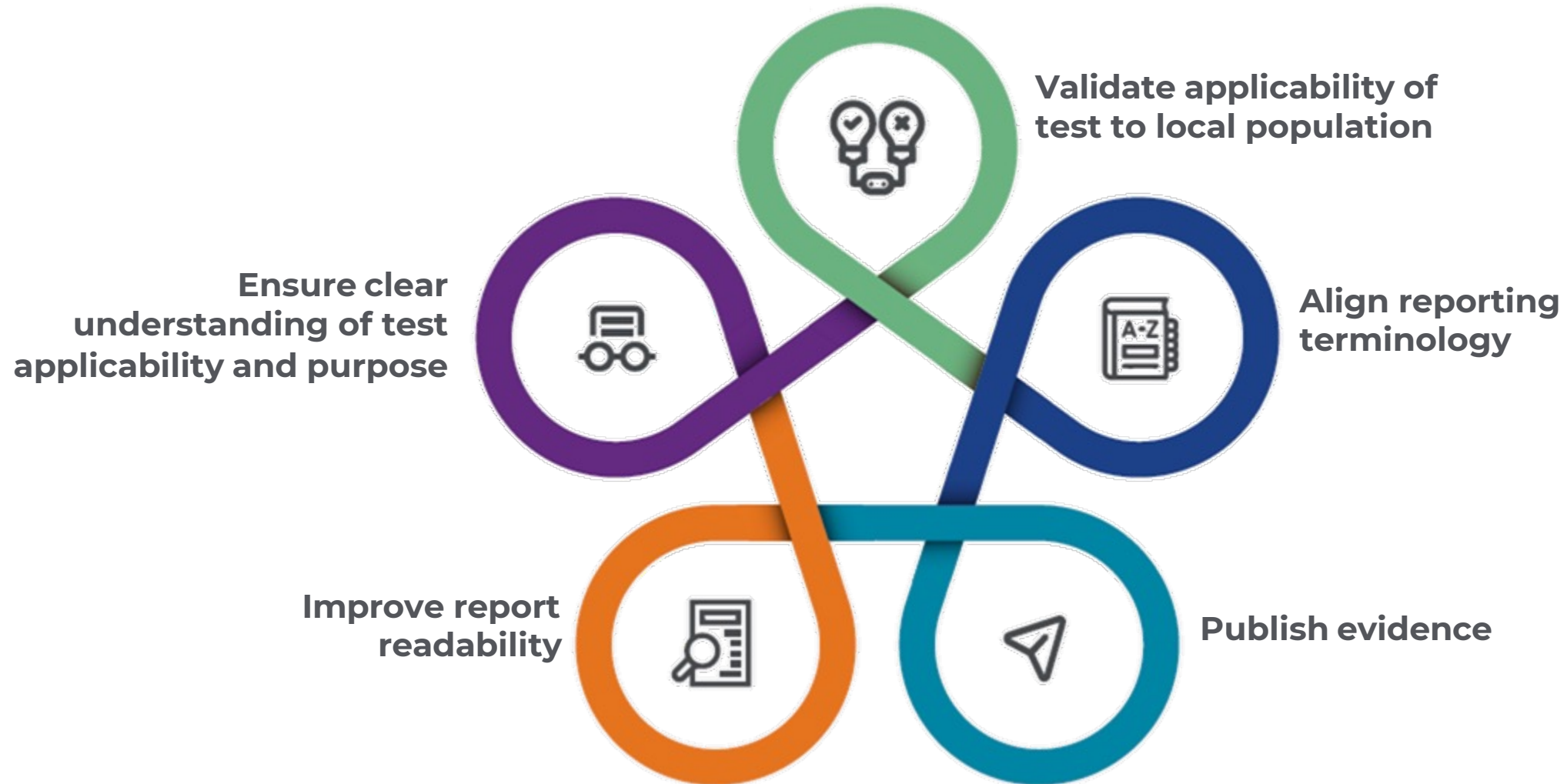
Enforcement of laboratory accreditation/certification

3

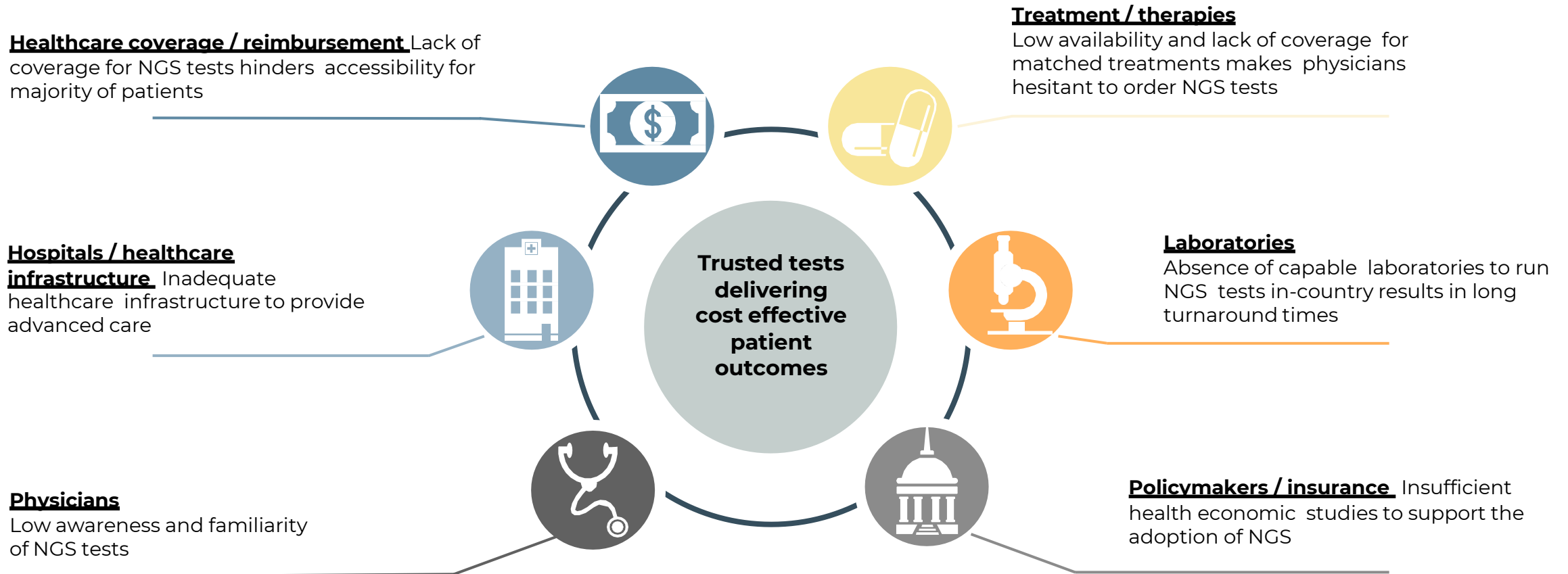
Restrict routine clinical use to only tests validated (preanalytical, analytical, clinical validity) with clear clinical utility

Covering clinical use of targeted biomarker NGS tests for cancer for the more widely used targeted biomarker NGS tests, such as single biomarker, hotspot panel and CGP

The white paper also elevates a number of 'tier 2' areas which have an impact on NGS quality



Important note: Having quality NGS is the first step to ensuring NGS tests can deliver value. There are other factors that also impede adoption and the realisation of patient and payor benefits NGS can bring



The white paper can now be used to raise the profile of NGS with policy makers and influence policy



Key Take Aways

1

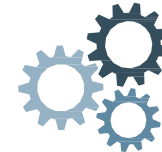
The white paper is a solid body of referenceable insight from credible, independent sources as well as some well-considered talking points



2

There is a need for improved guidance and regulation from public bodies in three specific areas

- a) Standardisation and quality NGS across the entire workflow*
- b) Laboratory accreditation and certification*
- c) Restriction of / guidelines for routine clinical use*



3

**There are other levers (i.e., beyond quality) that need to be pulled regionally/locally to support further NGS adoption, and deliver on the better patient outcomes and cost effectiveness promise.
For example, improving affordability is also key**



Panel discussion

Panelists



RICHARD VINES

Chair and Chief Executive,
Rare Cancers Australia



SAYYIDI HAMZI

Deputy Lab Director and Senior Clinical
Scientist at Pantai Premier Pathology



DR SUYOG JAIN

Associate Director, Medical Affairs, AMEA
Guardant Health



DR AMOL ZIMUR

Head of Medical Affairs, Asia
Pacific & Japan at Illumina

Moderator



STEPHEN SUNDERLAND

Partner,
L.E.K. Consulting

NGS project: 2022 and 2023 activities

2023 activation plan

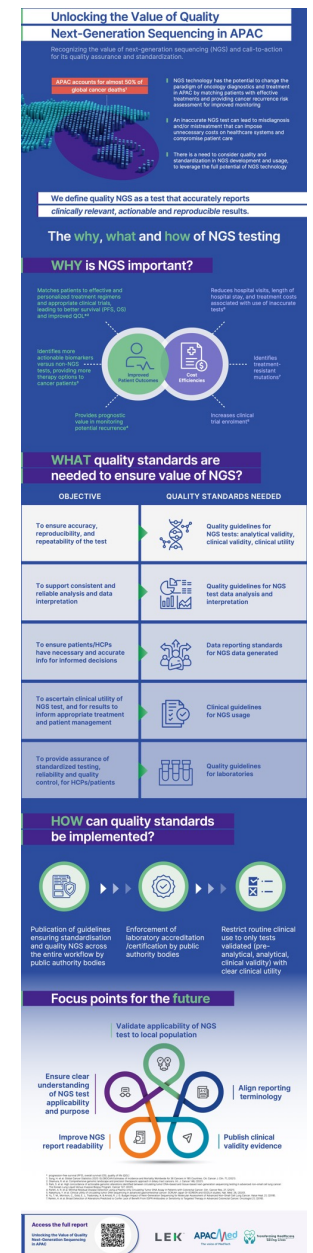
- **Translation:** Mandarin, Korean, Japanese
- **Activities:**

Sharing sessions with public and private sector, workshops

- **Objectives:** advocate for the recognition of higher quality NGS and implementation of guidance for quality assurance and standardization to ensure this value is realized.
- **Focus territory:** (1) Australia, Korea, Taiwan (2) Japan, Singapore (3) China, HK

White paper on the barriers to access NGS solutions in APAC

- **Objectives:** share recommendations on how to tackle the barriers to access, in the different APAC markets
- **Focus actors:** HCPs, regulators, policymakers



The background of the slide is a solid dark blue. Overlaid on this background is a large, abstract graphic consisting of numerous spheres of varying sizes. The spheres are primarily purple and light blue, with some appearing to have a gradient or a slight glow. They are arranged in a way that suggests movement or a dynamic structure, possibly resembling a molecular model or a cluster of particles. The spheres are more densely packed in the upper right and lower right areas, with some trailing off towards the left.

Thank you!

For more info, please contact
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