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Advancing Clinical Evidence in Infectious Diseases

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CARB-X
Combating Antibiotic-Resistant Bacteria

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Open Call for AMR Diagnostics

23rd June 2026
6pm to 7pm, SGT

Webinar outline

What makes a rapid diagnostic clinically useful? Lessons from the FAST trial

Prof Ritu Banerjee
Professor of Pediatrics
Vanderbilt University

Regulatory challenges in bringing diagnostics to Asia

Dr Weng Ruifen
Chief Executive Officer
Diagnostics Development Hub
(DxD Hub)

Steering your innovation through product development: common gaps and oversights in the early phases

Dr Beth Amiott
Alliance Director
CARB-X

DETECT Open Call: What we are looking for

Adj Assoc Prof Mo Yin
Co-Director
ADVANCE-ID
(National University of Singapore)

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What makes a rapid diagnostic clinically useful? Lessons from the FAST trial

Prof Ritu Banerjee

Professor of Pediatrics

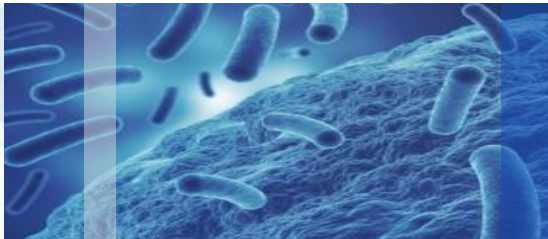
Vanderbilt University Medical Center

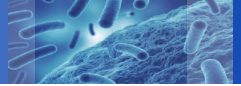
ARLG
Antibacterial Resistance Lead

Lessons Learned From the FAST Trial

Ritu Banerjee, MD, Ph.D
Professor of Pediatric Infectious Diseases, Vanderbilt Health
June 23, 2026

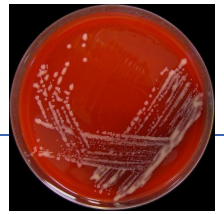




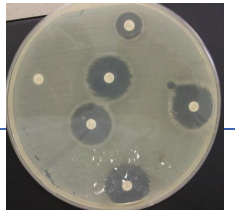


Disclosures

- None



Background: Blood Culture Diagnostics



- **Sepsis due to bloodstream infections**
  - 30% mortality with ineffective treatment
- **Conventional blood culture evaluation**
  - Organism ID and antimicrobial susceptibility testing (AST) results >2 days AFTER a positive culture
- **Early treatment** critical but empiric
  - Ineffective → poor outcomes
  - Overtreatment → antibiotic resistance, AEs
- **Faster tests** shorten time to optimal therapy
  - Costly, unclear clinical impact
  - Prior studies: Limited power, not conducted in areas with high antibiotic resistance

Objective: To compare clinical outcomes among patients with Gram-negative bloodstream infections who have isolate AST determined using rapid method vs. standard methods *in areas with high antibiotic resistance rates*

Fast Antibiotic Susceptibility Testing for Gram-negative bacteremia (FAST)

FAST
Antibacterial Resistance Leadership Group

Patients with blood cultures with Gram-negative bacilli on Gram stain (N=850)

RAPID testing
- Organism ID using rapid MALDI ToF
- Rapid AST
- Standard AST
- Antimicrobial Stewardship review

Standard testing
- Standard organism ID
- Standard AST
- Antimicrobial Stewardship review

- VITEK REVEAL™
- Measures changes in volatile organic compounds
- TAT ~5 hours

Enrolled Dec 2023-May 2025, 7 sites in Greece, India, Israel, Spain

Outcomes

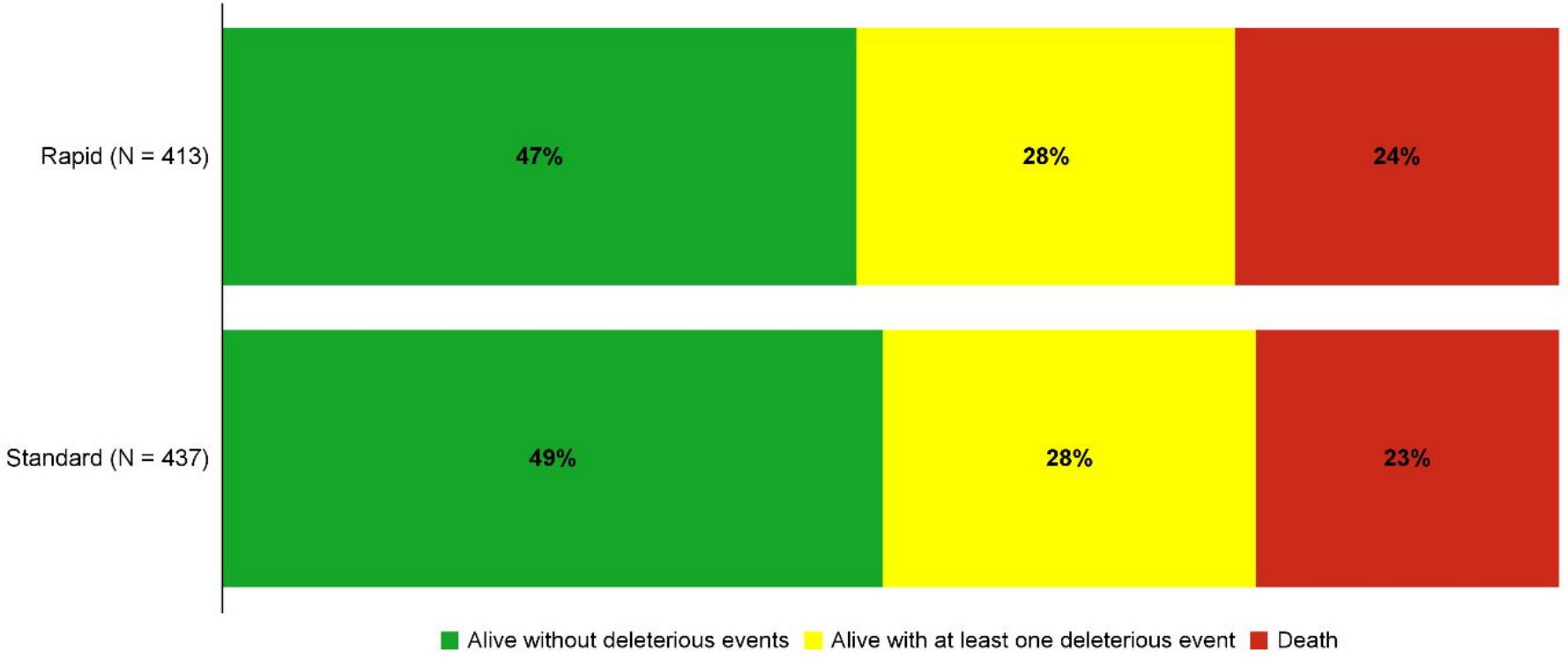
- Primary - Desirability Of Outcome Ranking (DOOR) at 30d
  - Alive no deleterious events
  - Alive with 1 to 3 deleterious events
  - Death

Deleterious Events		
Unsuccessful discharge: • Not discharged from index hospitalization • Readmission	Lack of clinical response: • Relapse of bacteremia • Local suppurative complications • Seeding distant sites	Undesirable event: • Acquisition of hospital-acquired infection *C. difficile* Multidrug resistant organism • Post-randomization renal failure

- **Secondary**: Mortality, LOS, individual components of DOOR, time to antibiotic modification within 72h, time to effective antibiotic treatment within 72h

Banerjee et al, JAMA (2026) 335:

Primary Outcome
Desirability of Outcome Ranking (DOOR) at 30 Days, As Randomized Population



testing

Secondary and Exploratory Outcomes, As Randomized Population

Outcome	Rapid AST (N=413)	Standard AST (N=437)	Difference in proportions or medians (95% CI)
Clinical Outcomes			
Mortality, no (%)	100 (24.2)	99 (22.7)	1.6 (-4.1, 7.3)
Length of stay, median days, (95% CI)	8 (7,8)	8 (7, 9)	0 (-1, 1)
Remained hospitalized at 30 days, no (%)	38 (9.2)	58 (13.3)	-4.1 (-8.3, 0.2)
Readmission, no (%)	51 (12.3)	41 (9.4)	3.0 (-1.2, 7.2)
Multidrug-resistant organism[1] acquisition, no (%)	55 (13.3)	51 (11.7)	1.6 (-2.8, 6.1)
Relapse of infection	12 (2.9)	24 (5.5)	-2.6 (-5.3, 0.1)
Antibiotic Treatment and Stewardship			
Time to effective antibiotic, median h (IQR)	0	0	0
Time to antibiotic escalation/deescalation, median h (IQR)	22 (14, 25)	36 (30, 45)	-14 (-22, -6)
Antibiotic stewardship recommendations made, no (%)	314 (76.0)	255 (58.4)	17.7 (11.5, 23.9)
Antibiotic stewardship recommendations followed, no (%)	287 (69.5)	239 (54.7)	14.8 (8.4, 21.2)

[1]Multidrug-resistant organisms: MRSA, VRE, ESBL Enterobacterales, CRE, carbapenem-resistant *Pseudomonas* or *Acinetobacter*, *Candida auris*

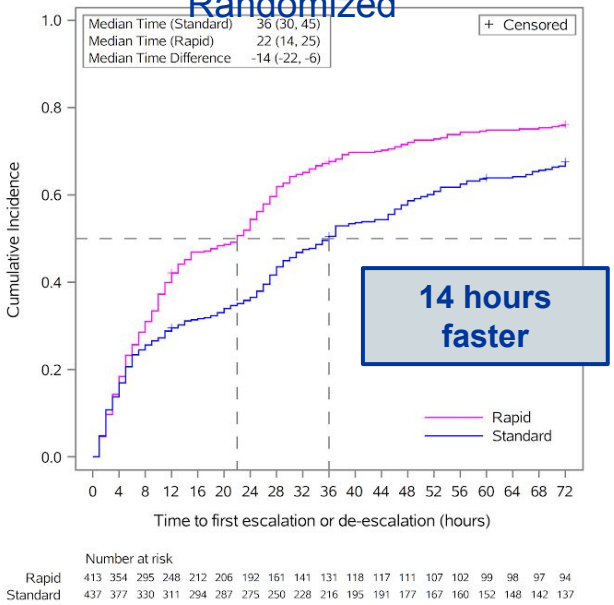
Secondary Outcomes in Subgroups with Antibiotic Resistant Infections

Outcome	Cephalosporin-resistant			Carbapenem-resistant		
	Rapid AST (N=164)	Standard AST (N=154)	Difference in proportions or medians (95% CI)	Rapid AST (N=86)	Standard AST (N=75)	Difference in proportions or medians (95% CI)
Mortality, no (%)	52 (31.7)	43 (27.9)	3.8 (-6.3, 13.8)	41 (47.7)	30 (40.0)	7.7 (-7.6, 23.0)
Length of stay, median days, (95% CI)	8 (7,12)	11 (9,13)	-3 (-6, 0)	11 (6, 14)	13 (8,18)	-2 (-9, 5)
Remained hospitalized at 30 days, no (%)	20 (12.2)	26 (16.9)	-4.7 (-12.4, 3.1)	13 (15.1)	21 (28.0)	-12.9 (-25.6, -0.2)
Readmission, no (%)	13 (7.9)	18 (11.7)	-3.8 (-10.3, 2.8)	3 (3.5)	4 (5.3)	-1.8 (-8.2, 4.6)
Multidrug-resistant organism[1] acquisition, no (%)	28 (17.1)	21 (13.6)	3.4 (-4.5, 11.3)	20 (23.3)	16 (21.3)	1.9 (-10.9, 14.8)
Relapse of infection	6 (3.7)	5 (3.2)	0.4 (-3.6, 4.4)	4 (4.7)	4 (5.3)	-0.7 (-7.4,6.1)

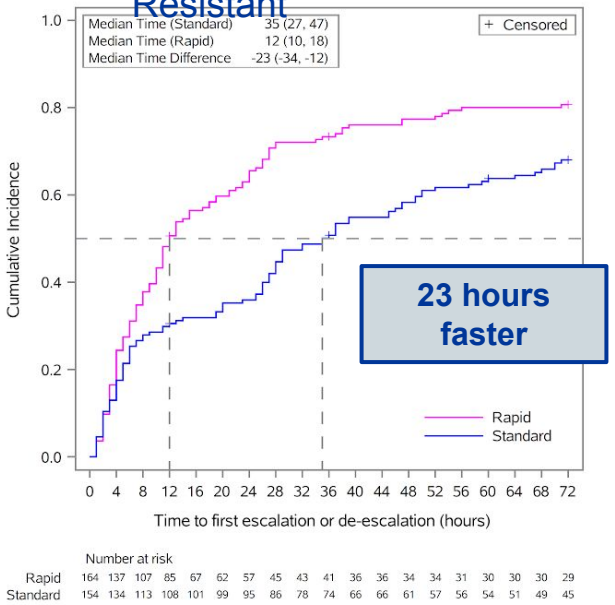
[1]Multidrug-resistant organisms: MRSA, VRE, ESBL Enterobacterales, CRE, carbapenem-resistant *Pseudomonas* or *Acinetobacter*, *Candida auris*

Time To First Antibiotic Change
Subgroups with Antibiotic-resistant Infections

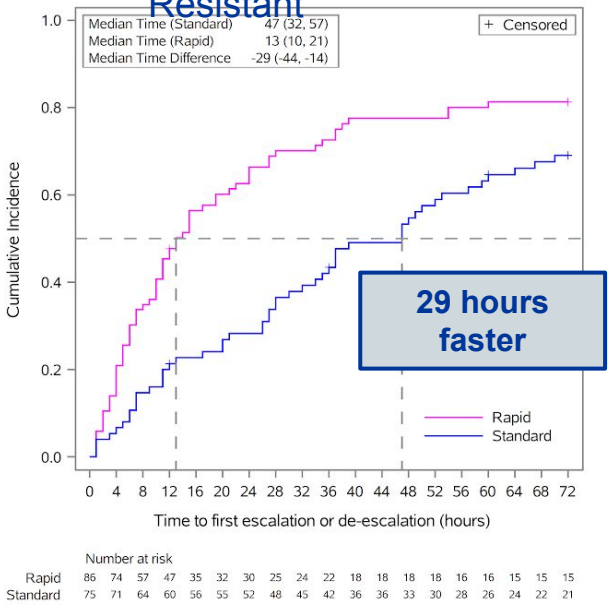
As Randomized



Cephalosporin Resistant

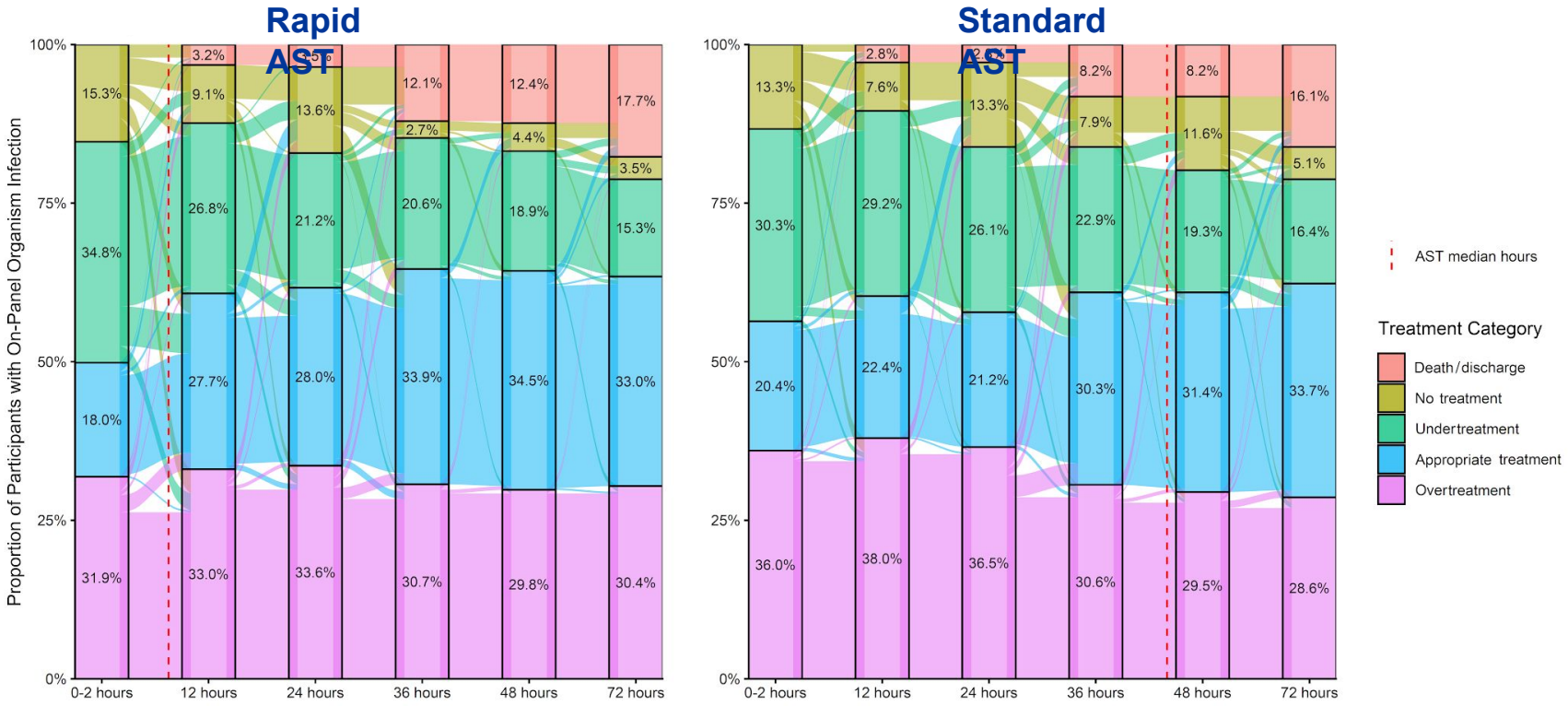


Carbapenem Resistant



Standard AST RAPID AST

Rapid AST Arm
Faster Appropriate Antibiotic Treatment

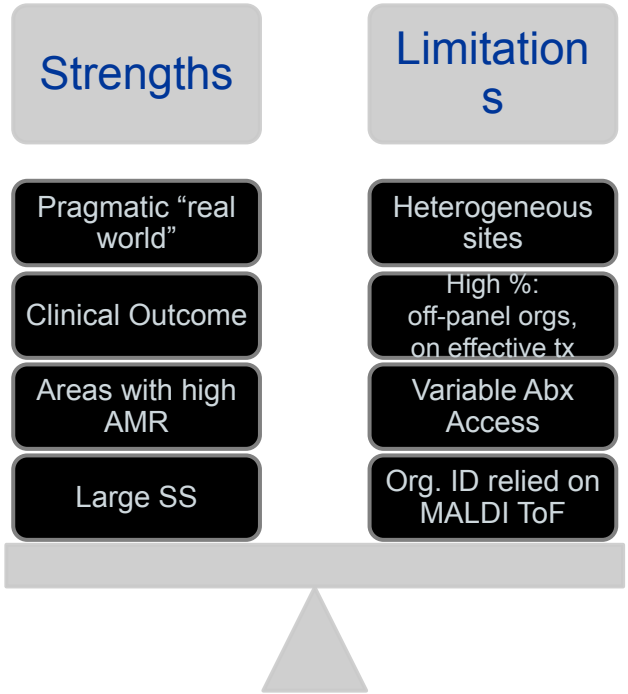


Banerjee et al, JAMA (2026) 335:

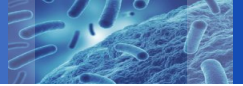
Conclusions

Rapid AST:

- Not superior to standard AST based on DOOR primary clinical outcome
- Faster, targeted antibiotic therapy; greater provision and adherence to stewardship guidance
- Fewer patients hospitalized at day 30 in carbapenem-resistant subgroup
- Trend towards shorter LOS in subgroups with resistant infections



Banerjee et al, JAMA (2026) 335:



What influences clinical impact of new blood culture diagnostics?

- Breadth of target organisms
- Target organisms and resistance markers that align with local epidemiology
- Susceptibility results for antibiotics that are available and used in clinical practice
- TAT that is clinically relevant and faster than SOC (may be setting dependent)
- Workflow and throughput that align with laboratory staffing, specimen volume
- Implementation: pair diagnostics with effective therapeutics, stewardship and clinician education
- There are many measures of clinical impact beyond mortality

Acknowledgements

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  - Amos Adler (Tel Aviv Sourasky Medical Center)
  - Mical Paul (Rambam Health Care Campus)
  - Shrikala Baliga (Kasturba Medical College)
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Thank you

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Steering your innovation through product development: common gaps and oversights in the early phases

Dr Beth Amiott

Alliance Director

CARB-X

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Combating Antibiotic-Resistant Bacteria

BOSTON UNIVERSITY

Innovative diagnostic product development:
Common gaps and oversights in the early phases

DxDHub Industry Webinar & ADVANCE-ID Open Call for AMR Diagnostics:
Accelerating AMR Diagnostics from Innovation to Clinical Impact

23 June 2026

Speaker: Beth Amiott, PhD
Diagnostics Alliance Director @ CARB-X

My association/disclosure

CARB-X is the leading global non-profit partnership dedicated to accelerating the research and development of diagnostic, preventative, and therapeutic products to address the rising threat of drug-resistance bacteria.

Today's viewpoints are mine and do not reflect official positions of CARB-X or its funders

Perspective: CARB-X Dx Portfolio is Early-Stage Projects

Current Portfolio = 7 Diagnostics (+6 seed awards)

STIs (NG)
BSI/AST
Typhoid
LRTI

Today's Aims:

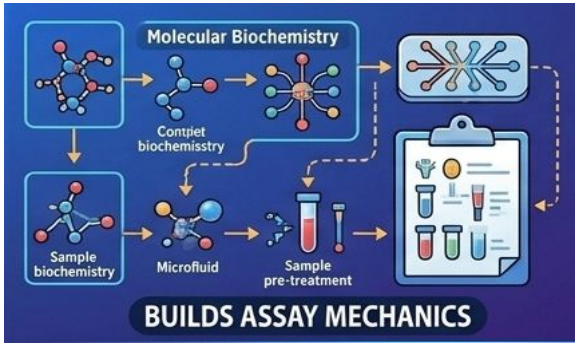
- Introduce early considerations and tips to de-risk Dx innovation
- Share common gaps and pitfalls in early product development
- Understand what funders and partners may look for beyond technical performance

Early Considerations to De-risk Innovations

Adopt a ‘Fit for Purpose’ **PRODUCT** mindset combined with your **TECHNOLOGY** mindset

IVD PRODUCT MINDSET
FOCUS ON CLINICAL UTILITY & PATIENT

IVD TECHNOLOGY MINDSET
FOCUS ON ASSAY PLATFORM & PERFORMANCE



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Define 'Fit for Purpose' Product Requirements Early – Re-Visit Often

What is your test – **where** and **how** (and by **whom**) will it be used?

Intended Purpose, Use & Scientific Validity of the Test

- **Syndrome or infection (pathogen)** and **analyte** (nucleic acid, antigen, antibody, host biomarker, etc)
- **Infection status**: active or acute infection, colonization/screening, treatment monitoring, surveillance, etc
- **Patient population**: adult, pediatric, immunocompromised [also consider contraindications/exclusions]
- **Sample type**: volume, time since symptom onset, analyte concentration, stability, quality, interference
- **Test setting**: laboratory, 'point of care', emergency, community health clinic, self or at-home testing

Sample Collection, Testing Workflow, Use Environment

- **Complexity/Ease-of-Use**: user skills, qualifications, training for sample collection, testing & results
- Risk of **poor sample collection** or sample/test **contamination or mix-up** (mis-labeling)
- **Storage & operating conditions** of test kit and/or equipment
- **'Full' test turnaround time:** sample collection, transport, processing or batching, testing, result reporting
- **Single vs. multi-test capacity**; random access vs. batching
- **Critical test steps** and **stopping points**; sensitivity to **time, error, or misuse ('flex' testing)**
- **Disposal** and **environmental impact;** regulatory restrictions on biological or chemical imports

‘Fit for Purpose’: **How** and **Why** will your test be used?

Can you deliver what the users need at a price they will pay?

Interpretability & Actionability of Results

- Are results **quantitative** or **qualitative**? **Simple or complex**? **Manual (visual)** read or **digital**? Are a**lgorithms** or **thresholds** needed? Printed or electronic report transmission?
- How do the **results** you report and **how** you report them affect **actionability**?
- How and how often is the test expected to drive **action** and **changes in clinical care relative to current standard of care**?
- How does actionability change with different performance metrics?
- Does testing fit with current **clinical guidelines**?

Manufacturability, Shelf-life & Stability, Regulatory Requirements

Costs, Market Access/Demand, Willingness to Pay

What is the **minimum viable product** for each potential **use case**?

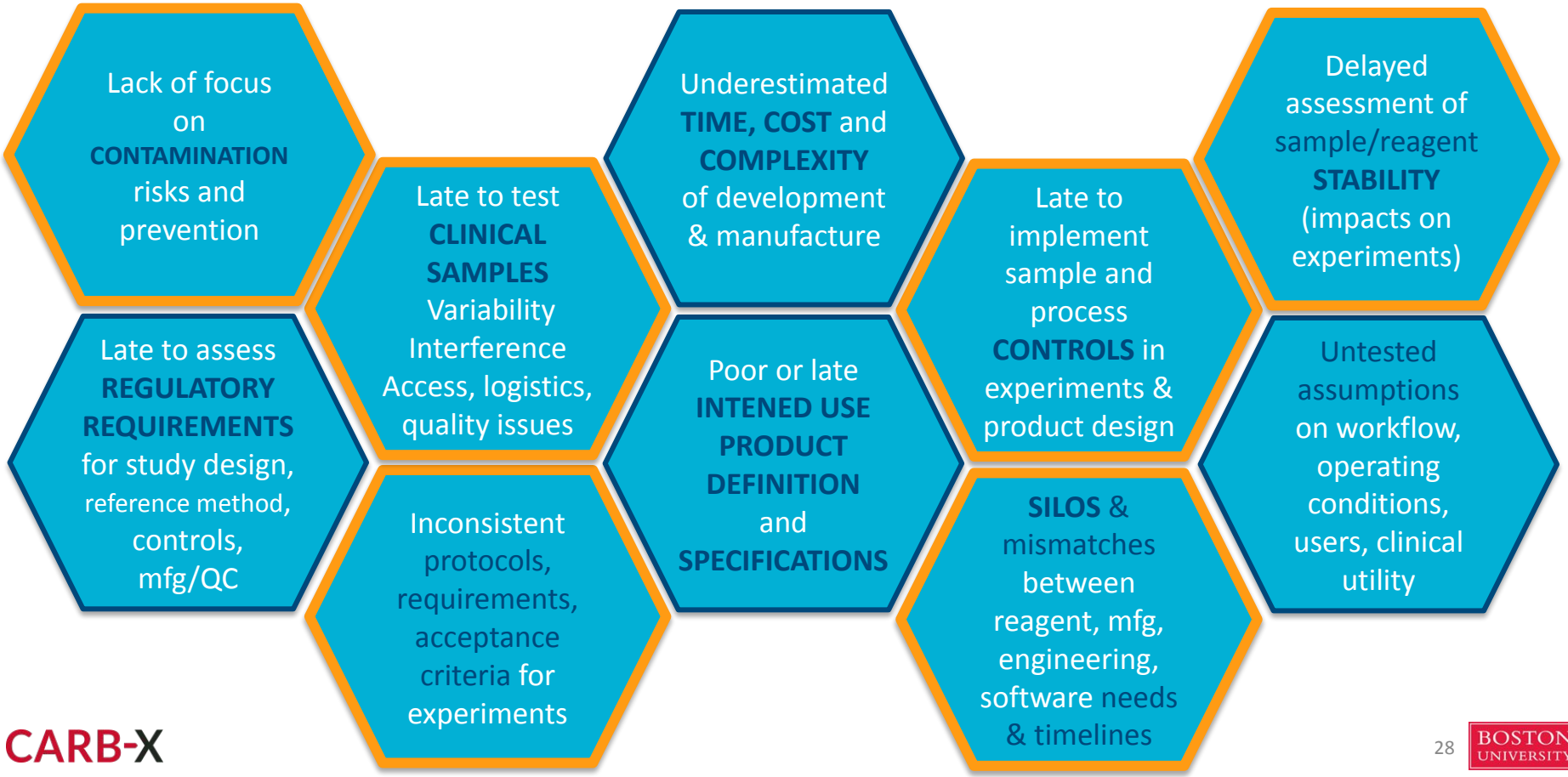
Tips for early de-risking of intended use, workflow, interpretability & actionability

- Draft a preliminary ‘Instructions For Use’ for your product vision
- Revisit and adjust IFU draft as the product develops & matures

- Visit clinical/testing site(s) for observation and interviews
- Do a ‘walk-through’ from patient and sample collection to testing & reporting
- Look for ‘pain points’ and risk of error or contamination in the workflow – design to mitigate
- Assess ‘acceptable’ test failure/invalid rates
- Draft mock test results and show to testers/users to check interpretability

- Prepare patient-test scenarios and distribute to clinicians to assess the type and likelihood of action based on test results
- Match minimum performance targets to intended use & actionability

Gaps and pitfalls in early product development



What product development funders and partners may look for beyond technical performance

Company structure and culture

- Access to well-rounded **expertise & experience in** science, engineering/manufacturing, data science, software, project mgmt, QA/RA, clinical and laboratory practice, commercialization
- **Clarity** and **robustness of data** and **communication**
- **Openness** to collaboration and input
- Resilience and success in **identifying and overcoming challenges**
- Clear and strong **decision-making** processes

Clinical partnerships for pilot studies and plans for evidence generation

Realistic planning & prioritization: scope/MVP, time, budget & resources

Progress on manufacturing, QMS/risk assessment, regulatory needs

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Combating Antibiotic-Resistant Bacteria

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Regulatory challenges in bringing diagnostics to Asia

Dr Weng Ruifen

Chief Executive Officer

Diagnostics Development Hub (DxD Hub)

Regulatory Landscape for IVDs – An overview of Asia LMICs

Ruifen WENG PhD, EMBA, GCMDRA

CEO, Diagnostics Development Hub, A*Star

Lead, PREPARE Diagnostics Co-Op, CDA

Visiting Advisor, National Centre for Infectious Disease

An Overview of the Regulatory Landscape for Asia LMICs

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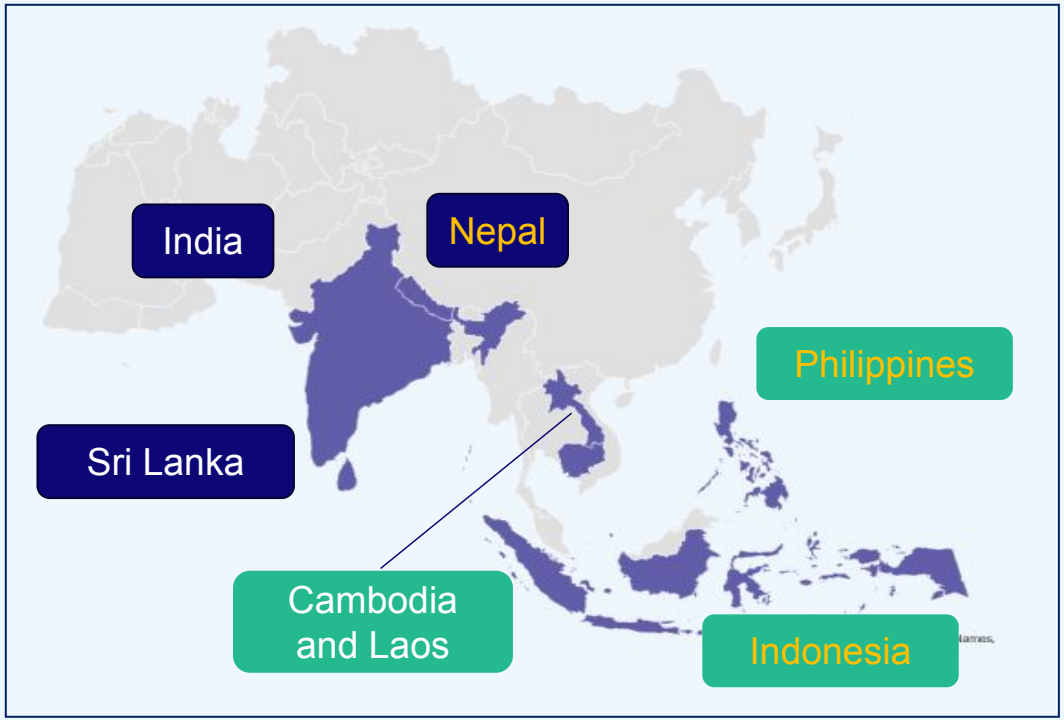
No existing regulatory harmonization framework



Ongoing Harmonization within ASEAN to the AMDD

- **Regulatory Heterogenicity among Asia LMICs**
  - **No CE mark equivalent** pathway that allows access to multiple countries simultaneously
  - An ongoing harmonization effort within ASEAN through **ASEAN Medical Device Directive (AMDD)** - a common framework to reduce technical barriers for pre-market registration and post-market surveillance

Regulatory Harmonization Efforts in ASEAN through the ASEAN Medical Device Directive (AMDD)

What & Why

- An agreement signed by all 10 ASEAN member states in 2015 to harmonize regulatory frameworks for all medical devices, incl. IVDs
- To facilitate trade and market access of medical devices in ASEAN by reducing technical barrier
- AMDD implementation and updates are coordinated through the ASEAN Medical Device Committee (AMDC, est. 2014)

Overview of AMDD as ASEAN's Common Regulatory Frameworks

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Key Provisions

- All devices, incl. IVDs. be registered with the **national regulatory authority** in **each member state**
  - Method of submission - whether paper-based or electronic – is determined by each authority
- Setting up common risk classification guidelines across ASEAN member states
- Pre-market technical and compliance requirements:
  - Adoption of ASEAN *Common Submission Dossier Template (CSDT)*
  - Harmonized *Declaration of Conformity (DOC):* requirement for compliance with *essential principles of safety and performance*
  - *Conformity assessment*: review of QMS (ISO13485 or equivalent) and post-market surveillance systems
  - *Harmonised labelling standards: meet local language and symbol requirements*
- Post-market alert system (PMAS): mandatory *adverse event reporting* and *field safety corrective actions*

Understanding the ASEAN CSDT to Streamline Product Registration in ASEAN

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What & Why

- Is the standardized format for technical documentation required for IVD product registration
- A common template accelerates market entry to ASEAN markets by reducing the time required to prepare technical documentation for each country.
- Alignment with Global Standards: Core elements of CSDT is based on global standards such as the **IMDRF** □ easier for companies already exporting to Europe or other regulated markets to adapt existing technical reports and other documentation

Who Needs It?

- All IVD manufacturers registering Class A, B, C, and D products in ASEAN

Language Requirement

- Generally in English, but TH, ID, VN, MM, LAO require translation

Common Country-specific Requirements within ASEAN

Language

- While CSDT submissions are almost universally accepted in English, **labelling and IFU** translation into the **national language** of the respective ASEAN member states is a frequent requirement for market approval
    - National language required for **ALL** labeling and IFU: ID, VN, TH (with exceptions)
    - National language required for **SOME** products/end-user products: MY, BN, PH, (KH, LAO, MM)

In-country Testing

- Most ASEAN countries accept international performance data for many IVDs, but require local testing for high-risk, novel, infectious disease-related products, or self-testing and near-patient IVDs
    - Mandatory for **most IVDs:** PH – designated labs, eg RITM

Country Representative

- Local Authorized Rep (LAR) – for pre-market registration, imports, post-market surveillance/reporting - **required for all**
    - multiple LARs per products: MY, SG, PH, *TH, VN (multiple indep product registration)*
    - **only 1 LAR per product: ID**
        - Market-specific nuances on regulatory process to change LAR, eg. In ID, LAR acts as holder of marketing authorization (Nomor Izin Edar, NIE), changing LAR requires cancelling of existing NIE, followed by new application with new LAR product off-market during new review process

Implementation of ASEAN Medical Device Directives (AMDD)

Progress

- The "ASEAN Way": ASEAN's **consensus-based** decision-making and respect for **national sovereignty** - Member states may choose when they would fully implement the AMDD

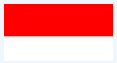
Country	AMDD Progress	Key Aspects Implemented	Aspects In Progress
ID, MY, SG, TH	Advanced	Full risk classification, CSDT, PMAS, *e-registration*	Ongoing updates, technical refinements
PH	Partial	CSDT for Medical Devices only, transition guidelines	Full-scale adoption of AMDD systems, requirements for IVDs
VN	Partial	CSDT, regulatory updates ongoing	Full AMDD alignment
KH	Early	Initial alignment steps	Risk classification, PMAS
LAO	Early	Initial alignment steps	Major regulatory development
MM	Early	Initial alignment steps	Major regulatory development
BR	Early	Yet to implement AMDD	Full AMDD alignment

Regulations in India, Sri Lanka, and Nepal

- Independent regulatory frameworks among these countries
- No shared technical dossier formats

Country	Regulatory authority	Risk Classification	Governing legislation	Dossier formats
Nepal	Department of Drug Administration (DDA)	No official risk class system – but DDA published 17 categories of regulated devices	Directive on Health Technology Product and Equipment, 2074 (Year 2017)	Limited information publicly available
India	Central Drugs Standard Control Organization (CDSCO); Central Licensing Authority vs the State Drug Controllers	4 tier risk class (A to D)	Medical Device Rules, 2017	Defined in the Medical Device Rules, 2017
Sri Lanka	NMRA	4 tier risk class (A to D)	National Medicines Regulatory Authority Act, No. 5 Of 2015	Refer to form F-MDR-035 on NMRA website

Regulatory Reliance within Asia LMICs

- **India** 
  - IVDs registered in **Australia, Canada, Japan, EU, USA, or UK** are eligible for reliance pathway
    - Products with predicate devices in India: in-country clinical performance evaluation is waived;
    - Products without predicates in India: in-country clinical performance evaluation is required for Class B, C and D IVDs
- **Sri Lanka** 
  - IVDs registered in Australia, Canada, Japan, Norway, USA, UK, Switzerland, Singapore, and EU are eligible for reliance pathway
    - Eliminates the need for local product testing
- **Laos and Nepal**  
  - No officially announced reliance program, although specific reference agencies have been mentioned for some product registration requirements consult early with local representatives
- **Cambodia, Indonesia, and Philippines**   
  - No reliance exists for IVDs in these countries currently

Recommendations for Manufacturers

- **Common Mistake:**

  Regulatory and quality requirements considered late in product development
  - Costly reworks and rethinking of market entry strategies significantly delay product entry timelines

- Some Suggestions
  - Define intended use and claims **early** in the development life cycle
  - Review regulatory landscape and consider **local requirements** from the beginning
    - Requirements on local product testing, and/or local clinical evidence
  - Engage early with local authorized representatives and regulatory authorities
  - Leverage **reliance programs** for faster multi-country access (where applicable)
  - **Build sustainable local partnership**
    - Product Co-development with local KOLs/hospitals – stronger **Product-Market-Fit** & better **Fit-For-Purpose**
    - Regional manufacturing - support resilience in supply; leverage government support; global diversification

DxD Hub, Singapore's National Platform for Diagnostics Productization - Hands-on Product Development Partner

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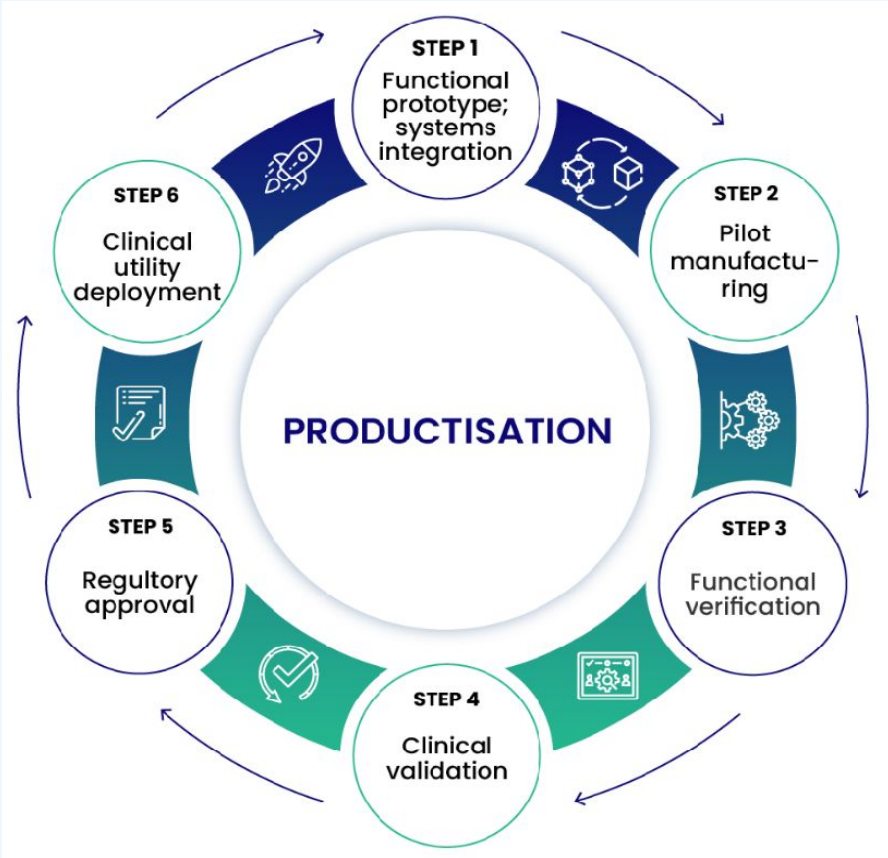

Partnerships over the years

MiRXES – TO KNOW IS TO ACT
LUCENCE
KYAN TECHNOLOGIES
CorDx
MP Biomedicals
PREPARE
NUH National University Hospital
National Cancer Centre Singapore SingHealth
Singapore General Hospital SingHealth
DukeNUS Medical School
Changi General Hospital SingHealth
Tan Tock Seng Hospital

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Thank You!

Nurturing a vibrant research network

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DETECT Open Call: What we are looking for

Adj Assoc Prof Mo Yin

Co-Director

ADVANCE-ID

- Warm clinical trial network >200 hospitals
- >13,000 patients enrolled
- Antimicrobial resistance as main focus
- ‘Scientific discovery’ to ‘applied implementation’
    - Therapeutic, diagnostic, prevention trials, surveillance
    - Innovative trial designs
    - Driving clinical practice and policy change

DETECT: Diagnostics Evaluation and Translation through Evidence for Clinical Testing

Programme led by ADVANCE-ID to strengthen diagnostic capacity, surveillance, and pandemic preparedness across Asia and globally.

FUNDING

Total budget: **S$8.38M (~USD 6.5M)**

Temasek Foundation: **S$1.0M (12%)**

Novo Nordisk Foundation: **S$1.0M (12%)**

Wellcome Trust & NMRC: **S$6.38M (76%)**

OUR PARTNERS

GLOBAL HEALTH INSTITUTIONS / POLICY DRIVERS

World Health Organization · GARDP · wellcome · European Medicines Agency

- Co-design and implementation to ensure global relevance
- Future expansion and maintenance

ASIAN HOSPITALS AND LOCAL GOVERNMENT

icddr,b · PGH · NIHD · Christian Medical College Vellore · Amrita Hospitals

Adoption, implementation and future maintenance → Maximise local relevance and uptake

ACADEMIC CENTRES

DukeNUS Medical School · Centre of Regulatory Excellence · Nanyang Technological University Singapore · MORU Tropical Health Network · oucru · Mahidol University

- Strengthen regional and local partnerships
- Maximise data utility for scientific discoveries

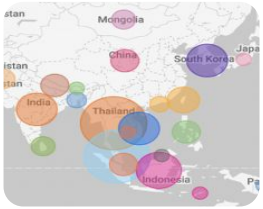
INDUSTRY PARTNERS

Pfizer · BIOVERSYS · Roche · BIOMÉRIEUX

- Trial-ready platform to attract private industry co-funding

DETECT: Diagnostics Evaluation and Translation through Evidence for Clinical Testing

Four concurrent streams of work



Laboratory capability standardisation tool

1. Baseline standards and practices
2. Gaps and needs assessment
3. Engagement with local stakeholders, WHO, global health partners

Locally driven solutions

1. Faster recognition of AMR infections
2. Efficient communication between lab and physicians
3. Laboratory information management systems

Rapid diagnostics

1. Training for operations and interpretation
2. Assimilation into routine care
3. Compare various technologies

Evaluation of patient impact

1. Clinical outcome assessment
2. Health economics

Global survey on microbiology laboratory capacity

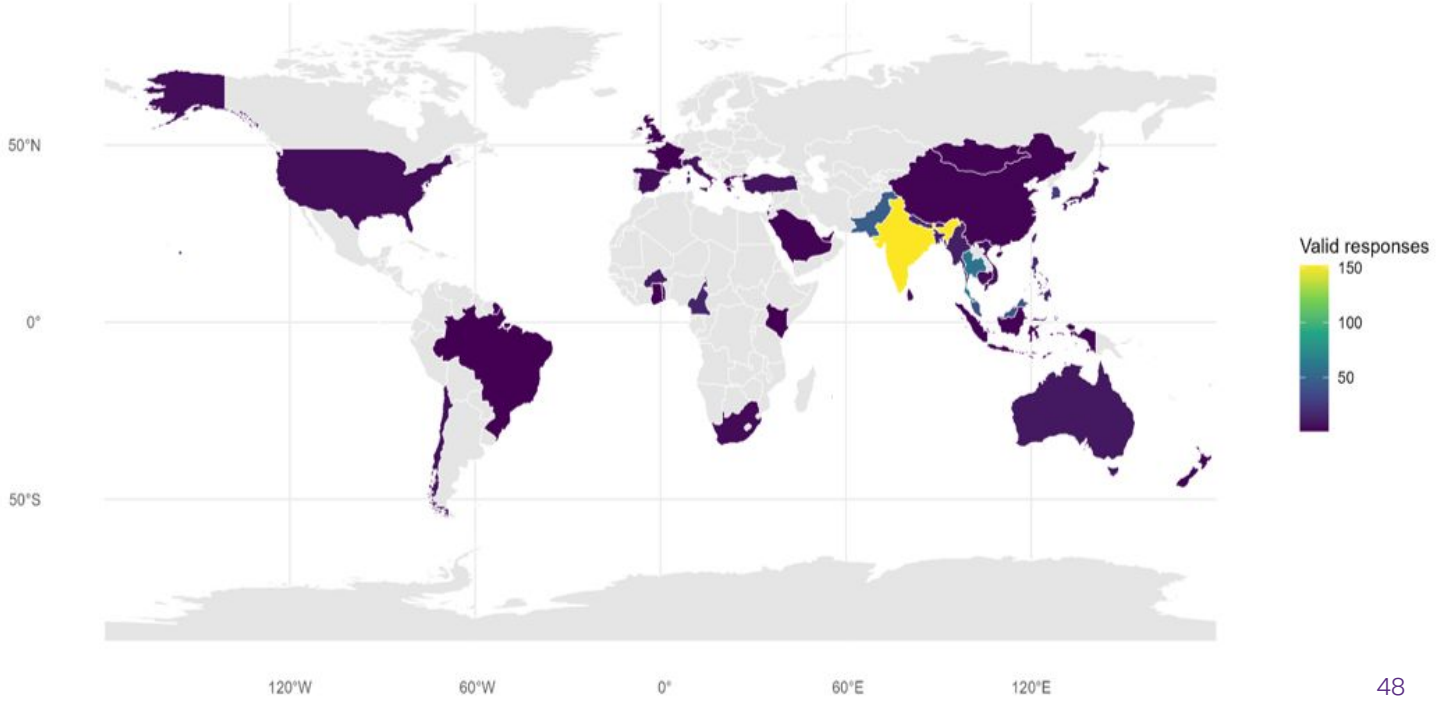
Assessment of microbiology laboratory capacity and gaps and barriers affecting diagnostics across diverse healthcare settings.

SURVEY SUMMARY

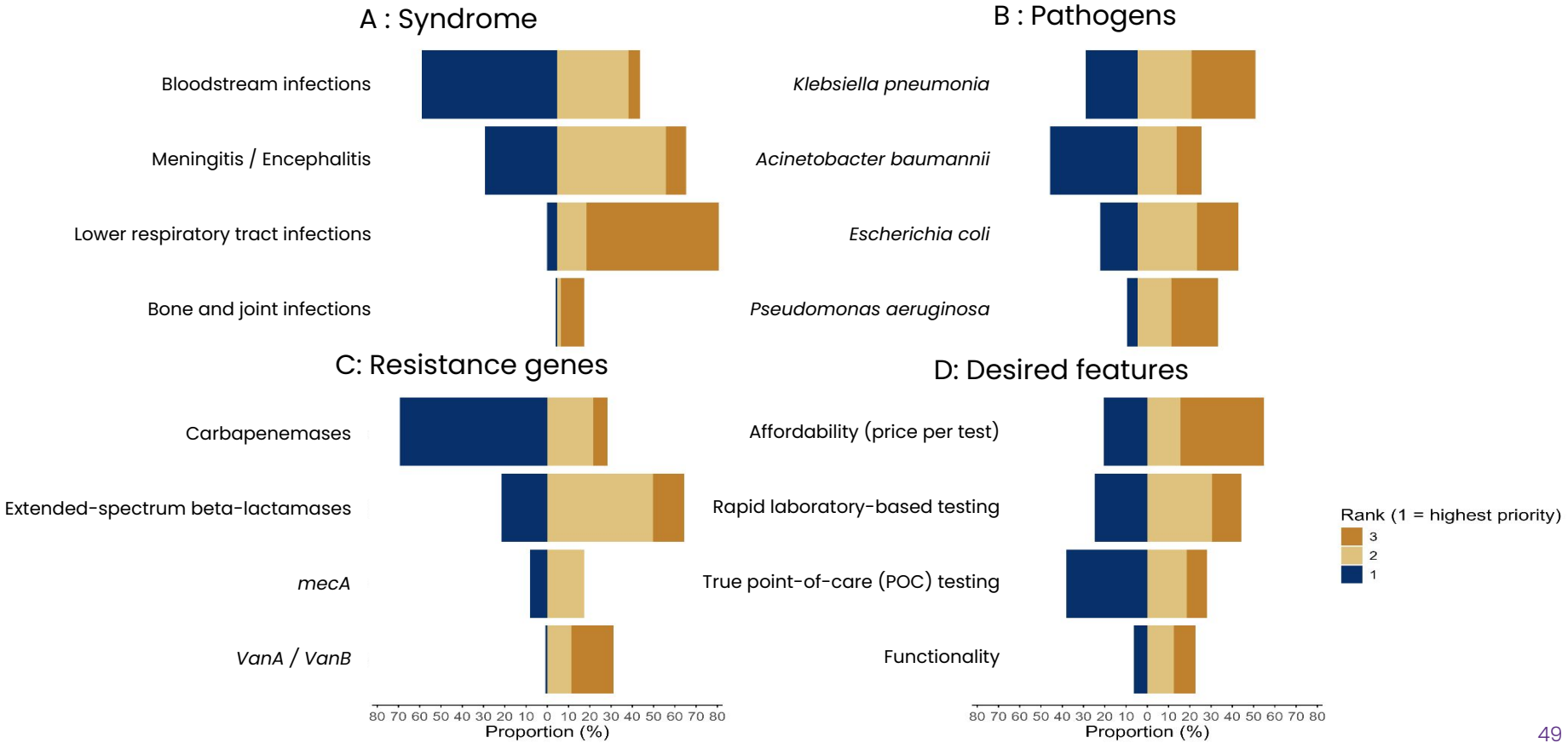
As of 22 June, 2026:

Valid responses
524

Countries with responses
47



Top-ranked priorities across four domains of rapid diagnostics



Mapping of respondents' priorities and preference clusters

01	**Prefers POCT**	• Values affordability • Prioritises testing near patient/bedside
02	**Prefers advanced AMR testing**	• Values functionality • Prioritises AST profiling

Our Target Product Profile (TPP)

Characteristic	Minimum requirement (Must-have)	Optimal requirement (Good-to-have)
Intended use	1) Detect one or more priority pathogens as listed (*Escherichia coli*, *Klebsiella pneumonia*, *Enterobacter spp.*, or *Pseudomonas aeruginosa* or *Acinetobacter baumannii*) AND 2) Detect genetic determinants of antimicrobial resistance (Carbapenem resistance : *blaKPC, blaNDM, blaOXA, blaIMP, blaVIM* OR Extended-spectrum beta-lactamases : *blaCTXM, blaTEM, blaSHV)*	1) Detect multiple pathogens (Enterobacterales such as *Escherichia coli*, *Klebsiella pneumonia*, *Enterobacter spp.*, and/or *Pseudomonas aeruginosa* and/or *Acinetobacter baumannii* or *Candida spp.*, or *Staphylococcus aureus*) AND 2) Phenotypic antimicrobial susceptibility for all antibiotics AND/OR genetic determinants of antimicrobial resistance (Carbapenem resistance : *blaKPC, blaNDM, blaOXA, blaIMP, blaVIM* AND Extended-spectrum beta-lactamases : *blaCTXM, blaTEM, blaSH* AND *mecA/mecC*)
Clinical specimen	Blood (e.g. whole blood, plasma, or serum) AND/OR Upper respiratory specimen (e.g. sputum, bronchoalveolar lavage, tracheal/endotracheal aspirate)	

Our Target Product Profile (TPP)

Characteristic	Minimum requirement (Must-have)	Optimal requirement (Good-to-have)
Culture-dependence	-	Blood: Directly from whole blood draw (e.g. bypassing BACTEC) Respiratory: Directly from clinical specimen
Sample capacity	Perform single runs of ~5 samples per run	Perform single runs of >10 samples per run
Point-of-care (POC)	Near POC defined as requiring processing in laboratory	True POC defined as result readout available at bedside
Automation	Semi-automated (excluding sample preparation)	Fully automated (including sample preparation)
Training requirements	Trained laboratory technician with basic microbiology skills	Minimal training required and non-laboratory staff may also operate

Our Target Product Profile (TPP)

Characteristic	Minimum requirement (Must-have)	Optimal requirement (Good-to-have)
Ease of use	Few manual steps for sample preparation or addition of reagents with clear instructions provided	No need for additional consumables outside of kit; sample to result cartridge/closed system
Power requirements	Operate with standard and stable AC supply	No need for electricity or battery-operable
Price per test (at 100,000 tests per year)	≤ US$ 20 at volume production	≤ US$ 15 at volume production
Time to result - ID and phenotyping/genotypic results	≤ 90 minutes	≤ 60 minutes

Evaluation process by Technical Evaluation Committee (TEC)

- Assess using a structured semi-quantitative questionnaire based on Likert scale
  - 5-point scale with supporting qualitative comments
- Each application will be evaluated by 3 members independently
- Domains assessed:
  - Clinical & stewardship impact
  - Technical feasibility & usability
  - Implementation & sustainability in LMIC settings
  - Scalability and affordability

Overall timeline

6 July 2026
Start of Open Call (~6 weeks)

Submission portal opens
Applicants submit EOIs & supporting documents

End Aug 2026
Start of evaluation (4 weeks)

Independent evaluations by Technical Evaluation Committee (TEC)

Mid-Sept 2026
Receipt of evaluation results from TECs

Discussion of tied scores and final ranking

End Sept 2026
Notification of outcomes

Applicants will be notified of the outcome

Oct 2026
Invitations for pitch

Selected applicants (e.g. tied applications) invited to deliver a pitch

Final selection

Shortlisted technologies (2 to 3)

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Evaluation supported by DxD Hub (Singapore)

Wet Lab Evaluation

- Assess key diagnostic performance characteristics: sensitivity, specificity, PPV, NPV, LOD
- Evaluation of early-stage or investigational technologies

Evaluation at Asian sites from ADVANCE-ID

Clinical evaluation

- Evaluation across hospitals in Asia
- Comparison with current standard-of-care diagnostics
- Assessment of operation feasibility and user experience
- Performance in routine clinical practice

Evidence generation

- Diagnostic turnaround times in real-world setting
- Health economic outcomes (cost-effectiveness)
- Patient clinical outcomes (e.g. 28-day mortality, length of stay)

For further enquiries, please contact DETECT team via:

1) **Enquiry form:** https://linktr.ee/DETECT_Advanceid

2) **Project Leads**

(Dr) Alec Aligui | alec.aligui@u.nus.edu
(Mr) Cleven Tan | weicong@nus.edu.sg
(Dr) Luca Mezzadri | l.mezzadri3@campus.unimib.it