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From Innovation to Clinical Impact: The Strategic Role of NATA Accreditation

ACCREDITATION MATTERS CONFERENCE

7TH JULY 2026

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Today's Agenda

From scientific discovery to patient impact: how accreditation transforms innovation into clinical adoption.

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01

Scope and Scale of the IVD Industry

Patient impact and the economic value of the Australian pathology market

02

Cancer Diagnostics Innovation: Saving lives by early disease detection

Why innovation matters and the impact on patient lives

03

NATA Accreditation as a Strategic Enabler

Building trust, quality and market access

04

Rhythm Biosciences: Accreditation Journey

From laboratory innovation to commercial reality

What is the *In Vitro Diagnostic* Industry

Providing insight into health to support clinical practice

In Vitro (Latin: "in glass") — tests performed on biological samples **outside** the living body: blood, urine, tissue, swabs.

Pathology underpins 70% of all clinical decisions, 100% cancer & contagions

Common specimen types:

- Blood (serum, plasma, whole)
- Urine
- Tissue biopsy
- Swabs (nasal, cervical, wound)
- Cerebrospinal fluid
- Faeces

IVD spans the full clinical journey:

- Screening & prevention
- Diagnosis & disease staging
- Treatment selection
- Monitoring & response
- Population surveillance

The Seven Pillars of Clinical Testing

MBS pathology groups P1–P9 map to these core technology domains

1

Clinical Chemistry

Metabolites, enzymes, electrolytes — glucose, cholesterol, liver & kidney function

2

Haematology

Full blood counts, coagulation, anaemia, leukaemia, thrombosis disorders

3

Immunodiagnostics

Hormone assays, cardiac markers, tumour markers, autoimmune testing, allergy

4

Molecular Diagnostics

PCR, NGS — pathogen detection, cancer mutation profiling, hereditary genetics

5

Microbiology

Culture, sensitivity, and molecular ID of bacteria, viruses, fungi, parasites

6

Tissue Pathology

Histology, cytology, immunohistochemistry — cancer diagnosis and staging

7

Point-of-Care Testing

Rapid, near-patient tests: glucose monitors, pregnancy tests, troponin, COVID-19

Australia's IVD Industry at a Glance

~0.5bn

pathology & diagnostic services per year (2022–23)
Medicare 30% of total

AIHW 2024

67%

of all Australians had at least one pathology test in 2022–23

AIHW 2024

AUD ~$6B

IVD product market size in Australia (2024)
Growing ~5–6% per year

Mordor Intelligence 2026

6.4 tests

per person per year (MBS average, 2022)

$3.4B

total MBS investment in pathology per year (2023)

500+

distinct pathology test types on the MBS

~1,000,000

pathology tests conducted every single day

Why Diagnostic Innovation Matters:

Continual improvement on the ability to Predict, Prevent and Personalise

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Clinical Impact

Earlier detection = better survival. For most cancers, stage I detection delivers 80–90% survival vs <20% at stage IV.

Treatment precision. Companion diagnostics match the right drug to the right patient, avoiding toxic therapies that won't work.

Speed matters. Rapid diagnostics (e.g. sepsis, cardiac troponin) reduce time-to-treatment and mortality.

Prevention, not just treatment. Genetic carrier screening, risk polygenic scoring and hereditary cancer tests enable preventive intervention before disease onset.

Economic Impact

~$190

per person per year — Australia's entire MBS pathology spend

One of the most cost-efficient healthcare investments possible

~3%

of total healthcare spending on pathology

Informs 70% of all clinical decisions

US$1.5 –3.5B

potential US cost savings from stage-shift in 4 common cancers

Early detection reduces treatment burden system-wide

Colorectal Cancer Case Study:
Early detection leads to better outcomes

15,500+ new colorectal cancer cases diagnosed every year in Australia

>50% Diagnosed as late-stage disease – Stages III or IV

10% 5-year survival rate when diagnosed at Stage IV

Earlier detection significantly improves survival outcomes and lowers treatment costs.

Detecting Cancer Earlier

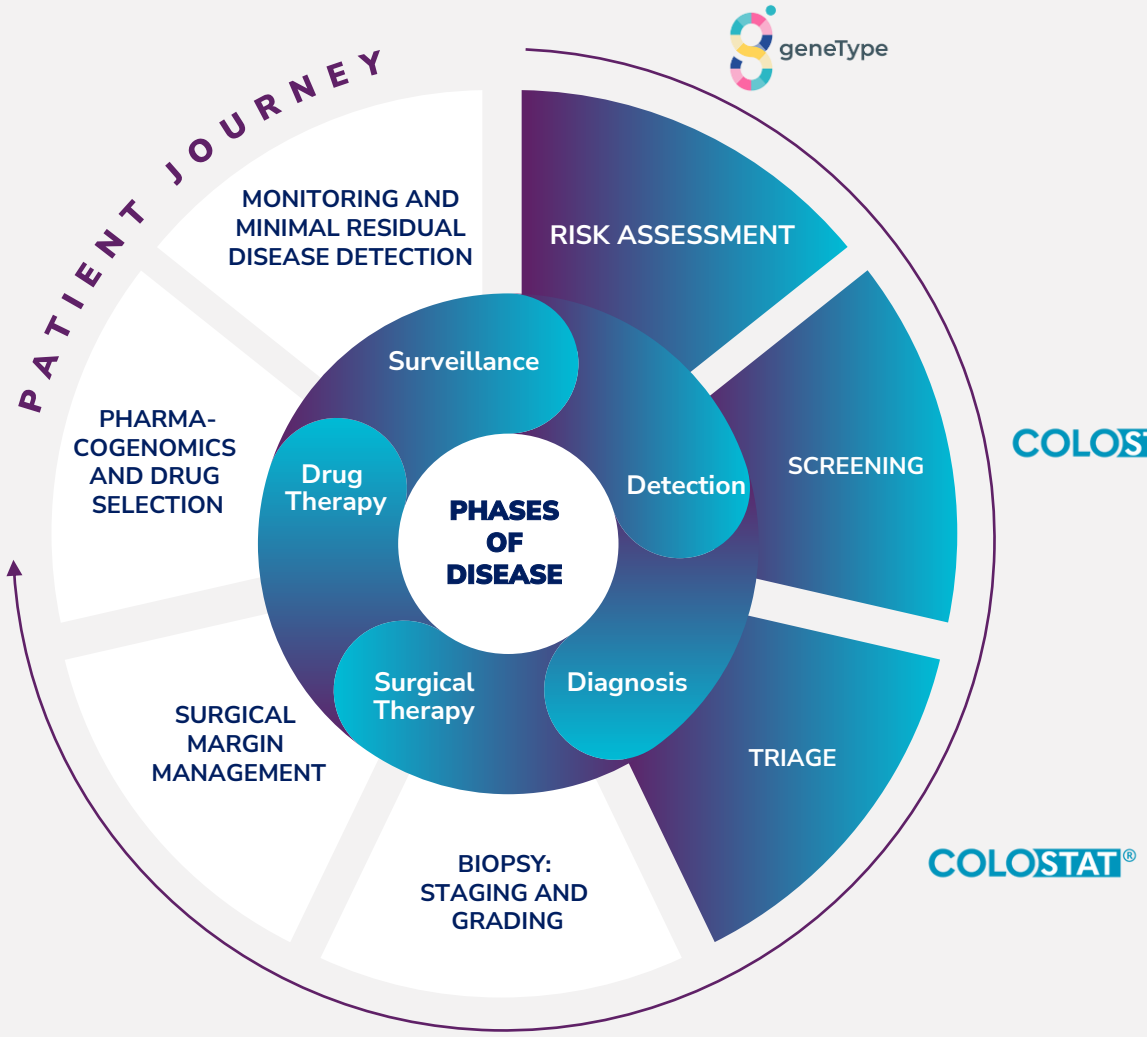
Rhythm Biosciences is an ASX listing company building precision diagnostics platform focused on earlier cancer detection, risk assessment and improve patient outcomes.

COLOSTAT®	Non-invasive blood-based bowel cancer detection test
geneType	Assessing cancer risk before symptoms appear

Rhythm is positioned at the intersection of precision medicine, preventative health care and scalable diagnostics.

The Patient Ecosystem

Rhythm is building a scalable precision diagnostics ecosystem across the cancer care pathway.



geneType

Risk Assessment

Genomic cancer risk assessment

Identify elevated risk before symptoms emerge

COLOSTAT®

Disease Screening

Blood-based cancer detection

Improve screening accessibility and compliance

Building the future of precision cancer diagnostics:

- Earlier cancer detection
- Improved patient outcomes
- More personalised healthcare
- Better screening participation
- Scalable precision diagnostics

Supporting earlier detection through risk assessment and screening

geneType™ helps identify elevated cancer risk, supporting more targeted ColoSTAT® screening and earlier intervention.

* Future clinical indication

What Does It Take for a Diagnostic to Reach Clinical Practice?

Four elements that turn scientific innovation into clinical adoption

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1. Clinical Evidence

- Demonstrates analytical and clinical performance
- Builds clinician confidence
- Supports economic analysis

2. Quality & Accreditation

- ISO 15189 laboratory systems
- NATA accreditation
- Reliable and reproducible results

3. Clinical Logistics

- Sample collection network
- Laboratory capability
- Clear referral pathway
- Reporting capability

4. Commercial Readiness

- Manufacturing
- Supply chain
- Partnerships
- Scalability

A clinical diagnostic only reaches patients when science, quality, clinical access and commercial capability come together.

Innovation creates possibility. Accreditation creates trust. Trust enables adoption.

Regulatory Oversight is a Growth Driver

Ensuring the IVD industry provides safe and effective products and services

False Positives

Unnecessary surgery, chemotherapy, and psychological harm from incorrect diagnoses. Each false positive triggers a cascade of clinical interventions with real patient cost.

False Negatives

Missed diagnoses allowing disease to progress untreated. A cancer missed at stage I may become untreatable by the time it re-presents at stage IV.

Analytical Failure

Instrument calibration errors, reagent degradation, or laboratory contamination can invalidate entire test runs — affecting dozens or hundreds of patients simultaneously.

Safe and Effective Innovation

New tests entering clinical use following analytical and clinical validation have a high probability of being safe and effective.

In diagnostics, quality and safety failures do not affect products — they affect patients.

Balancing the Demands facing an Emerging Business

Embracing Regulatory Approval: worthwhile hurdle for innovative businesses

Emerging businesses are resource constrained

- >400 Domestic Emerging Medtech businesses
- Access to capital is highly competitive
- Innovation demands speed — regulatory processes take time
- Investors expect rapid results

Accreditation enables market access

Accreditation builds the trust that can create adoption at scale

International evidence standards ensures a common understanding of accreditation

Robust frameworks can attract global investment in diagnostic innovation

Accreditation is a non-negotiable requirement

Ongoing collaboration between industry and TGA/NATA will support better outcomes for patients

How Accreditation Enabled Commercialisation

Rhythm's journey confirms accreditation transforms validated science into clinical adoption.

Dec. 2024
NATA ISO 15189:2012 Accreditation
Genetic Technologies Laboratory accreditation in place at Genetype acquisition

Aug. 2025
ColoSTAT NATA Submission
2nd-gen ColoSTAT® Multiplex assay submitted for accreditation

Oct. 2025
ISO 15189:2022 Assessment Completed
ISO15189 Confirmed for RHY for first time

Dec. 2025
ISO 15189:2022 Updated
ColoSTAT® revenue begins; 4Cyte network live; NHS England analytical evaluation starts

Dec. 2025
ColoSTAT: First Commercial Sale
ColoSTAT® revenue begins with investigational product; 4Cyte network live

March 2026
ColoSTAT: NATA Variation to Scope
Assessment conducted; accreditation scope expanded

March 2026
Accredited ColoSTAT Sales Commence
Accredited clinical available in Australia

Without accreditation there is no clinical adoption.

Without clinical adoption there is no patient impact.

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Thank you!

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