UNIVERSITY OF BIRMINGHAM | Clinical Immunology Services

A view from academia

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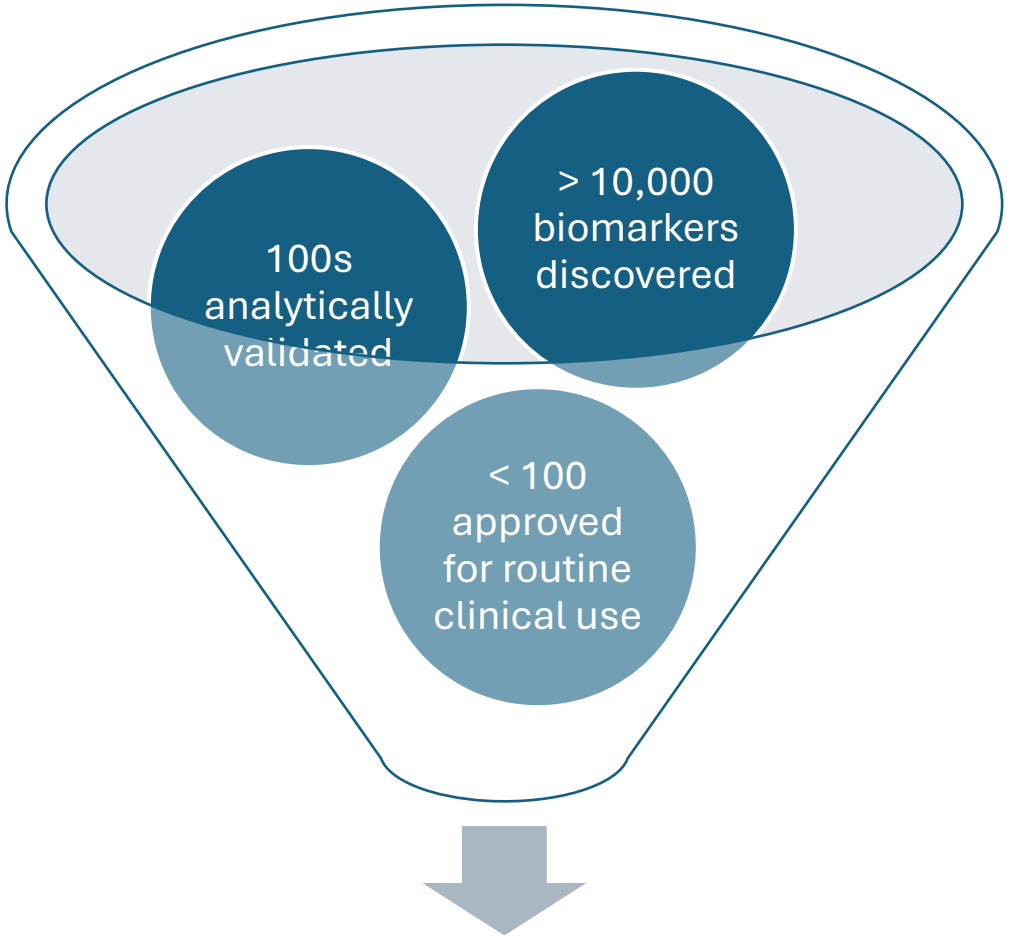
From Discovery to Diagnosis – The Biomarker Bottleneck

The vast majority of biomarkers never translate into validated, regulatory-approved diagnostics.

- ***Discovery isn't the bottleneck*** — clinical validation, utility and adoption are

Bridging academic innovation and clinical need is the real translational challenge.

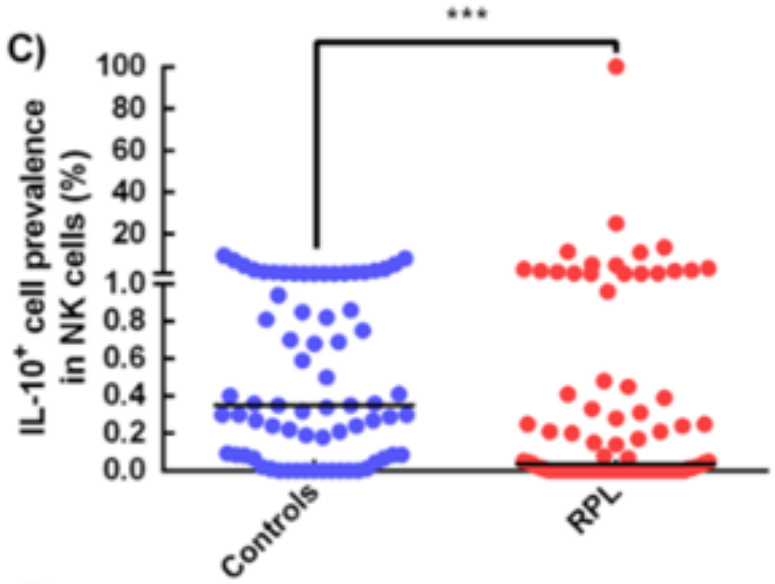


From p-value to patient benefit: *mind the gap!*

- **The Real Bottleneck** = The gap between innovation and impact

- Great p-value, no adoption

- Analytical performance ≠ Clinical utility



- NHS labs need: reproducibility, affordability, integration

What is a diagnostic test?

A test must tell you something **useful** and must be

reliable and

must **progress** care

To do this you need to undertake

the **right test** for the **right patient** in the **right place** at the **right time**

Precision Diagnostic Test X adoption

A story

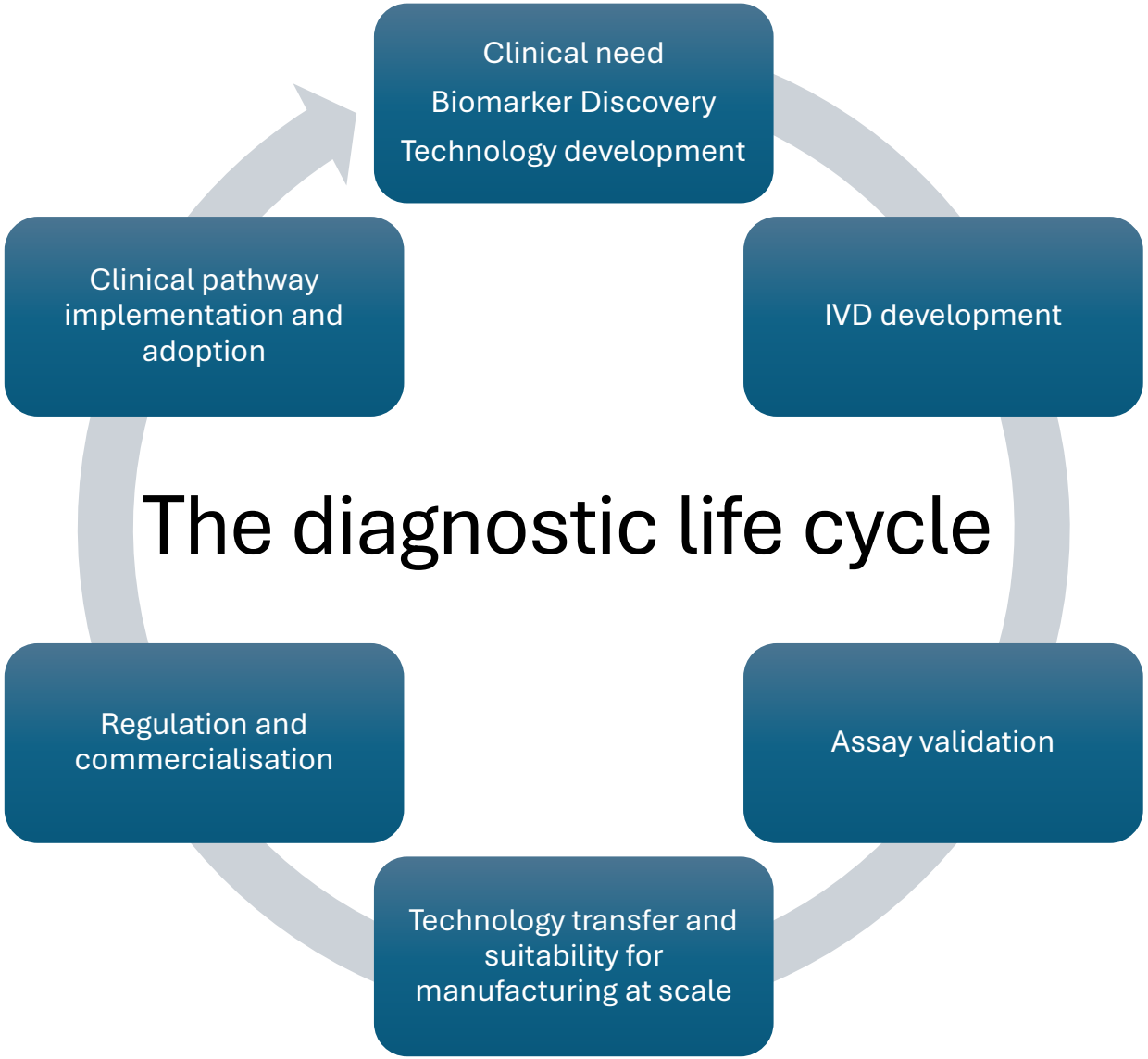
Defines a cancer enabling new tailored curative treatment to be used in identified patients

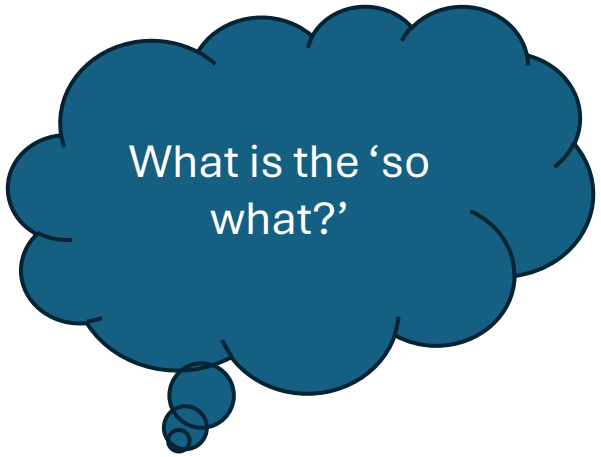
- Reliable test with high PPV and NPV
- This will improve survival
- Reduce costs of inappropriate treatment and hospital admissions for common side effects
- The oncology department will save money
- Reduction in palliative care costs
- Increased economic activity by patient

- ✗ Relies on a new technology for the lab
- ✗ The platform requires expensive outlay
- ✗ Lab budget different to Oncology budget
- ✗ No space in current lab for machine
- ✗ New trained staff are needed
- ✗ The platform doesn't interface with lab IT
- ✗ Test requires new type of blood tube and needs to be processed within 30 mins of sampling
- ✗ Lab not collocated with clinic
- ✗ ~ 6 tests will be undertaken a month

Test has not been designed with adoption in mind – needs to be fit for workflow

Establishing the “Value Proposition” early in development pathway





We can measure a lot of stuff but is what we are measuring actually useful?

Key demographic factors in the ‘use case’

Demographics

- Age
- Gender
- Deprivation
- Ethnicity

Location of demand

- Self testing
- Remote community-based health care
- State of the art secondary care hospital

Direct to consumer

Community

Hospital

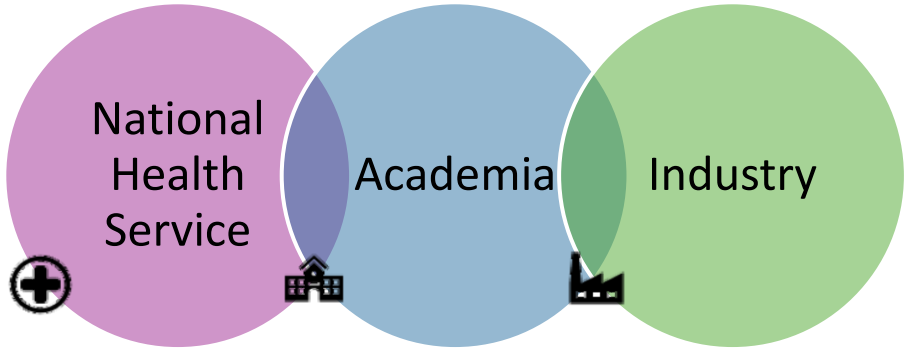
📚 What Does Success (and Failure) Look Like?

A few examples from our own pipeline — where we got it right, and where the field can do better.

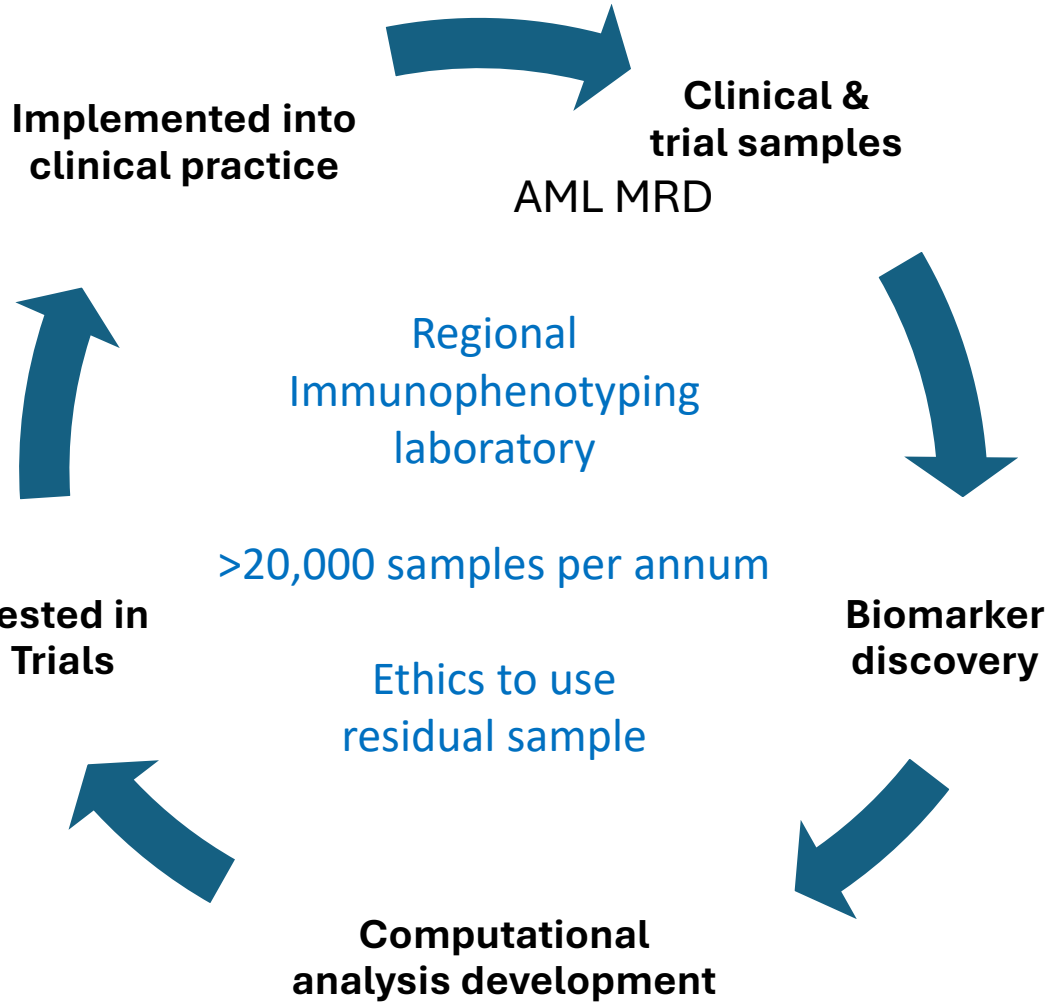
Implementing biomarkers for AML MRD

CYTEK
TRANSCEND THE CONVENTIONAL

Partnership working



Sylvie Freeman
Deputy Director



- UK Flow cytometry reference service for Acute Myeloid Leukaemia measurable residual disease (MRD) monitoring

Now standard of care test for NHS

- Establishing MRD panel on spectral cytometers – first clinical use of spectrals in UK

***Success enablers*: ethics on residual samples, standardisation, external demand**

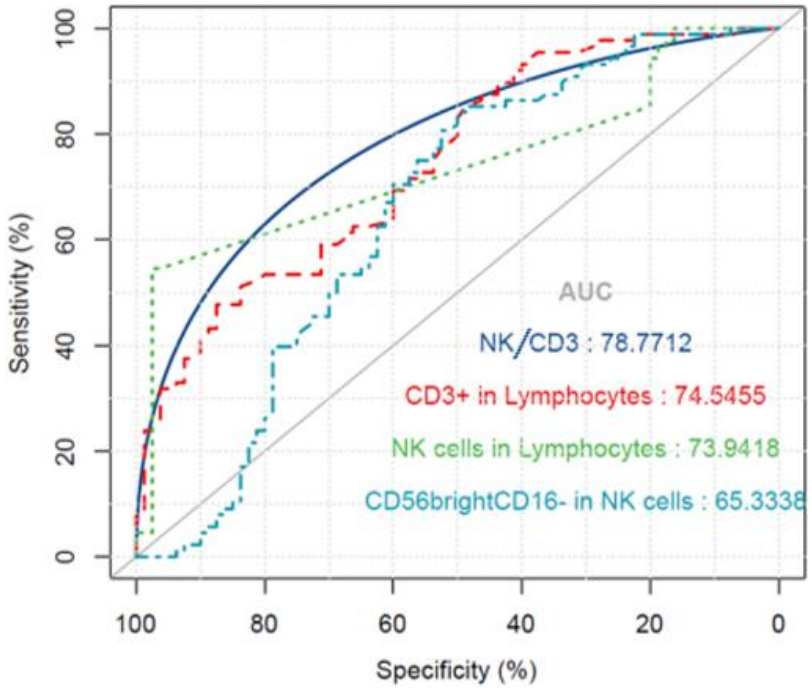
1. Freeman et al JCO 2013 2. Freeman et al JCO 2018 3. Craddock et al, JCO 2020 4.Short et al JAMA Oncology 2020 5.Heuser, Freeman et al Blood 2021, 6. Freeman et al, Blood 2023 7. Loke, McCarthy et al Blood Adv 2023 8. McCarthy et al Leukemia 2024

High promise: Test for recurrent miscarriage

Danai Bagkou

- A **clinical unmet need** for a biomarker and treatments
- Expensive tests offered but NOT adopted in guidelines
  - These tests set up with rigor required for a clinical diagnostic
  - Verified in 100 women with recurrent miscarriage and 100 controls
- No NK or T cell phenotyping or functional assays had strong enough predictive power to differentiate
- **Repurposing** of lymphocyte count has strongest predictive value (already in widespread clinical use)

Success enablers: **Unmet need, robust assessment of market options, repurposing of test/platform**



Evaluation of peripheral NK tests offered to women with recurrent pregnancy loss and a search for novel candidate biomarkers. Bagkou Dimakou D, Tamblyn J, Lissauer D, Richter A. J Reprod Immunol. 2025 Mar 18;169:104522.

Direct to consumer tests (DTCT): When Innovation Misses the Mark

Jon Deeks

Clare Davenport

- Explosion in products for direct sale in the UK

thebmj

Publication next week!

Direct-to-consumer self-tests sold in the UK in 2023: an investigation into their regulation and the evidence of their performance

| ❌ No clear clinical pathway
| ❌ Performance unverified
| ❌ Regulatory grey zone
| ❌ No health system integration

Potential to embed into NHS clinical pathways and reduce barriers testing in UK and globally

Translating Differently: Building for Impact from the Start

- Engage end users from project inception
- Assess adoption barriers early
- Focus on test logistics & usability
- Build economic and regulatory thinking into development

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💡 Key Lessons

1. Discovery is just the beginning — design for adoption.
2. Success demands diverse expertise from day one.
3. The best diagnostics are those that get used.