



# Strategic Update

July 2023

Transforming kidney transplant outcomes

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A black and white photograph of a hand pointing at a laptop screen. The screen displays a DNA double helix structure. The laptop keyboard is visible in the foreground. The image is partially overlaid by a vertical bar with blue and green segments.

# Strategic Update

Sara Barrington, CEO

- Strong progress on commercial rollout strategy
  - Tutivia™ commercially launched
  - Clarava™ on track for initial commercial launch by the end of this year
  - Provisional pricing from Medicare of \$2,650 for both Tutivia™ and Clarava™
  - Opportunities for further value-enhancing partnerships from emerging data asset
- Clear differentiation and competitive advantages of lead products meeting large unmet clinical needs
  - Large total addressable market
  - Differentiated, leading-edge, technology platform for end-to-end kidney transplant testing
  - Validated by growing body of robust clinical data



- Prudent balance sheet management and cash runway extended
- Delivered key operational milestones
  - Company laboratory in Tennessee received CLIA Certification by the Centers for Medicare & Medicaid ('CMS') in 46 states and filed in remaining States
  - Completed analytical validation for Clarava™ and Tutivia™
  - Granted CPT® codes for Clarava™ and Tutivia™ by AMA
  - Two key patents granted in the United States underpinning both of Verici Dx's lead products
- Driving innovation and broadening revenue through value-enhancing collaborations
  - Potential opportunities facilitated by partnership with Illumina Connected Analytics



*“In the first few months post-transplant there are many rejection events and yet in my opinion we have not really had a biomarker that can assist at this critical time. Tutivia™ is able to give the clinician reliable test results as soon as the first week post transplant and so is an early biomarker test which addresses this critical need”*

**Dr Nicolae Leca Professor, Medical Director, Kidney and Pancreas Transplant - University of Washington**



*“Having a risk score is helpful in clinic time management. Low risk patients can be monitored under standard protocols, but the high-risk patients will need more focus and more time from the clinician who has the expertise to give the patient the best treatment possible. Tutivia™ demonstrated that a patient reporting a high-risk score was six times more likely to have a rejection than the patient with a low-risk score in a trial where the study design was of a high level and the results could be trusted to be representative of what we experience in our clinics”*

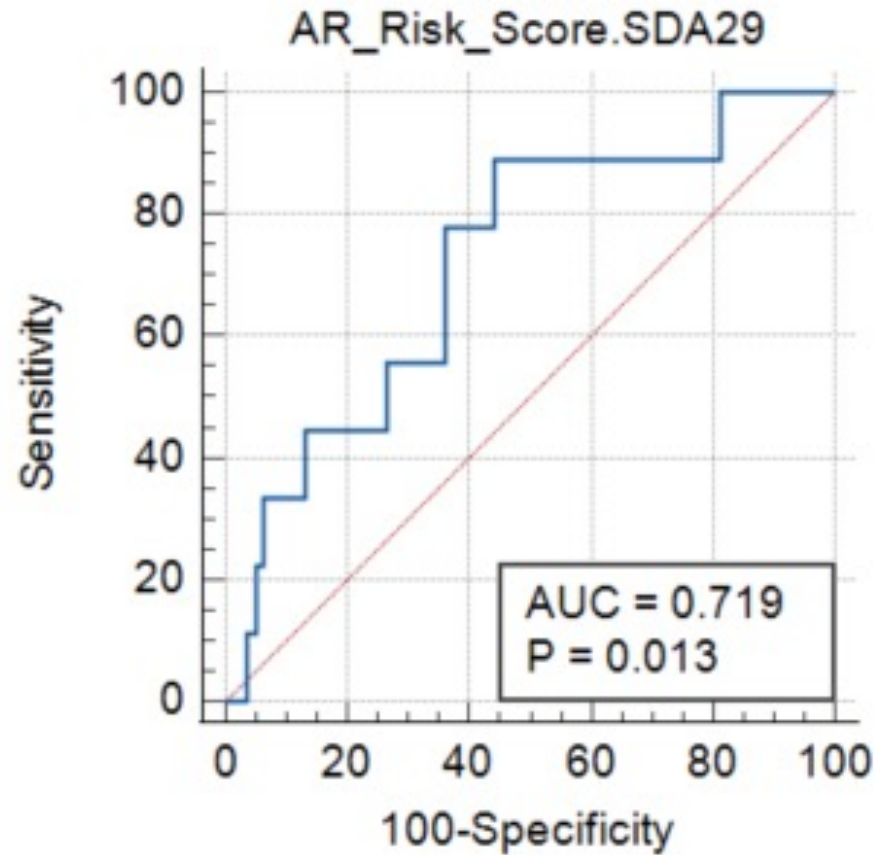
**Dr Rich Formica, Professor of Medicine (Nephrology) and Professor of Surgery (Transplant), Director of Transplant Medicine - Yale University**



*“Tutivia™ has been demonstrated to accurately predict the development of early acute rejection in the kidney transplant recipient, with an impressive positive predictive value of 60%, even better than our usual monitoring tool of serum creatinine. This test performance means that patients may be monitored with a blood test, with more convenience and ease, giving both patient and physician information that is both reassuring and actionable.”*

**Dr. Roslyn Bernstein Mannon is a Professor of Medicine, Pathology and Microbiology at the University of Nebraska Medical Center, Vice-Chair for Research and Associate Chief of Nephrology for Research.**

# Clarava effectively identifies patients at increased risk of rejection in the critical first 60-90 days



- Data was statistically significant, with:

AUC	72%
Sensitivity	78%
Specificity	64%
Odds ratio	6.2

- High-risk patients c.6 times more likely to have a rejection than low-risk

Further analysis to come and discussion with Clinical Advisory Board

A black and white photograph of a person's hand pointing at a laptop screen. The screen displays a DNA double helix structure. The laptop keyboard is visible in the foreground. The image is partially obscured by a vertical bar with blue and green segments on the right side.

# Overview of FY 2022 Results

David Anderson, CFO



# Cash Flow Statement



## Year to 31 December 2022 - Audited

	\$'000
Net outflow from operating activities	(10,068)
Investing activities	(1,308)
Financing activities	12,674
Net increase in cash	1,298
<b>Cash at 31 December 2022</b>	<b>9,805</b>

## Comments

- Operating flows: minimal movement in working capital in period, but includes \$90k costs of share issue, so underlying net cash outflow \$9,978k
- Investing flows: capital spend on CLIA lab (\$823k), other assets (\$217k) and spend on licenses / patents (\$268k)
- Financing flows: net inflow from share issue after balance of costs of issue
- With post year actions, and revenue assumptions, cash runway to mid 2024

# Income Statement

## Year to 31 December 2022 - Audited

	\$'000
Administrative expenses	(10,497)
Depreciation and amortisation	(640)
Share based payments charge	(318)
Interest expense	(5)
Interest income	53
<b>Loss for the year</b>	<b>(11,407)</b>

## Comments

- Largest items of expenditure:
  - Wages: \$2.9m
  - R&D: \$4.8m

## Balance Sheet



### As of 31 December 2022 - Audited

	\$'000
Tangible assets	2,010
Intangible assets	1,970
Receivables	520
Cash at bank	9,805
Trade and other payables	(2,096)
Lease and right of use	(700)
Share capital	(219)
Share premium / share-based payments / foreign exchange reserves	(35,762)
Accumulated losses	24,472

### Comments

- Tangibles: \$823k spent in period on CLIA lab
- Intangible: \$1.5m cost of original license from Renalytix and additional spend on licenses and patents
- Receivables: mainly prepayments \$343k
- Payables: mainly accruals \$1.1m, of which main component is \$0.9m from trial sites not yet billed
- Leases: finance lease for sequencer (\$239k) and right of use asset for property lease (\$461k)



clarava™

tutivia™

protega™

## Summary and outlook

Sara Barrington, CEO



About 300k globally people waiting for transplants

100,000 global kidney transplants p.a.  
24,000 US / 25,000 Europe

Average cost of transplant is \$443k

37-50% rejection events

- Failure rate at 5 years
  - 16-28% US
  - 13-21% EU
- c.\$10B failure cost –
- \$20B incl. additional dialysis costs

- **US Executive order 2019**  
**“Advancing American Kidney Health”**

- Goal: to double supply of transplants

- **EU Directives and Joint Statements**

- 17% increase in transplants
- Move to opt-out and living donors

End-to-end suite of products have a total addressable market circa \$5bn over 5 years

*Pre-Transplant Evaluation*



\$300 million p.a.  
\$1.5 bn  
over 5 years

Assumes 2 tests  
per patient



*Late –Stage Follow-up*



\$1.4bn over 5 years

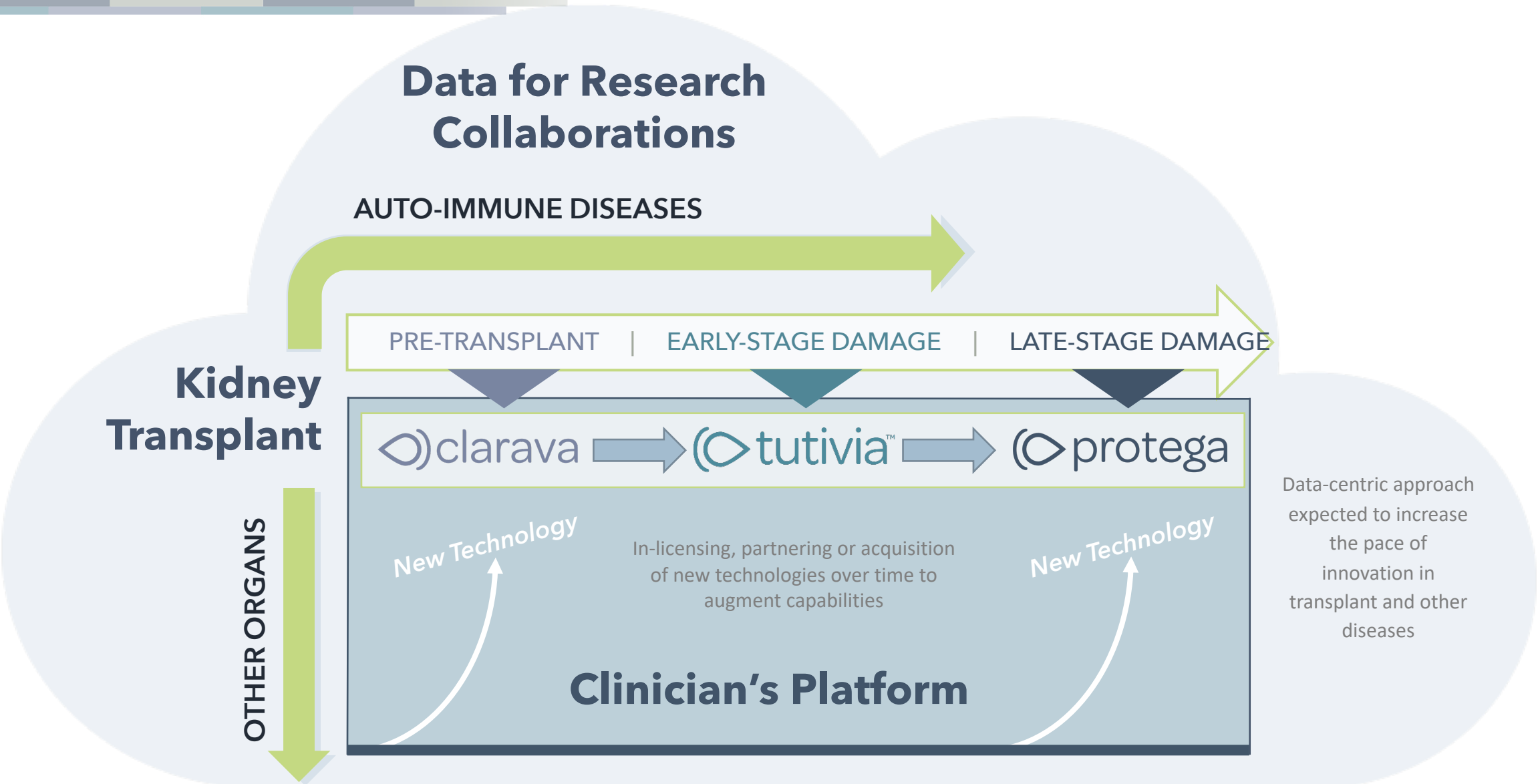
Assumes up to 3 tests per patient

*Post-transplant Follow-up*



\$450 million p.a.  
\$2.25bn  
over 5 years

Assumes 3 tests  
per patient



# Further significant milestones expected over next 18 months



Milestones	Estimate	Next Steps
Clinical Trial enrollment complete	✓	Protega review interim end points
Medicare preliminary pricing	✓	To be finalized at the end of the year for National price
NY/CA CLIA completion	Ongoing	Submitted waiting for review and audit
Research collaborations	Q4	Utilisation of the data asset
Tutivia™ coverage determination	Q4/Q1	File pending publication
Further regulatory approvals	Ongoing	Various certification workstreams in progress



With continued recognition through medical publications and presentations



Milestones	Estimate	Next Steps
Tutivia™ Publication	Q3	Review comments received
Clarava™ Publication	Q1 '24	Pending Clinical Review Board input
Health Economics Publication	Q4	Tutivia™ will be first and then followed by Clarava™
ASN presentation	Q4	Abstract submitted for Clarava™ under 'late breakers'

# Strong progress in our transitional year and well positioned to continue delivering on our strategy



- Focus for rest of 2023 and beyond is on commercial expansion of Tutivia™ and the commercial pathway for Clarava™
- Developing health economics model to support commercialization, aiming to submit for publication by year-end
- Engaging in clinical utility and real-world evidence studies later this year and into 2024, to support adoption of both lead products
- Pricing determination route for both lead products will be known by year end
- Well positioned and sufficiently funded to attain further commercial and other milestones this year and into next

The logo for Clarava, consisting of a stylized eye icon followed by the word "clarava" in a lowercase, sans-serif font.The logo for Tutivia, consisting of a stylized eye icon followed by the word "tutivia" in a lowercase, sans-serif font.The logo for Protega, consisting of a stylized eye icon followed by the word "protega" in a lowercase, sans-serif font.

## Appendix

- Summary Investment Thesis
- Board
- Scientific Advisory Board
- Market Need and Verici Dx Products

# Investment Thesis

## Significant Unmet Need and Large Market

- Unacceptably high rate of transplant rejection (37-50%) with inadequate standard of care
- Large addressable market opportunity worth over \$5bn and growing

## Innovative Product Platform

- RNA signature-based transplant technology producing high performing and actionable diagnostics enabling accurate, data-driven support for critical decisions where there is now guesswork
- Three complementary tests covering full transplant lifecycle with expansion opportunities into new organs and technologies

## Strong Clinical Data and Validation

- Technology developed over 10 years with three peer reviewed publications
- 1 product in commercial launch, 1 finishing validation and 1 product validation endpoints in 2 years
- Highly curated data within an innovative environment to promote collaboration and scalability

## Experienced Team and Accelerated Path to Market

- Experienced diagnostics and transplant teams and early adopting centres
- Accelerated regulatory & reimbursement path for commercial launch within 24 months



# Experienced Leadership for developing and commercializing kidney transplants assays



**Julian Baines**  
*Non-executive Chairman*  
EKF Diagnostics, BBI



**Sir Ian Carruthers**  
*Senior Independent*  
*Non-executive Director*  
Chancellor UWE, Snr Director NHS



**Lorenzo Gallon**  
*Independent Non-executive*  
*Director, Chair of SAB*  
NorthWestern Medical Prof.



**Erik Lium**  
*Non-executive Director*  
President, Mount Sinai  
Innovation Partners



**James McCullough**  
*Non-executive Director*  
Renalytix,  
Exosome Diagnostics



**Sara Barrington**  
*CEO*  
LungLife AI, BBI,  
Exosome Diagnostics

\* Chair of the Samuel Bronfman Department of Medicine, Dean for Clinical Integration and Population Health Management at the Icahn School of Medicine at Mount Sinai

Lorenzo Gallon, MD (Chair)



Tony Dorling, MD



Richard Formica, MD



Roslyn Mannon, MD



Peter Nickerson, MD



Philip O'Connell, MD



Emilio Poggio, MD



David Rothstein, MD



Kathryn Wood, Dphil

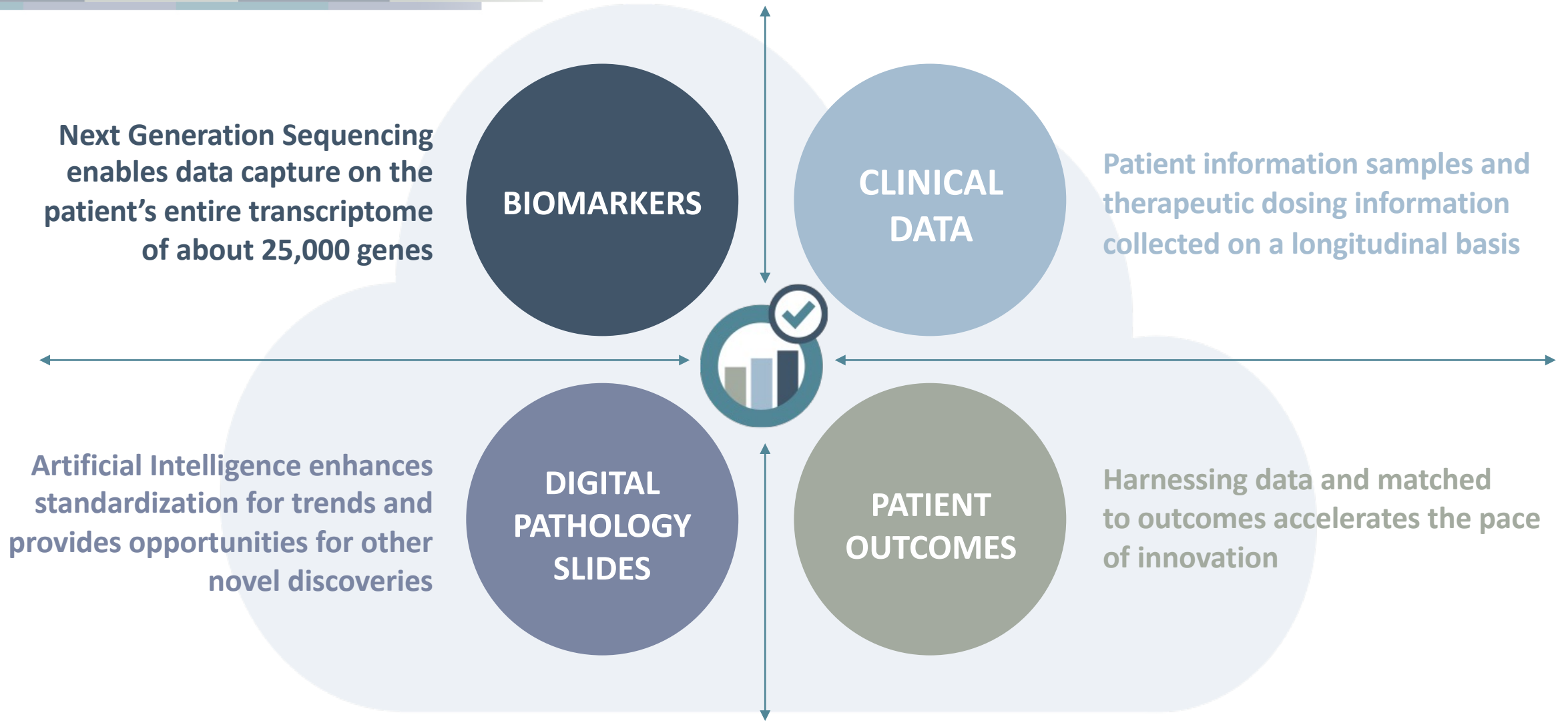


Weijia Zhang, PhD



- Five (5) past presidents of major international Transplant organizations (AST, TTS, ASTS)
- Current President of American Society of Transplantation
- Represent transplant centers processing about 2,000 transplants annually

AST: American Society of Transplantation  
TTS: The Transplantation Society  
ASTS: American Society of Transplant Surgeons



DELIVERING INCREASINGLY PERSONALISED TRANSPLANT MEDICINE

## What is the risk of rejection?

### Current practice:

#### **Broad Clinical Factors/Score**

- Too general and largely ignored

#### **No prognostic information**

- “One Size Fits All” therapy protocol



Under-treatment

Over-treatment

can lead to **Immune System-caused rejection**

can result in **drug toxicity, viral infections and malignancy**

## Is the graft being rejected or damaged?

### Current practice:

#### **Standard of Care**

- Misses 30% of all cases

#### **Competitive tests**

- cfDNA is non-specific
- Measures the “debris” after damage has occurred

Clinicians needs better diagnostics to replace the guesswork



## Pre-Transplant Prognostic

mRNA 10 gene Signature

Advantages:

- Provides risk score for early acute rejection within the first 6 months
- Informs therapeutic modulation
- No current competitors



## Fibrosis/Long-term Prognostic

mRNA 9 gene Signature

Advantages:

- Replaces biopsy on a monitoring basis



## Post-Transplant Prognostic

mRNA 17 gene Signature

Advantages:

- Specific real time diagnostic of immune activation before irreversible damage occurs
- Sequencing is more accessible and stable than microarray