

Evolutions In Transplantation: Blood Tests That Measure Graft Rejection

Reginald Seeto, MB.BS – President and Chief Business Officer – CareDx, Inc.

May 21st, 2019

Joyanne F. – Kidney Transplant Recipient,
AlloSure Patient



Maxine Moir
Kidney Transplant Recipient

CareDx in a Nutshell

- **20 Years of dedication** to transplantation
 - Believes in **partnering** with transplant centers and the transplant community
 - Builds a **sustainable transplant company** - “Unicorn” in transplantation
- Has become a leader in **science** in transplant diagnostics
 - Advances science based on **multi-center clinical trials**
 - Believes in **peer reviewed publications** in high impact journals
- Focused on **patients** and long-term outcomes
 - Committed to **innovation** in transplant care
 - Delivering **meaningful** products and services for transplant patients

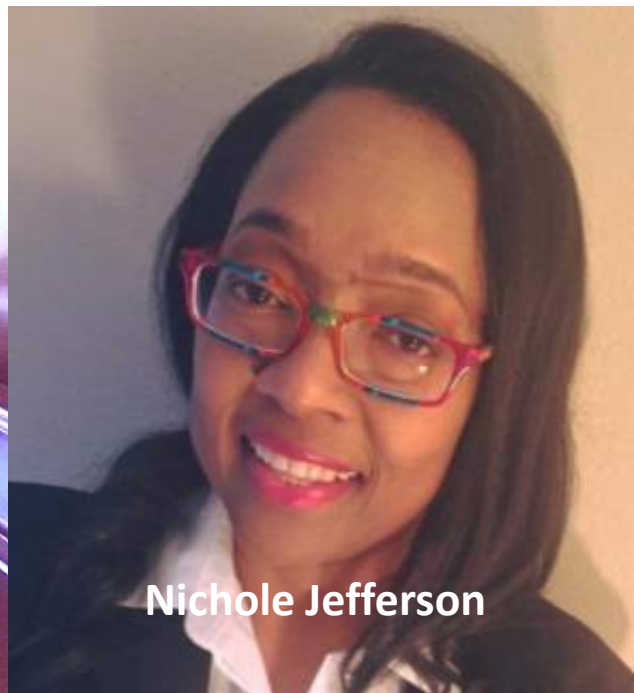
Patient Guest Speakers



Paul Conway AAKP



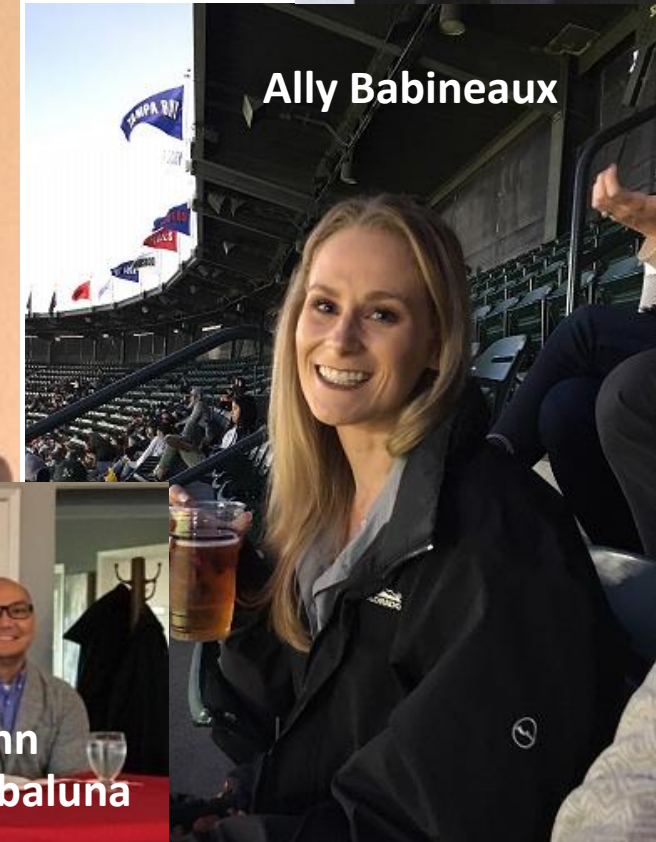
Edward Drake, II



Nichole Jefferson



Joseph Cepeda



Ally Babineaux



Angelica Hale



Wilson Du



Derek Forfang

David White

Ted Conrads

Doris Lew

Lenora Coss

Joanne Garcia

John Cabaluna





CareDx Patient Symposium January 2019

Honor the Gift Campaign

Sign the pledge www.honorthegift.org



Honor the Gift is a national patient-centered campaign, supported by CareDx and promoted by a coalition of kidney and transplant organizations, focused on extending Medicare coverage of immunosuppressive medication for kidney transplant recipients beyond the current three-year cap.



OUR VISION

The Leading Partner for
Transplant Patients and
The Transplant Ecosystem

OUR MISSION

We are committed to
improving transplant
patient outcomes through
innovative, non-invasive
testing solutions throughout
the entire patient journey.

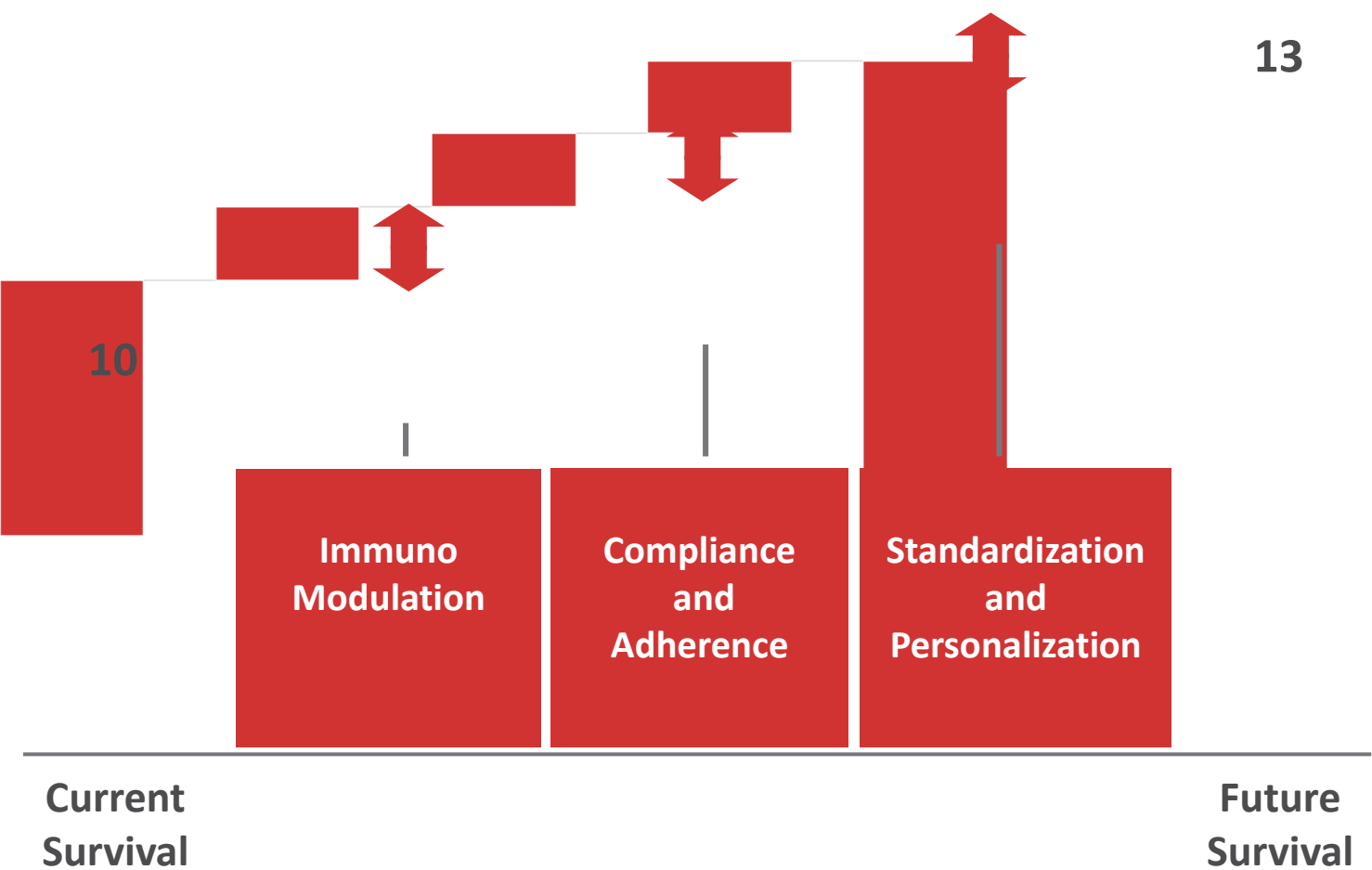


**Better Matching + Better Surveillance
=
Better Outcomes**

CareDx Focuses on Long-Term Outcomes

Conceptual

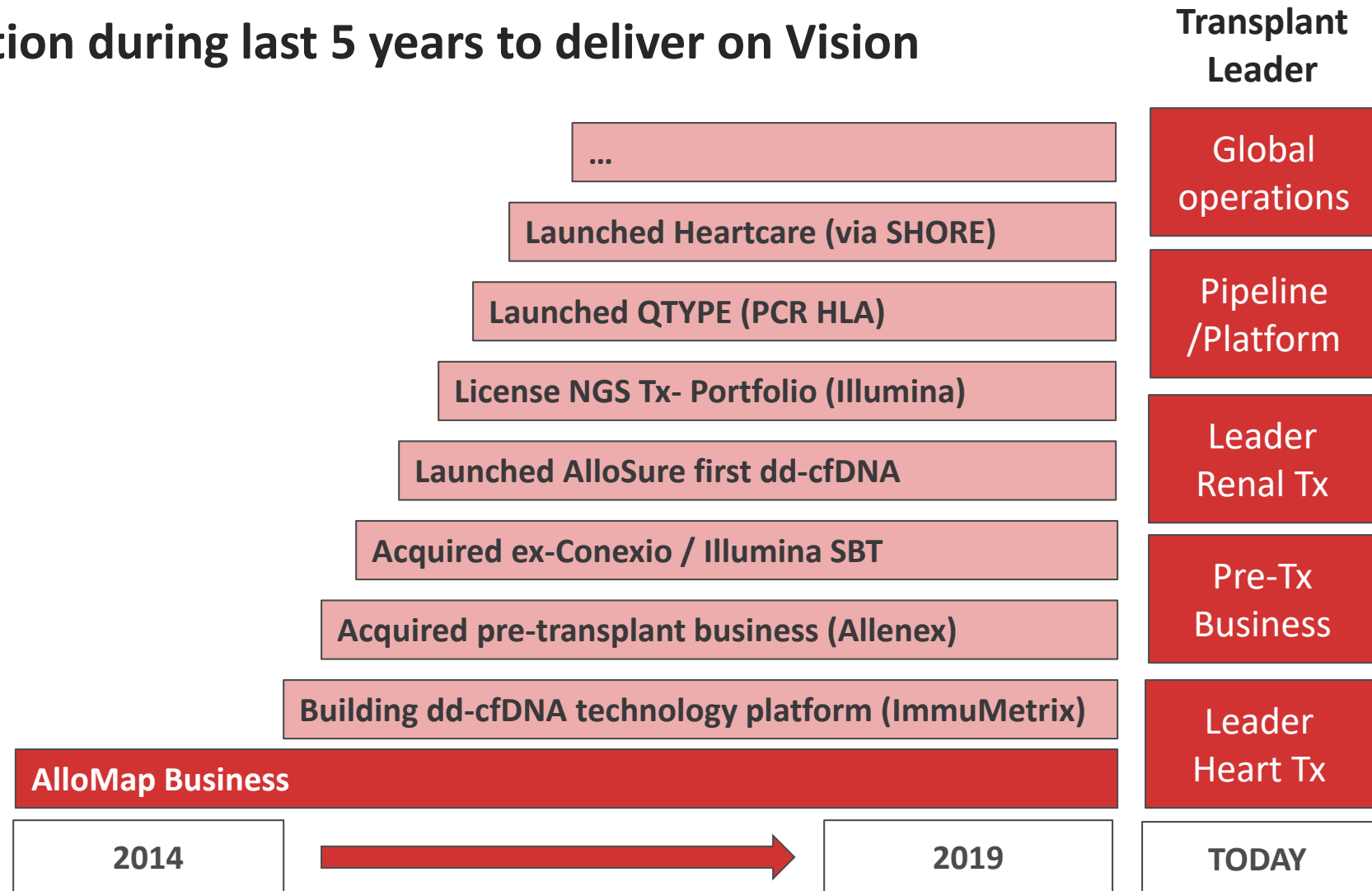
Years



Source: Team Analysis

CareDx – 20 Years of Focus on Transplantation

Evolution during last 5 years to deliver on Vision



Ongoing Unmet Needs in Transplantation



Availability of Organs

Quality of Match

Lifelong Immunosuppression

- Rejection
- Infection
- Function

Quality of Care

 ***Organ Shortage***

Donor identification
and qualification

Waitlist management

 ***Organ Matching***

Typing Products with
right resolution and
turnaround time in
transplant centers

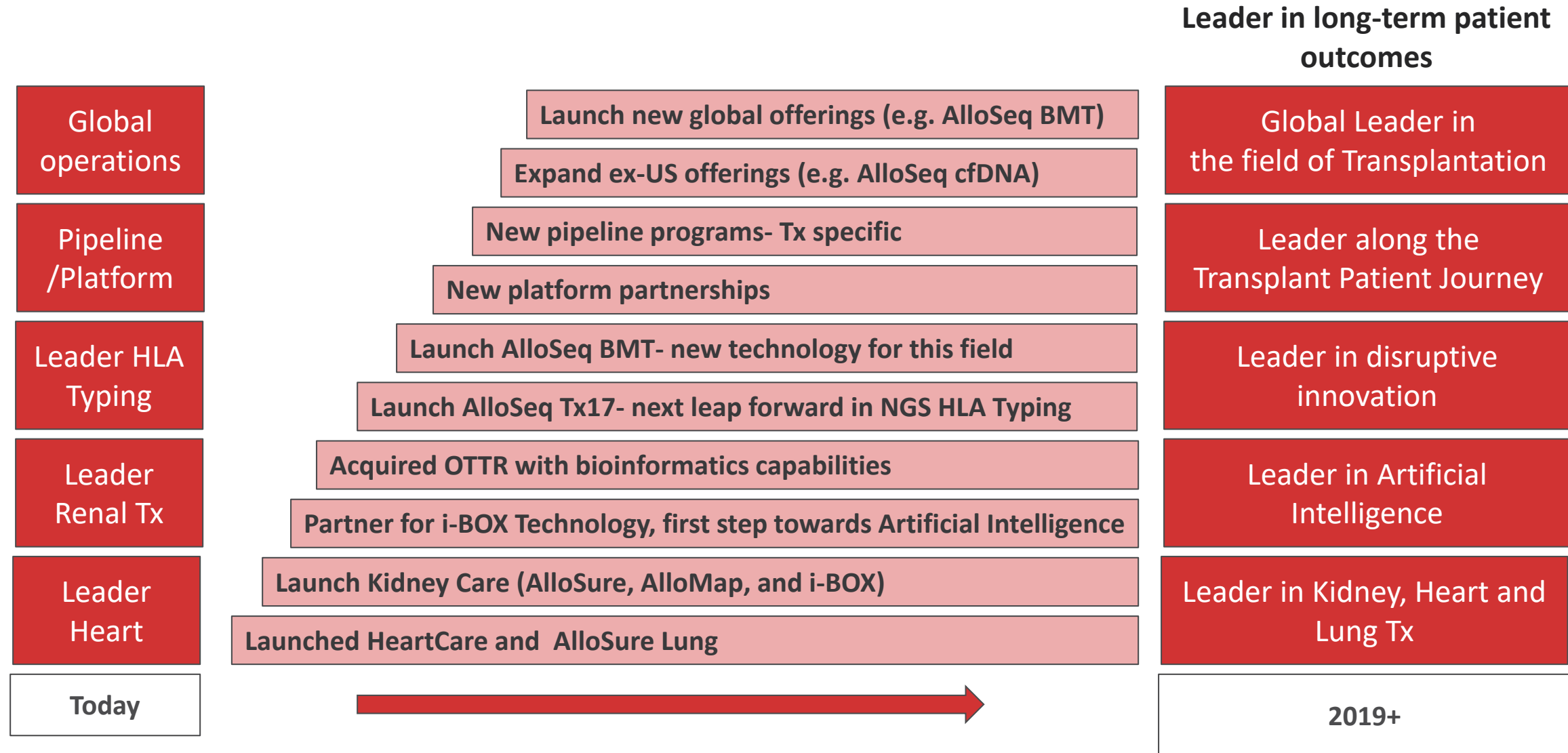
 ***Precision & Compliance***

Services & Products to
ensure personalization and
surveillance, partnering with
centers and clinicians

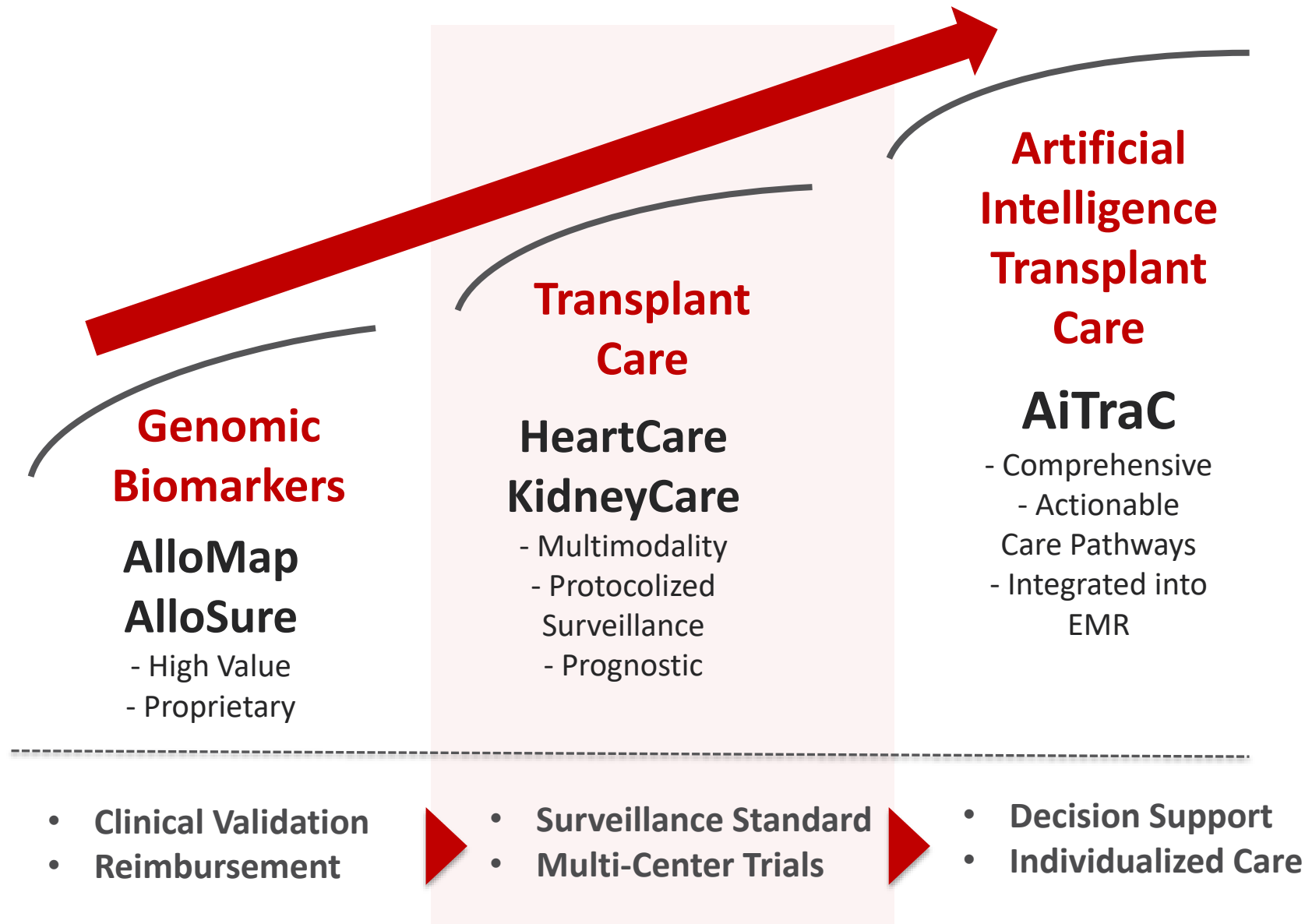
Longitudinal Data Management

Laying Foundation to Lead in Patient Care Management

Evolution during next 12 months for Longitudinal and long-term patient management



Our Approach to Precision Medicine in Transplantation



CareDx – Your Dedicated Partner in Transplant Care

2019 Plan

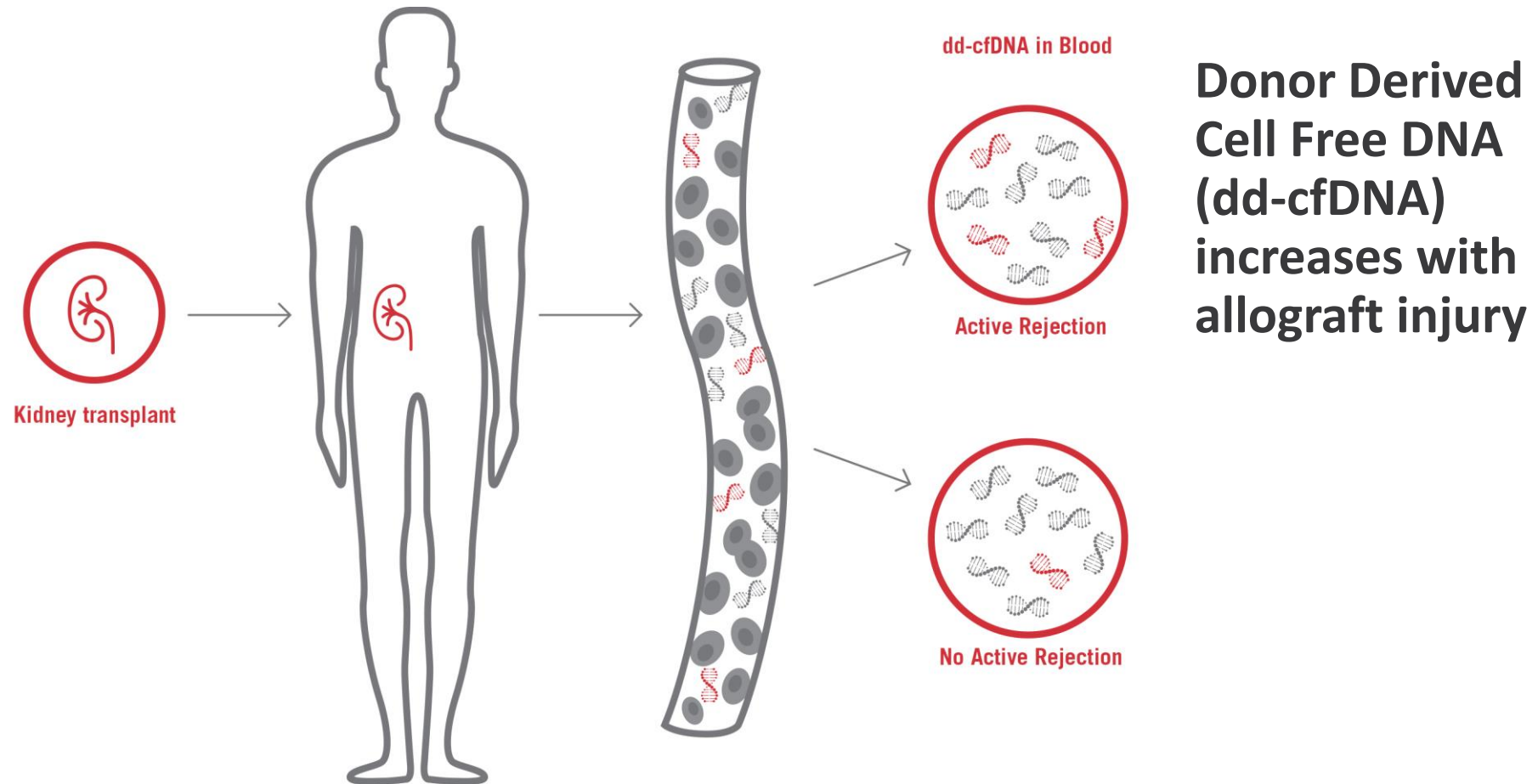
2019 New

2019 Coming

	Typing Products	Testing Service	Surveillance Products	
Kidney	<div>OLERUP SSP <small>GENOMIC HLA TYPING</small></div> <div>OLERUP SBT <small>SEQUENCE BASED TYPING</small></div> <div>QTYPE</div> <div>TruSight HLA</div>	<div>KidneyCare[®]</div> <div>AlloSure[®]</div>	<div>AlloSeq cfDNA</div>	
Heart		<div>HeartCare[®]</div> <div>AlloMap[®]</div> <div>AlloSure[®] HEART</div>	<div>AlloSeq cfDNA</div>	
Lung		<div>AlloSure[®]</div>	<div>AlloSeq cfDNA</div>	
BMT		<div>AlloSeq[®] Tx 17</div> <div>AlloSeq[®] HLA</div>	TBD	<div>AlloSeq BMT</div>
Software Solutions		<div>Assign Score6</div>	<div>AlloMap Variability Score</div> <div>Ottr[®]</div>	<div>AiTraC[®]</div>

Case Example: Rationale for Disruptive Technology

There is an increase in dd-cfDNA when there is injury to the transplanted kidney



1. Grskovic M et al. Validation of a Clinical-Grade Assay to Measure Donor-Derived Cell-Free DNA in Solid Organ Transplant Recipients. *J Mol Diagn*. 2016;18(6):890-902.
2. Bloom RD et al. Cell-free DNA and active rejection in kidney allografts. *J Am Soc Nephrol*. 2017. doi:10.1681/ASN.2016091034.

Clinical Context: Loss of a Transplanted Kidney is a Major Issue for Transplant Recipients

It's time for innovation

KIDNEY TRANSPLANT PATIENTS DESERVE A BETTER WAY

**DETECTION
OF ALLOGRAFT
INJURY**
— IS OF THE —
UTMOST IMPORTANCE

20%

Of kidney transplants fail within 5 years¹

500%

A study of over 110,000 patients from the United States Renal Data System (USRDS) showed a 500% increase in cost burden for patients with renal transplant failure²

1. Rao PS, Schaubel DE, Jia X, et al. Survival on dialysis post-kidney transplant failure: Results from the Scientific Registry of Transplant Recipients. *Am J Kidney Dis.* 2007;49:294-300

2. GAO report to Congressional requesters. End-stage renal disease. Characteristics of kidney transplant recipients, frequency of transplant failures, and cost to Medicare. 2007. GAO-07-1117.

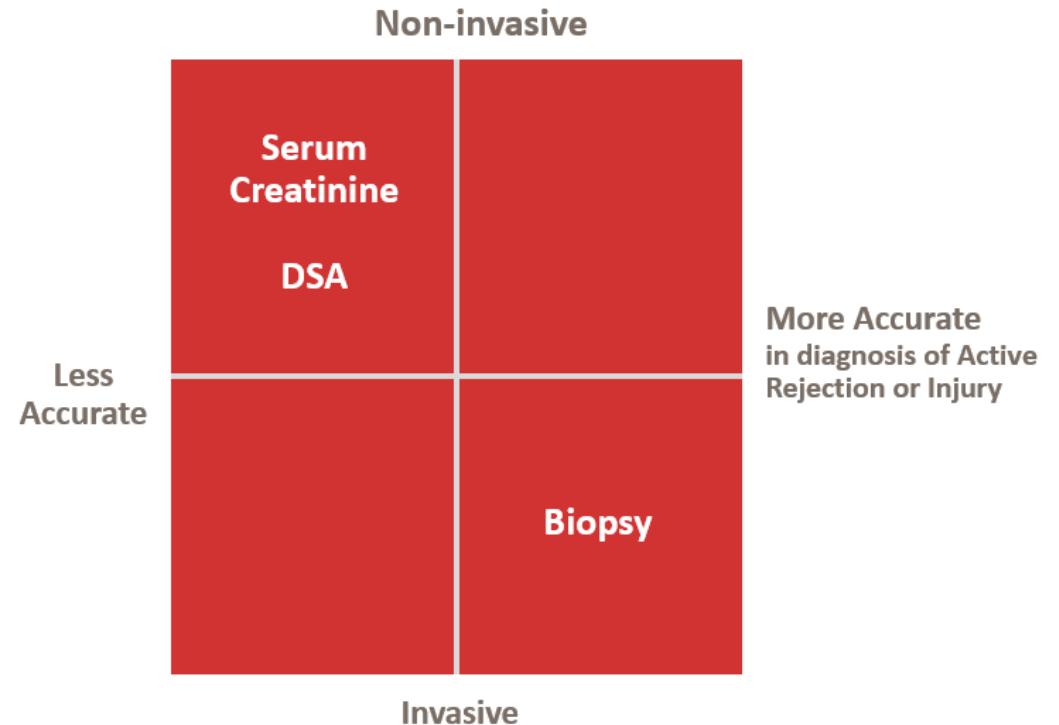
CareDx Developed AlloSure to Assess Organ Health by Directly and Non-Invasively Measuring Allograft Injury



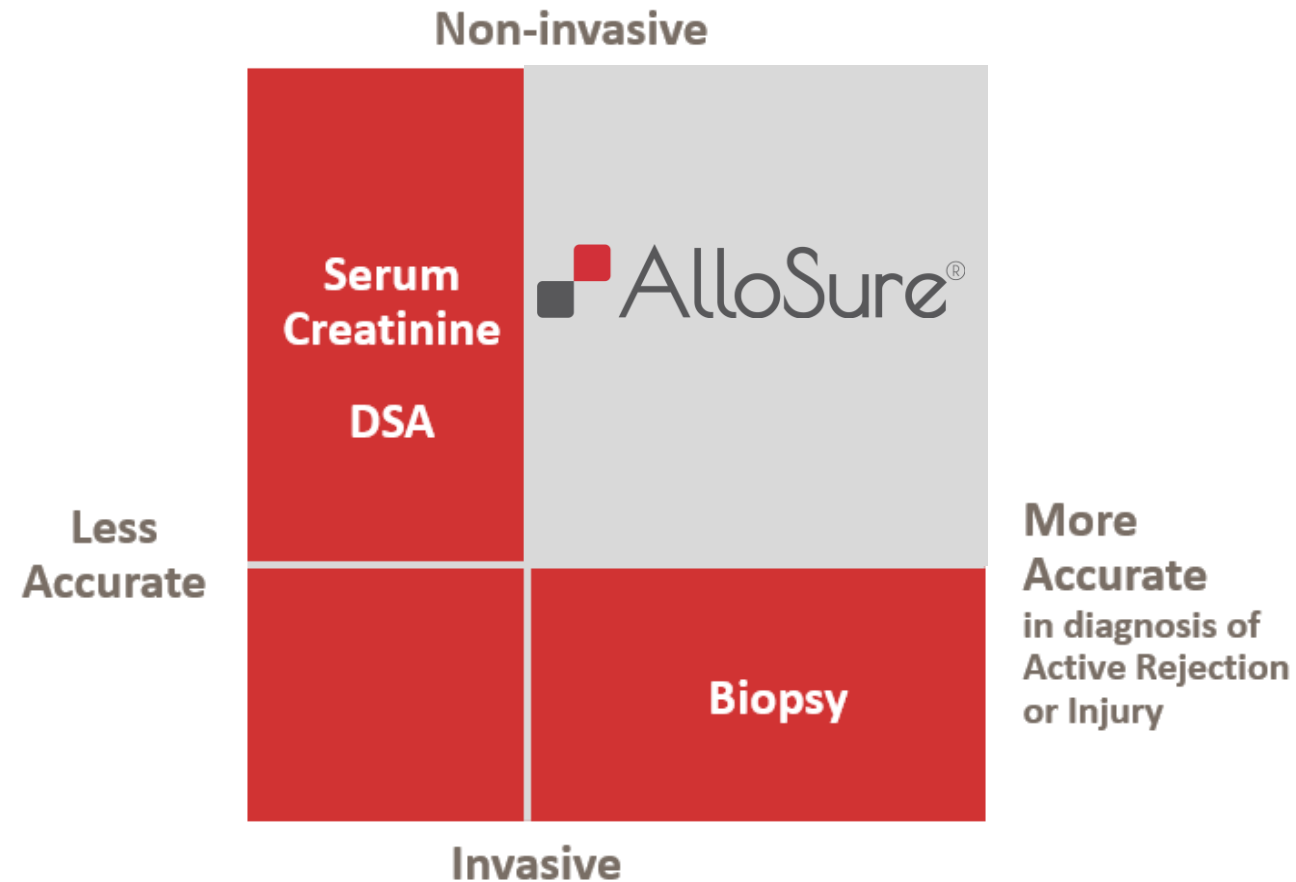
AlloSure provides significant utility in the early diagnosis, assessment, and management of allograft rejection

Current Transplant Surveillance Options Have Limitations in Diagnosing Rejection

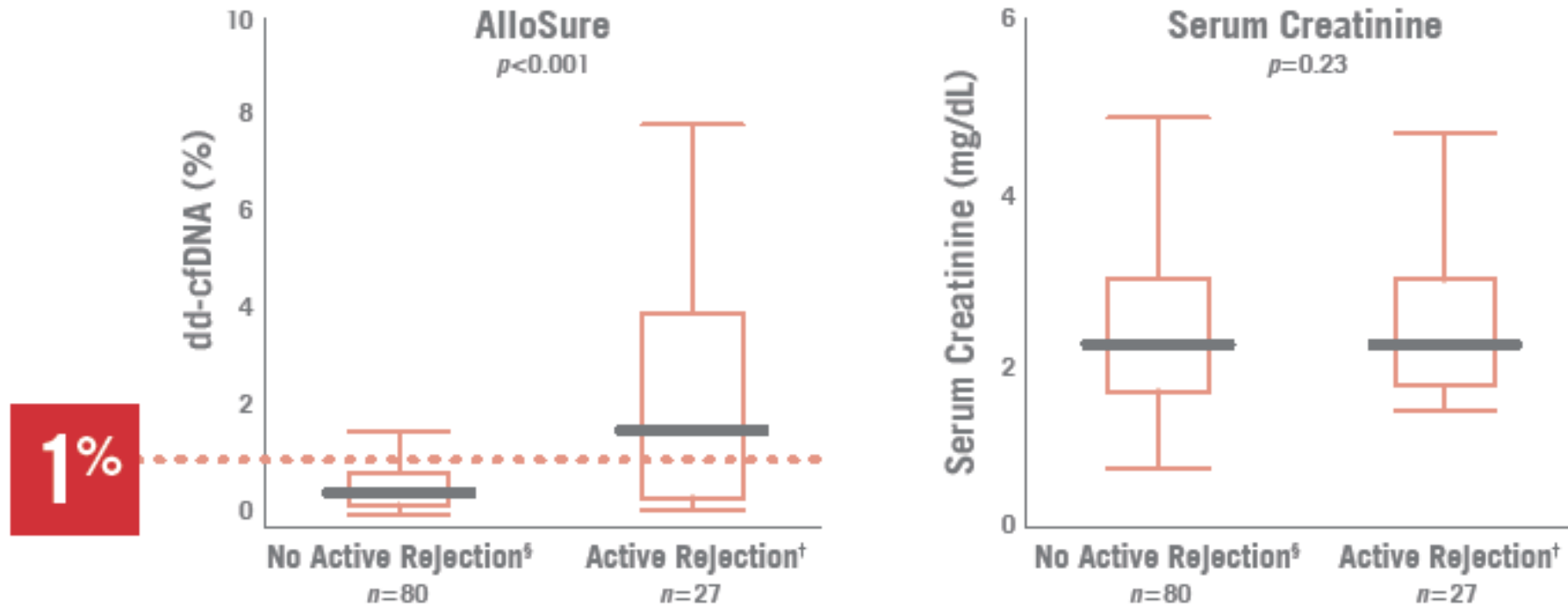
- Current surveillance options
 - Creatinine:
 - May increase for reasons such as dehydration
 - May increase only after significant kidney injury
 - Donor Specific Antibody (DSA)
 - Poorly predicts antibody mediated rejection
 - Biopsy
 - Expensive
 - Inconvenient
 - Interpretation is challenging



AlloSure is a Blood Test that can Provide Non-Invasive and Accurate Rejection Surveillance



AlloSure Outperforms Serum Creatinine for Detecting Active Rejection



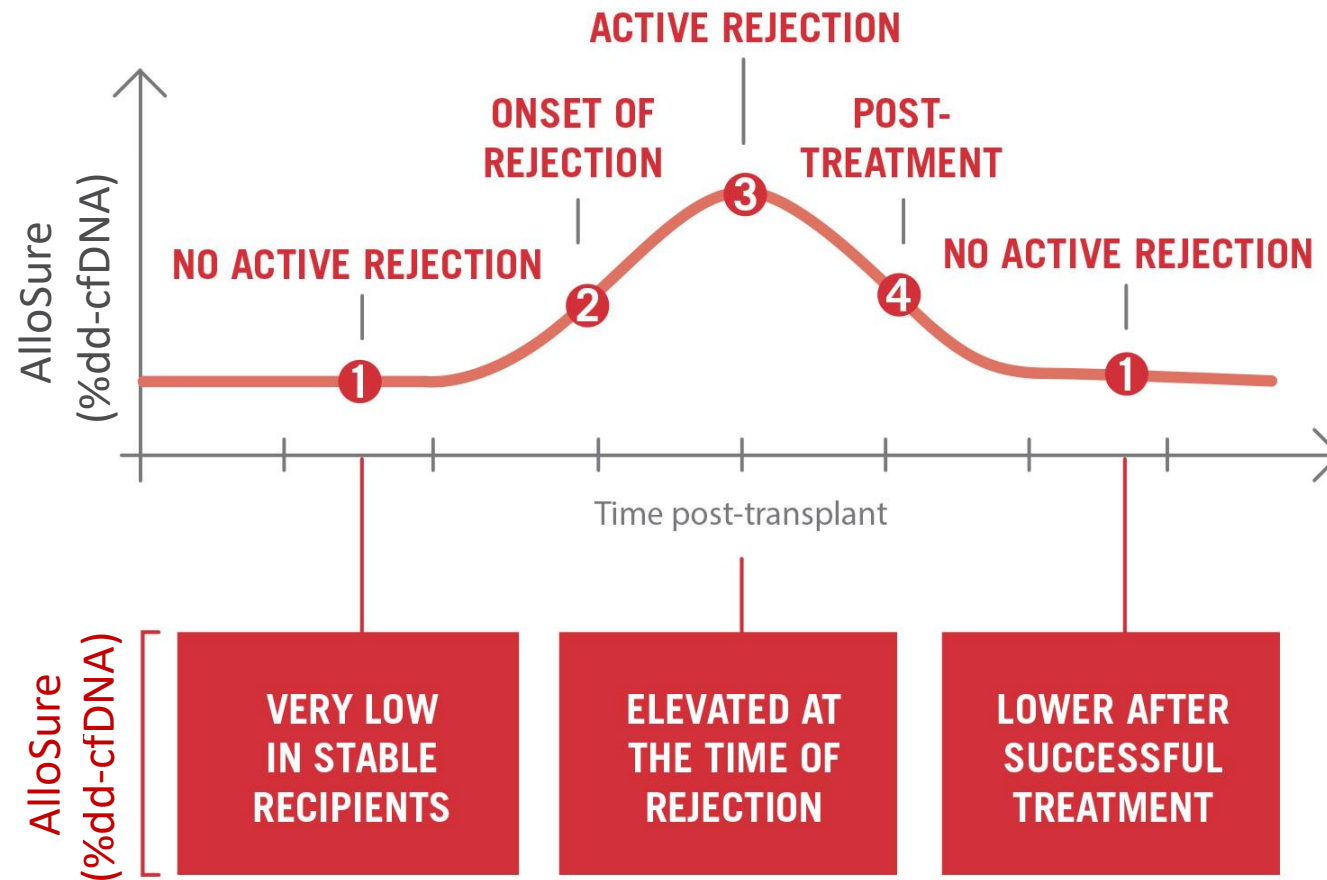
[§] No Active Rejection, n=80 samples from 75 patients

[†] Active Rejection = Acute/active ABMR; Chronic, active ABMR; and TCMR IA and greater, n=27 samples from 27 patients.

Bloom RD et al. Cell-free DNA and active rejection in kidney allografts. *J Am Soc Nephrol*. 2017. doi:10.1681/ASN.2016091034.

* In patients with clinical suspicion of active rejection, the most common cause for the clinical suspicion of active rejection was elevated serum creatinine

AlloSure: First and only Clinically and Analytically Validated dd-cfDNA Test for Identifying Kidney Injury



1. De Vlaminc STM 2014 (heart), Grskovic JMD 2016 (heart), Bromberg JALM 2017 (kidney), Schutz PLOS Med 2017 (liver)
2, 3. De Vlaminc STM 2014 (heart), Grskovic JMD 2016 (heart), Schutz PLOS Med 2017 (liver), Bloom JASN 2017 (kidney)
4. De Vlaminc STM 2014 (heart), Grskovic JMD 2016 (heart), Brennan AJT 2017 (kidney, abstract)

We Care About Strong Clinical Data and Evidence in Transplantation

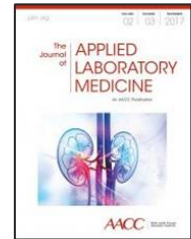
Commitment to Evidence & Clinical Data

Analytical Validity



PUBLISHED
Oct. 2016

Definition of Reference Population



PUBLISHED
Nov. 2017

Clinical Validity/Utility



PUBLISHED
July 2017

Use in Repeat Kidney Transplant



PUBLISHED
Nov 2018

High Value Diagnostics

- Long-term dedication, trailblazer
- Partnering with Transplant Centers
- Large Multicenter studies
- Peer reviewed Publications
- Supports Innovation in Transplant Care



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