

A decorative background pattern of light blue circuit board traces and nodes on a dark blue background, primarily visible on the left side of the slide.

# **THE URGENT NEED FOR THERAPEUTIC INNOVATION IN KIDNEY TRANSPLANTATION**

**KEVIN J. FOWLER**

**PRINCIPAL, THE VOICE OF THE PATIENT**



## PRESENTATION OBJECTIVES

- **Deconstructing the Kidney Transplant False Narrative**
- **State of Kidney Transplant Therapeutic Innovation**
- **Aligning Federal Policy with Therapeutic Innovation**
- **Activating the Patient Voice Within TAVI Forum**

# 2003

- **Kelley: 5 Years Old**
- **Jack: 3 Years Old**
- **Will I be a part of their lives?**





# Characteristics and Outcomes of Kidney Transplant Recipients with a Functioning Graft for More than 25 Years

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Brenda Muth<sup>a</sup> Maha Mohamed<sup>a</sup> Michael J. Armbrust<sup>a</sup> Brad C. Astor<sup>a, b</sup>  
Arjang Djamali<sup>a, c</sup>

112 patients with functional kidney graft for >25 years

0.04% 25 years or longer

Baseline Characteristics	
Male: n (%):	60 (54%)
Mean age at transplant (years)	34.0 ± 8.9
Caucasian	107 (96%)
Living donor transplant n (%):	74 (66%)
Living related (biological):	68 (61%)
HLA 0 mismatch	29 (25%)
Preemptive kidney recipients n (%):	45 (40%)
DSA present at last follow up	17 (15%)
Not on CNI at last follow up:	70 (63%)

Complications:

- Acute rejection: 24 (21%)
- Malignancy: 49 (44%)
- Infections: 86 (77%)

Mean follow up: 29.8 ± 4.0 years

Last follow up serum creatinine: 1.4 ± 0.6 mg/dl

Fig. 1. Summary of patients with functional allografts for >25 years.

# OFFICE OF INSPECTOR GENERAL WAITLIST REPORT

**48% of Patients Added to Waitlist**

```
graph TD; A[48% of Patients Added to Waitlist] --> B[15% of Waitlisted Patients Receive a Kidney Transplant]; B --> C[1/2 of KTX grafts fail at 10 Years];
```

**15% of Waitlisted Patients Receive a Kidney Transplant**

**1/2 of KTX grafts fail at 10 Years**



**William Fitzsimmons** ✓ · 2nd  
Founder, Tutela Pharmaceuticals Inc.; Co-Founder, Alani...  
23h · 🌐

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April 8 is always a special day to celebrate the FDA approval of Prograf (tacrolimus) in 1994. It was 5 years and 1 month from the date the first person received tacrolimus, Robin Ford, at the U of Pittsburgh. Happy 32nd birthday FK506.



# LACK OF FDA APPROVED TREATMENTS

**Antibody  
Mediated  
Rejection**

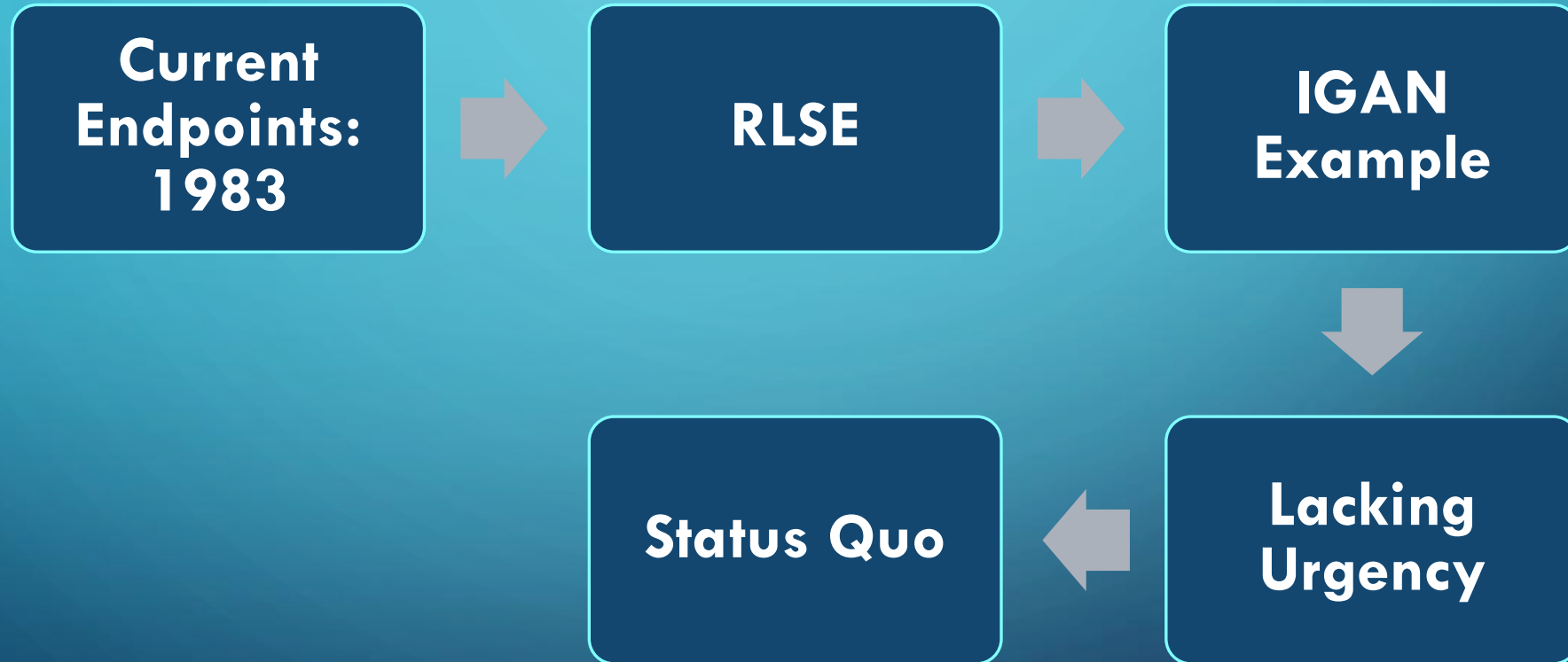
**BK Virus**

**Delayed  
Graft  
Function**

**Sensitized  
Patients**

**PTLD**

# IBOX: 2019- APRIL 2026?




# Increasing Organ Transplant Access (IOTA) Model

# Paragonix KidneyVault®

## The Next Generation of Kidney Preservation

The Paragonix KidneyVault® Portable Renal Perfusion System marks a new chapter in kidney transplantation. This FDA-cleared hypothermic preservation device is equipped to perfuse and monitor a kidney throughout the entire transplant journey.





# INCLUSION OF PATIENT VOICE WITHIN TAVI

- **Enabling Patient Voice To Be Heard:**
  - **Paternalism**
  - **Regulatory Challenges**
  - **Risk-Benefit Discussions: Allowing recipients to define acceptable risk**
  - **Defining Patient Burden: Discordance between Transplant Physician and Recipients**

# NEXT STEPS: TAVI FORUM SURVEY

- **What Are Your Needs?**
- **Elevation of Patient Voice**
- **Build on successful legacy**

# KEVIN FOWLER

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