

KidneyX: Accelerating Innovation in the Prevention, Diagnosis and Treatment of Kidney Diseases

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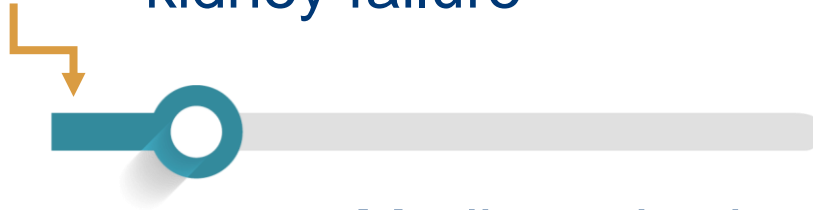
Kidney X Mission:
**Accelerate innovation in the
prevention, diagnosis, and treatment
of kidney diseases.**

- **How public-private partnerships can drive progress in otherwise neglected areas**
- **How a small organization can create transformative changes**
- **How realigning incentives can help patient needs come first**



700,000
Americans have
kidney failure

1% Medicare population has
kidney failure



7% Medicare budget
dedicated to their care

100,000 START DIALYSIS
every year: >50% of them will
DIE WITHIN 5 YEARS



\$35 BILLION
Annual Medicare Spend



12 Hours

A typical in-center hemodialysis patient spends 12 hours a week attached to a machine



93% Patients

Among patients ages 18-54 years old at the start of dialysis, 93% were classified as disabled



100,000

Each year, more than 100,000 Americans begin hemodialysis as a result of kidney failure



40 Million

40 Million adult Americans are currently classified as having chronic kidney disease



13 Patients

Every day 13 patients die waiting for a kidney transplant



48%

Of Stage 4 CKD patients, 48% were unaware of their severe CKD



3.5 Times

African-Americans are 3.5x more likely to develop kidney failure



1.5 Times

Hispanics are 1.5x more likely to develop kidney failure

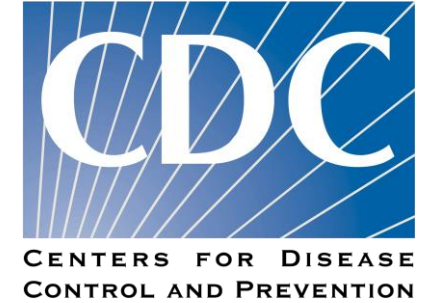


HHS

Research funder
Market regulator
Primary payer
Public health steward

ASN

Nephrology expertise
Global reach
\$25 million committed
Fundraising capacity



“...One of the key reasons for our failing policies is that kidney care in particular has some of the worst incentives in American healthcare.”

– HHS Secretary Alex M. Azar II

Incentivizing New Products

- 1. Offer funding opportunities**

Series of prize competitions

- 2. Improve coordination across HHS**

Clarify paths to commercialization (NIH, FDA, CMS)

- 3. De-risk commercialization**

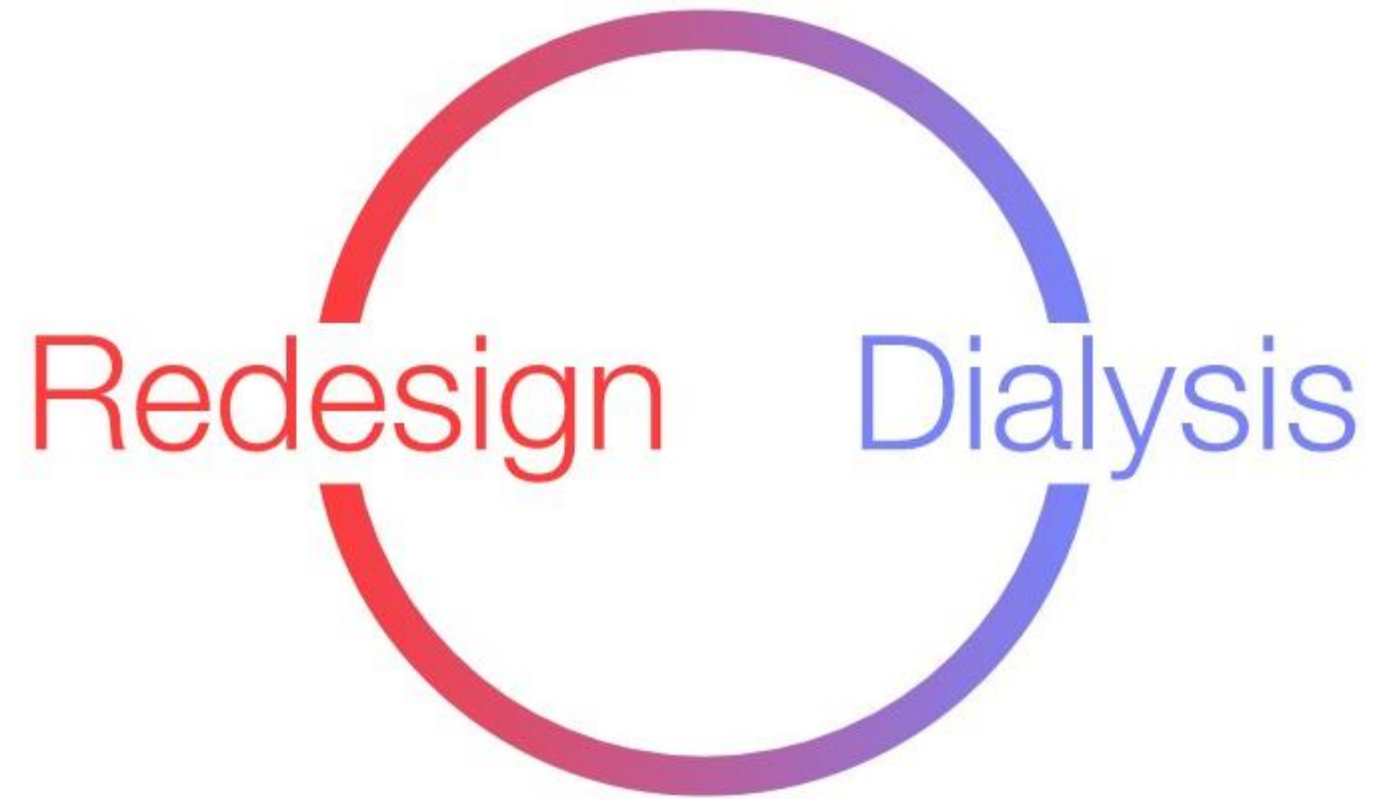
Attract outside investment capital

- 4. Create a sense of urgency**

On behalf of people living with kidney diseases

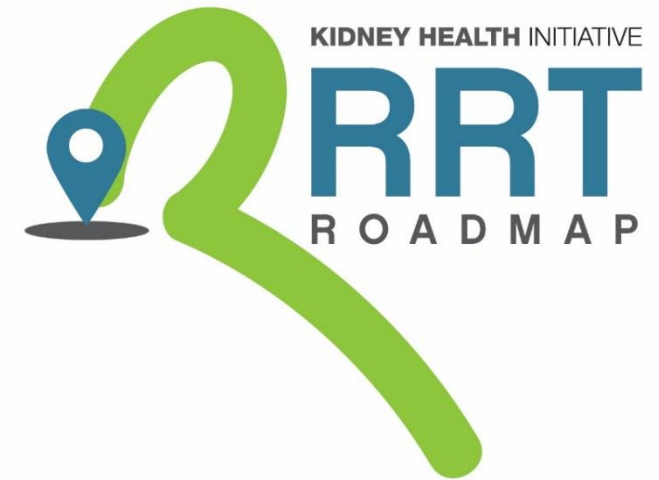
KidneyX Principles

- **Patient-Driven:** Ensure all product development is patient-driven
- **Urgent:** Create a sense of urgency
- **Achievable:** Ground in scientifically-driven technology development
- **Catalytic:** Reduce regulatory and financial risks to catalyze investment
- **Collaborative:** Foster multidisciplinary approaches
- **Additive:** Addresses known barriers to innovation
- **Sustainable:** Invest in a diverse portfolio to balance risk



Redesign Dialysis: Solutions Sought

- Replacing kidney functions
- Improving patient quality of life
- Addressing engineering challenges
- Ancillary technologies
- Biomaterials development
- Biological and immunological modulation
- Biosensor development and safety monitoring

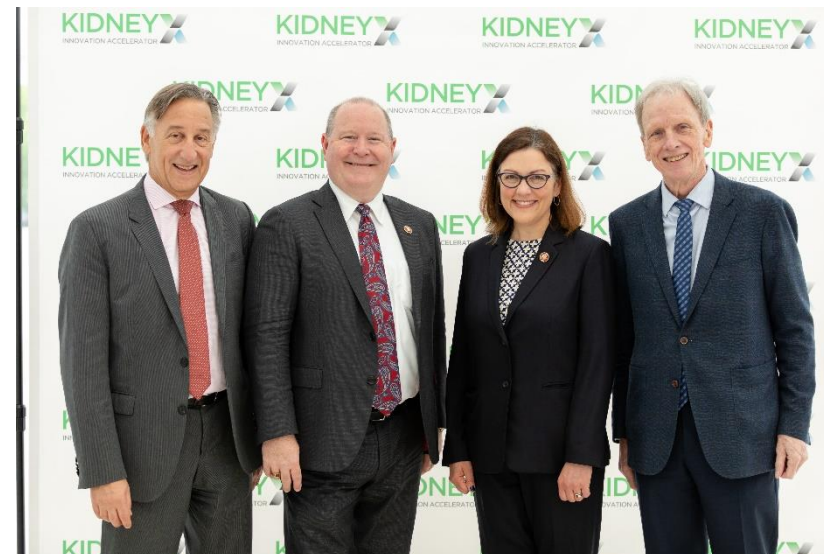
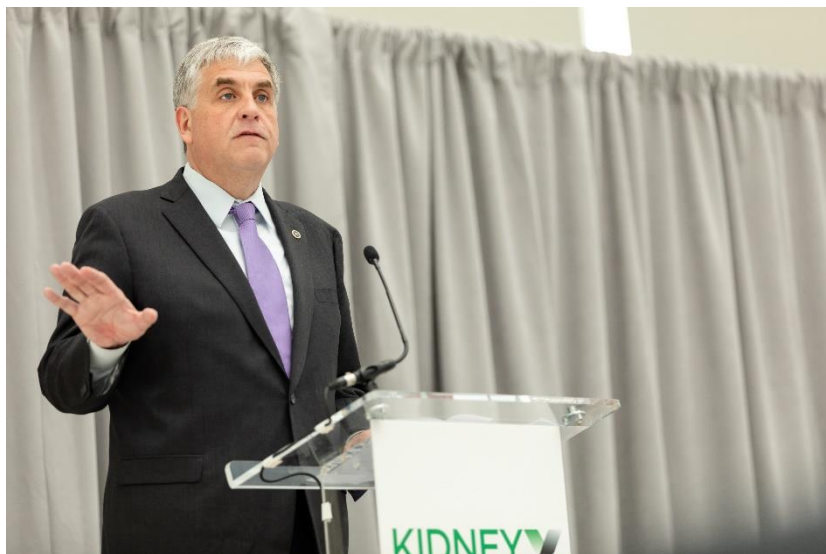


Phase One: Design Solutions

- Sought promising ideas *on paper*
- Awarded 15 teams \$75,000

“...we got 165 submissions, including a number of proposals that could help advance an artificial kidney...we’re thrilled with this level of interest, and it shows what a prize competition can drive.”

– HHS Secretary Alex M. Azar II



Phase Two: Develop Solutions

- Seek prototype or component technology
- Up to 3 prizes of \$500,000
- Submissions accepted Q4 2019 – Q1 2020



REDESIGN DIALYSIS: October 2018 - Q2 2020

Wearable or implantable dialyzers, bio-artificial kidneys, xenotransplant technology, etc.



MEDICATIONS

Drugs specifically designed to treat and slow progression of kidney diseases, as well as encompass the needs of kidney transplant patients



DEVICES

Devices that support the management and treatment of kidney diseases that are not dialyzers (such as vascular access technologies, etc.)



DIAGNOSTICS

Point-of-care or at home testing kits, real time kidney monitoring, etc.



PATIENT-CENTERED TOOLS

Tools designed to identify and track disease, applications to empower patients to manage kidney diseases (e.g., apps)

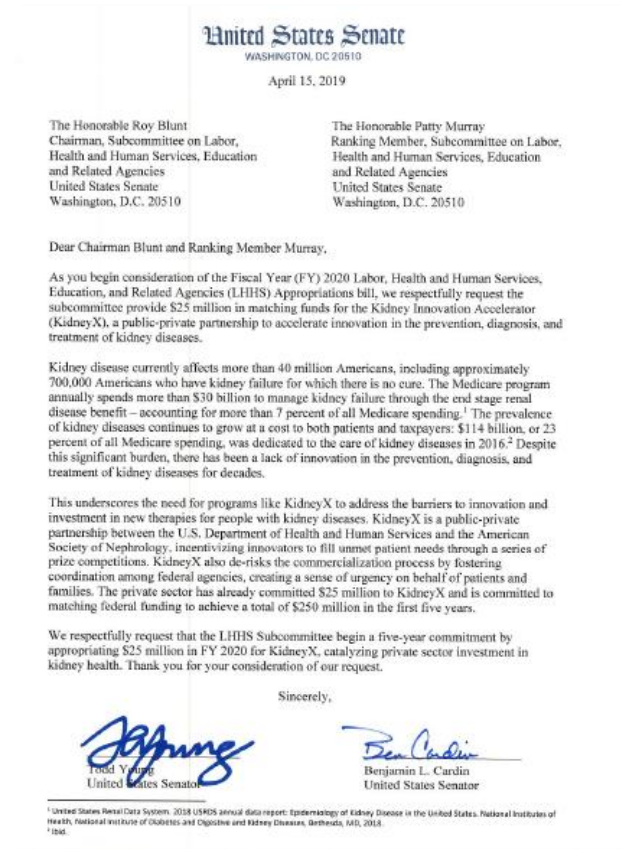
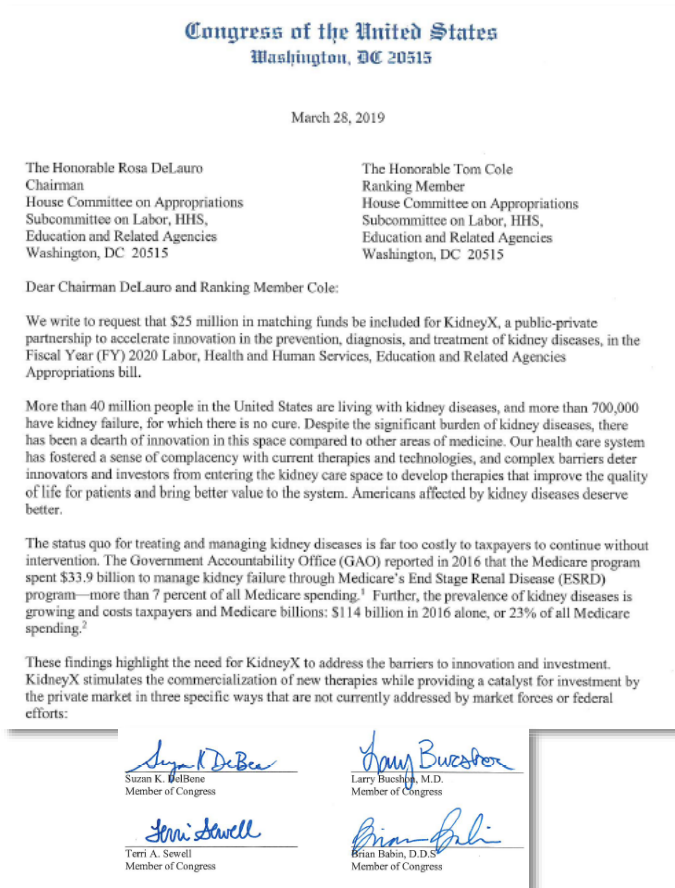
ASN and AAKP Advocacy for KidneyX



PUBLIC	PRIVATE
\$25M FY20 congressional appropriation support	\$25M committed by ASN
\$125M congressional funding over 5 years	\$100M in fundraising over 5 years
PARTNERSHIP	
\$250M total driving kidney innovation over 5 years	

ASN and AAKP Advocacy for KidneyX

- 57 bipartisan House signatories
- 5 bipartisan Senate signatories





Appropriations Committee Releases Fiscal Year 2020 Labor-HHS-Education Funding Bill

April 29, 2019 | Press Release

- \$10 million for **KidneyX**, a new public-private partnership to accelerate the development and adoption of novel therapies and technologies to improve the diagnosis and treatment of kidney diseases.

“KidneyX has given me hope. As I watch my husband's quality of life decline, I want to do more and proceed in a positive direction. We both worked hard all our lives so we could enjoy travel, grandchildren, gardening, etc.

Instead, we devote about 32 hours/week to home hemodialysis. It is like having a full-time job again. We are just searching for newer and better ways to treat my husband's kidney failure before he succumbs to it. Please keep us informed about KidneyX.”

–Wife of dialysis patient



KidneyX Contact Information

- ▶ KidneyX questions:

Connie Herndon, KidneyX Project Director cherndon@asn-online.org or
Sandeep Patel, PhD, HHS sandeep.patel@hhs.gov

- ▶ Advocacy-related questions:

Rachel Meyer, ASN Policy and Gov. Affairs rmeyer@asn-online.org

- ▶ Website: **KidneyX.org**

- ▶ Twitter: **@Kidney_X**

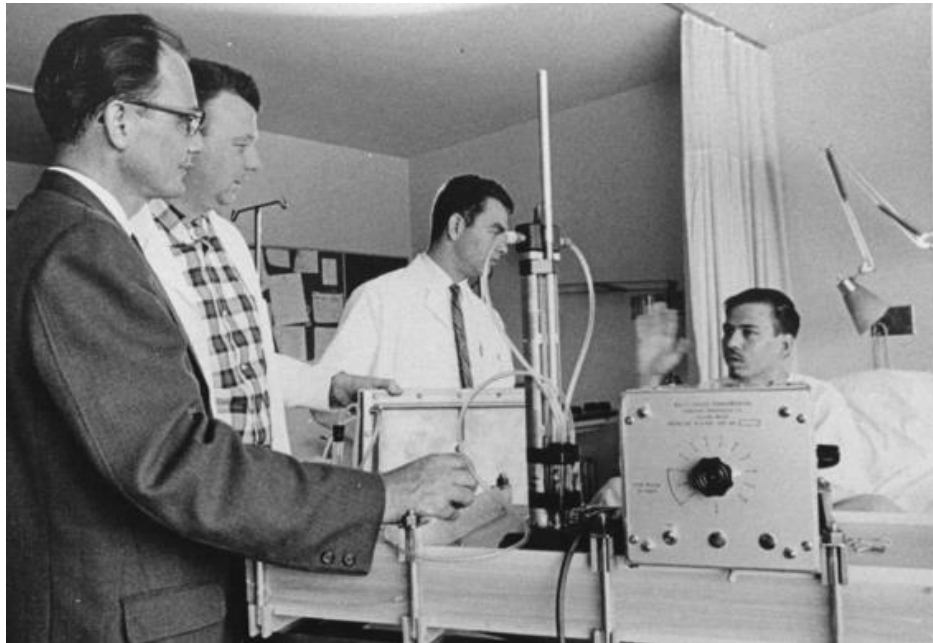


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1960s

Who gets dialysis?

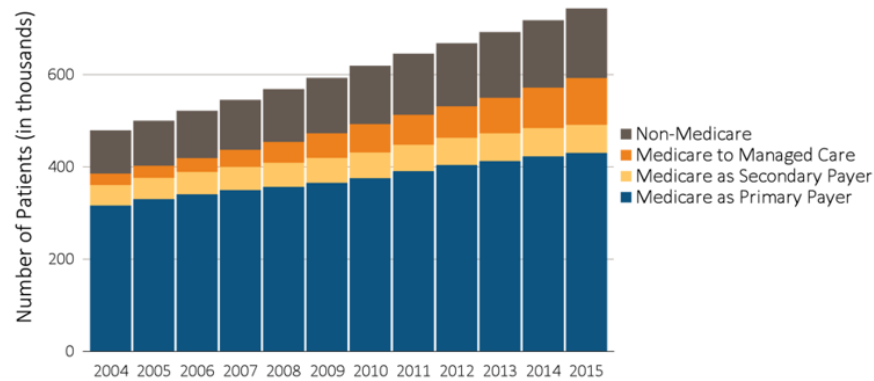


1972

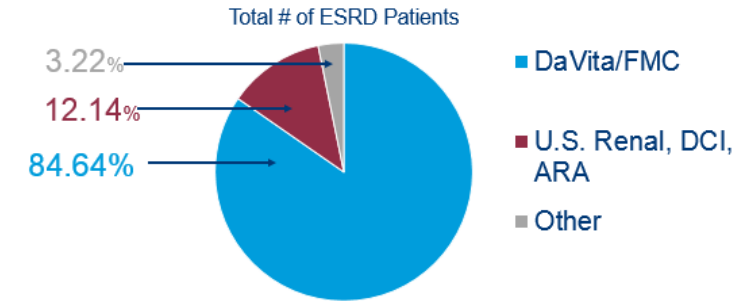
Medicare ESRD Program



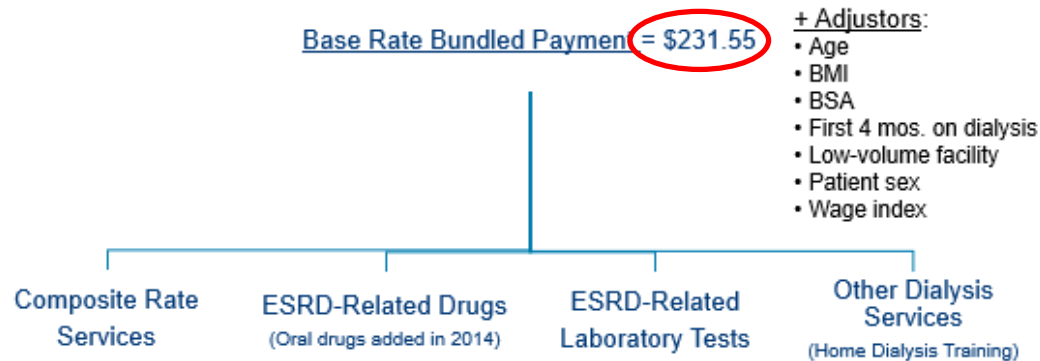
Single Payer (Virtually)



Consolidation



Fixed Bundled Payments



For-Profit Healthcare



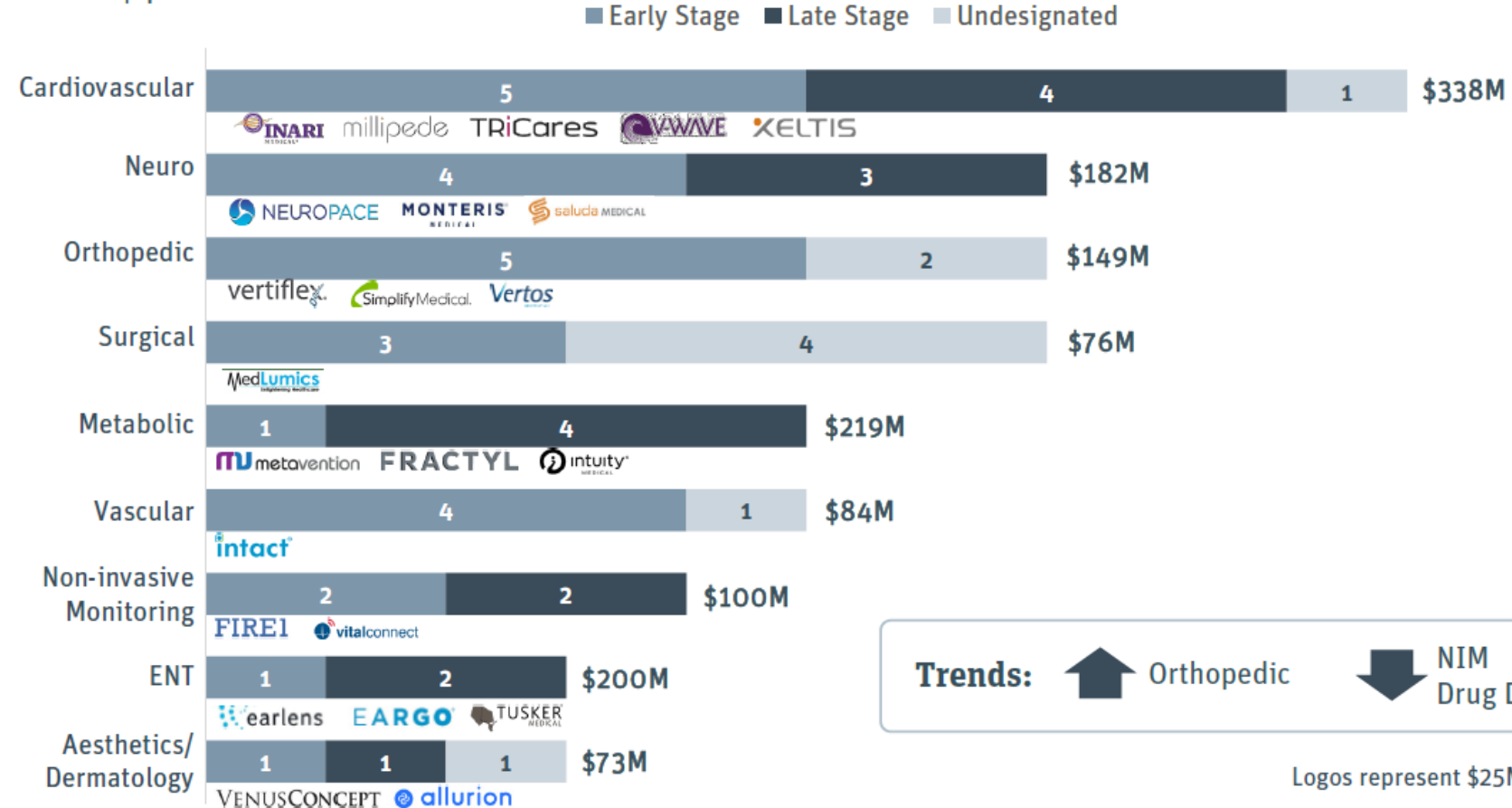


	Total Drug Approvals	Cancer	Kidney Diseases
2015	46	15	2 (patiromer for hyperkalemia and ferric pyrophosphate citrate for anemia)
2016	22	6	1 (calcifediol for SHPT)
2017	31	8	1 (etelcalcetide for SHPT)
Total 2015 - 2017	99	29	4 (all symptom management drugs)



For illustrative purposes only. Final packages may vary.

DEALS | \$ MILLIONS



Silicon Valley Bank, Trends in Healthcare Investments and Exits Mid-Year 2018, Pitchbook