



**FRESENIUS
MEDICAL CARE**



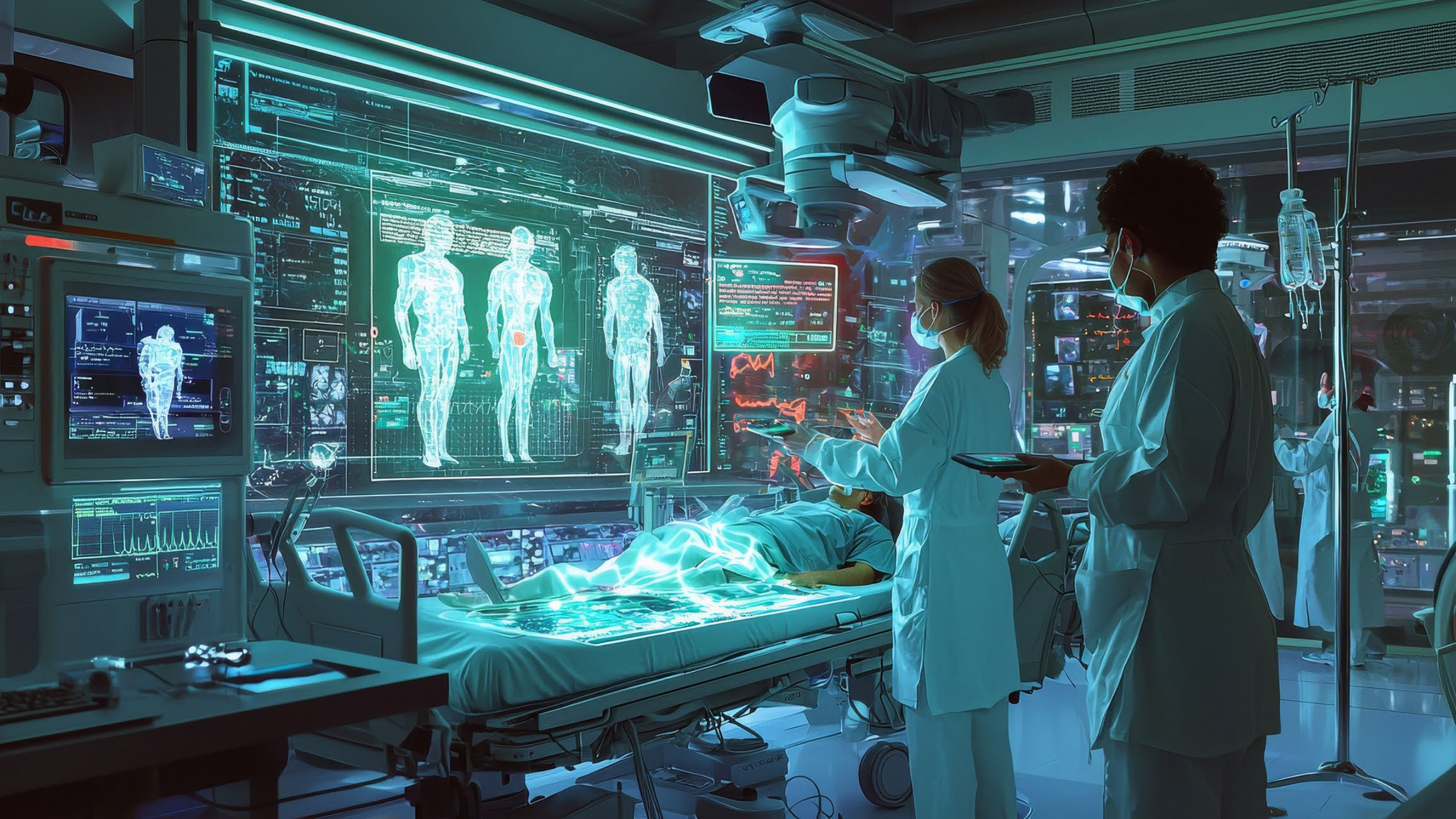
AI in Nephrology MedTech Design
*Accelerating Innovation, Personalization
& Safety in Kidney Care*

Robert J. Kossmann, MD, FACP, FASN
European Medical Device Summit

The Potential of AI and Digital Solutions is Broad and Deep

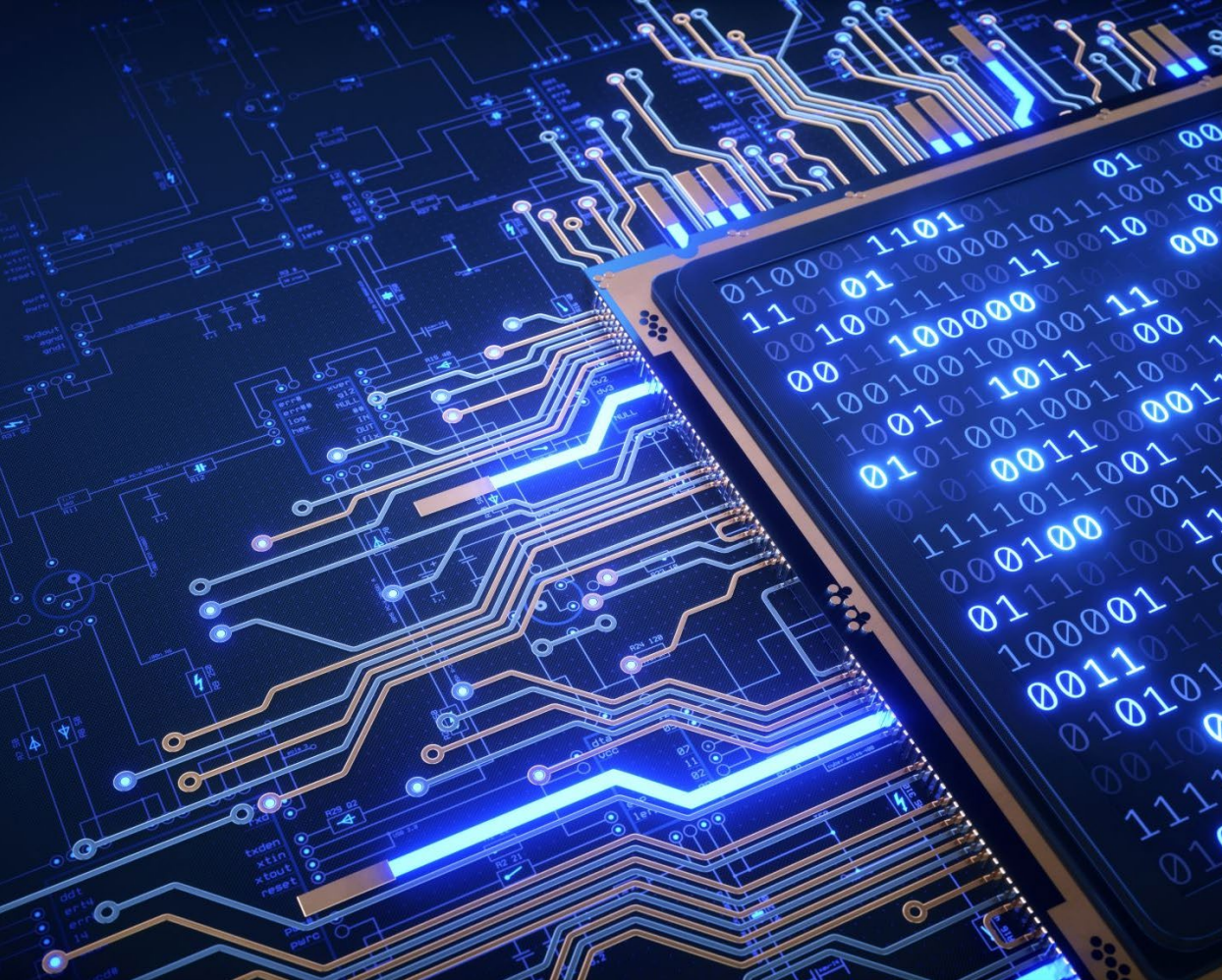
However, when funds are constrained, we must always ask a fundamental question: “**How does this AI solution deliver value?**”







What is AI?



Artificial Intelligence (AI)

- The field of computer science focused on creating systems or machines that can perform tasks that typically require human intelligence.

A commonly accepted definition of AI:

- The simulation of human intelligence processes by machines, especially computer systems.

Different types of AI based on capability and function:

- Narrow AI (specialized tasks)
- General AI (human-like capabilities)
- Superintelligent AI (beyond human intelligence)

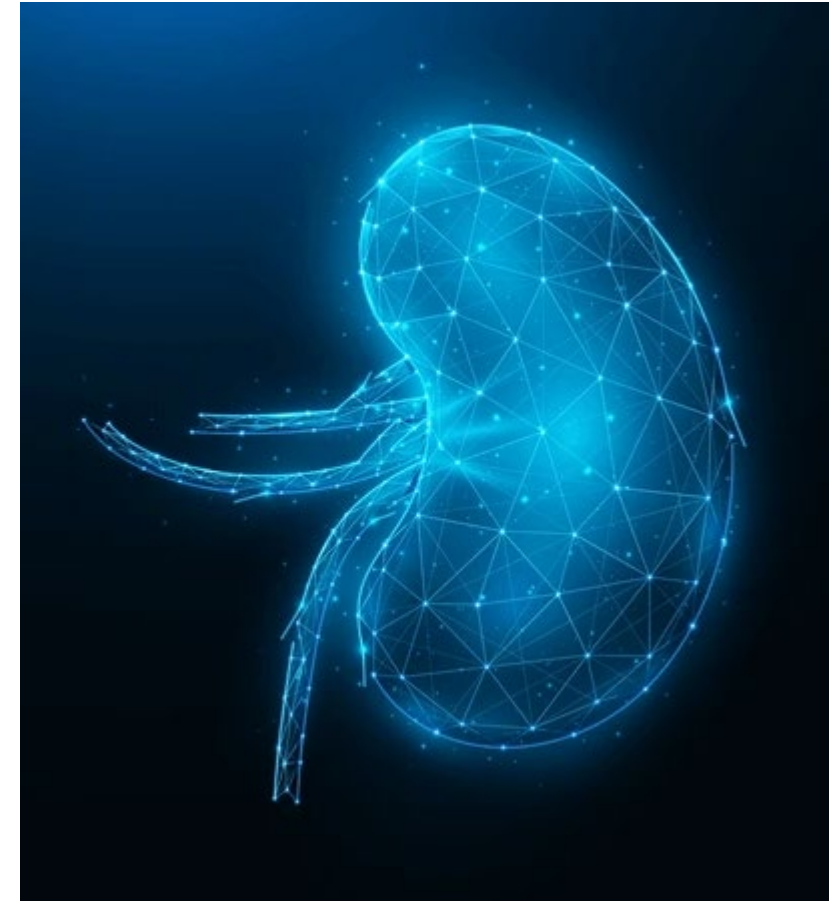
Most current AI systems are *narrow AI*.

Digital Solution vs Artificial Intelligence

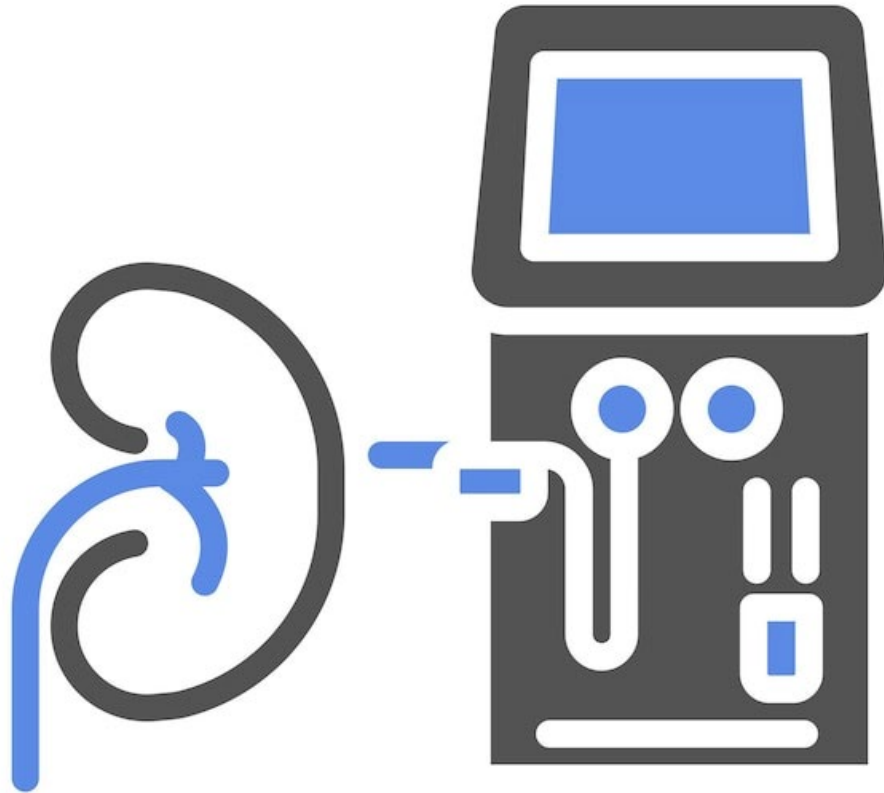
Aspect	Digital Solution	Artificial Intelligence (AI)
Scope	Broad – includes any digital tool	Narrower – focuses on replicating human intelligence
Purpose	Solves a problem using digital tech	Mimics or simulates human decision-making and learning
Requires Learning?	Not necessarily	Yes, often involves learning from data
Examples	Mobile app, website, database	Chatbot, recommendation engine, image recognition
Autonomy	Usually rule-based, manual logic	Often adaptive and autonomous

Overview | Key Applications of AI in Nephrology Device Design

- Real-time personalization of dialysis treatment
- Smarter home dialysis systems (PD & HD)
- AI-guided membrane and material design
- Digital twins for device testing
- UX & safety optimization via human factors analysis



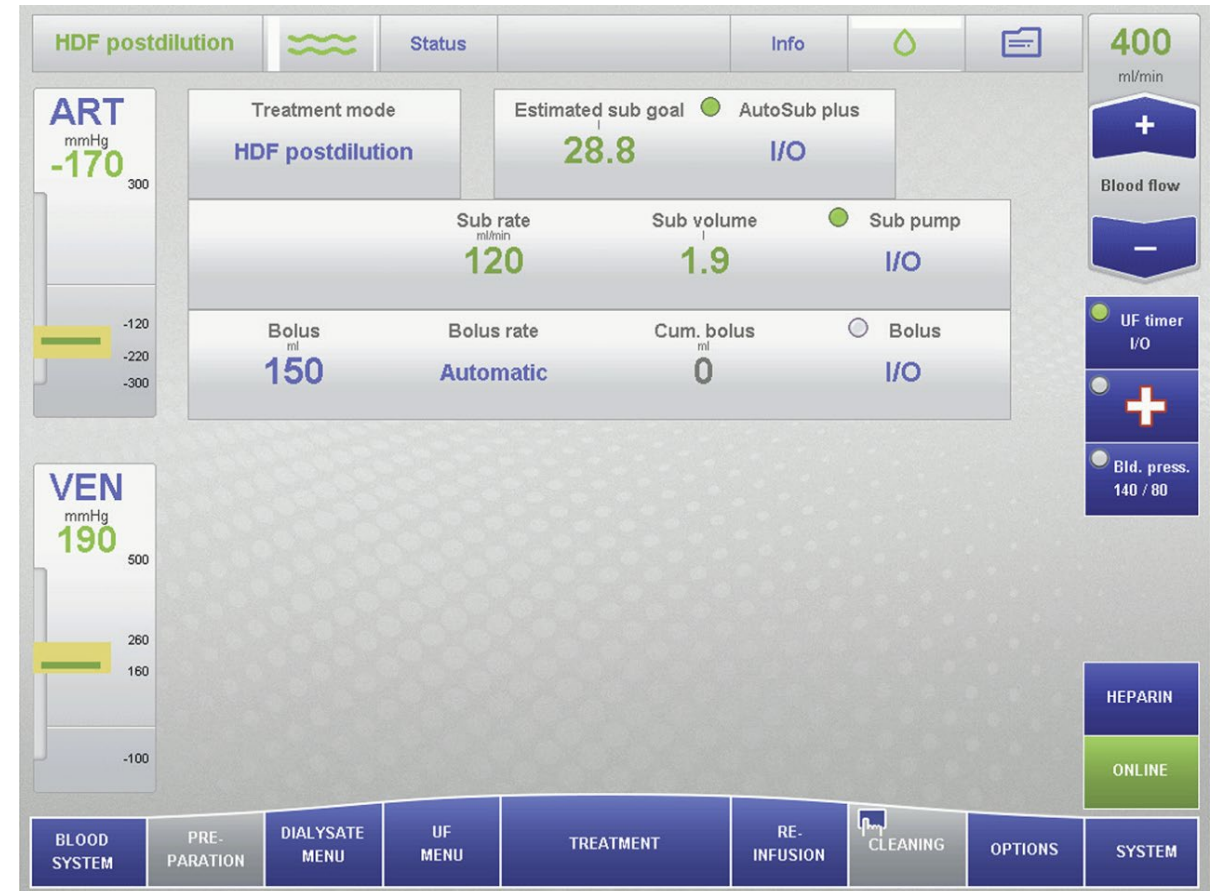
Personalized Dialysis Machines | Smart Dialysis Systems



- AI tailors ultrafiltration rate, session time, and dialysate composition
- Adaptive learning from patient responses
- Devices: *Outset Medical Tablo, Quanta SC+, Fresenius Medical Care 5008 & 6008 series hemodialysis machines*

Autosub+ on Fresenius Medical Care HDF-capable hemodialysis machines

- Physician prescription of net fluid removal goal
- Physician prescription of post-dilution substitution volume
- Device modulates filtration fraction real-time during treatment to optimize parameters during treatment time to ensure goal attainment in any single treatment



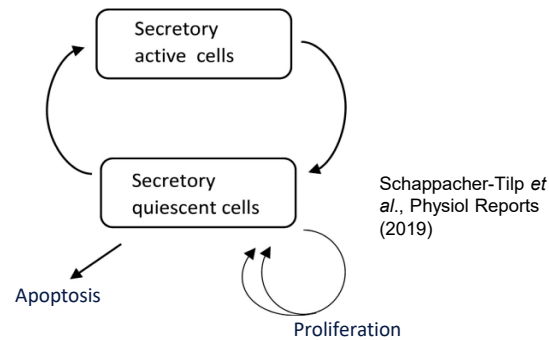
Cinacalcet 3x Weekly Through Mathematical Modeling

CKD patients have **high levels of parathyroid hormone (PTH)**, resulting in bone disease and vascular calcification

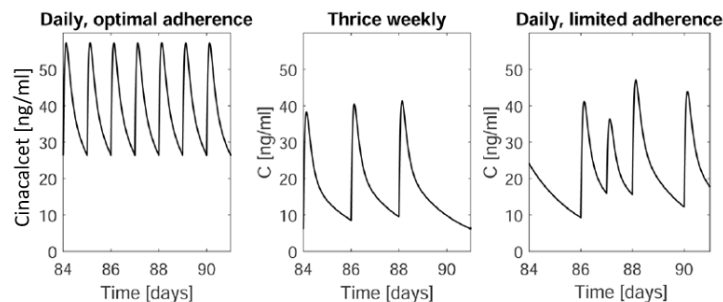
Cinacalcet is an oral drug that suppresses the release of PTH

Patients are supposed to take cinacalcet **daily**, but the drug has side effects, which is why **adherence is erratic**

Model of parathyroid gland biology



Model of cinacalcet pharmacokinetics



Outcomes

1

were able to show that thrice weekly controlled intake of cinacalcet during HD is sufficient to control PTH

2

Because of this, 60K HD patients use cinacalcet 3x per week instead of daily, resulting in lower cost and pill burden, and equally good control of PTH



Improving mortality rates



Reimbursement potential



Evolutionary or breakthrough innovations



Intelligent Peritoneal Dialysis | Smarter APD Systems



- Predict peritonitis & fluid imbalance
- Detect non-adherence or tubing issues
- Feedback loop via connected apps
- Example:
 - *Baxter Amia with Sharesource*
 - *Fresenius Medical Care with Kinexus*

Home Penetration Predictive Algorithms

Suite of modality predictive models with pilots starting **~2018**

Monthly predictions on “in-center to home” are displayed on a dashboard used by >200 KCAs. It is viewed about **450 times a month**

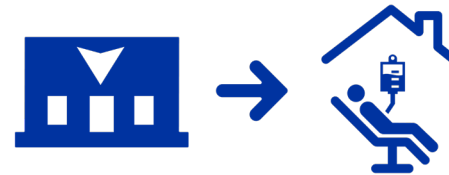
Weekly reports on “**PD failure**” are sent to nearly all PD clinics

Beginning a targeted pilot to measure outcomes from using report via dashboard

Penetration model: piloting adding these predictions to KCA’s HT Candidate worklist in two regions

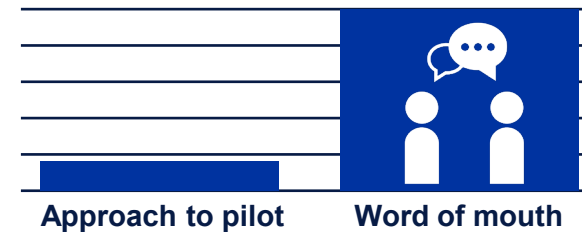
Chicago region took the predictions opting to use them as part of an ongoing blitz

Outcomes



In-center to PD

>600 patients clearly identified from the model in one year alone to move to home



PD attrition

~1200 FME (U.S.) clinics receive the reports and **200** are now interested in expanding



Improving mortality rates



Reimbursement potential

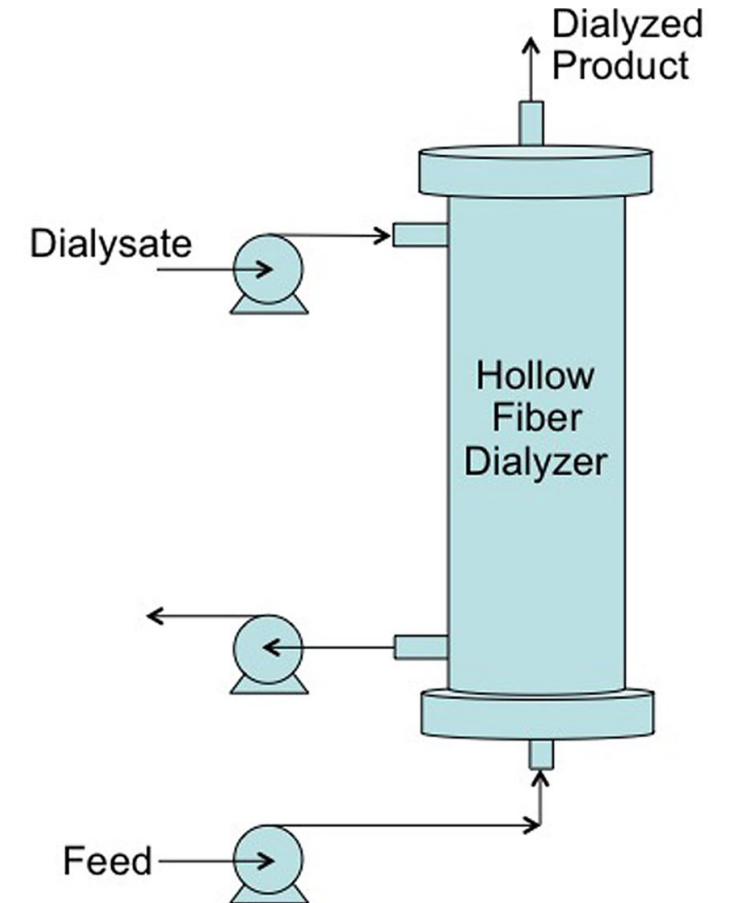


Evolutionary or breakthrough innovations



AI-Driven Materials Design | Next-Gen Dialyzer Membranes

- Machine learning simulates solute interactions
- Optimizes biocompatibility and clearance efficiency
- Reduces development cycles and trial costs



Digital Twin for the Kidney | Virtual Kidney Models

- Simulate fluid dynamics, solute kinetics, and acid-base regulation
- Supports testing of implantable and wearable dialysis concepts



Human Factors & UX | Design Optimization Through Behavior Analysis

- AI interprets real-world user interaction
- Refines UI/UX for aging and home-dialysis populations
- Improves safety, reduces training burden



Models to Reduce Hospitalizations

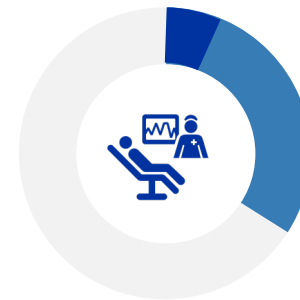
Suite of hospitalization prediction models: fluid admissions, infectious admissions, home hospitalization model

Fluid and infection models are used by 20 care navigation nurses with 40K predictions daily with IWH

Dashboards exist to help nurses. More **DTI integration** is needed.

New updates to provide direct actionable interventions

Outcomes



Up to **30%** reductions in fluid-related admissions



COST SAVINGS

~\$15M annual savings generated



Improving mortality rates



Reimbursement potential



Evolutionary or breakthrough innovations



Summary Table

Focus Area	AI Contribution
Dialysis Optimization	Personalized real-time control
Home Dialysis	Predictive maintenance, adherence
Material Innovation	Accelerated filter design
Digital Twin Modeling	Simulated testing, training
UX & Ergonomics	User-driven interface refinement

Overview of Renal Research Institute's AI Activities

30+

Current AI activities



Very small experienced team



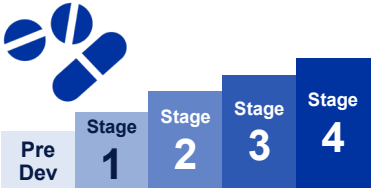
Existing models support



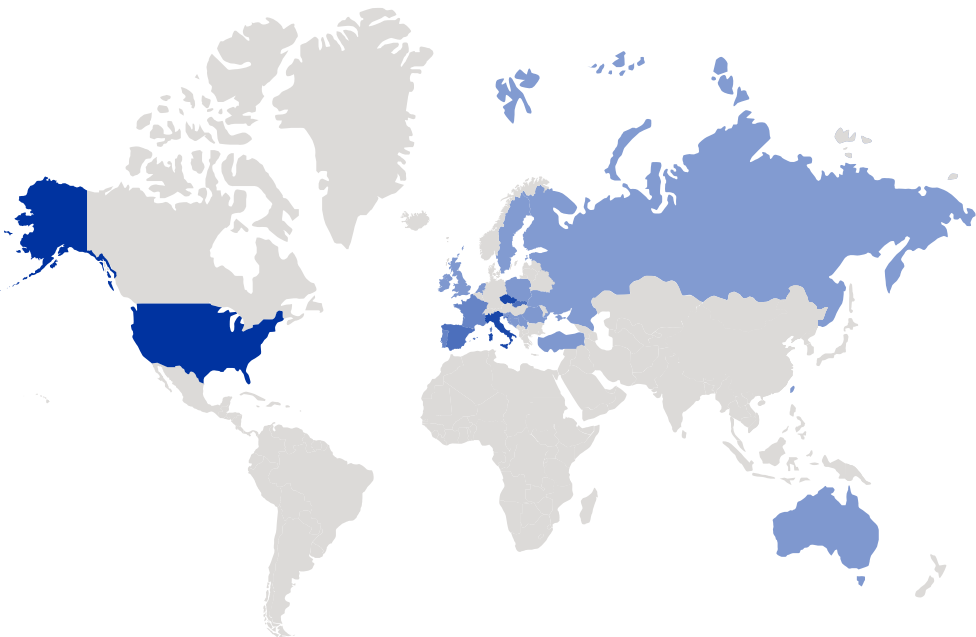
Based on business and clinical priorities



Medical device certification



AI development process



Most AI solutions we develop **cost under \$100K from conceptualization to bedside** in labor, licenses, and consultancies

Final Thoughts | AI in Nephrology Design is Enabling

- Safer, smarter home dialysis therapy and in-center hemodialysis therapies
- Faster product development
- More precise, patient-centric therapy



