

Welkom bij sessie 26

Updates klinische trials Nextkidney (HD)
en CORDIAL (PD)

Karin Gerritsen

A dark blue, stylized graphic of a kidney is positioned on the right side of the slide. It has a textured, slightly grainy appearance. The text 'NIERCONGRES' and '7 APRIL 2026' is overlaid on the kidney graphic.

NIERCONGRES
7 APRIL 2026

Dé dag voor professionals
in de **nierzorg**

Disclosure

Voor bijeenkomst mogelijk relevante relaties

- Sponsoring of onderzoeksgeld

Bedrijfsnamen:

Nextkidney



“Dialysis made portable”



Inspired by Kolff

Karin Gerritsen

Nephrologist, Associate Professor

Inspired by Willem Kolff (1911-2009)



1976

Kolff met de draagbare nier, juli 1976. Het W.A.K. is 3 kg.

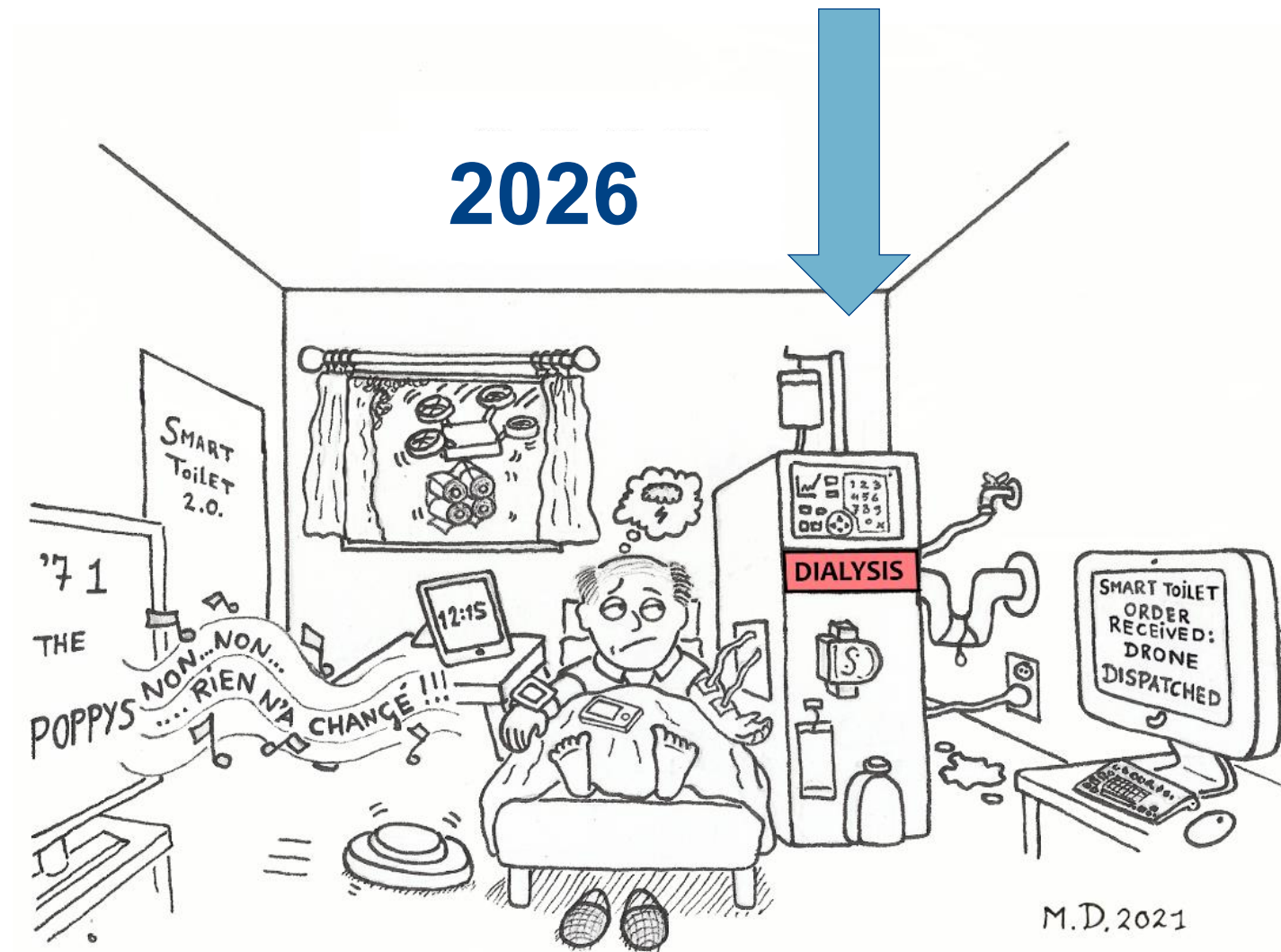
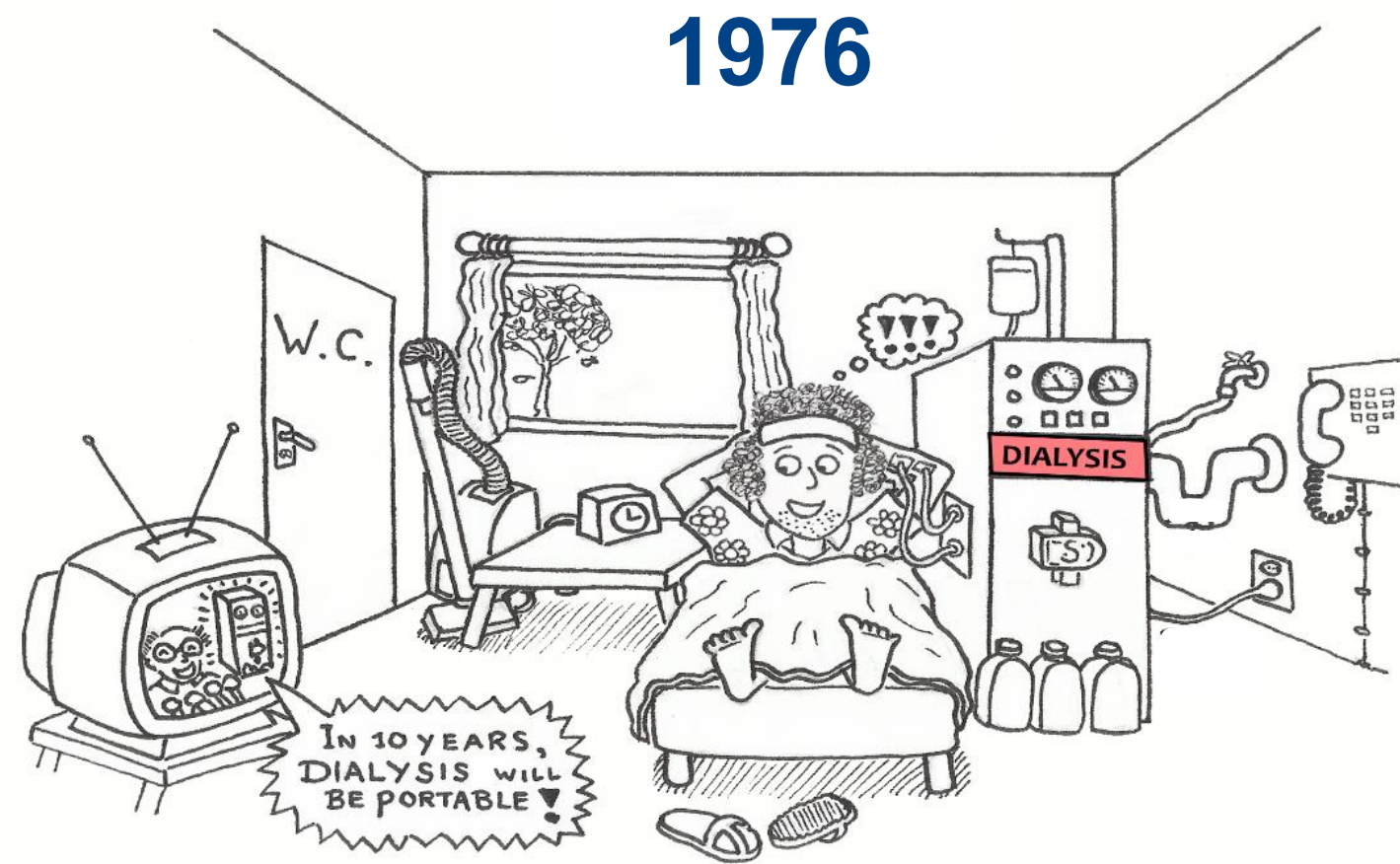


1982

Figure 3. Bruce from Santa Ana, CA, dialyzes with the WAK-II (wearable Artificial Kidney - Model II) on the beach at Maple Creek, Salmon River, ID. Bruce was one of 10 hemodialysis patients who spent a week in the Salmon River wilderness - an experience which was made possible by the WAK and the team from Dialysis in Vondderland. July 1982.



50 years of adding smartness into (nearly) everything



© Henning Søndergaard



Technology Roadmap for Innovative Renal Replacement Therapy



Now

Miniaturization

Improved blood purification

Biohybrid systems

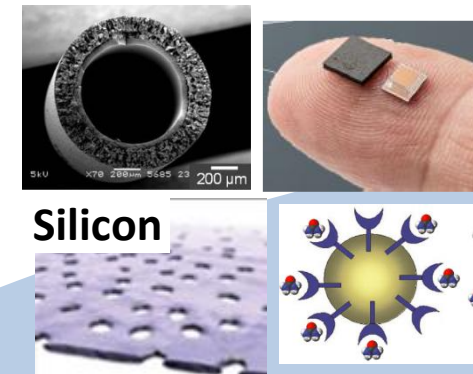
Short frequent hemodialysis (20-30L/ treatment)



NxStage Physidia
Transportable
23-34 kg



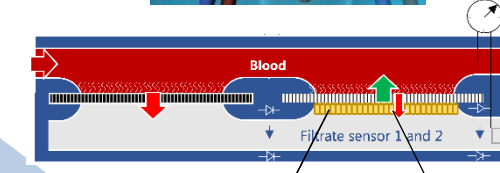
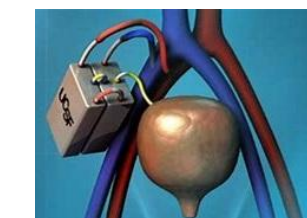
1st Generation portable devices
10-20 kg



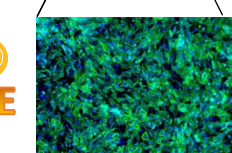
Wearable devices
Implantable dialyzer

KIDNEW

UKID

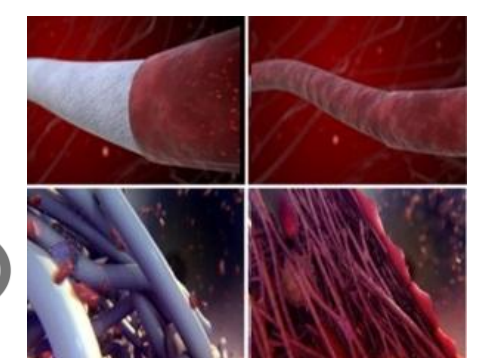


BAKO TO THE FUTURE



Implantable kidney

XELTIS
a KESS



Biorestorative graft
Vascular access



NXT GEN
hightech

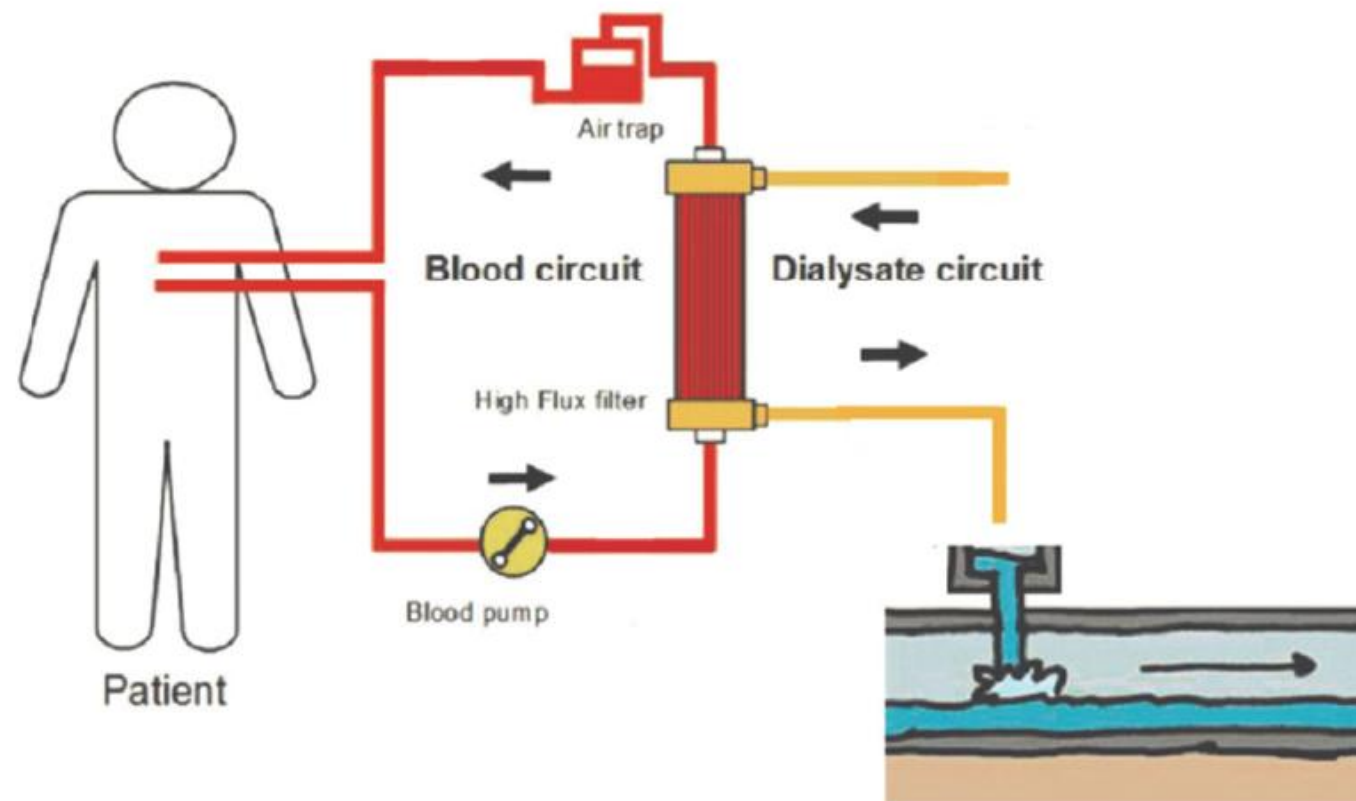
REGMEDXB

Dialysate regeneration Concept

Conventional hemodialysis

Single pass

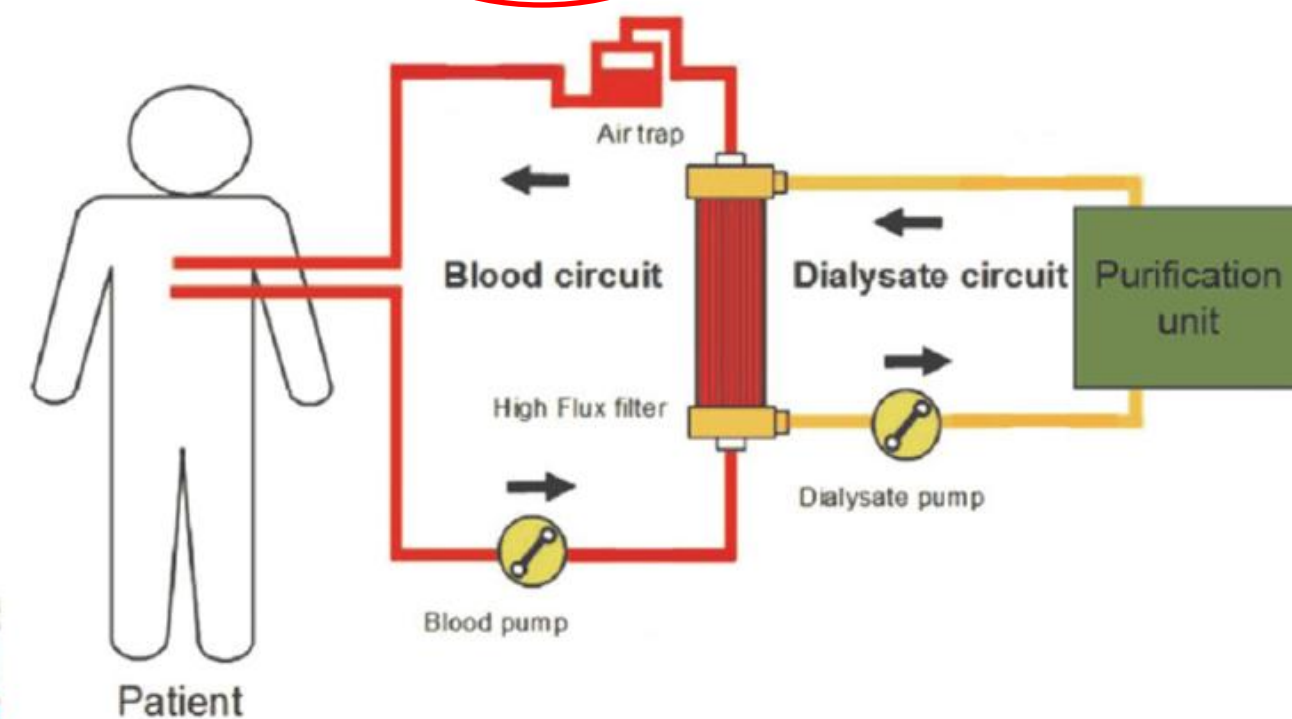
$\geq 25L$

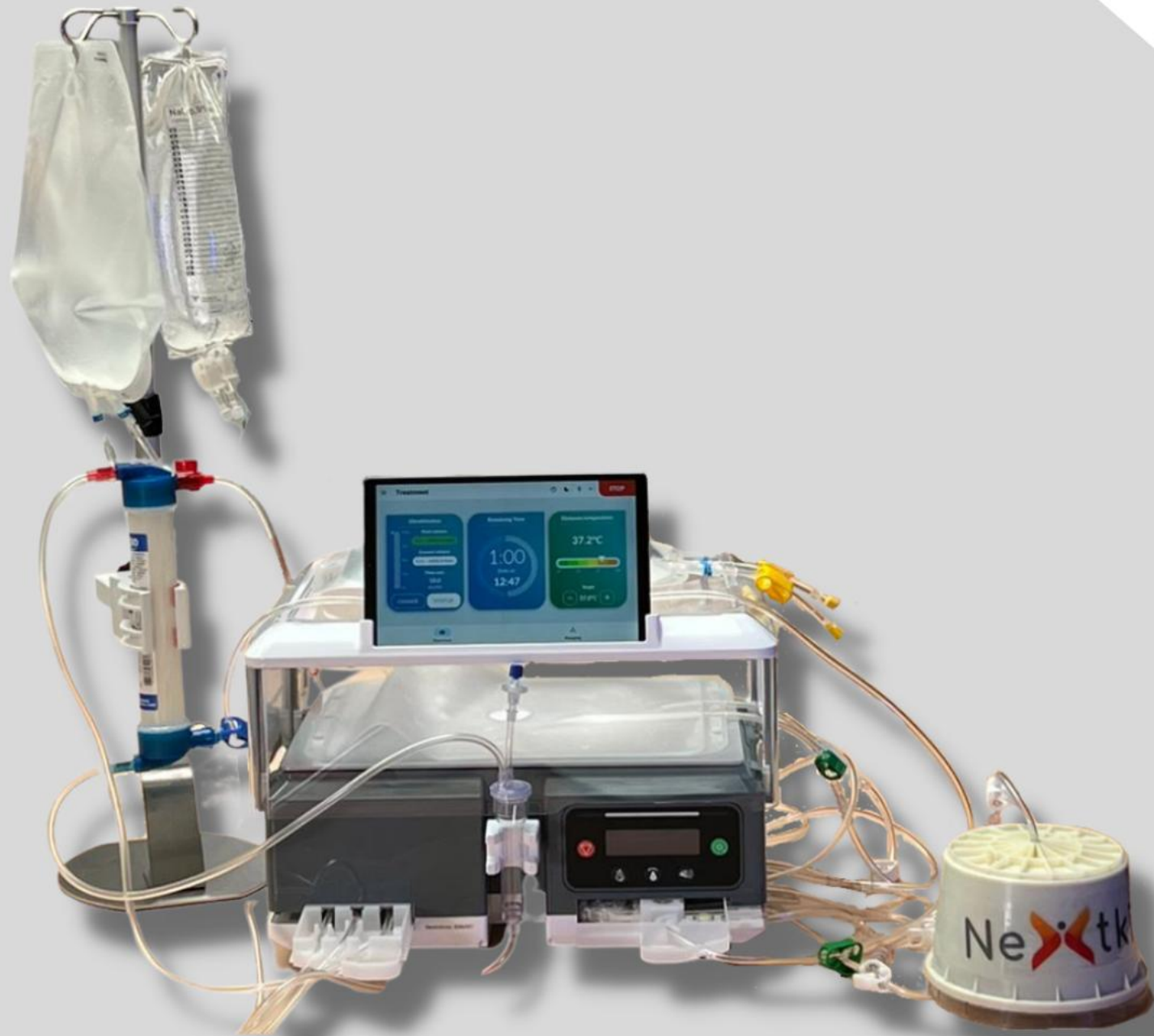


Miniature artificial kidney

Regeneration of dialysate

$< 5L$





NeXtkidney

DIALYSIS ANYTIME, ANYWHERE

In partnership with:

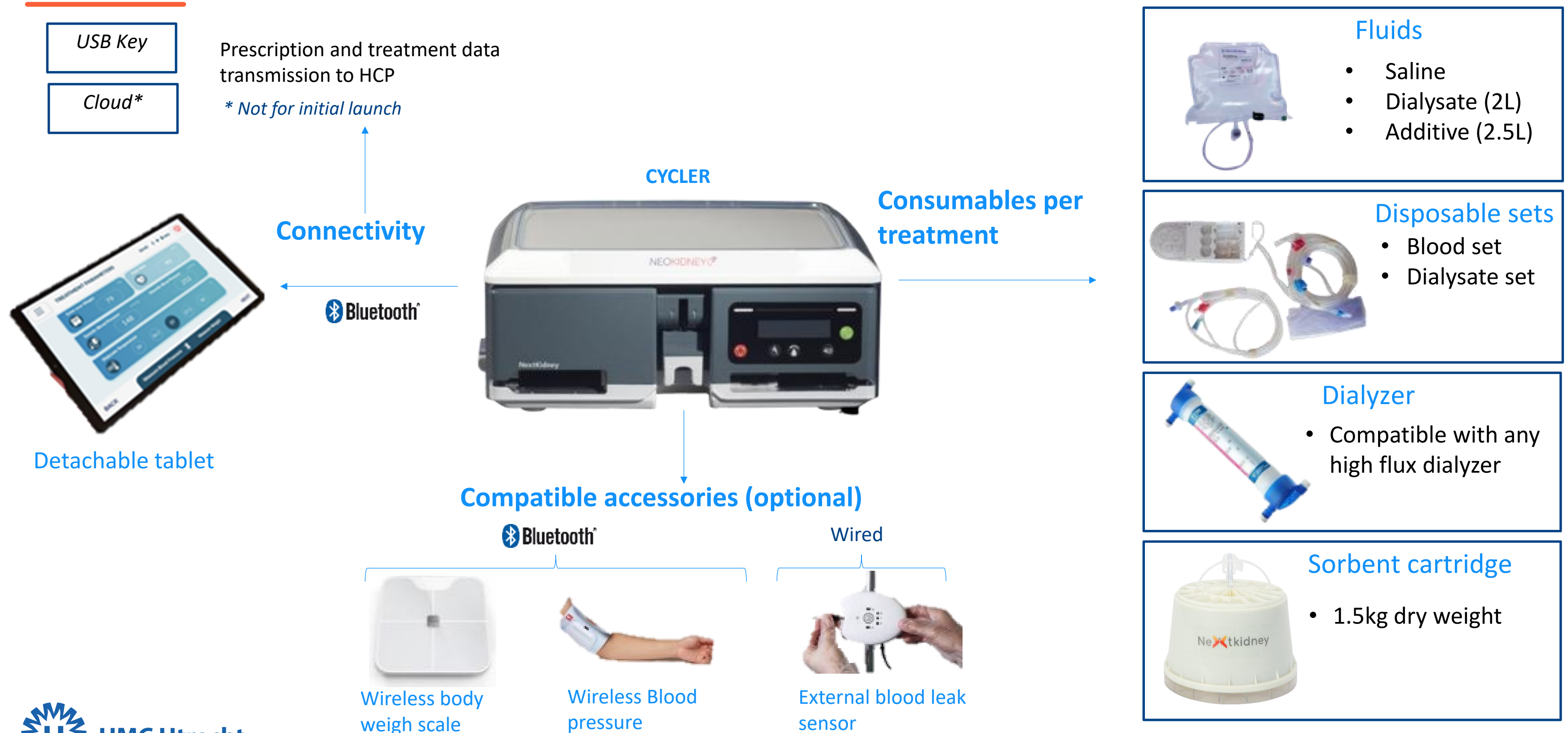


Portable hemodialysis device

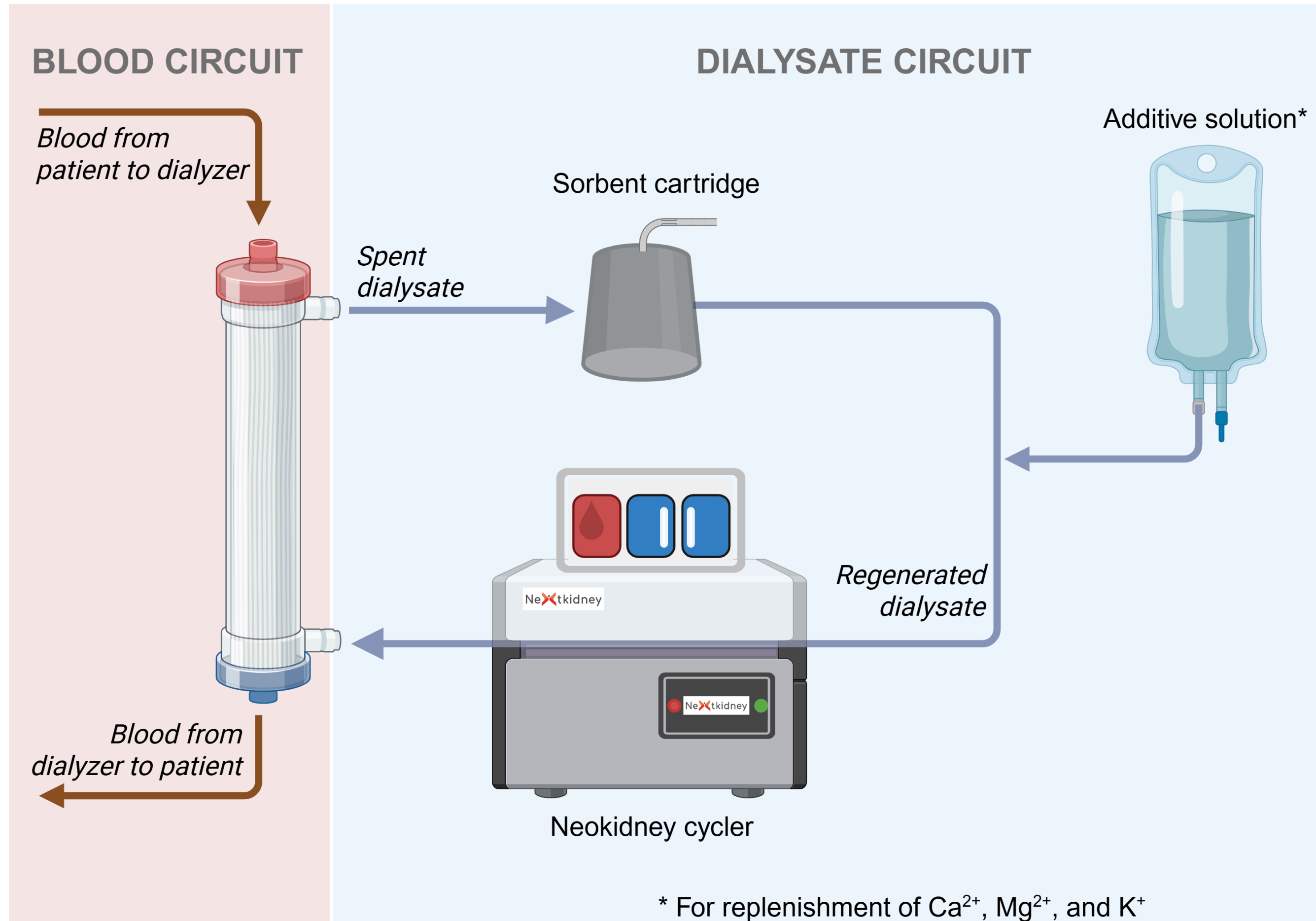
- ~13kg; fits in standard carry-on luggage (IATA)
- Per treatment ~4.5L fluids + 1.5kg cartridge
- 4-7x2h per week
- Dialysate flow 300 mL/min
- Blood flow (150 – 300 mL/min)
- No grounding required
- No infrastructure needs
- Two needles/ CVC



Overview of Neokidney



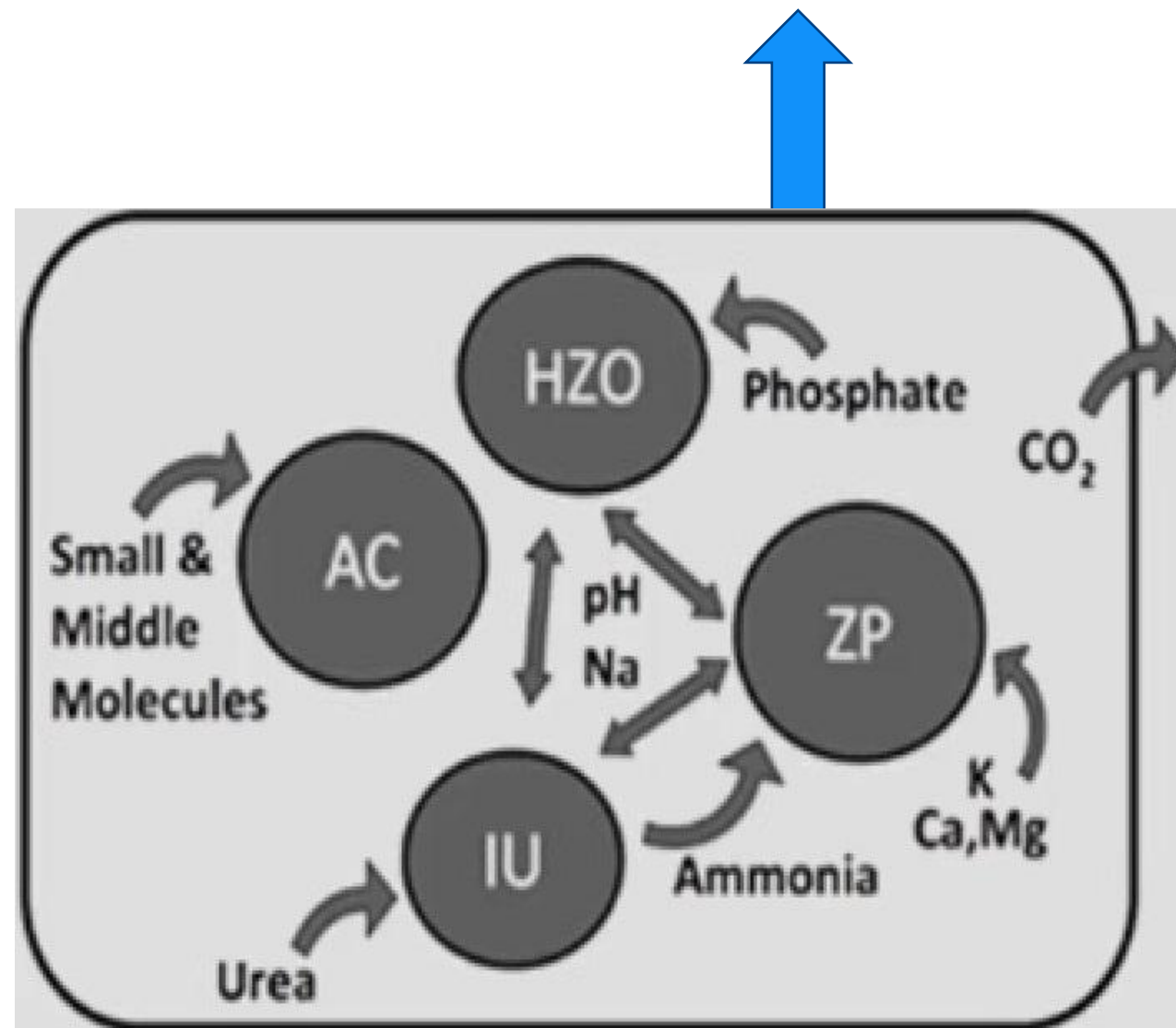
Continuous dialysate regeneration



(Modified) REDY technology



Jack bean

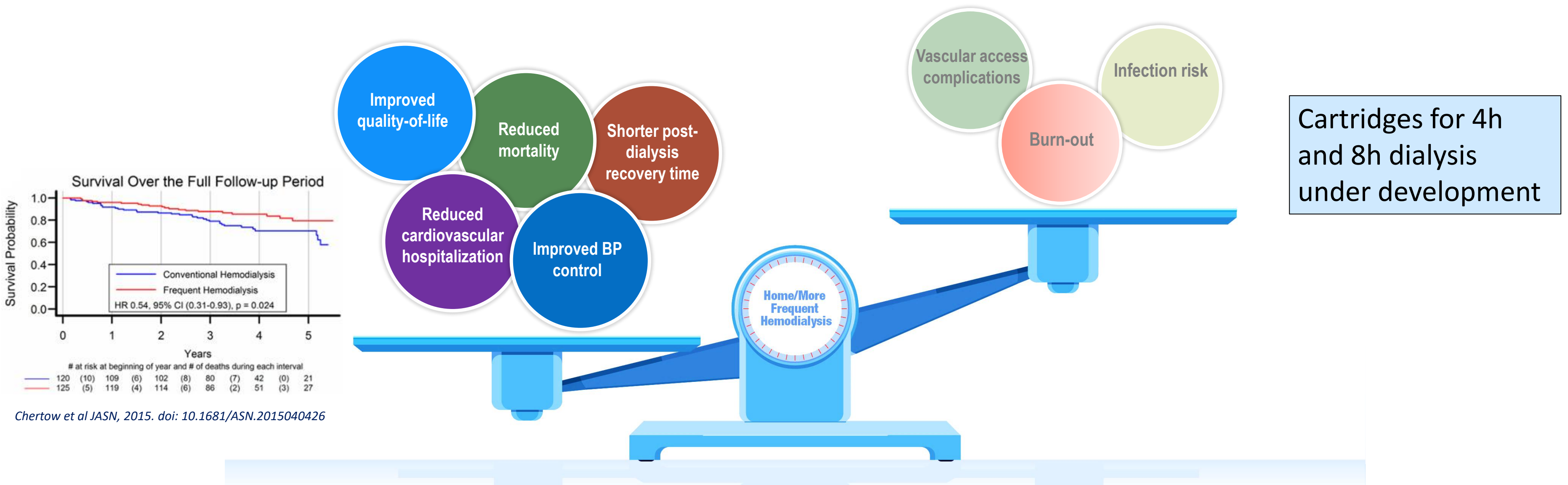


Bounds	Releases
Phosphate	Hydroxide Bicarbonate
Ammonium Potassium Calcium Magnesium	Hydrogen Sodium
Nothing (converts urea)	Ammonium Bicarbonate
Non-urea organic compounds	Nothing

- Postcartridge additive solution:
- Ca²⁺/ Mg²⁺/ K⁺ infusion
 - Neutralize sodium



Balance of benefits and risks for short frequent hemodialysis



Successful first in human trial – 2024



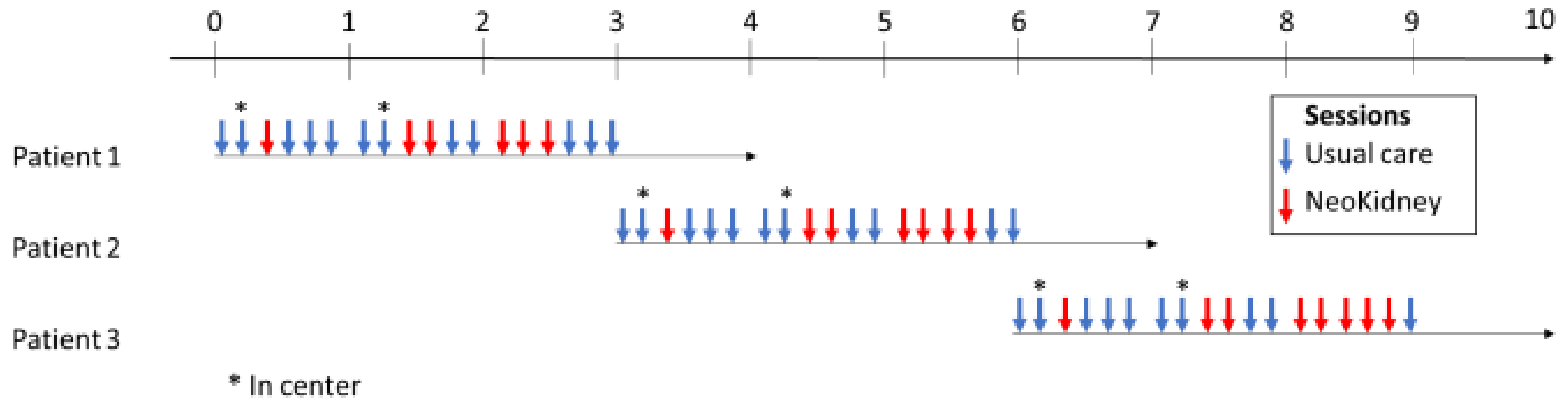
Dian Bolhuis



Maxence Ficheux

Successful first in human trial – 2024

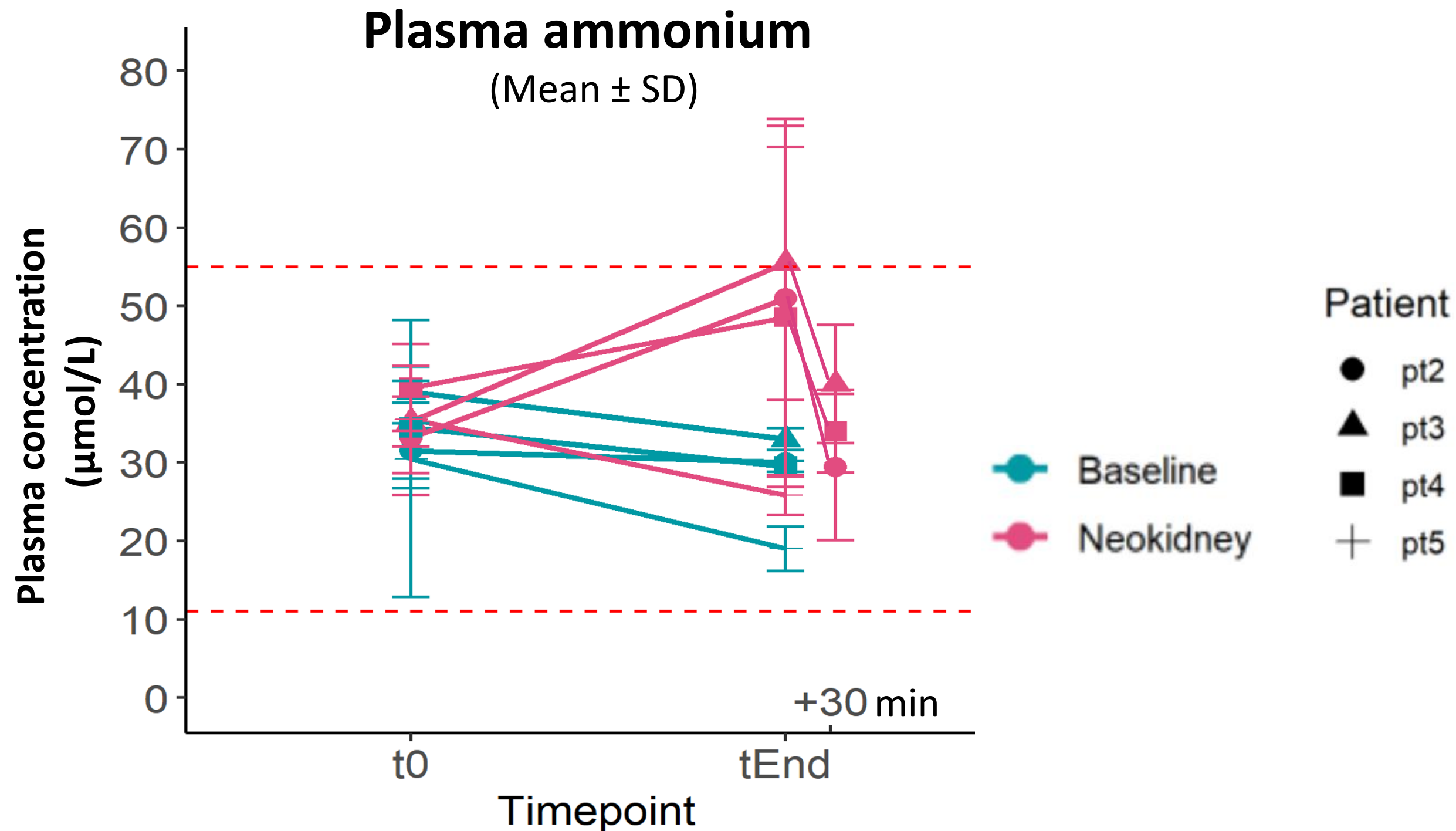
- Primary objective – To assess clinical safety & technical safety
- Secondary objective – To assess efficacy



4 Patients included; premature ending in 1 due to arteriovenous fistula thrombosis

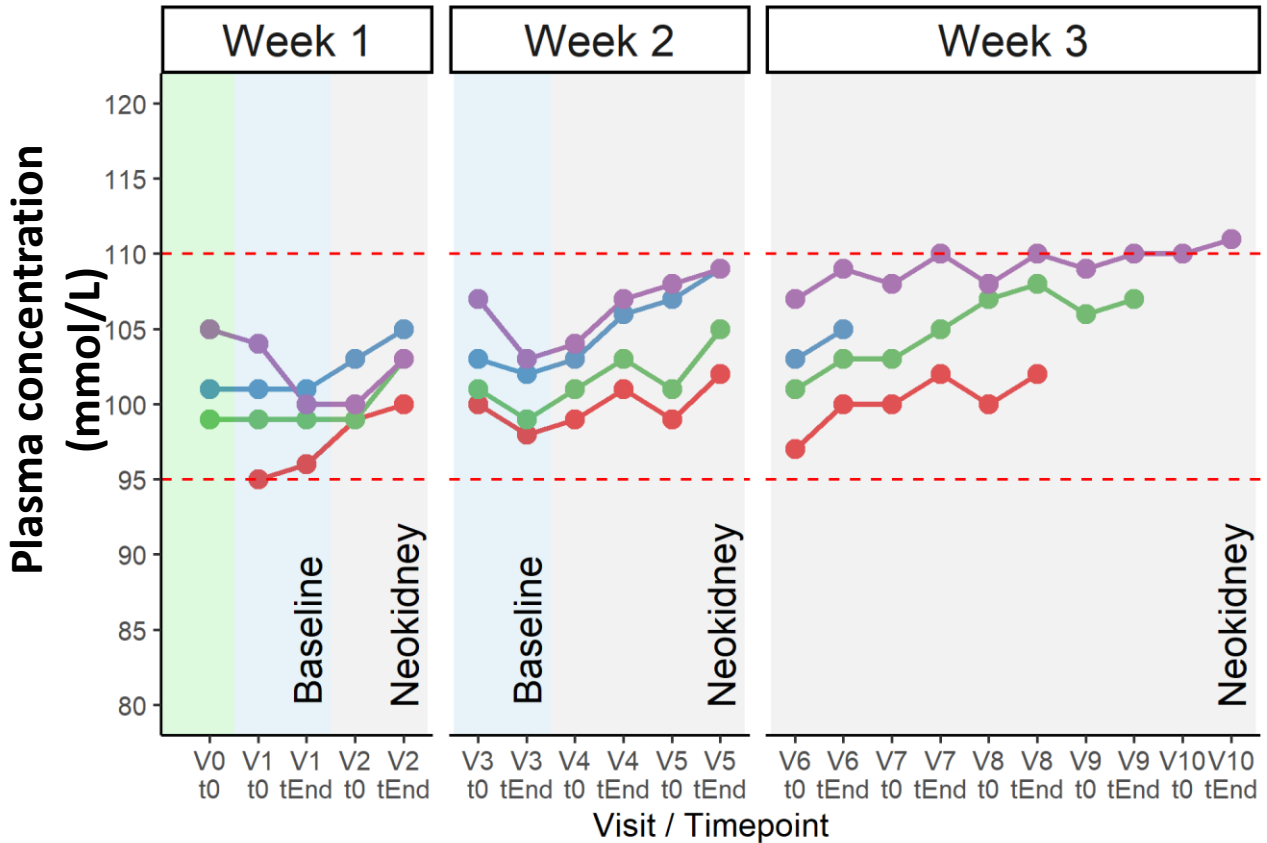
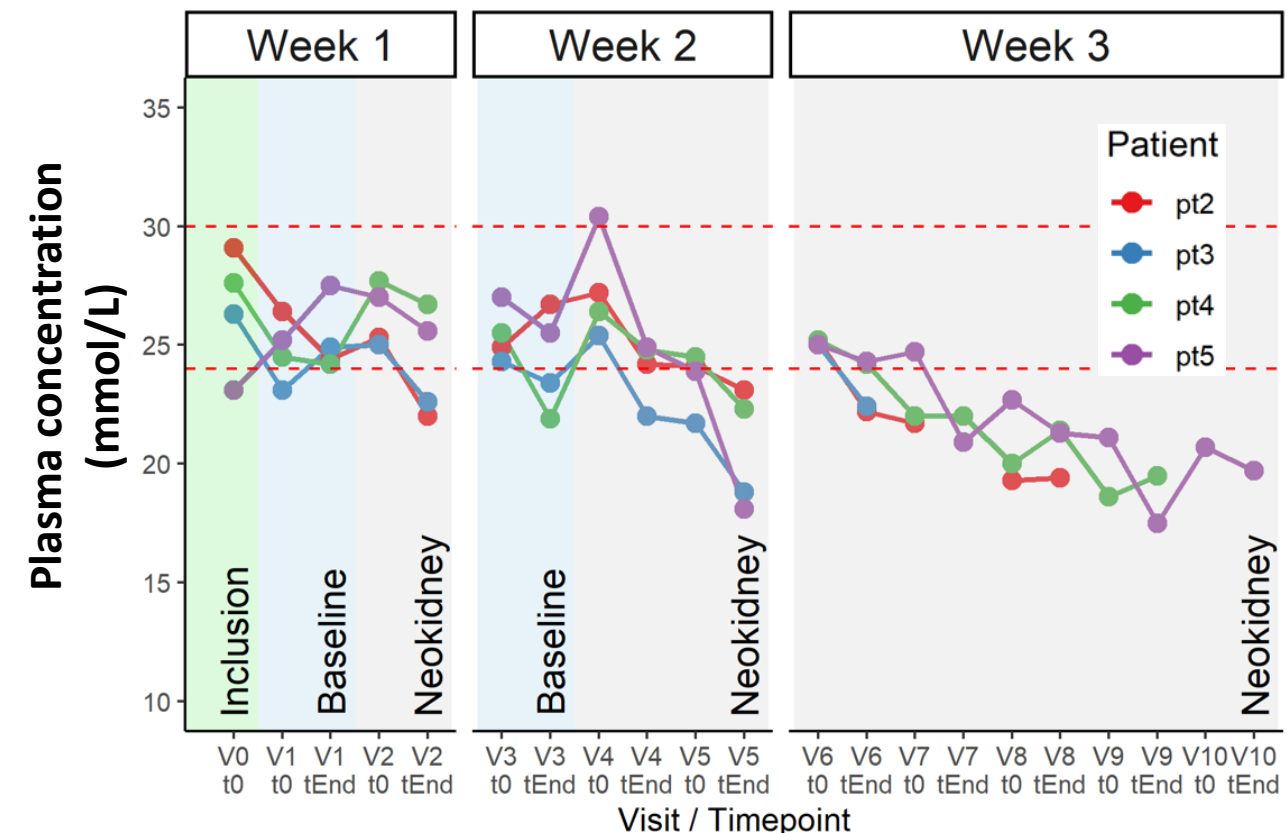
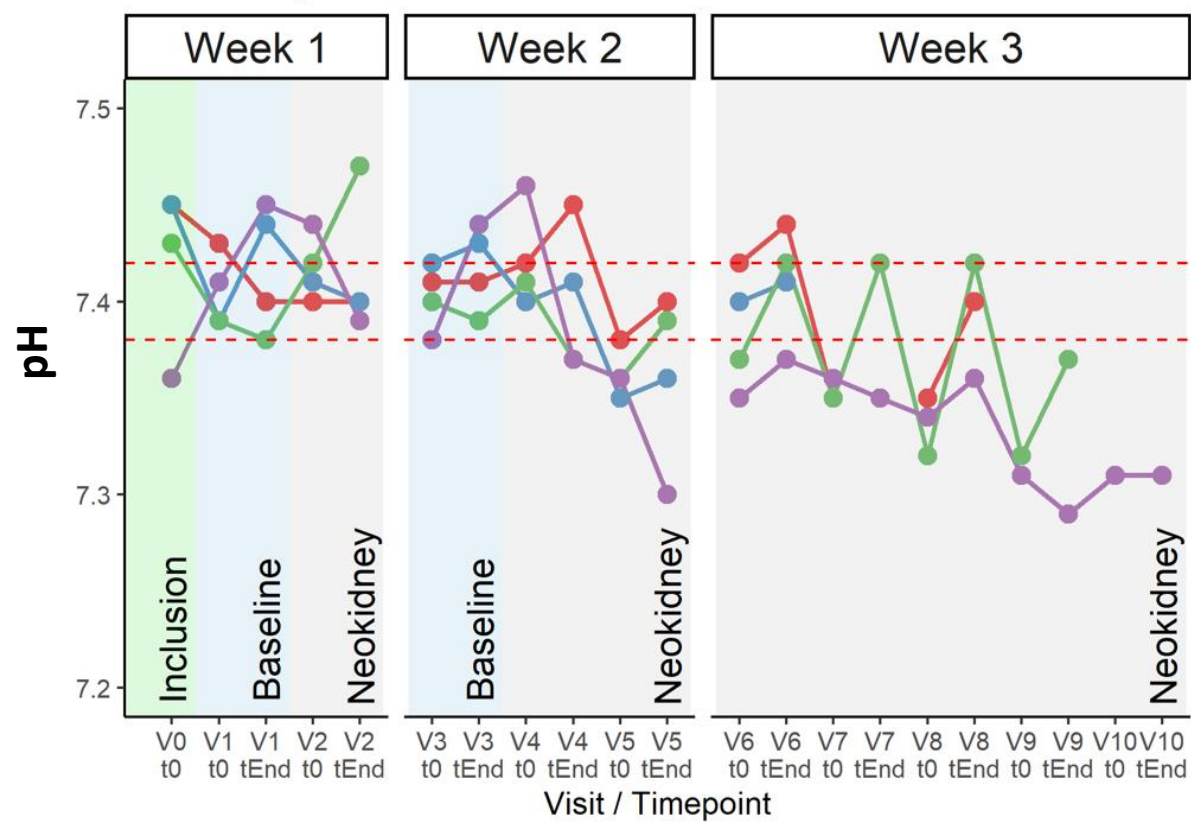
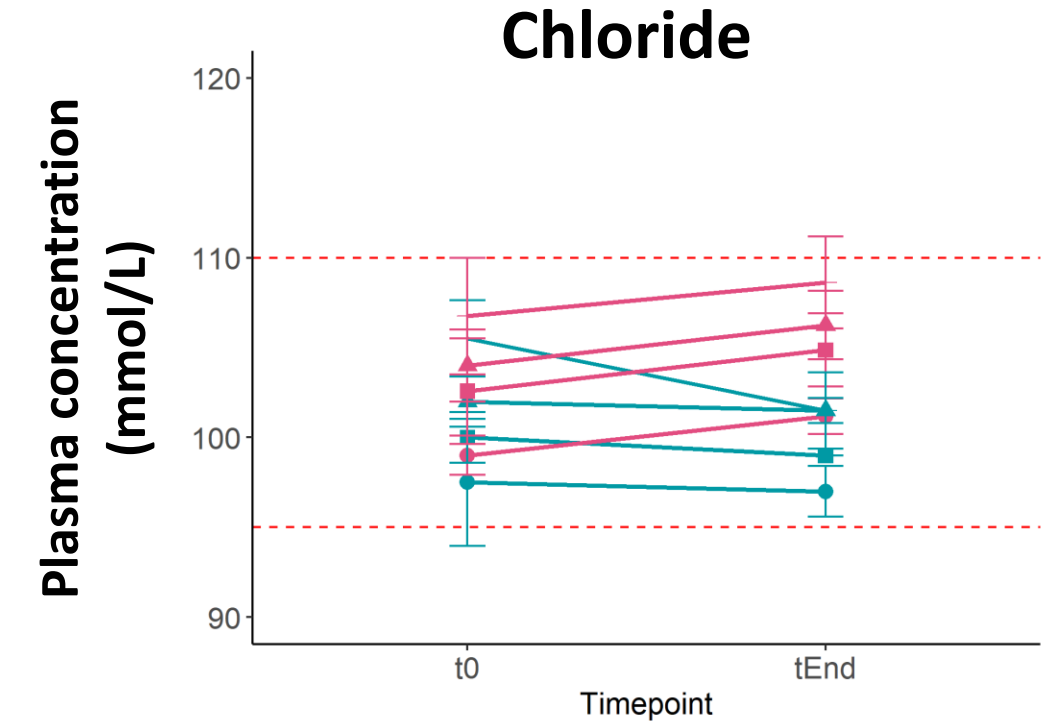
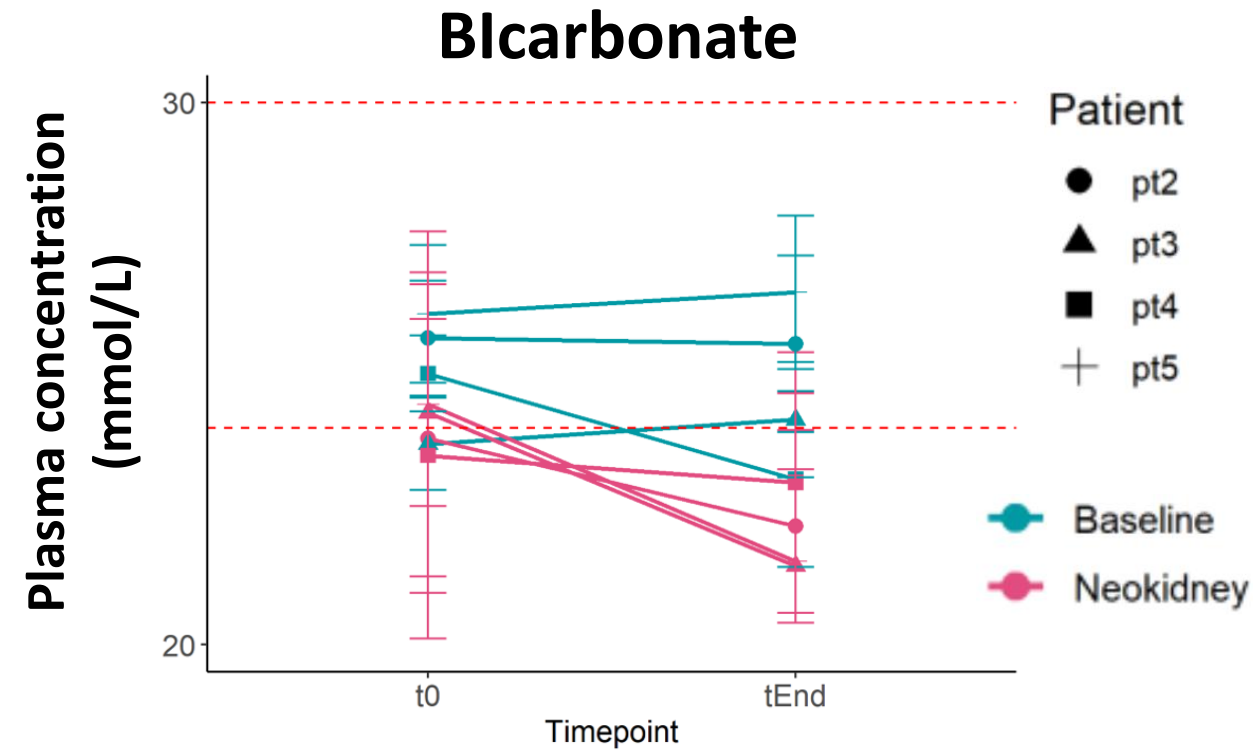
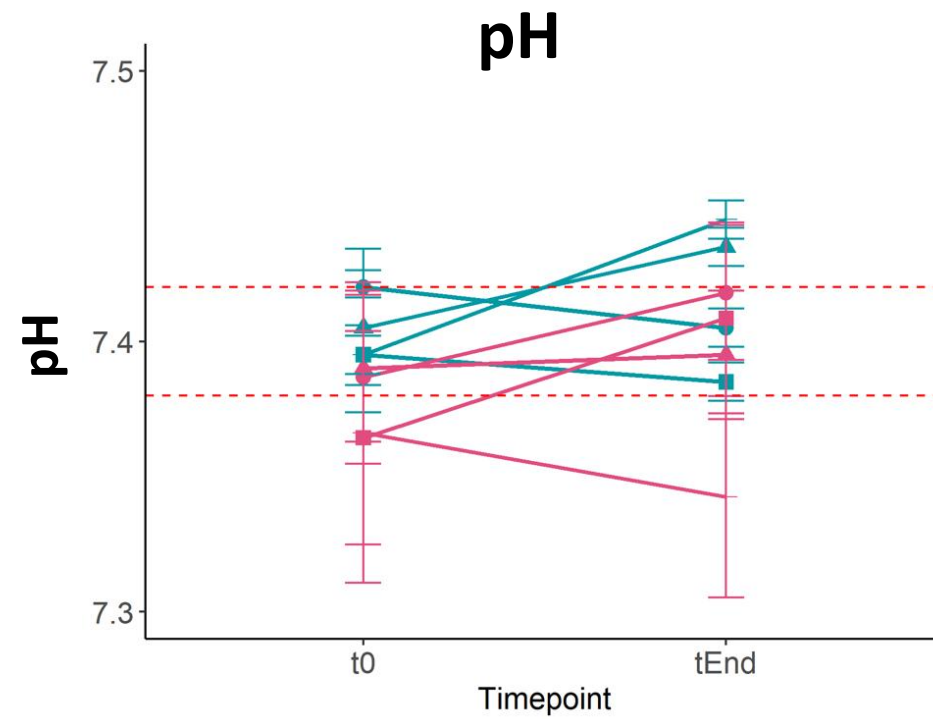
First in human trial – results

- **No serious adverse device effects**
- 6 Adverse events related to the device
 - 5x Hyperammonemia

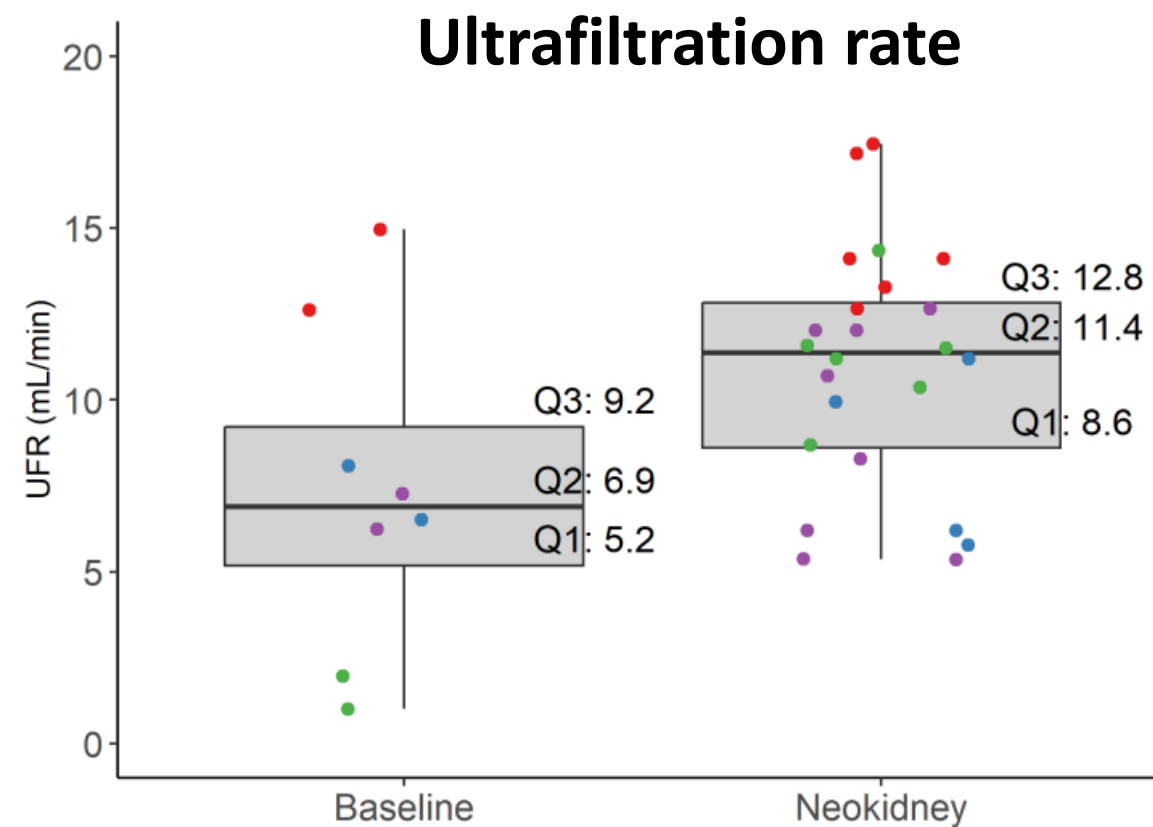
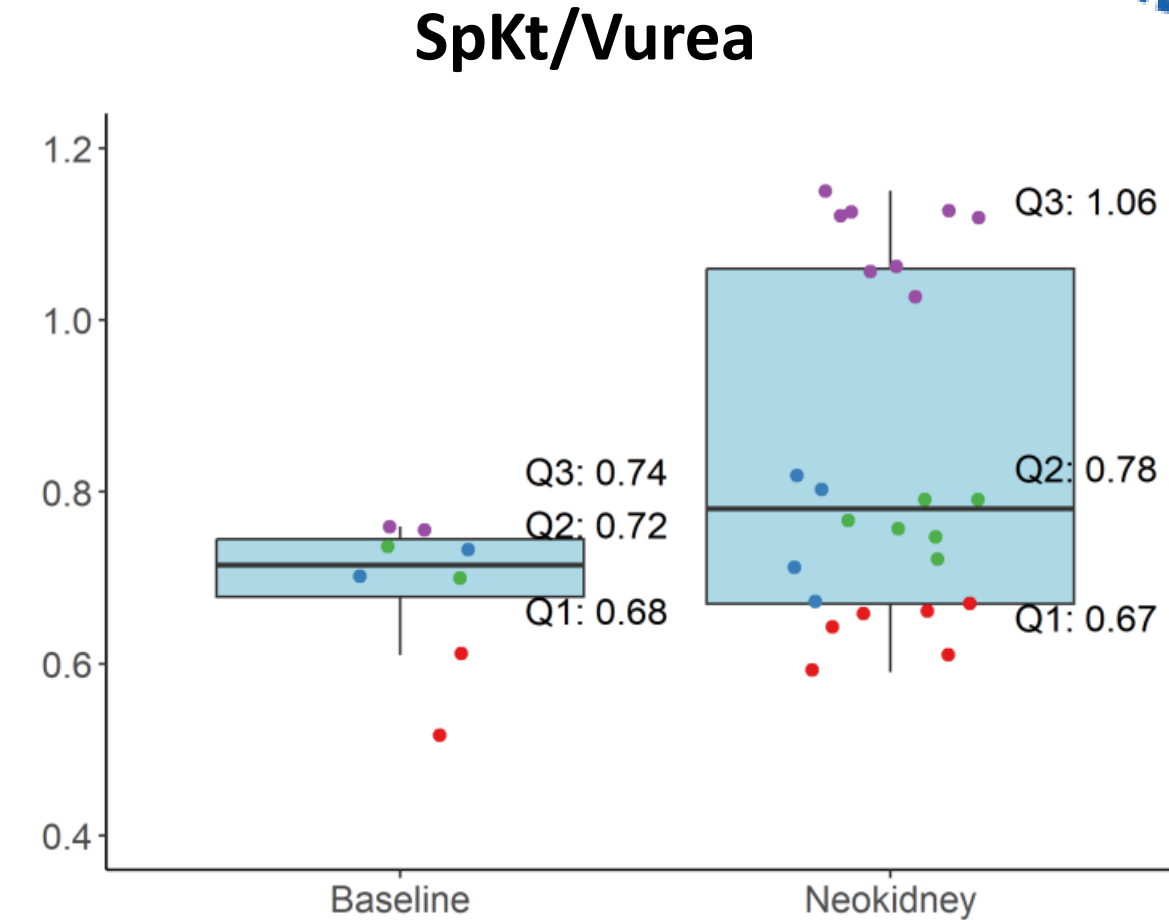
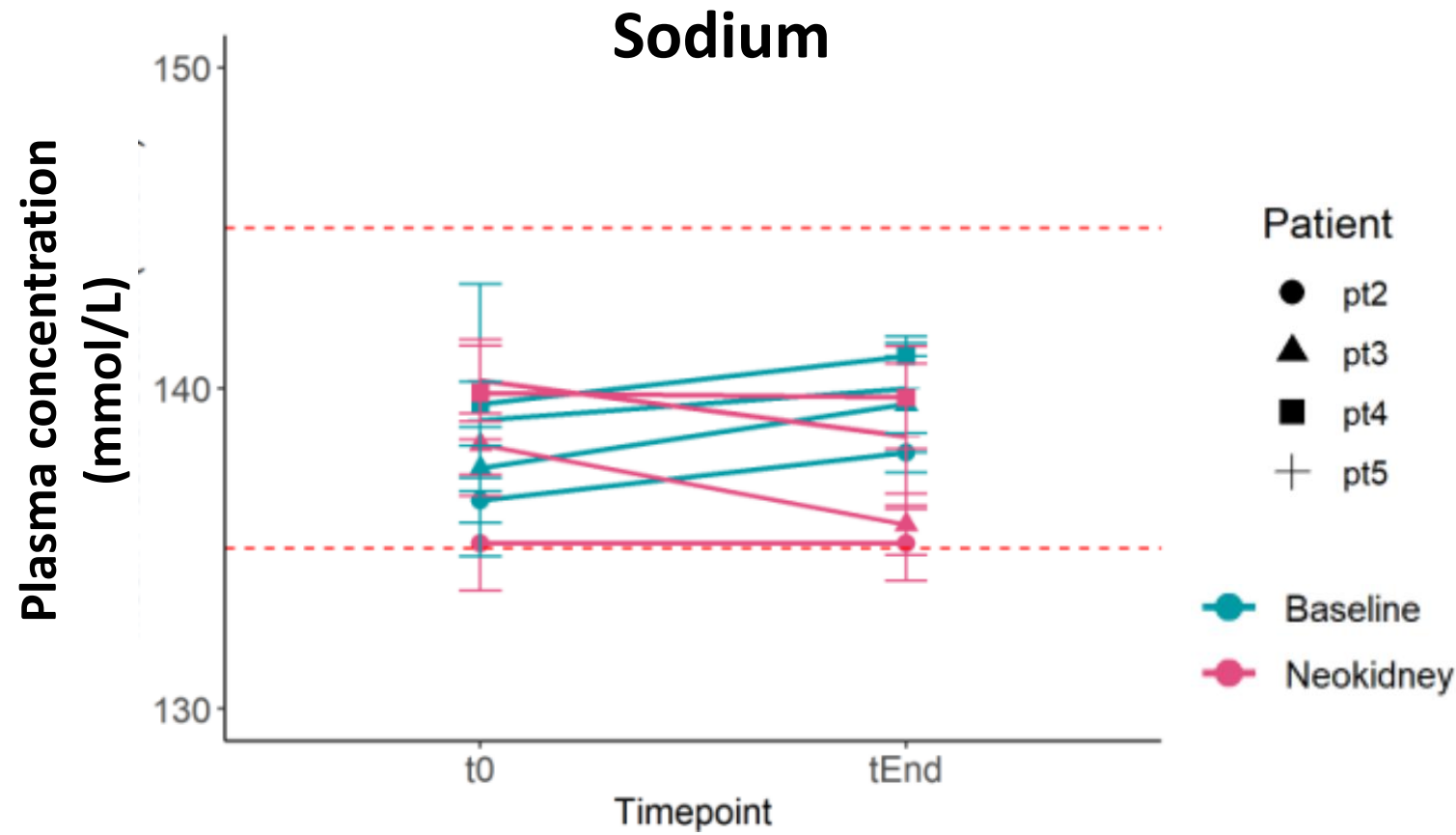


First in human trial – results

Gradual decline in plasma pH and bicarbonate after consecutive treatments .



First in human trial – results



Reduction percentages

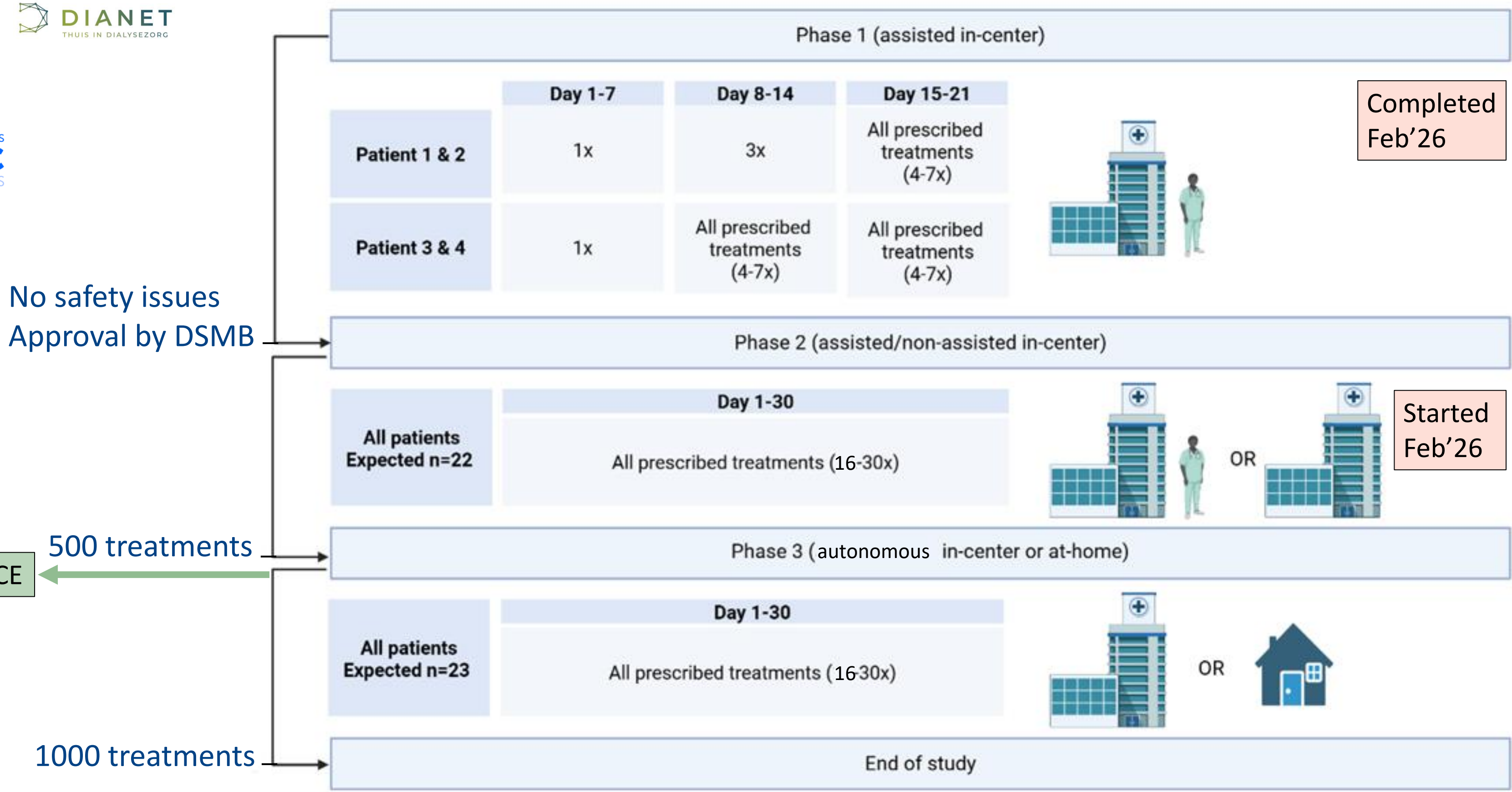
Solute	NxStage	Neokidney
Creatinine	44 [42-47]	48 [45-60]
Urea	45 [43-47]	49 [44-59]
Phosphate	44 [42-47]	55 [49-66]
Uric acid	54 [52-57]	57 [53-69]
B2M	46 [42-50]	48 [46-58]

Recent changes introduced before multi-center study

- Small software adjustment to improve UF accuracy
- Tighter manufacturing process control and automisation of the critical manufacturing steps
- Improvement of acid-base control:
 - Chloride partly replaced by lactate in the additive solution



Pivotal trial RENEW-HD: multi-center, single-arm, open-label, three-phases interventional trial



RENEW-HD: Primary & Secondary Outcomes

Primary Outcome (Performance)

- Average single-pool Kt/V (spKt/V) across all sessions
Success: lower bound of 95% CI ≥ 0.6 after ≥ 500 sessions

Safety Outcomes:

- Percentage of sessions with Serious Adverse Device Effects (SADEs)
- DDs, ADEs
- Changes in vital signs and laboratory parameters

Secondary Outcomes

- Dialysis efficacy: stdKt/V, total Kt/V, spKt/V per patient
- Fluid management accuracy and ultrafiltration performance
- Session characteristics (frequency, duration, blood flow, UF volume)
- Patient satisfaction and quality of life (KDQOL, DSI)



Key eligibility

Inclusion criteria

- Adult HD patients on, or willing to undergo, **short frequent HD**
(≥ 4 sessions/week, ≥ 2 hours/session)
- Age ≥ 18 years
- **Body weight 50–110 kg**
- **Stable on HD ≥ 1 month**
- **Well-functioning vascular access** (incl CVC)
- Able to provide written informed consent



Non-inclusion criteria

- Pregnant or breastfeeding women, incapacitated patients
- Recent:
 - Hemolysis (< 4 weeks)
 - **Vascular access revision or infection (< 4 weeks)**
- Severe comorbidities:
 - Significant liver dysfunction
 - **COPD**
 - Any medical or psychosocial condition compromising patient safety or study outcomes (investigator judgment)
- Planned **living donor transplantation within 2 months**
- Participation in another interventional study (< 4 weeks)
- Uncontrolled hypertension (SBP >180 mmHg or DBP >110 mmHg)
- Significant lab abnormalities <4 weeks:
 - **Hb <6.2 mM**
 - **Na <130 mM**
 - **K <3 or ≥ 6 mM**
 - Abnormal liver function tests ($>2x$ upper limit of normal)

Interested patient?

1 Identify interest

- (Quick eligibility scan)

2 Contact the study team

- Email or call us (with patient permission)

3 We take it from there

- Patient information
- Eligibility screening
- Referral letter & informed consent



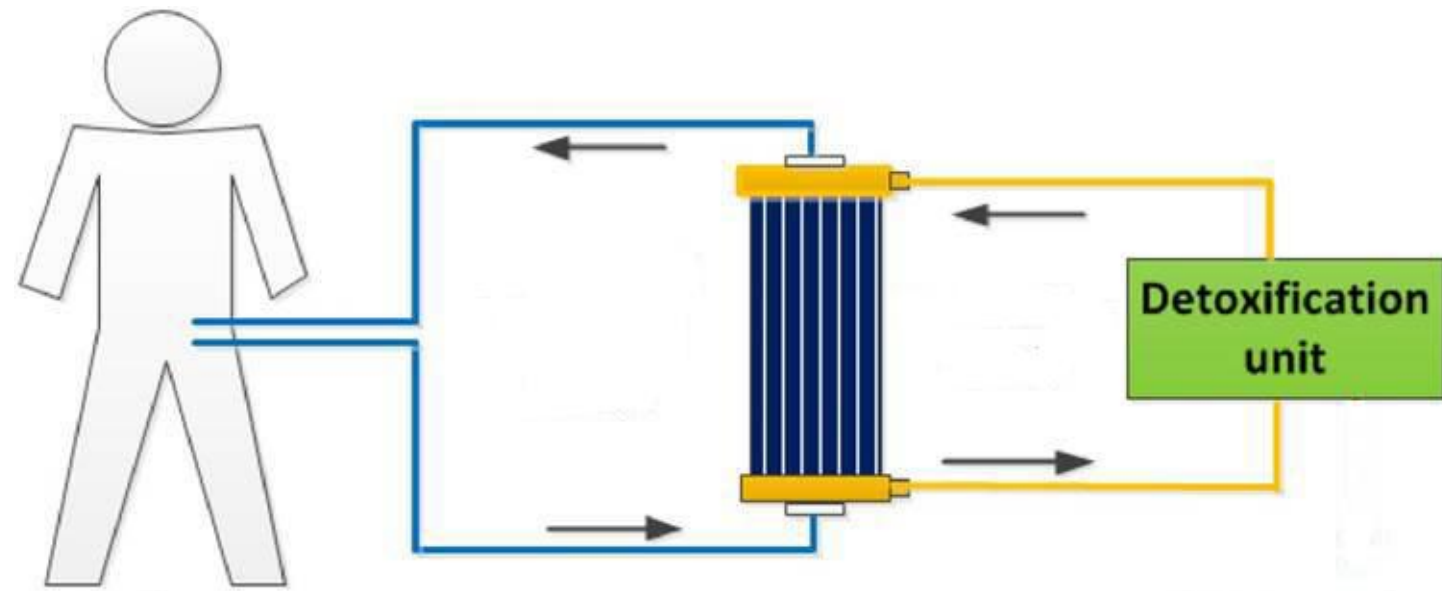
d.p.bolhuis-3@umcutrecht.nl
K.G.F.Gerritsen@umcutrecht.nl



+31 88 7557329



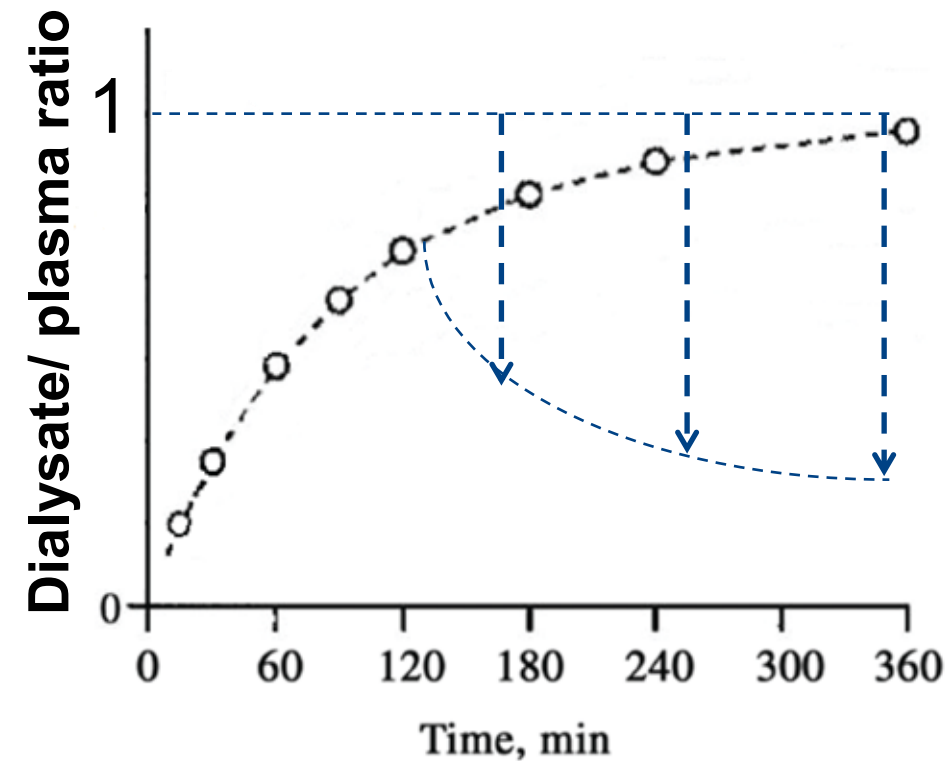
Peritoneal dialysate regeneration



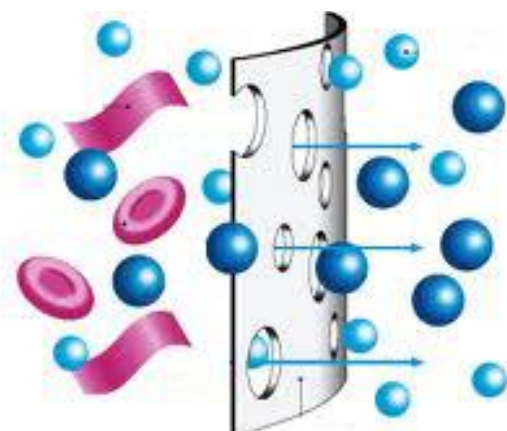
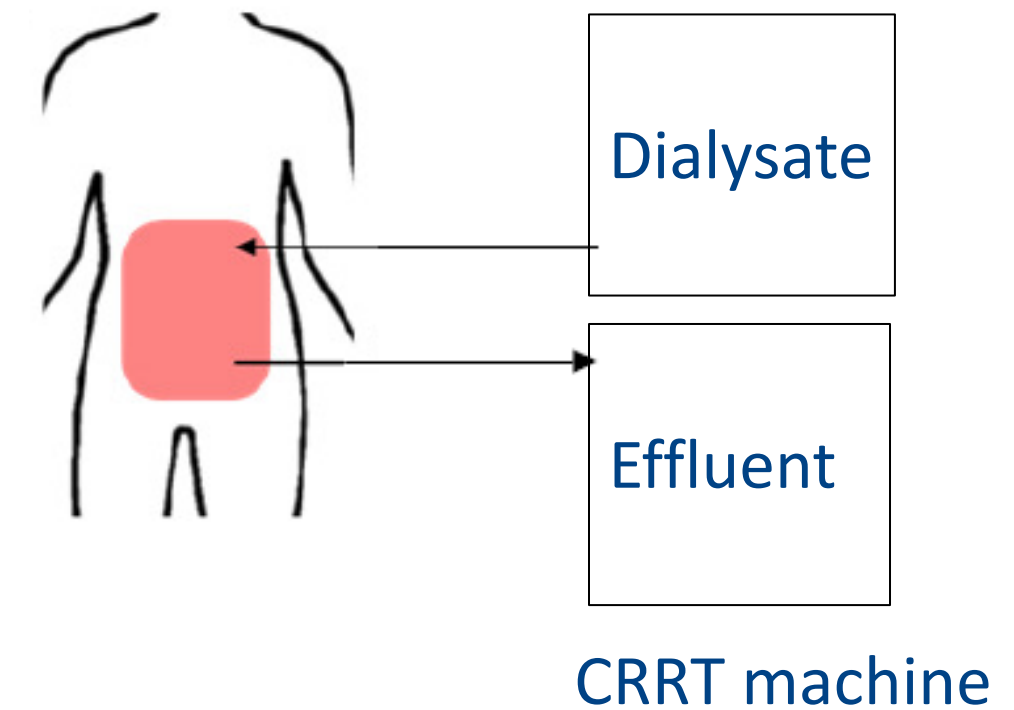
- ↓ Exchanges
- ↓ Glucose
- ↓ Peritonitis?
- ↓ Membrane failure?
- ↑ Technique survival?

↑↑ Clearance

Large concentration gradient between dialysate and plasma is maintained



Two single lumen catheters



↑ Mass transfer area coefficient

CORDIAL COntinuous ReGeneration of DIALysate



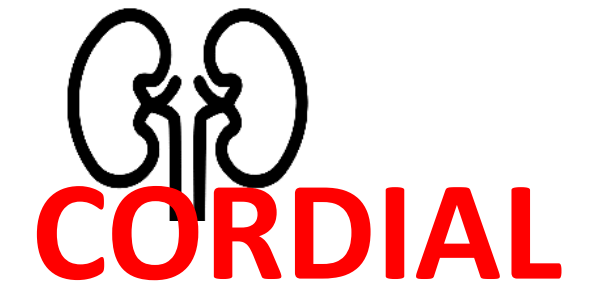
Homechoice® ~13 kg

2.3 kg

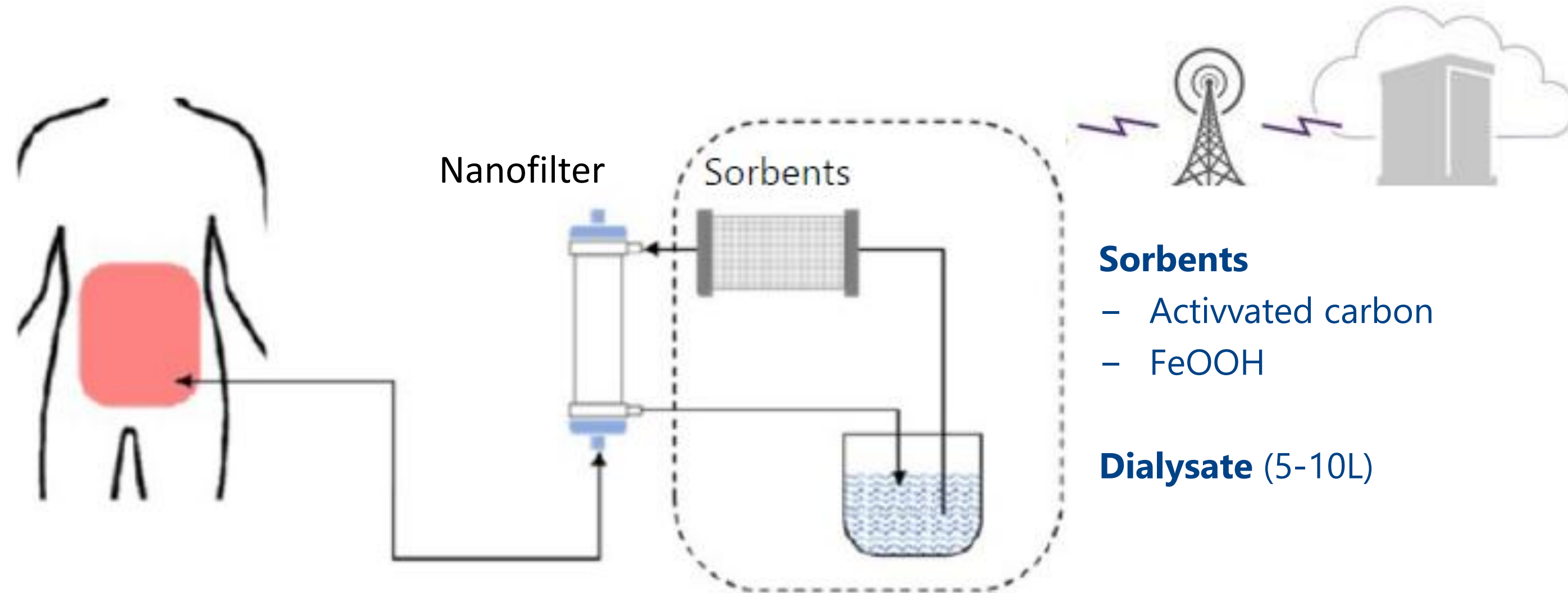


2 kg + dialysate

Portable nighttime system



Low risk system



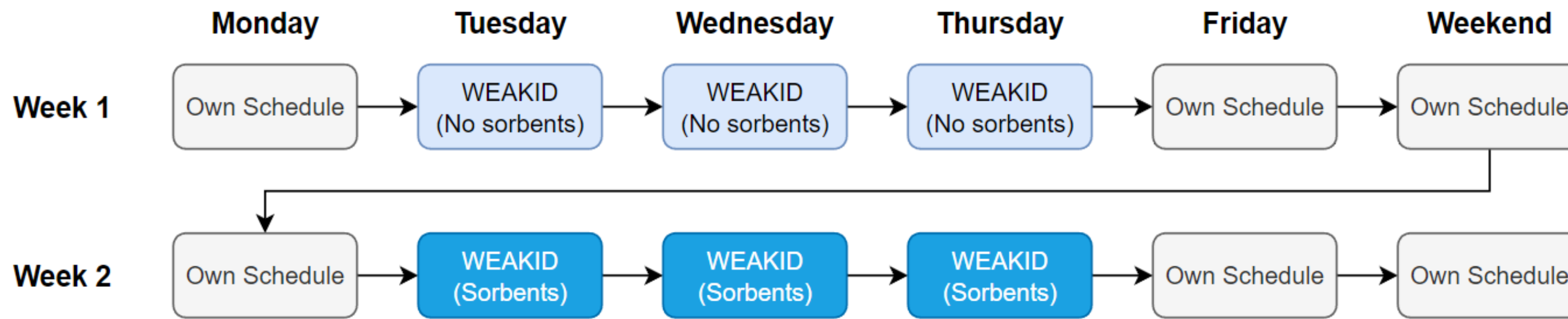
- Continuous rapid cycling (& regeneration) of dialysate
- Flow 50-150 mL/min, ~25L in 8h
- Tidal volume 300 mL, ~6 min per cycle
- No initial exchange, 1 exchange per day after treatment (1L icodextrin)

First in human trial – 2024/25



Dian Bolhuis

- Primary objective – To assess clinical safety & technical safety
- Secondary objective – To assess efficacy



12 Patients



University Medical Center
Utrecht



NANODIALYSIS



UNIMORE
UNIVERSITÀ DEGLI STUDI DI
MODENA E REGGIO EMILIA

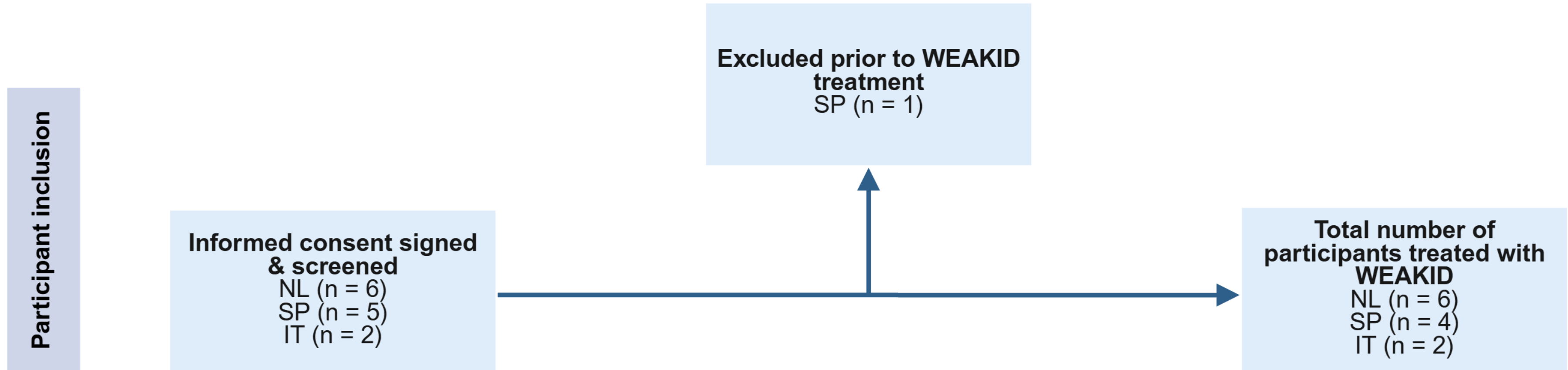


<https://doi.org/10.1093/ndt/gfae069.1637>

<https://doi.org/10.1093/ndt/gfae069.082>



Inclusion and study treatments



Baseline

Characteristics	
Male, n (%)	9 (75%)
Age, years	61[57-79]
BMI, kg/m ²	27.2[22.7-31.3]
Residual renal function >0.5L/24h, n (%)	9 (75%)
Current treatment	
Total dialysis vintage, months	17[12-24]
APD, n (%)	9 (75%)
Usage of tidal volume, n (% of APD patients)	2 (22%)
Usage of Extraneal, n (%)	11 (92%)
Usage of Nutrineal, n (%)	3 (25%)
Volume used per day, L	8[7-11]

Study treatments

Total study treatments	Baseline	
	APD	CAPD
	Aimed number	36
Missed or prematurely terminated treatments	0	0
Fully performed treatments	27	9
Fully performed treatments	36	

WEAKID			
4h no sorbents	8h no sorbents	4h sorbents	8h sorbents
72			
0	3	1	2
14	25	9	18
66			

Preliminary results

66 of 72 treatments completed

6x no or incomplete treatment, related to:

- Hypovolemia
- Use error (no icodextrin filling)
- Dialysate leakage due to error in line connection
- Cartridge leakage alarm due to use error
- Falsely elevated leukocyte count in peritoneal dialysate
- Many pressure alarms + abdominal discomfort score 3 (of 10)

Preliminary safety - Serious adverse event

1x in patient 5

WEAKID treatment started at ~575mL → mechanical irritation

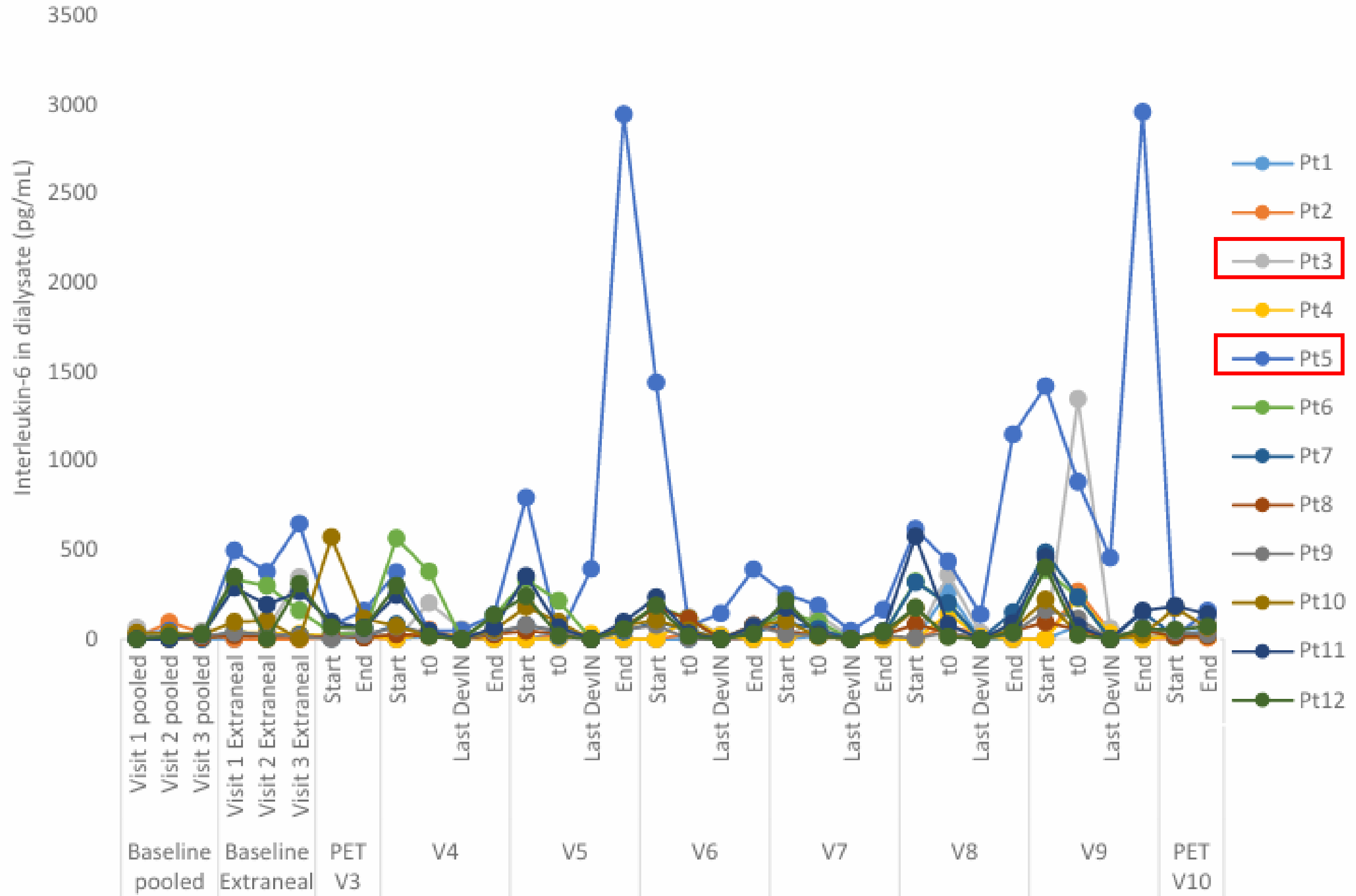
- Increase in leukocytes/neutrophils
 - Elevated IL6
 - Cloudy dialysate
 - No abdominal pain
-
- Prolonged hospitalization
 - Reversible after 1 day



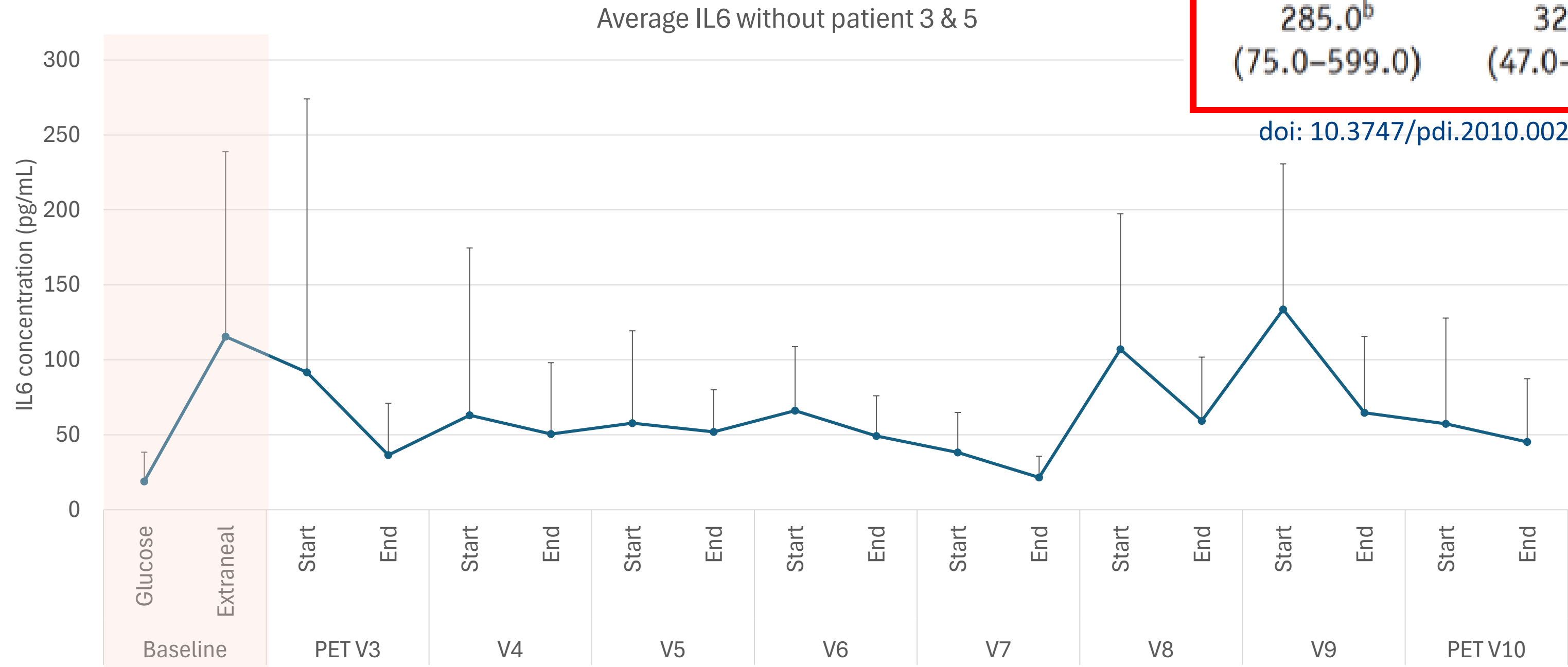
Adverse events (not including SAE)

- **24 non-serious AEs**
- **7x related to the study device/ procedure**
 - 1x causal → orthostatic hypotension
 - 5x possible
 - 3x abdominal discomfort
 - 1x increased neutrophils in dialysate
 - hypervolemia
 - IL6 increase in peritoneal dialysate

Interleukin-6



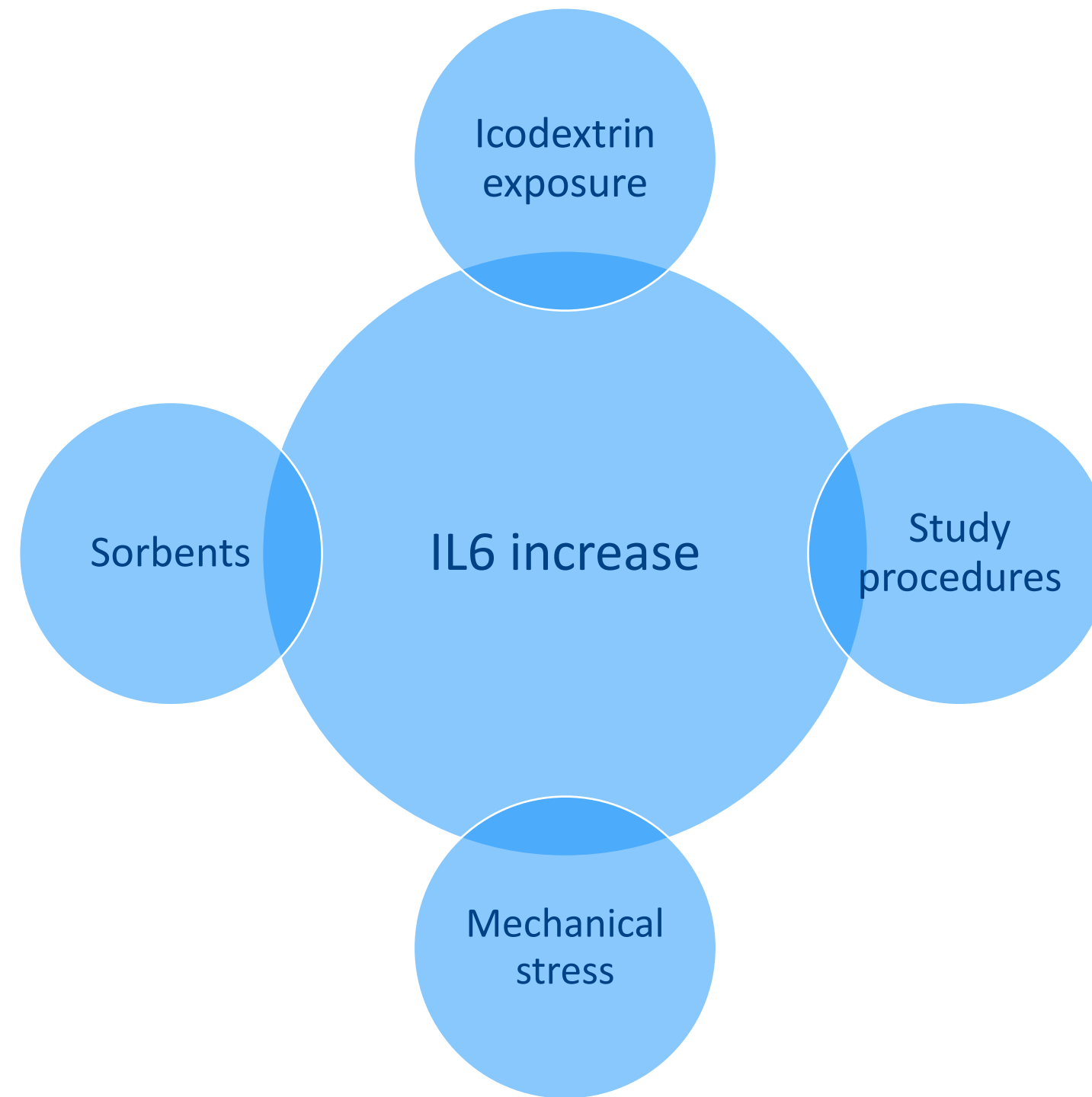
Interleukin-6



Icodextrin solution	6 Months	12 Months
	285.0 ^b (75.0–599.0)	329.0 ^c (47.0–450.0)

doi: 10.3747/pdi.2010.00235

Multiple factors probably play a role

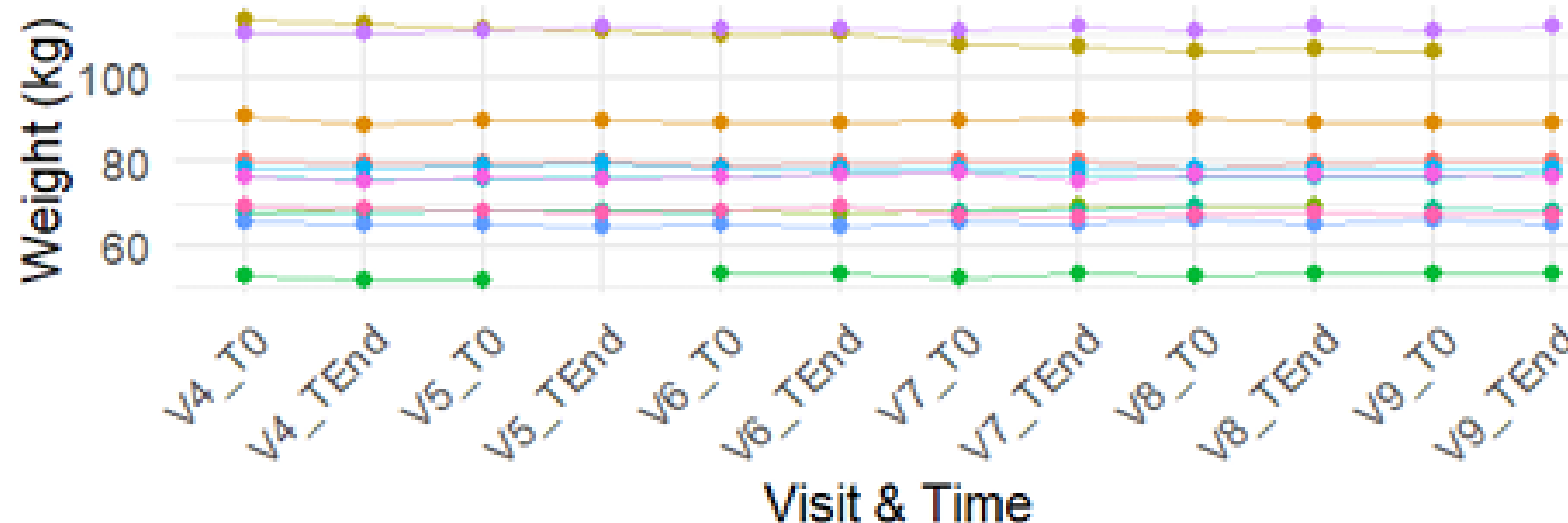


Device deficiencies

- **18 DDs**
 - **NONE could have led to a serious adverse event**
 - **3x led to a premature termination of WEAKID treatment**
 - 1x Dialysate leakage due to use error
 - 1x Cartridge leak due to use error
 - 1x Repeated pressure alarms in combination with abdominal discomfort (in pt3)
 - Pressure-dependent flow rate control
 - Change in line diameter

Vital parameters

- **No critical changes in vital parameters during WEAKID treatments**
- 1x AE regarding vital parameter (orthostatic hypotension) → skipped treatment, and 0.5L intravenous saline infusion
- **Bodyweight relatively stable**



Abdominal discomfort

- **Abdominal discomfort scored based on numeric rating scale (0-10)**
 - Almost ALWAYS scored 0
 - 2x score 1 (at the end of a WEAKID treatment)
 - 1x score 3 → Adverse event, in combination with pressure alarms and termination of WEAKID treatment in patient 3

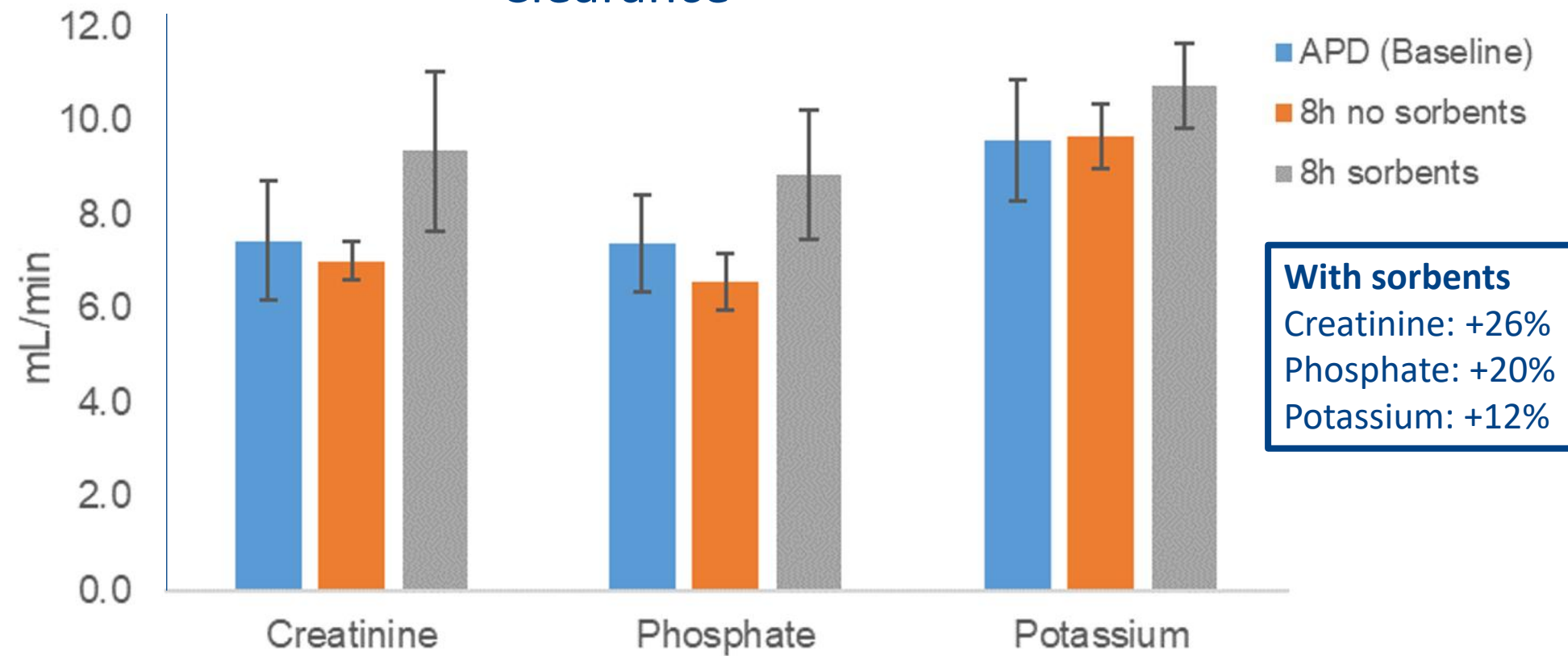
Preliminary conclusions: safety

Overall safe

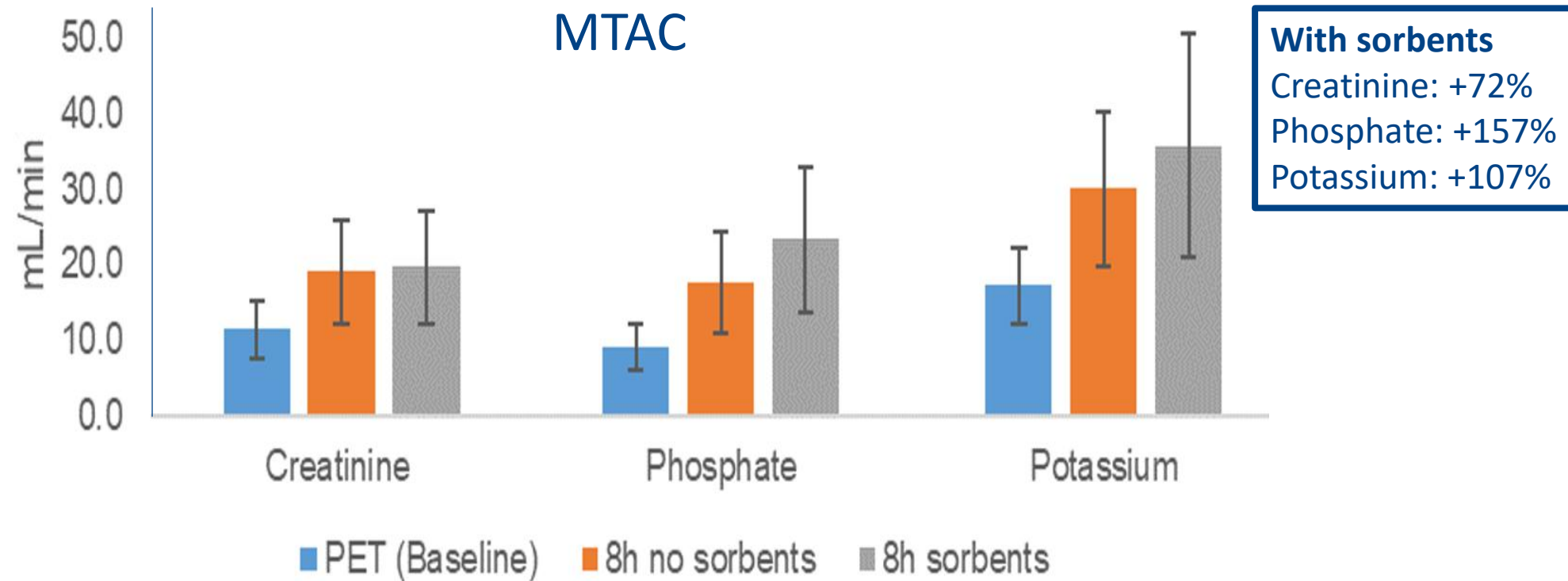
- No critical changes in vital parameters
- No critical changes in plasma concentrations
- **Continuous flow well tolerated → no abdominal discomfort, however increase in IL-6**
 - Non-serious in most participants
 - Explainable in two participants with highest levels
- Multiple DDs but none could have led to an SAE

Preliminary efficacy

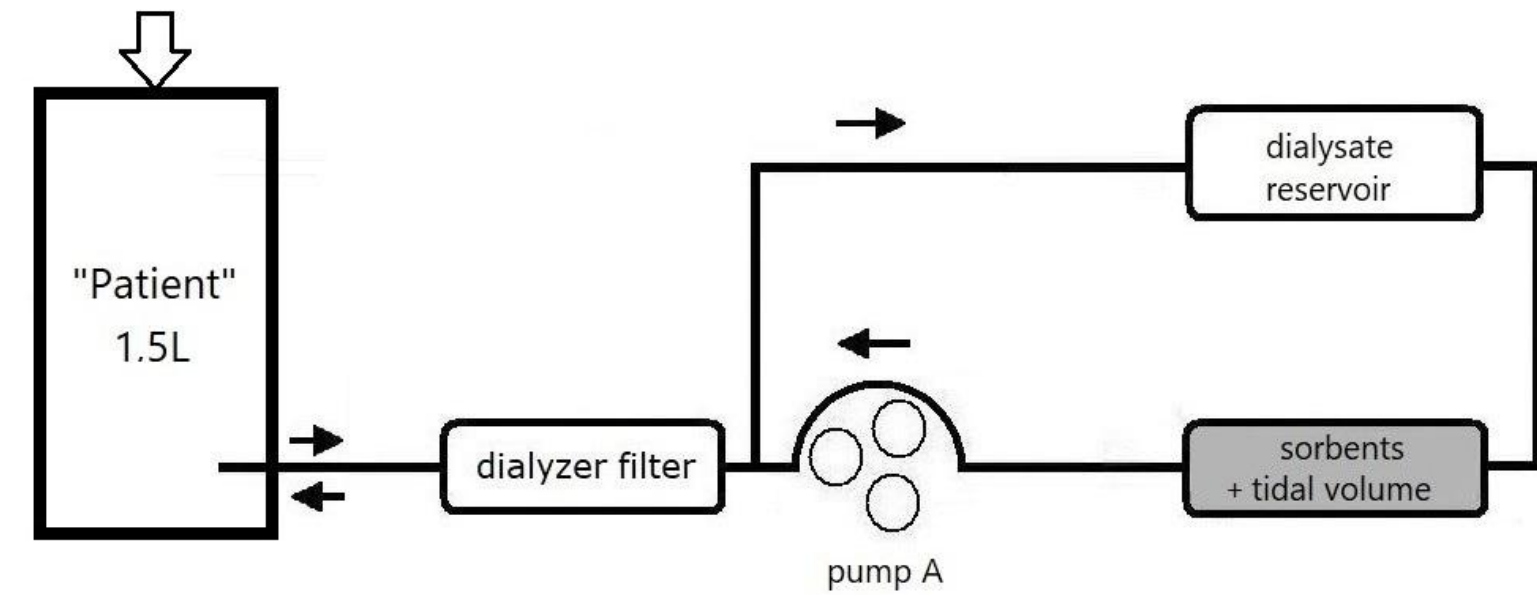
Clearance



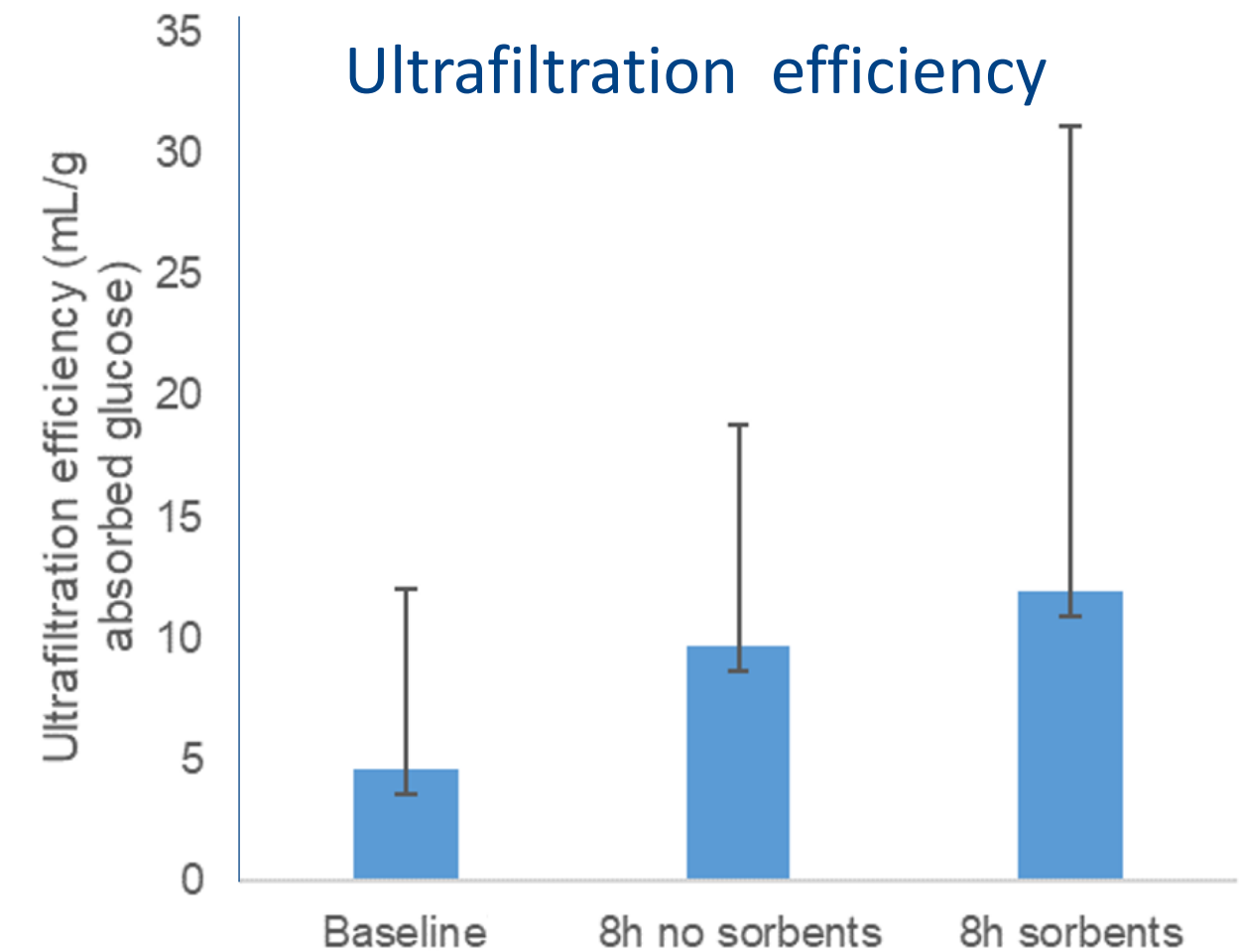
MTAC



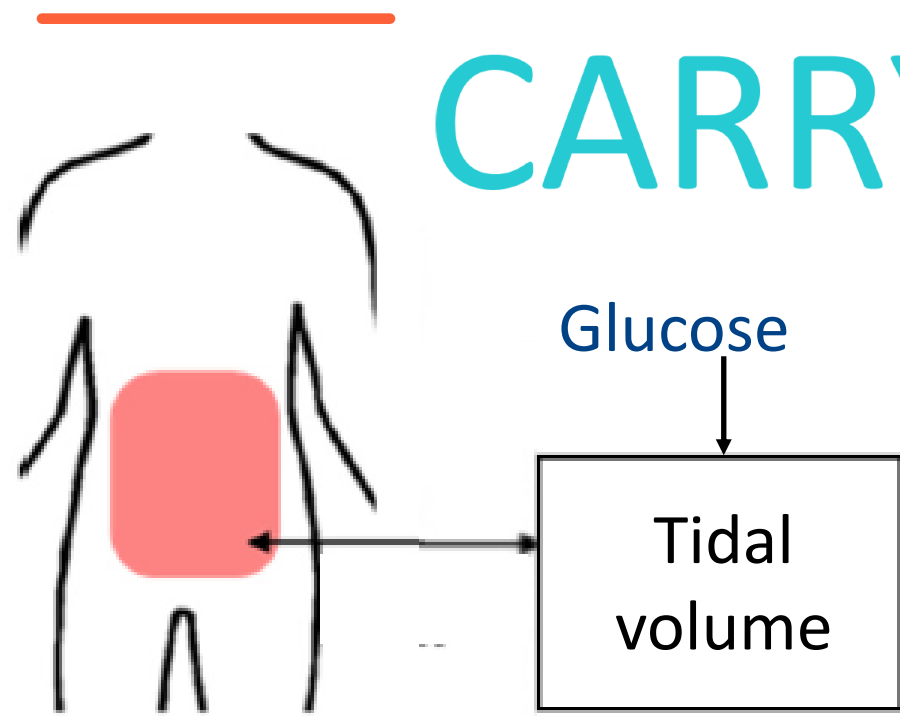
50% Recirculation!



Ultrafiltration efficiency



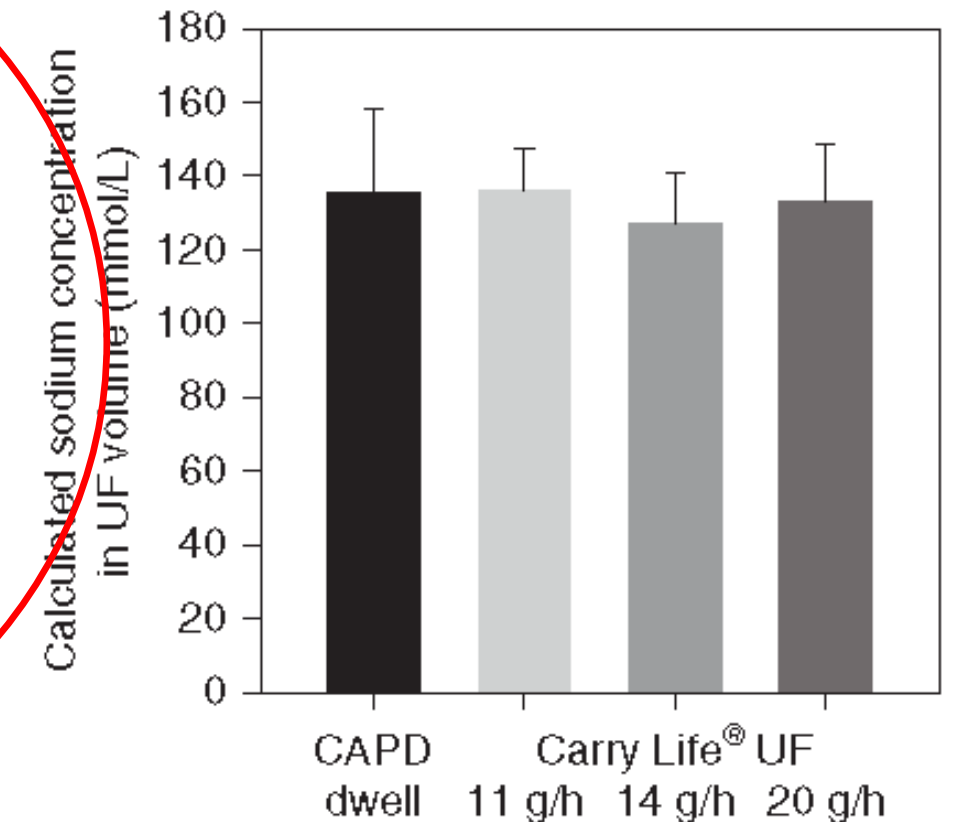
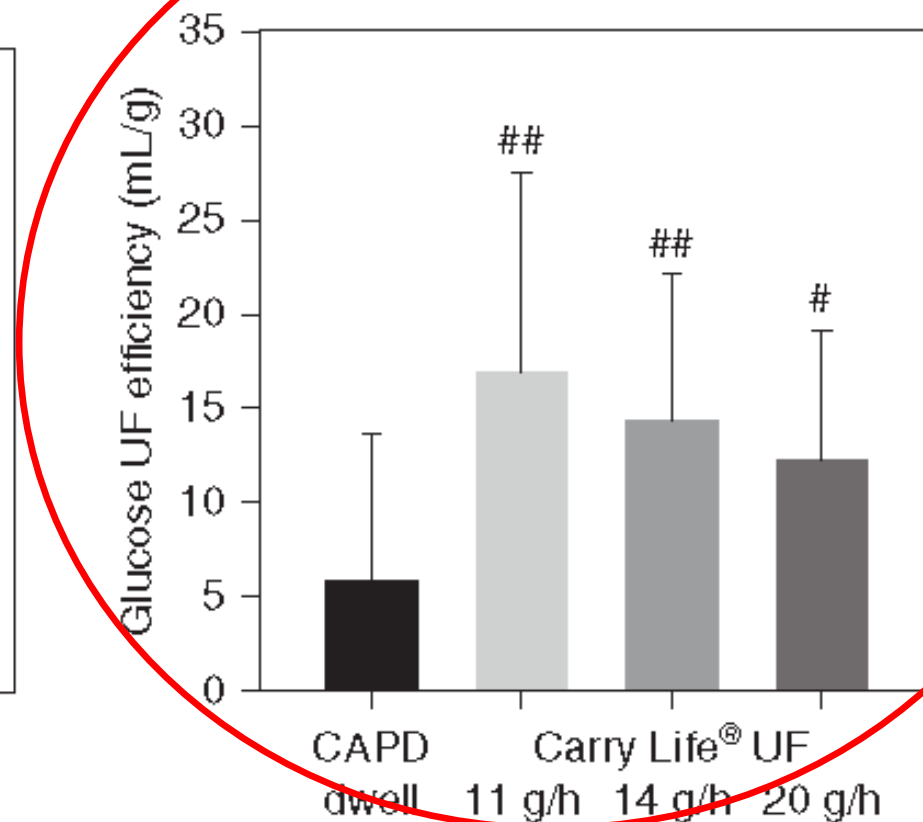
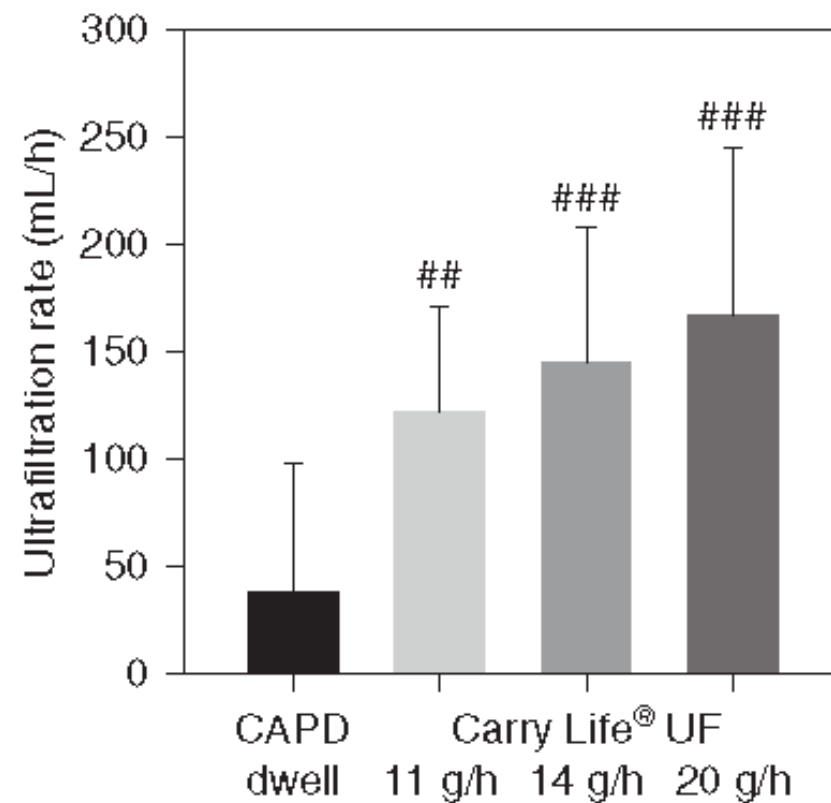
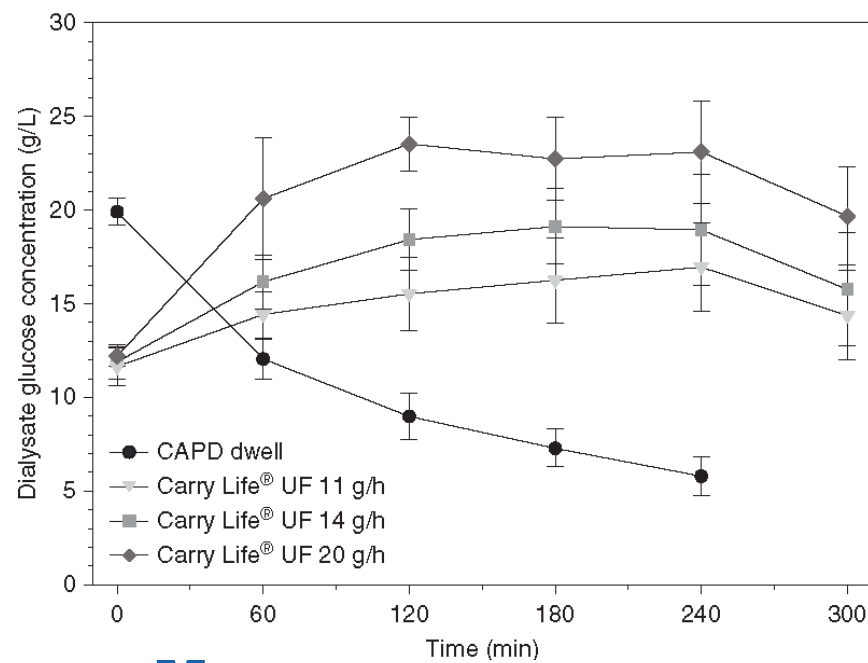
Steady glucose concentration PD (SCPD)



CARRYLIFE^{UF}



Triomed



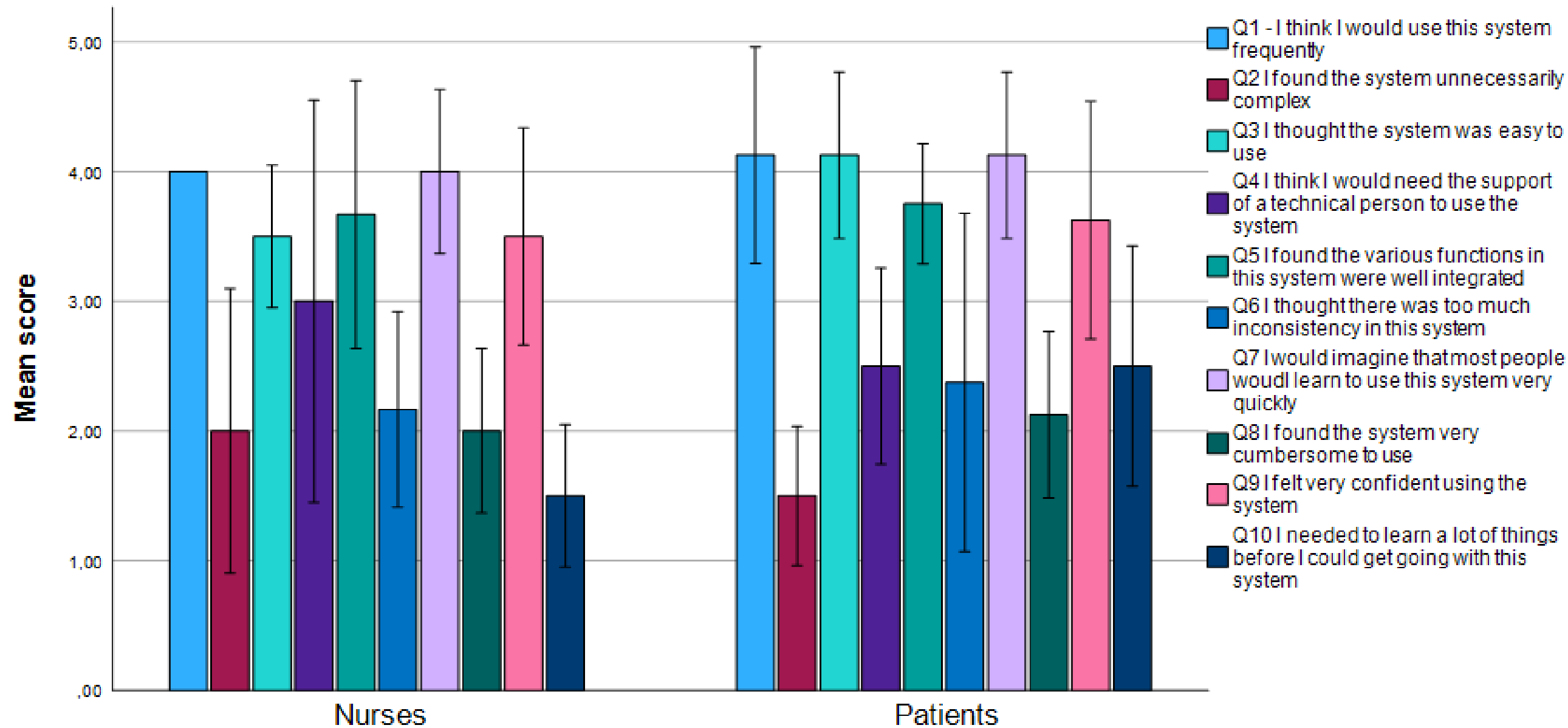
Usability trial (6 nurses, 8 patients)

Use errors

	N1	N2	N3	N4	N5	N6	P1	P2	P3	P4	P5	P6	P7	P8	%
Installing the cartridge															
Check the expiration date of the cartridge	✓	✓	✓	✓	✓	✓	✓	x	x	x	✓	✓	✓	✓	79
Check the cartridge for damages	✓	✓	✓	x	✓	✓	✓	x	x	x	✓	x	✓	✓	64
Place the carrier on the cartridge	✓	✓	✓	✓	✓	✓	1	✓	✓	✓	✓	✓	✓	✓	100
Lock the carrier	✓	✓	✓	✓	✓	✓	1	✓	✓	1	✓	✓	✓	✓	100
Turning on the device															
Connect the power supply to the controlled heater	✓	✓	x	x	✓	✓	1	x	✓	✓	x	x	✓	✓	64
Connect the power supply to the device	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Check if the device is ready for use	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Turn on the device	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Login to the device	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Check and adjust the device settings	✓	✓	✓	✓	✓	x	✓	✓	✓	x	✓	✓	✓	x	79
Check and adjust the patient data	✓	✓	✓	✓	✓	1	✓	✓	✓	✓	✓	✓	✓	✓	100
Connecting the device															
Take hygiene measures	✓	✓	✓	✓	✓	✓	✓	x	✓	✓	✓	1	✓	✓	93
Connect the priming bag to the patient line and start priming	✓	✓	1	✓	✓	✓	✓	✓	✓	✓	x	✓	1	2	93
Enter the weight of the drain bag (=1000 grams)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Check the patient line for irregularities	✓	✓	✓	✓	✓	✓	✓	x	✓	✓	✓	x	✓	✓	86
Enter the duration and speed of the dialysis session	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Connect the catheter to the patient line	✓	1	1	✓	1	1	✓	✓	✓	✓	✓	✓	✓	1	100
Open the catheter and start the dialysis session	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Using the device															
Pause and restart the dialysis session	✓	✓	✓	✓	✓	✓	✓	x	✓	✓	✓	✓	✓	✓	93
Check the duration of the dialysis session	✓	✓	✓	✓	✓	✓	✓	x	✓	✓	✓	✓	✓	✓	93
Handle an alarm (i.e. mute the sound, track down the problem and fix it)	✓	1	✓	✓	✓	✓	x	x	✓	✓	1	1	✓	✓	86
Disconnecting the device															
Stop the dialysis session	✓	✓	✓	✓	1	✓	✓	✓	✓	✓	✓	x	✓	✓	93
Take hygiene measures	✓	✓	✓	✓	✓	✓	✓	x	✓	✓	✓	1	✓	✓	93
Disconnect the device of the patient line	✓	✓	✓	1	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Enter the weight of the drain- and filling bad (=1050 and 1900 grams)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	x	✓	✓	✓	93
Turning off the device															
Turn off the device	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100

Usability trial (6 nurses, 8 patients)

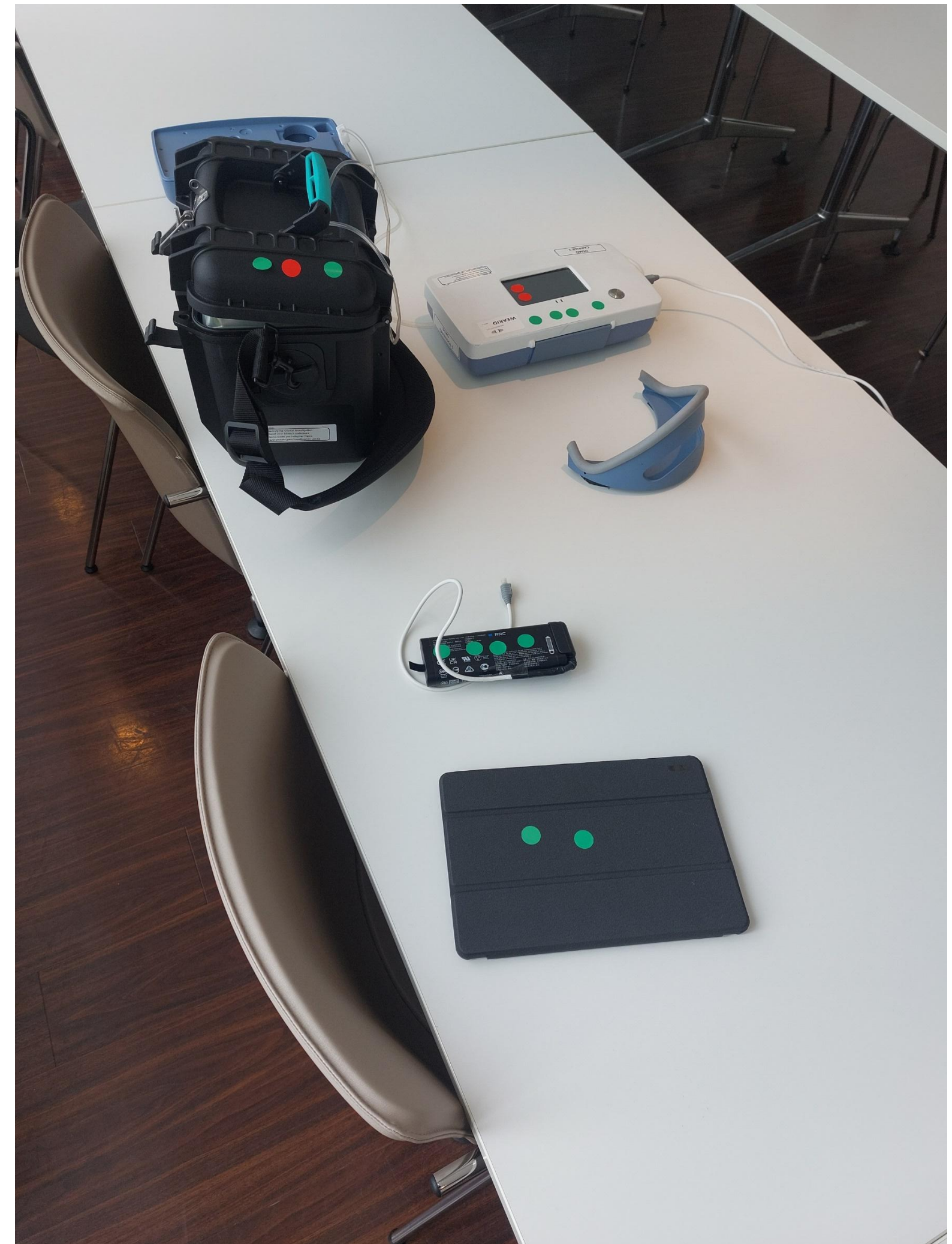
System usability score (Likert scale between 1-5)



Total SUS score:
70 (± 11) for nurses
72 (± 12) for patients

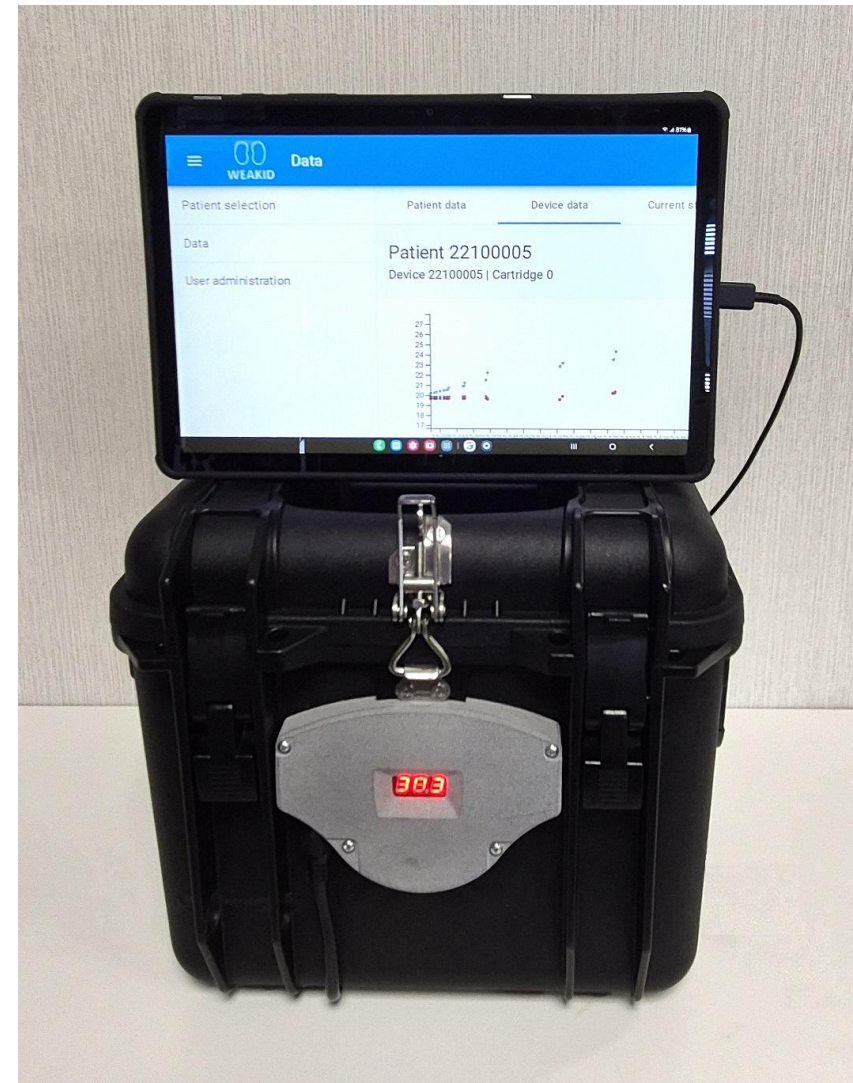
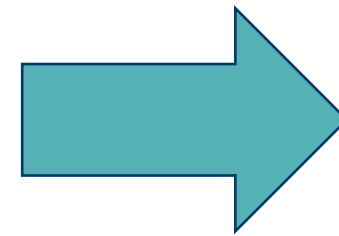
Patient focus groups

- Developed with NVN
- Focus groups (3x) performed in Netherlands, Spain, and Italy





REDESIGN-PD

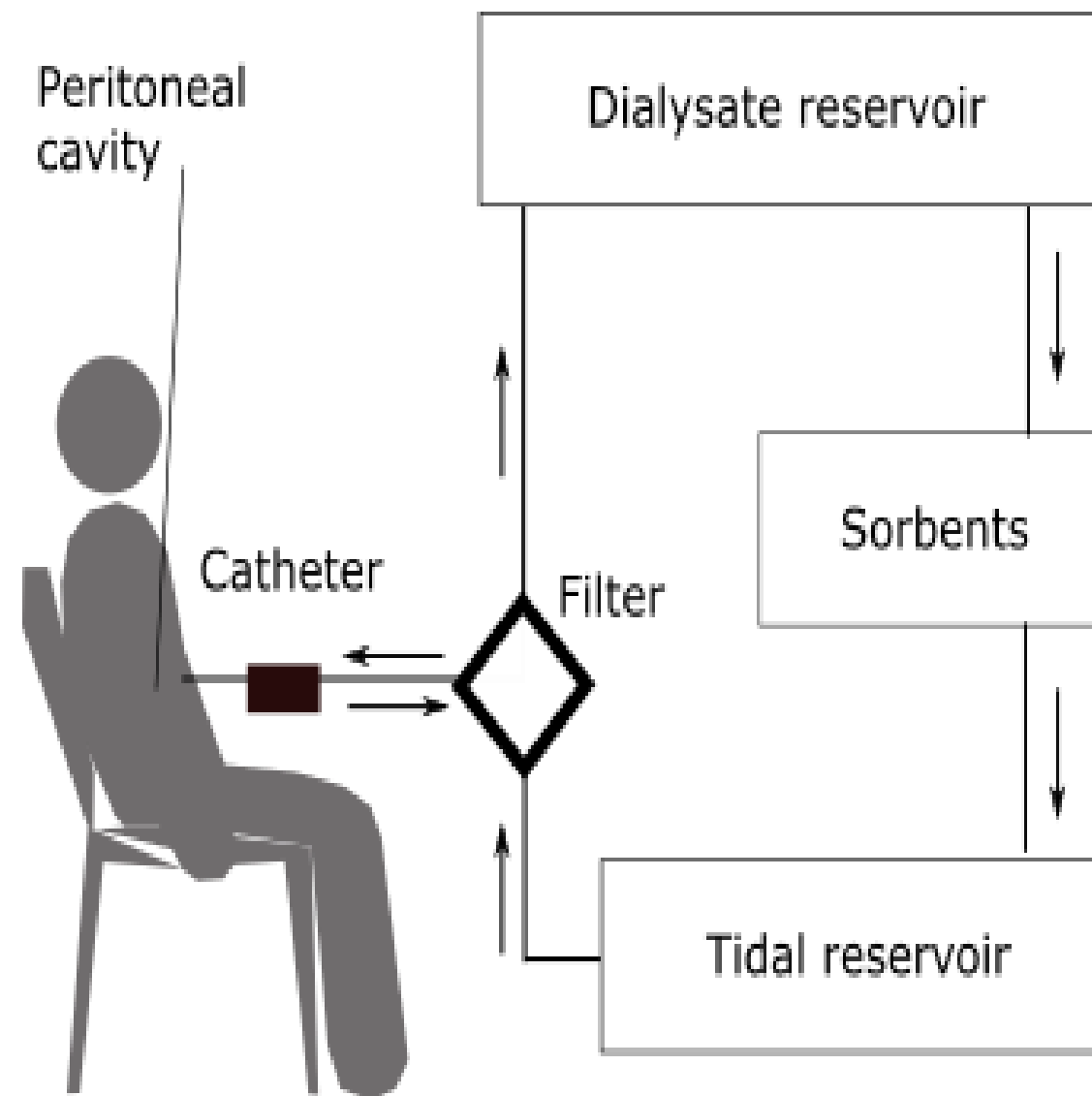


- Compact design (higher sorbent mass, less dialysate)
- Bypass of filter
- User interface

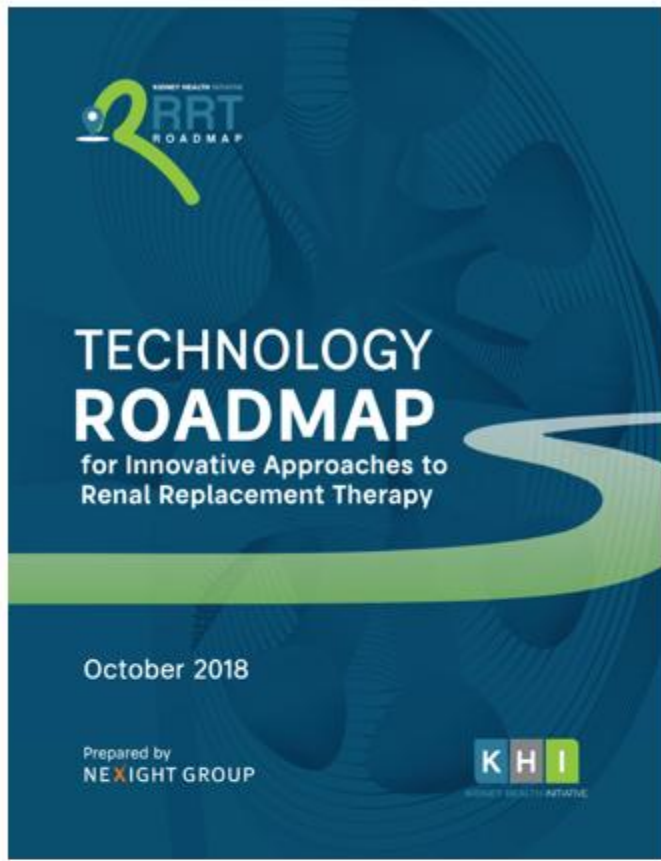
Portable nighttime system

Optimize settings → Computational modeling

- Intraperitoneal dialysate volume
- Dialysate volume
- Sorbent mass
- Tidal volume
- Flow rates



Sangita Swaprasnita

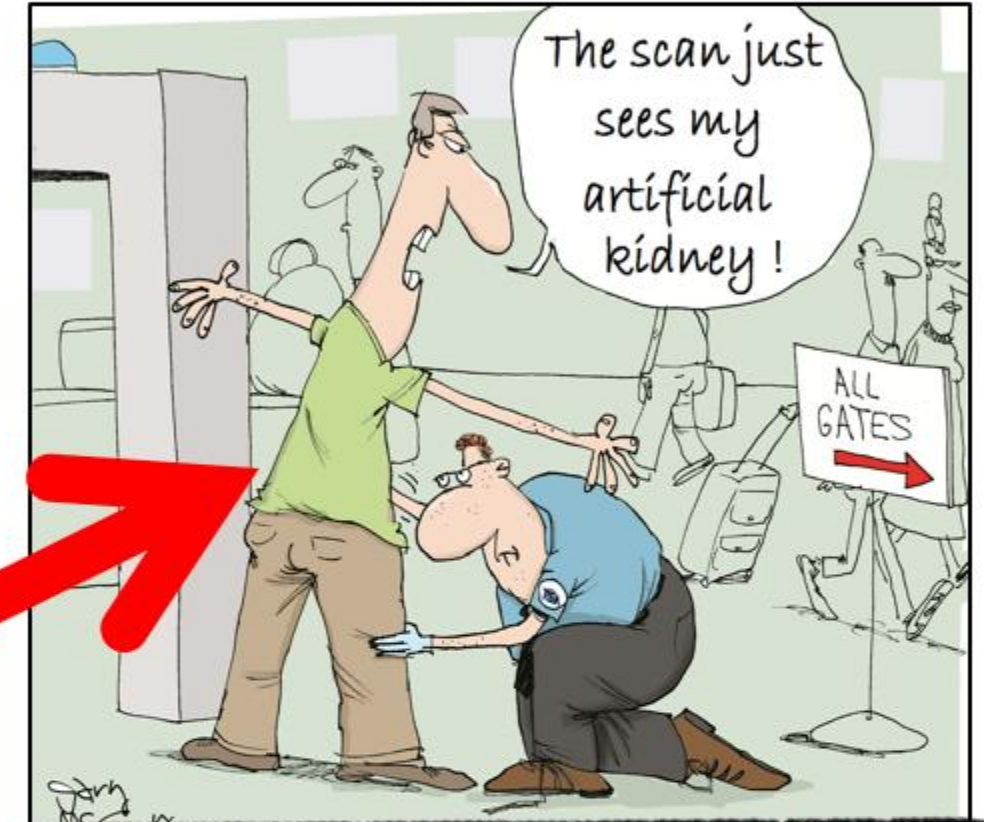
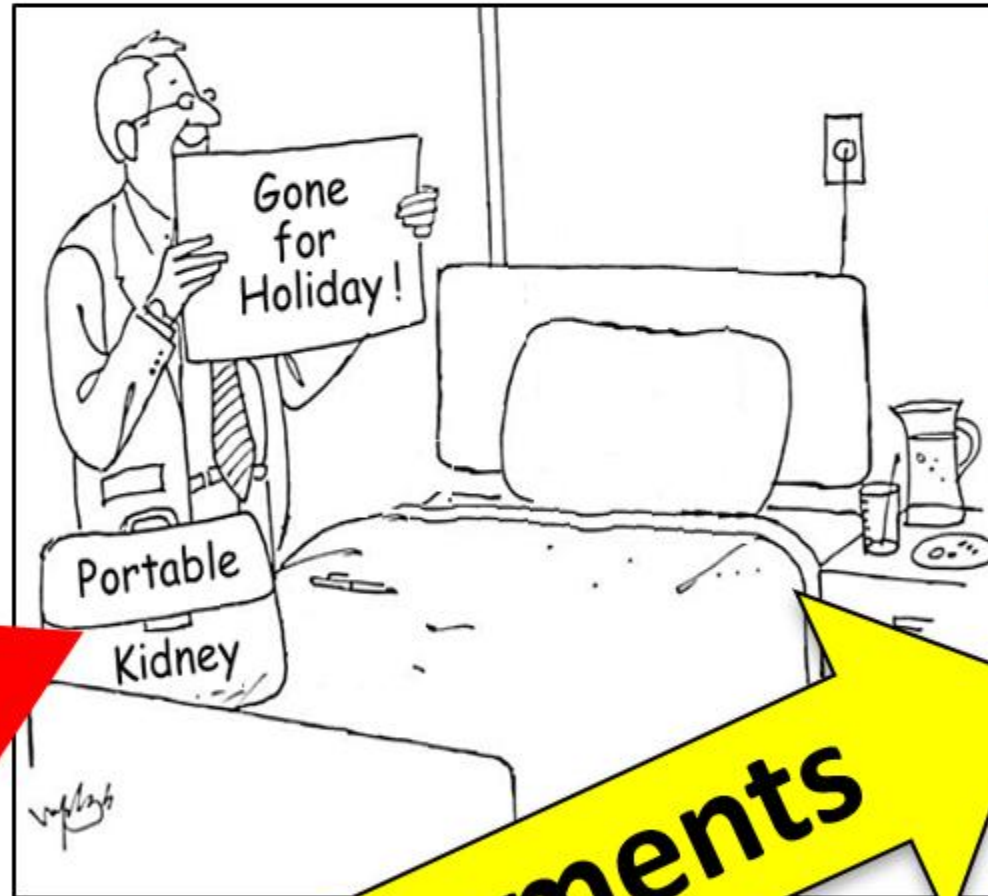


Roadmap to freedom...

24/7 (bio)artificial kidney

Able to travel

Stuck in a chair/bed



improvements

QUALITY OF LIFE

ECO FRIENDLY

COST-EFFECTIVE

Dialysate set

- Single use
- Dialysate cartridge includes:
 - 3 peristaltic pumps
 - 6 disposable pressure sensors
 - 1 disposable ammonia sensor
- A pre-connected dialysate collection bag (“weighing bag”)

Pressure sensor
disposable modules

Ammonia sensor
(not shown)

Peristaltic Pumps

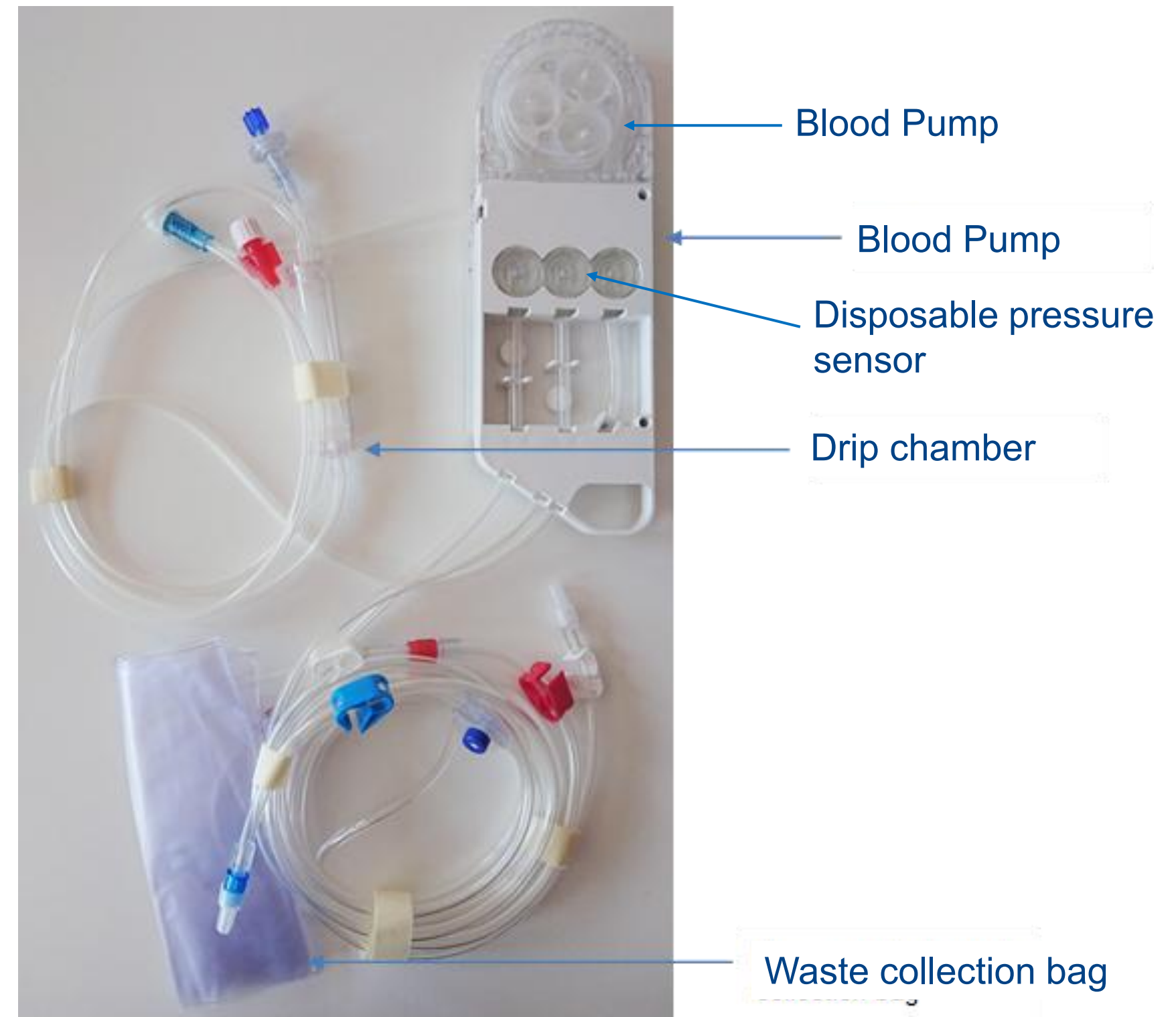
Dialysate cartridge

Weighing bag

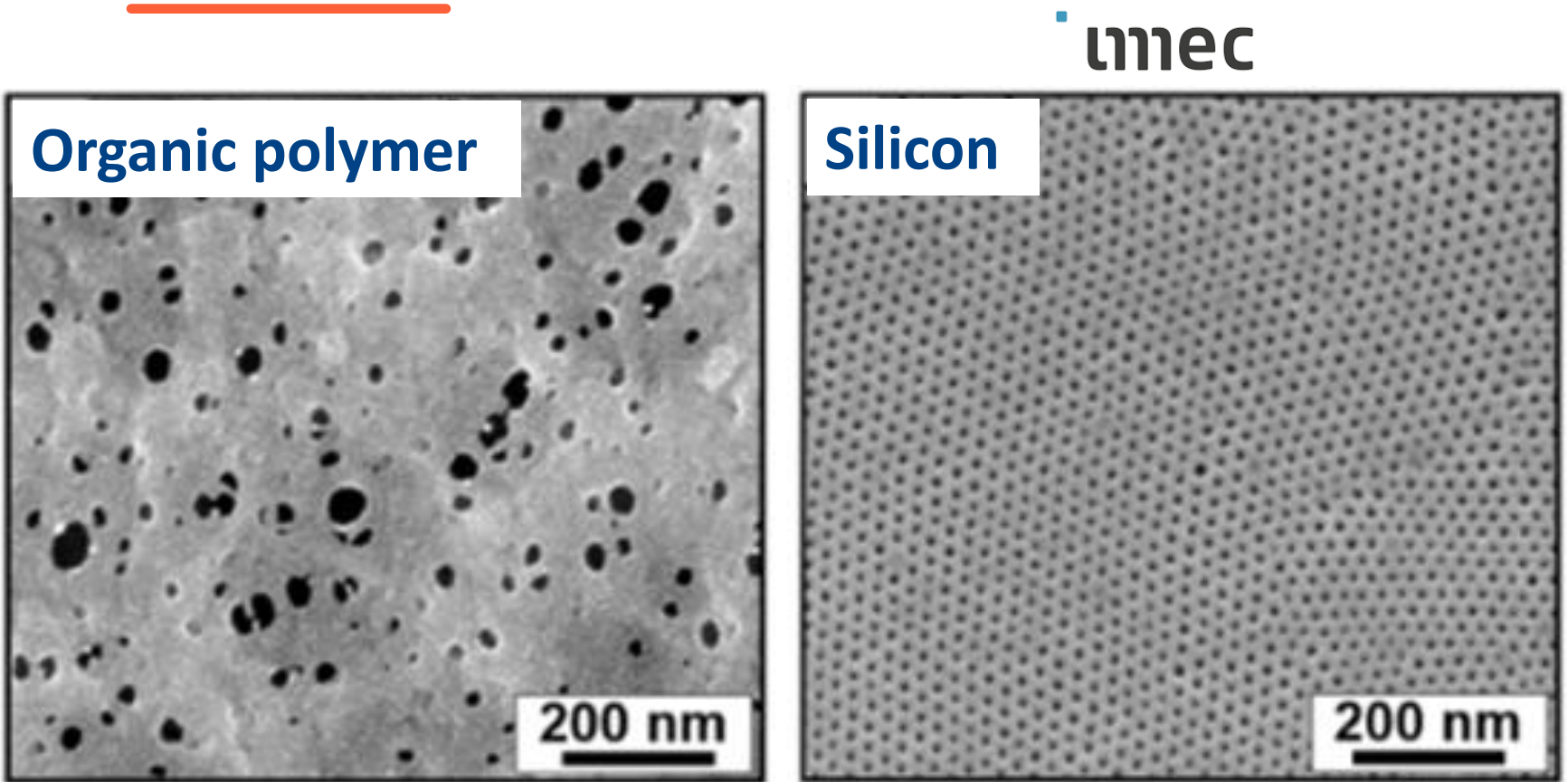


Blood set

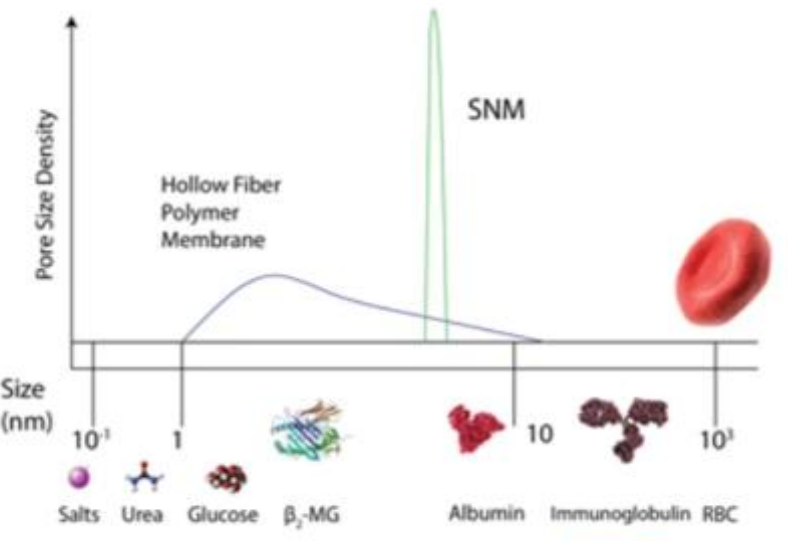
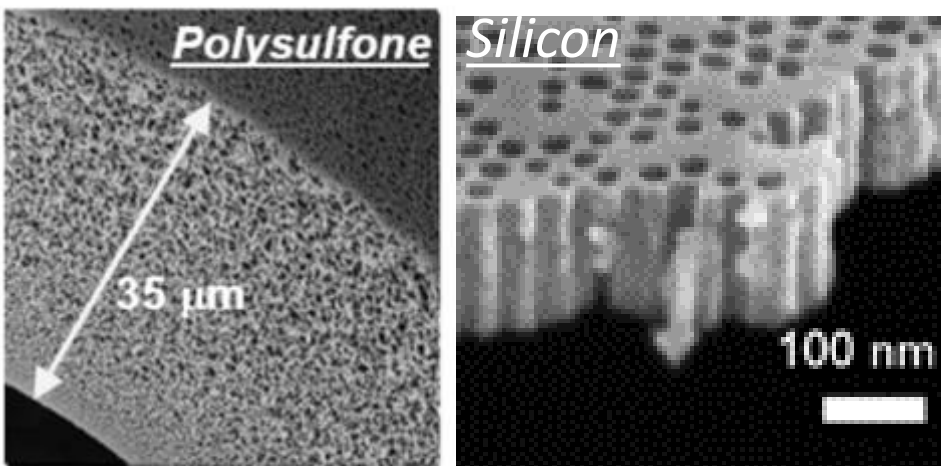
- Single use
- Drip chamber with vent and clot filter
- Blood cartridge includes:
 - 1 peristaltic pump
 - 3 disposable pressure sensors
- A pre-connected waste collection bag



Towards implantable - Silicon nanopore membranes

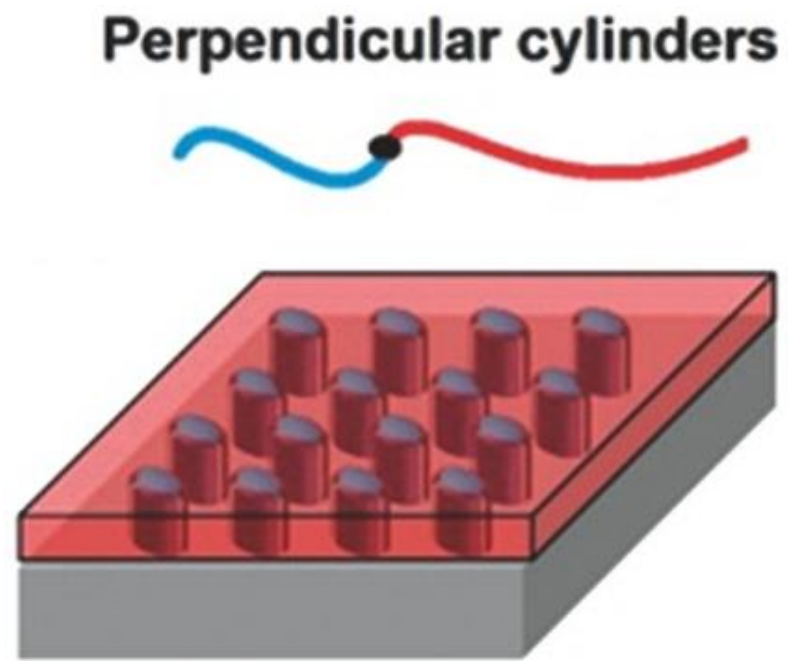


- High molecular selectivity
- Low flow resistance
- Batch manufacturing

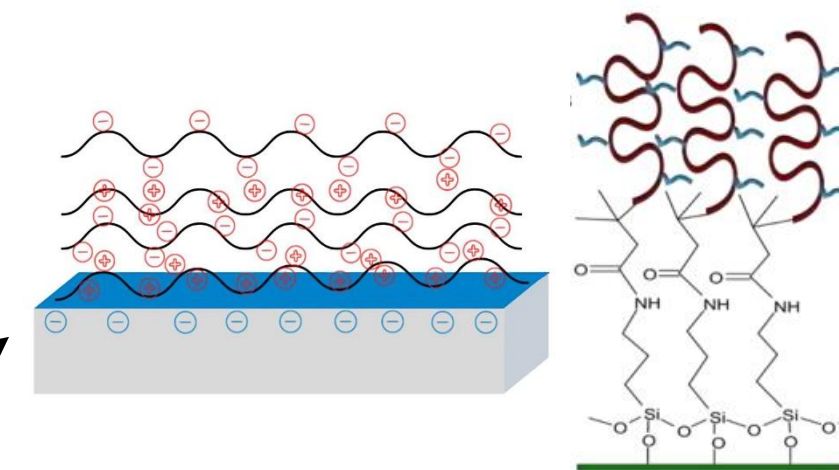
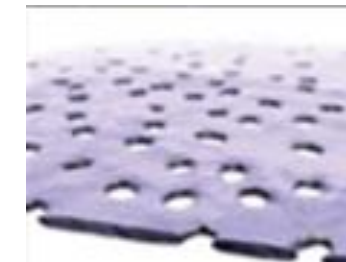
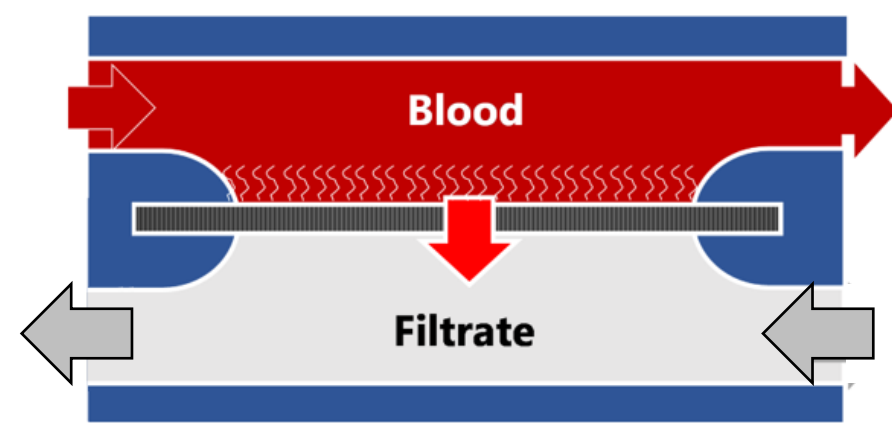
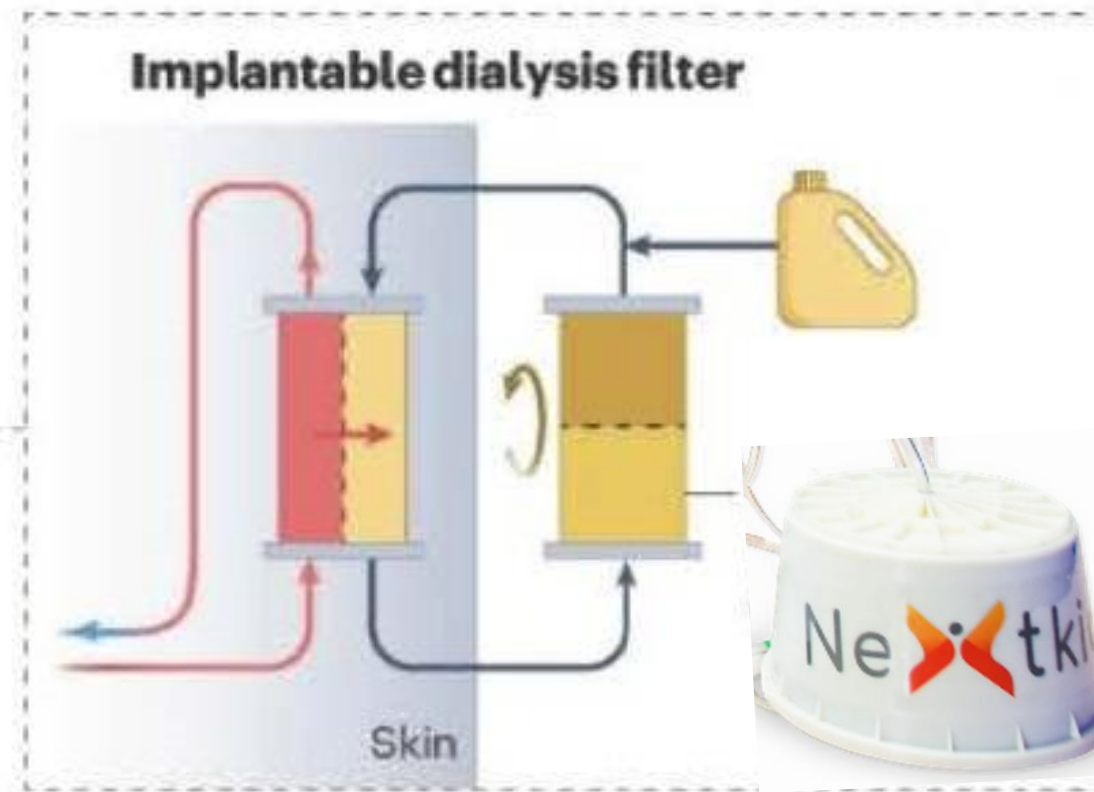
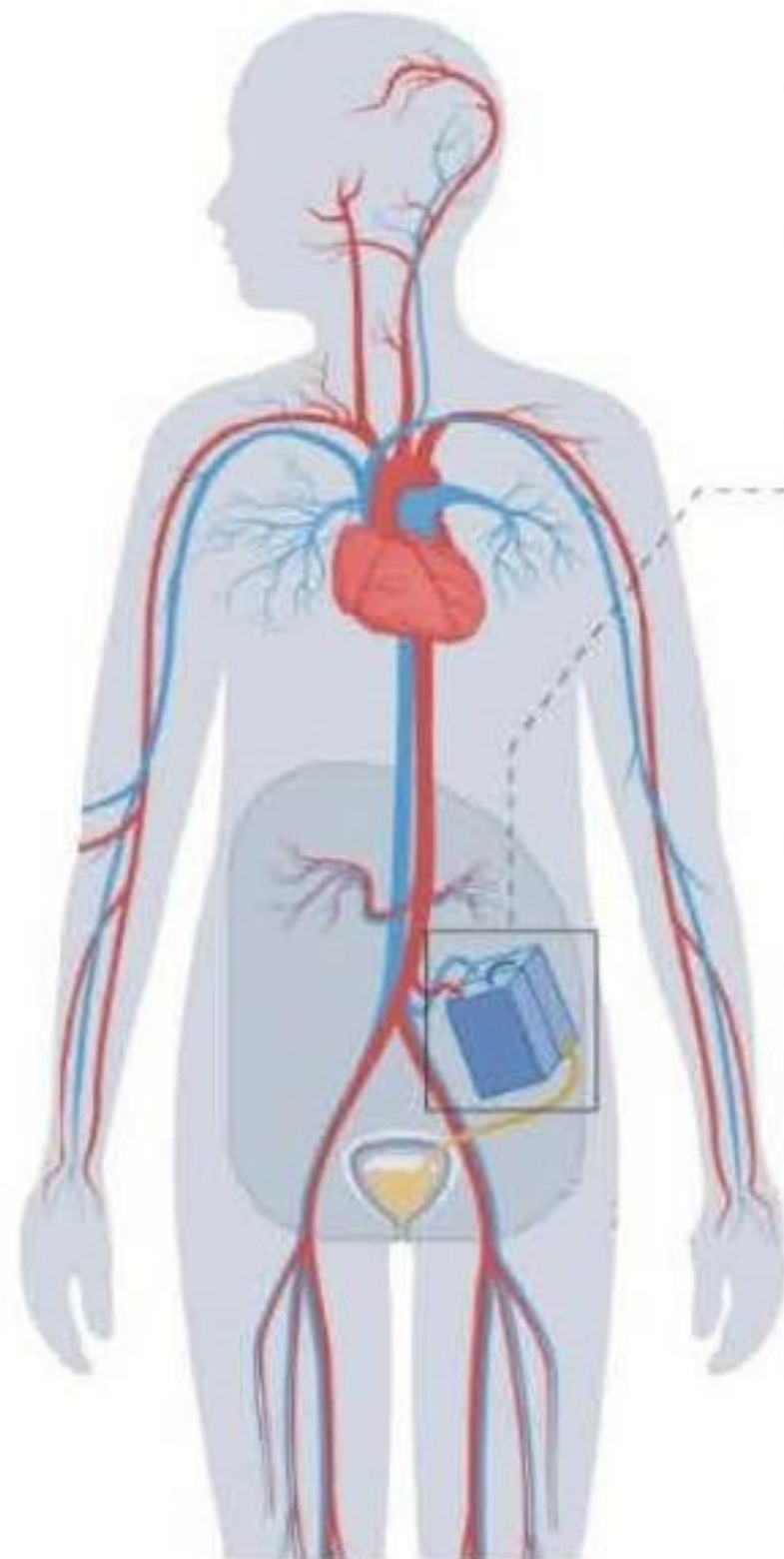


No Pumps **Improved Clearance**

Self-assembled block-copolymer patterning masks



Implantable hemofilter – ‘HD without needles’



Tugrul Irmak



Tadeo Alcerreca Valdez