XLI Annual School 2022

Startup companies for accessible medical devices: the IBD case study

Alan Fabbri

Bressanone
13/09/2022

If a solution is not affordable

it’s not a solution

DEVI PRASAD SHETTY

Cardio Surgeon

Outline

Reverse Innovation

Our Team

My Dial

Biorespira

Reverse Innovation overturns the way to think about medical devices design

Opposite of “glocalization”

Needs of emerging markets

Creates new markets in developed countries

«From value for money to value for many»
(Vijay Govindarajan)

Reverse Innovation pillars

Affordability

Robustness

Ease to use

Flexibility

IBD was founded in 2014 as a startup and it is currently an innovative SME

Conceived in London and **founded in Italy in 2014**

Development and certification of an innovative **device for hemodialysis**

Development, certification and market launch of an innovative **device for ventilation**

EN ISO 13485 and **EN ISO 9001** certified

Team with +15 years in medical device R&D

More than 1 M€ by BA and grants

Founders

Co-Founder, CEO, CFO

Corrado Ghidini

- → Doctor of Medicine (M.D), Doctor of Dentistry (DDS) specialized in Internal Medicine, University of Bologna, 1981-93.
- → Executive MBA at Imperial College London, 2013 - 2015.
- → Entrepreneur for over 20 years in the biomedical field.

Co-Founder, COO, R&D Manager

Andrea Visotti

- → Biomedical Engineer, specialized in artificial organs and biomechanics, University of Bologna, 2007-2012.
- → 10 years of experience in the design of low-cost medical devices.
- → He has filed 5 patents for industrial invention as inventor.

Team: R&D & Regulatory

Scientific Manager

Claudia Perazzini

- → Biomedical Engineer, University of Bologna, 2003-2010.
- → Researcher at the Interdepartmental Center for Industrial Research (ICIR-HST) of the University of Bologna, 2011-16.
- → 8 years of experience in dialysis, both in industrial research and technical design.

R&D Specialist

Alan Fabbri

- → Biomedical Engineer, University of Bologna, 2006-2013.
- → PhD Student, University of Bologna, 2014-2017; Postdoctoral Researcher, UMC Utrecht, 2018-2021.
- → 8 years of experience in research and development of medical products.

CE Regulatory & Quality Manager

Debora Drudi

- → Biomedical Engineer, University of Bologna, 2008-2016.
- → 5 years of experience in the biomedical regulatory environment.
- → She has led IBD to obtain the EN ISO 13485 and EN ISO 9001 certifications with the TUV Sud Body.

FDA Regulatory & Quality Manager

Silvia Scarpellini

- → Biomedical Engineer, University of Bologna, 2007-2012.
- → 8 years of experience in the international biomedical regulatory field (USA, Canada, Australia, China, Brazil ..)
- → She is working on the preparation of the technical documentation for obtaining the FDA marking.

Our goal is to overcome the hurdles to reach the unmet needs

Needs

State of the art

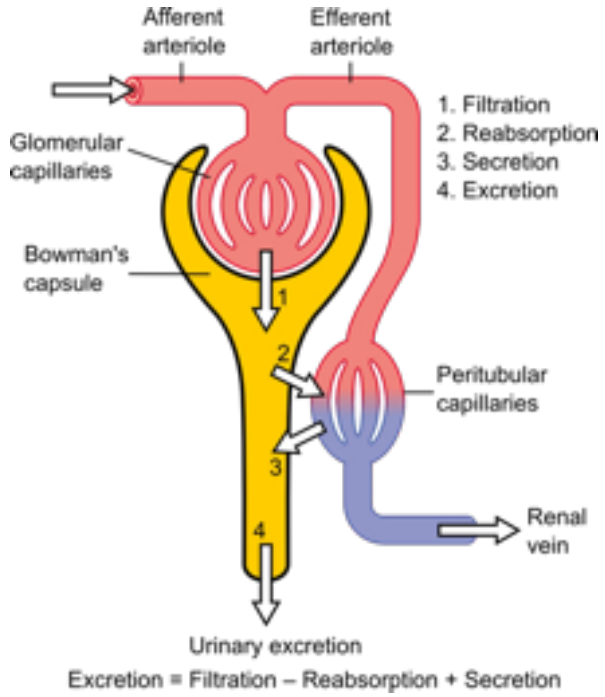
Hurdles

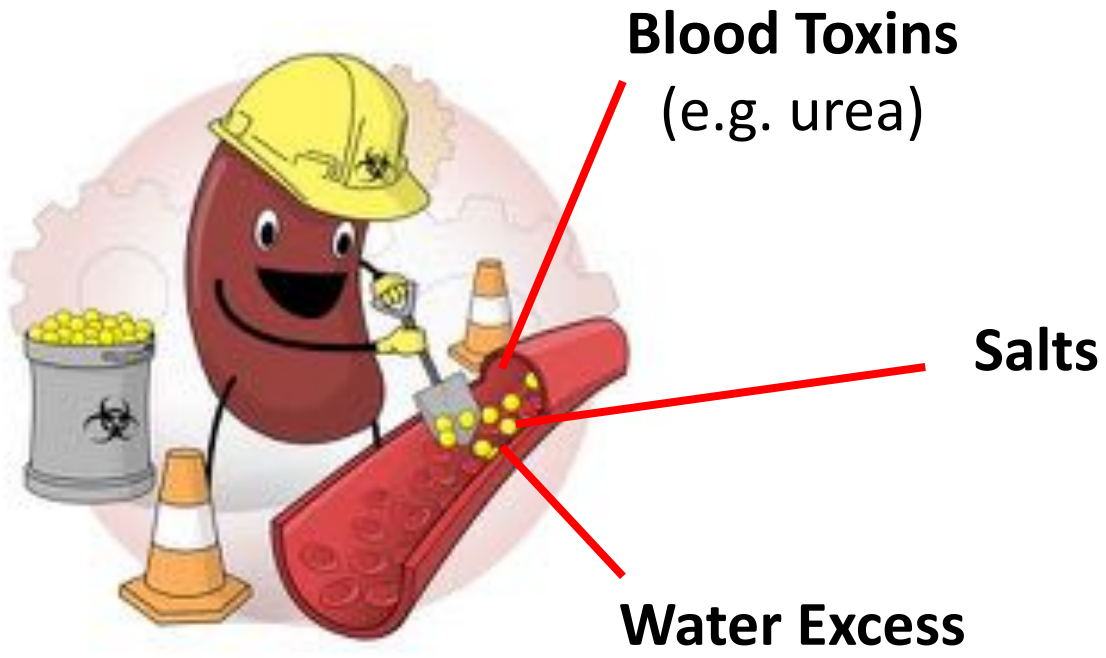
Solution

My Dial

An affordable system for home hemodialysis

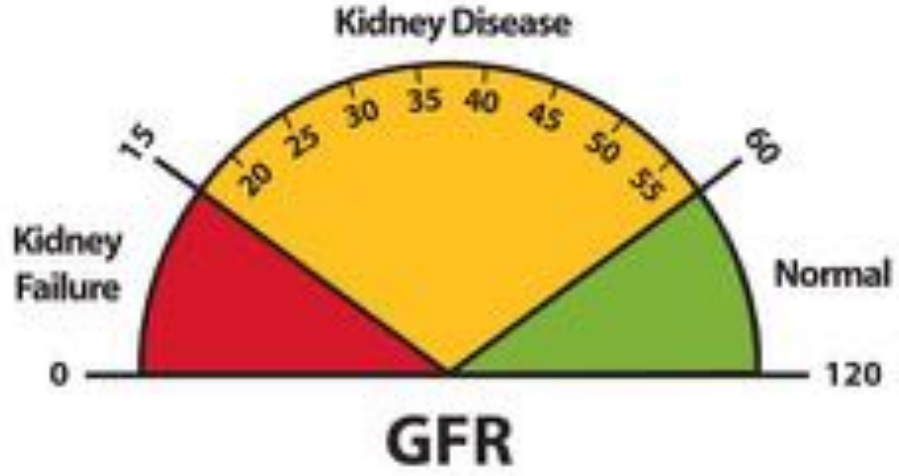
Kidneys filter our blood from waste resulting from metabolism





From (left) https://en.wikipedia.org/wiki/Glomerular_filtration_rate
(right) https://slmillustration.com/functions-of-the-kidneys

Glomerular Filtration Rate (GFR) shows how well our kidneys are filtering our blood



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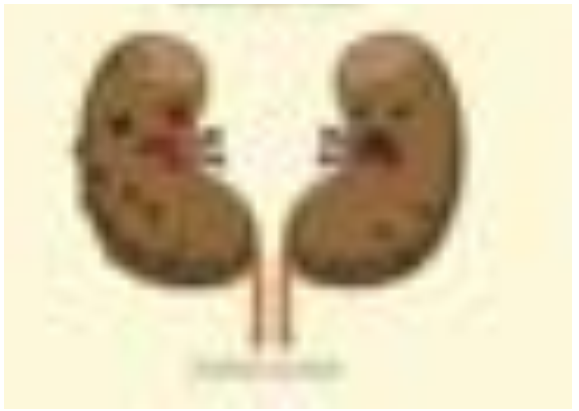
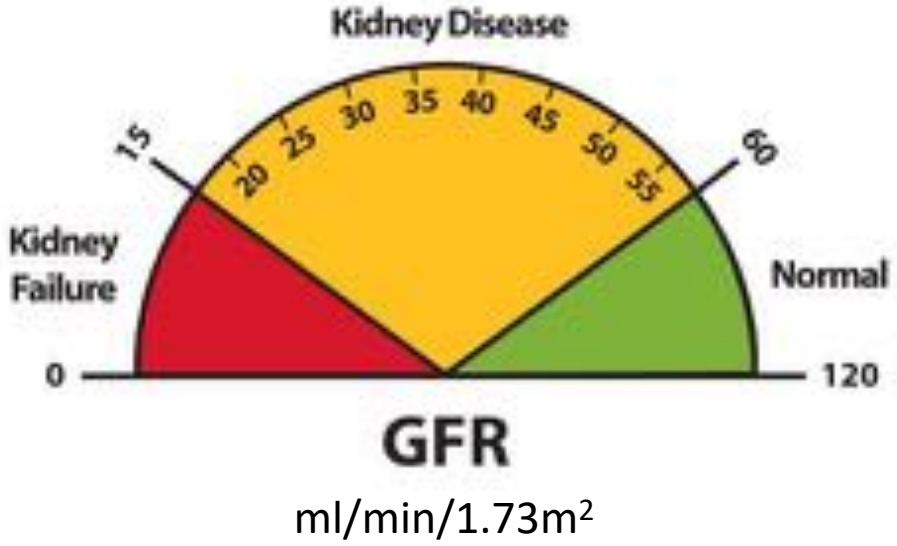


Adapted From: (left) https://www.niddk.nih.gov/health-information/professionals/advanced-search/explain-kidney-test-results
(right) https://www.123rf.com/clipart-vector/kidney_disease.html

GFR determines the stage of kidney disease

What are the stages of chronic kidney disease (CKD)?

Stage	Description	eGFR	Kidney Function
1	Possible kidney damage (e.g., protein in the urine) with **normal** kidney function	90 or above	90-100%
2	Kidney damage with **mild loss** of kidney function	60-89	60-89%
3a	**Mild to moderate** loss of kidney function	45-59	45-59%
3b	**Moderate to severe** loss of kidney function	30-44	30-44%
4	**Severe loss** of kidney function	15-29	15-29%
5	Kidney **failure**	Less than 15	Less than 15%



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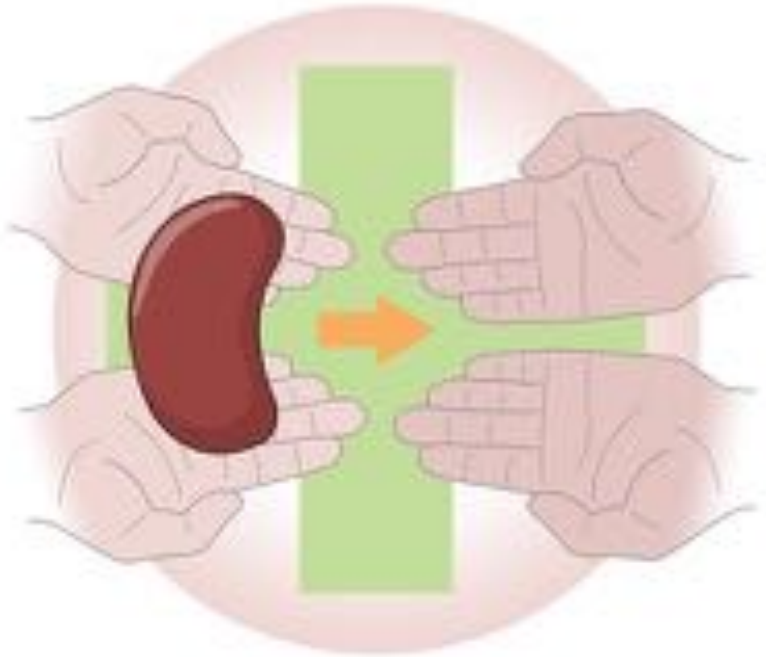
(right) https://www.niddk.nih.gov/health-information/professionals/advanced-search/explain-kidney-test-results

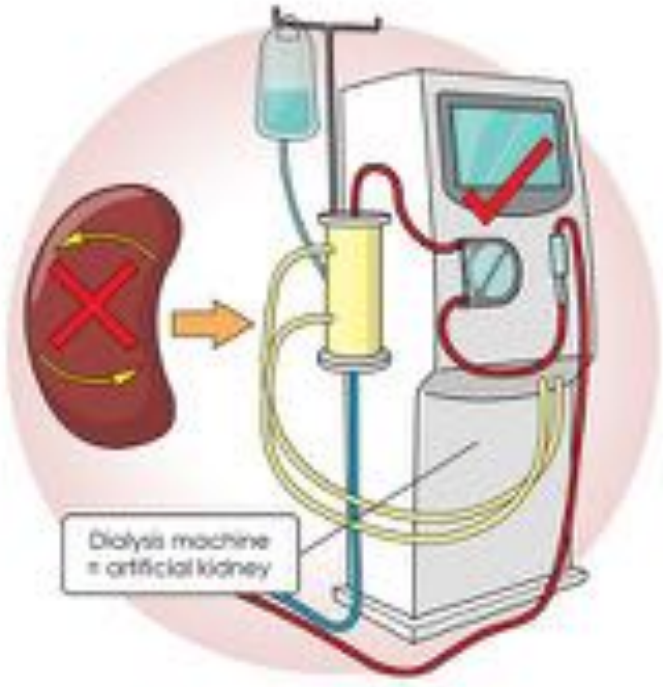
Chronic Kidney Disease (CKD) is a silent killer

http://ercpa.eu/index.php/facts-figures/

Renal Replacement Therapy (RRT) is the only option to treat end stage renal disease

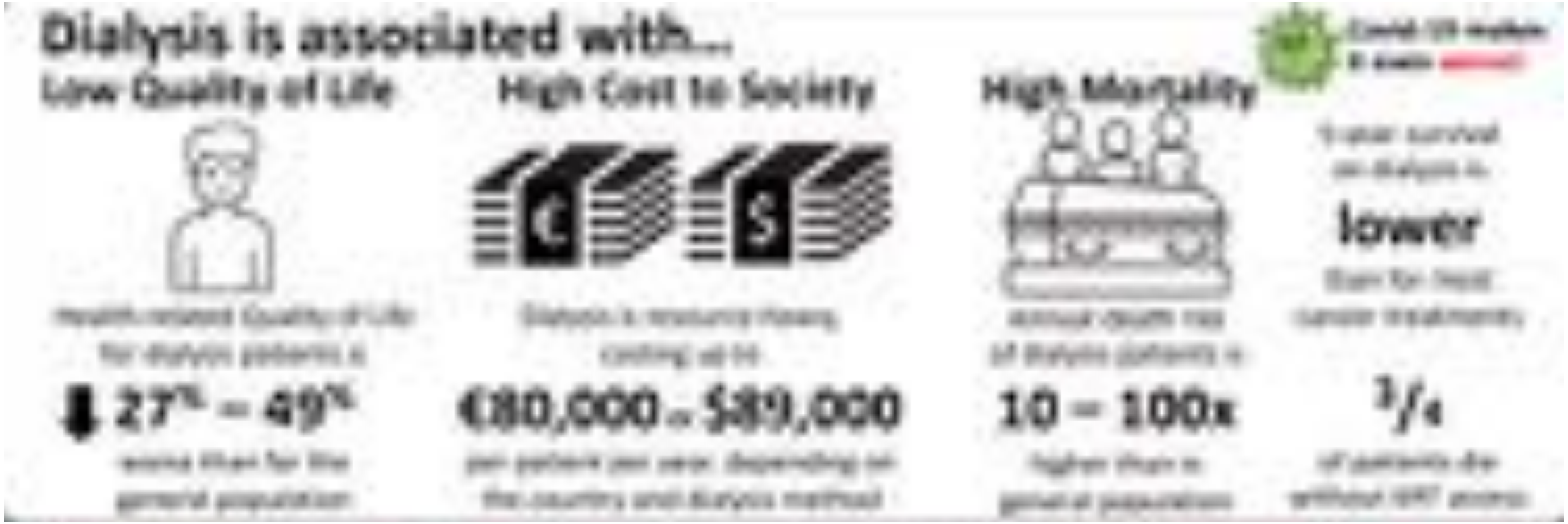


Kidney transplantation



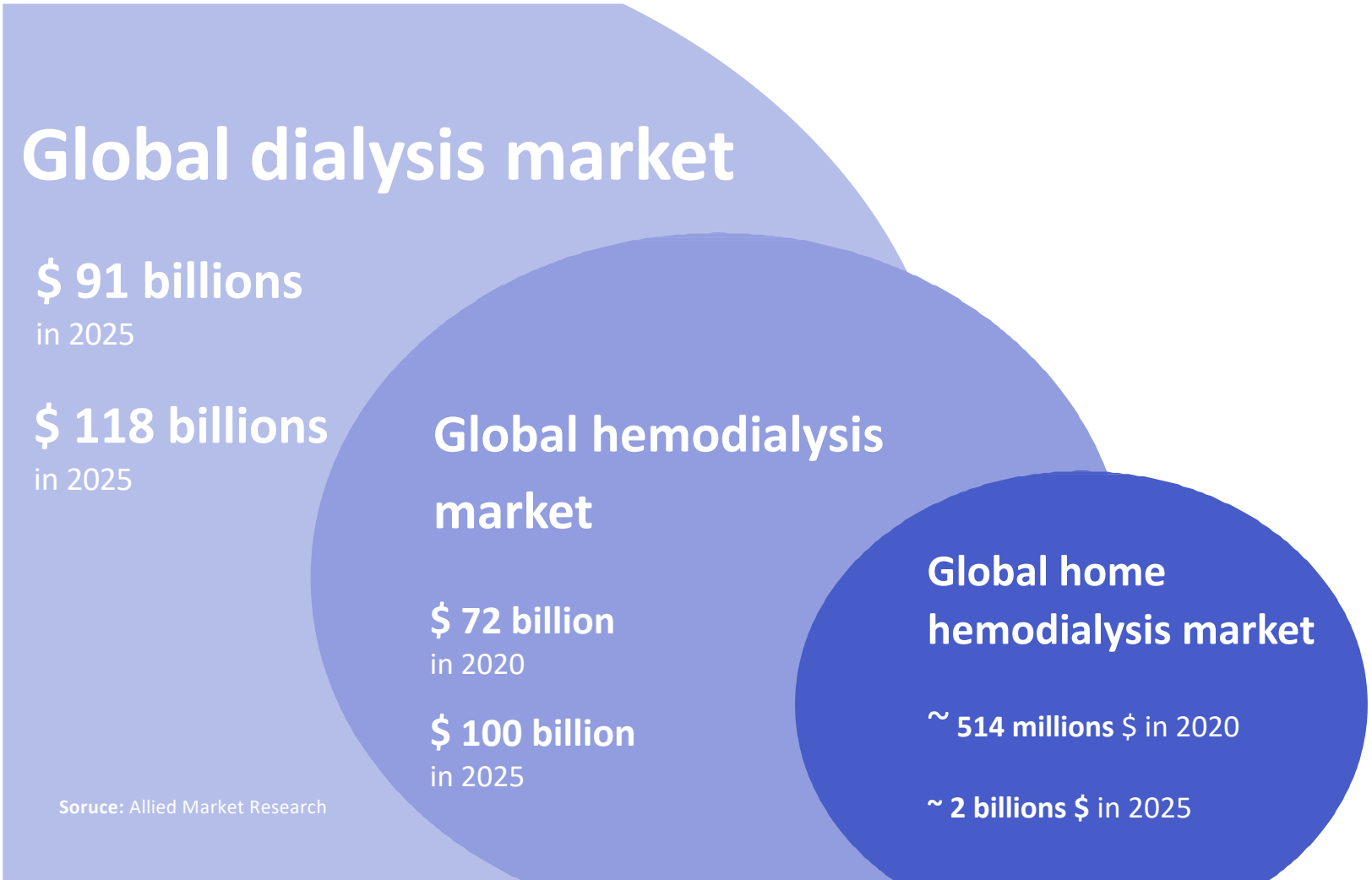
Dialysis

Dialysis has a huge impact in quality of patient's life (and her/his family)



Adapted from: https://ekha.eu/wp-content/uploads/2022/03/AAKP-EKPF-and-EKHA-Infographic_World-Kidney-Day-2022-1.pdf

Home hemodialysis is a powerful tool to improve patient's quality of life but it's still a small market



Soruce: Allied Market Research

Why home hemodialysis is so promising but still not popular?

Current home hemodialysis is not affordable

High cost per session

High impact on environment

Big changes in home environment

Expensive blood lines
Expensive hydraulic circuits

Blood lines and hydraulic
Circuits are disposable

Current machines need to set a
new domestic layout

My Dial aims to reduce by 70% the cost of therapy

Easy to install and use

Designed **without bulky equipment** or structural changes. It does not requires professionals skills.

Touch-screen monitor

With **intuitive interface**

Designed for home setting

Compact and light-weight
(Size: 40 x 38 x 32 cm / Weight: 18 kg)

Innovative disposable

Customized, low-cost and easy to connect

Bicarbonate dialysis therapy

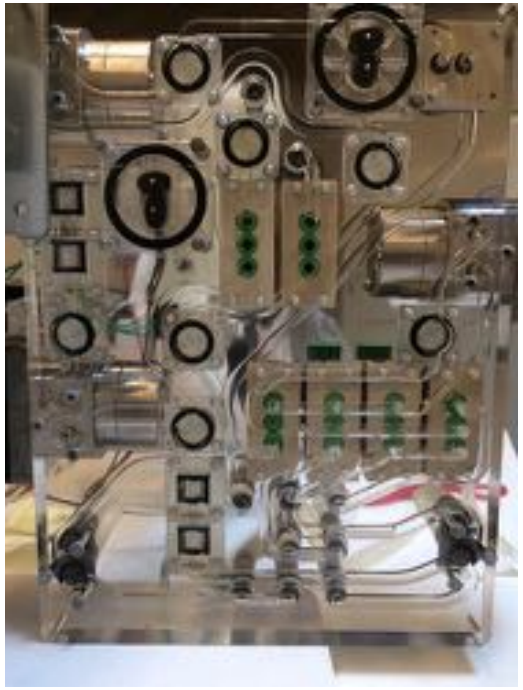
Easily adaptable to different metabolic and depurative needs of the patient.
Dialysate flow up **to 500 ml /min**

The manifold system leads to compact size and simplifies the assembly

State of the art

Inside of a hospital
Dialysis machine

My Dial



A4 size hydraulic system
Patented of My Dial

Compact and reusable

Integrates sensors and pumps

Simplifies manufacturing

A custom and low cost blood line lowers the cost of the therapy

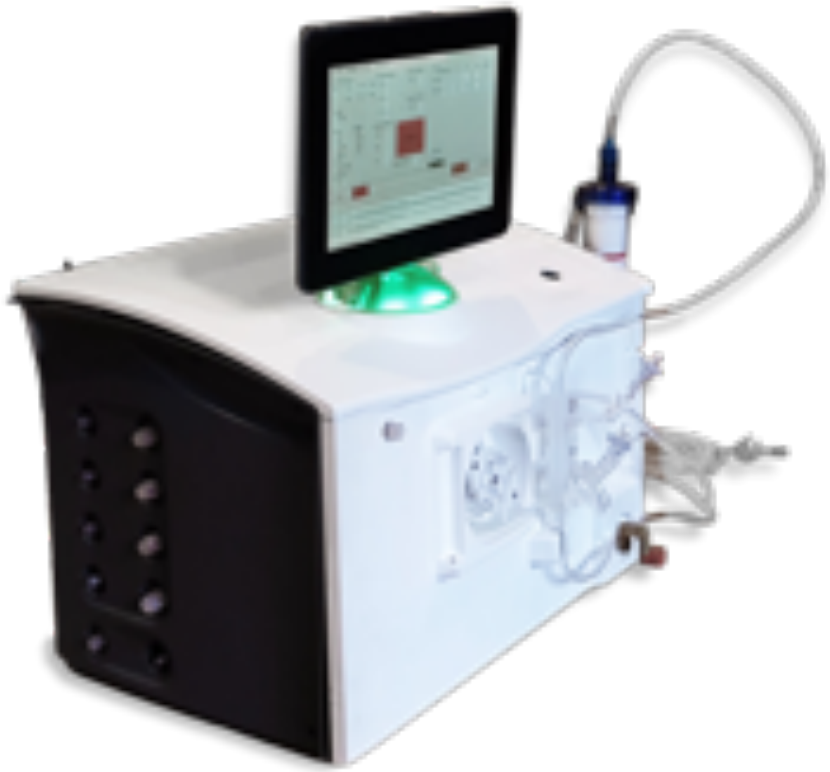
State of the art

+ High usability
- High cost

My Dial

+ Simplified Blood line
+ Standard filters and concentrates

My Dial is currently CE marked (MDD) but needs to be optimized for the industrialization



Next steps

Upgrade to the European
Medical Device Regualtion (MDR)

Pilot Medical Trial

Optimization for mass production

Biorespira

High Flow generator to alleviate the burden on ICUs

Acute Respiratory Distress Syndrome (ARDS) is a major complication of COVID-19

Thickening of walls
+
Fluid in the alveoli

Reduced gas exchange

High intubation rate
High mortality

Non Invasive Ventilation (NIV) is a first line approach in less ill patients with ARDS

Nasal Cannulae

Face Mask

Helmet

High Flow Oxygen Therapy (HFOT)

Continuous Positive Airway Pressure (CPAP)

Continuous Positive Airway Pressure (CPAP) improves oxygenation and reduces intubation rate

Helmet is the best option in case of COVID19

Venturi/ Blender

Intensive care unit ventilators

Venturi systems and blenders need high demand of oxygen

Venturi/ Blender

+ Cheap

+ Out of ICUs

- No closed loop control of flow and FiO_2

- No accurate FiO_2

- High demand of O_2

Intensive care unit ventilators should be employed for severe ARDS cases

An ICU ventilator

- Expensive

- Prone to CO_2 rebreathing in CPAP mode

Reduce O_2 consumption, relief ICU burden and stop spreading out of SARS-cov2 is crucial

Biorespira is a high flow generator with a built in turbine that monitors patients parameters

For **adult patients** (>40 Kg) that breath spontaneously

Built in **turbine** allows: a fine control of flow
an efficient O2 delivery

Patient parameters: SpO2
Pulse rate
Respiratory rate

Biorespira delivers both HFOT and CPAP with STANDARD patient interfaces

Humidifier

Nasal Cannulae

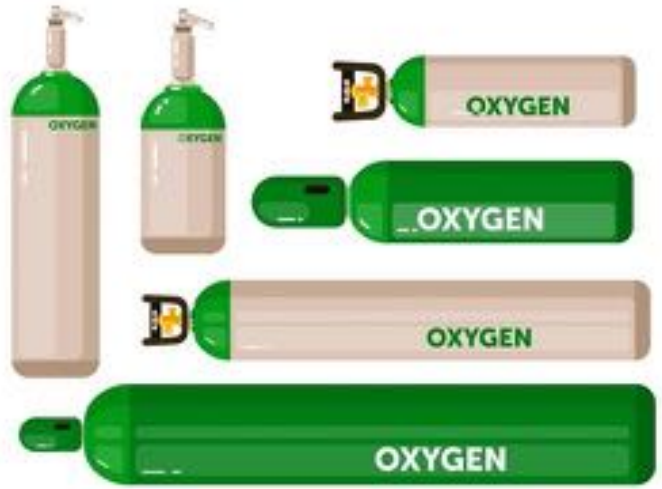
HFOT

PEEP valve

Helmet/Face Mask

CPAP

Biorespira works with O_2 tanks, O_2 concentrators and hospital O_2 system



O_2 Tanks

O_2 concentrator

Hospital O_2 system

Good for homecare

Biorespira is CE marked (MDD) and currently on the market

Take home messages

Reverse Innovation

Affordability

Flexibility

Few and cheap disposable

My Dial

Home hemodialysis can be game changing but still not affordable

IBD wants to unlock its potential

Biorespira

Flexible and Efficient

Enhances semi intensive care units

Easy to use

For hospital and homecare

Questions?

alan.fabbri@ibdsrl.com

Contact Us

corrado.ghidini@ibdsrl.com

andrea.visotti@ibdsrl.com

Italian Biomedical Devices
Corso G. Mazzini 132, 47121, Forlí