

A woman with grey hair, wearing a bright red helmet and a brown leather motorcycle jacket, is smiling and looking back over her shoulder. She is riding a motorcycle on a paved road that curves through a hilly, brush-covered landscape. The background shows a winding road and a car in the distance under a clear sky.

norm.

FIRE1

Novitas Introduction
16Apr2025

Our Mission and Vision

1

Empowering patients
with heart failure to get
their “*normal*” back

2

Revolutionizing heart
failure management as
Continuous Glucose
Monitoring did for diabetes



Introducing norm.



**Self-management
for heart failure**

FDA Breakthrough Device Designation –
September 2024



Heart Failure

One of the biggest unsolved problems in healthcare

1 in 5 people will suffer from Heart Failure (HF)

Biggest cause of hospitalization in >65-year-olds

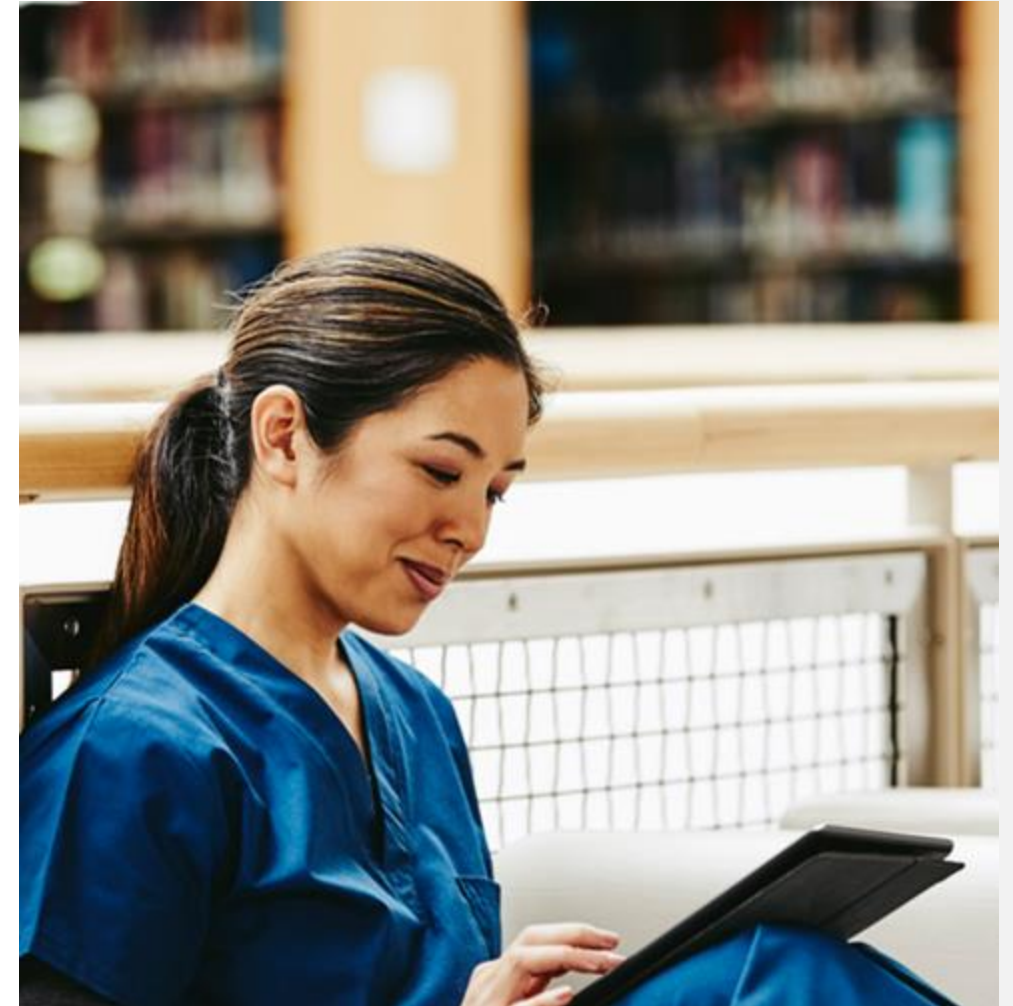
Devastating impact on quality of life

Heart Failure is projected to grow **by 46% from 2012 to 2030 in the US***



Volume accumulation drives symptoms, hospitalizations and death via “congestion”

Heart failure is a challenge of volume management

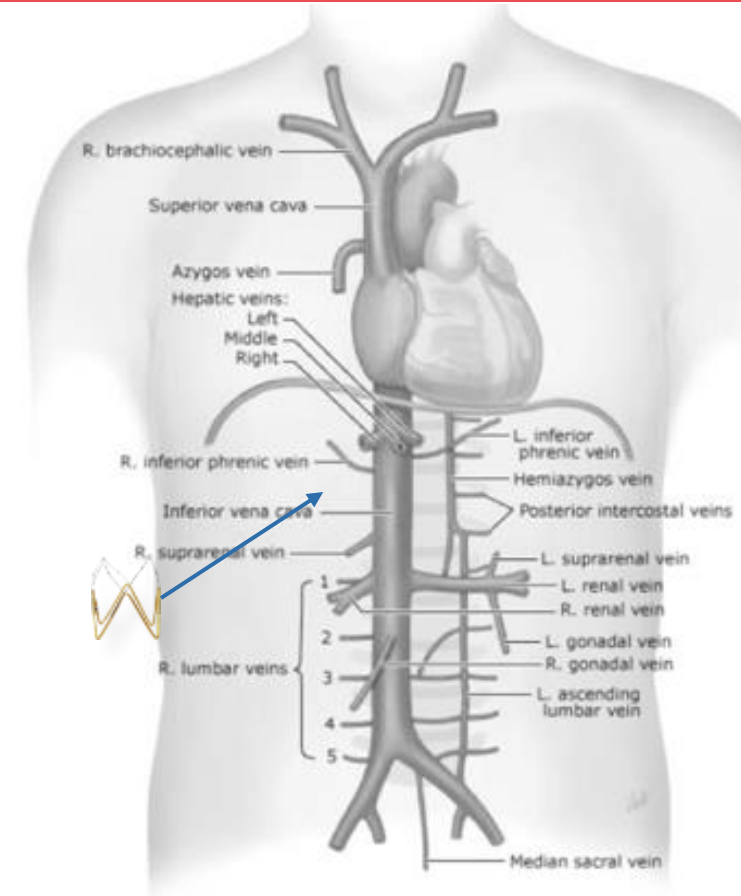


To manage volume, you need to measure volume. The best place to measure volume....

Why the IVC?

- 70% of blood is in the veins – most of it in the venous reservoir of the abdomen
- The IVC is the largest vein in the body
- Returns majority of the blood to the heart
- The intravascular storage vessels (e.g., splanchnic veins) feed into the IVC
- The IVC is a compliant vessel that buffers volume shifts to maintain cardiac preload
- IVC volume assessment is already included in Echo guidelines (IVC size increases and collapsibility)

Placed in the Inferior Vena Cava (IVC)





Volume ≠ Pressure

Unique advantages of volume monitoring



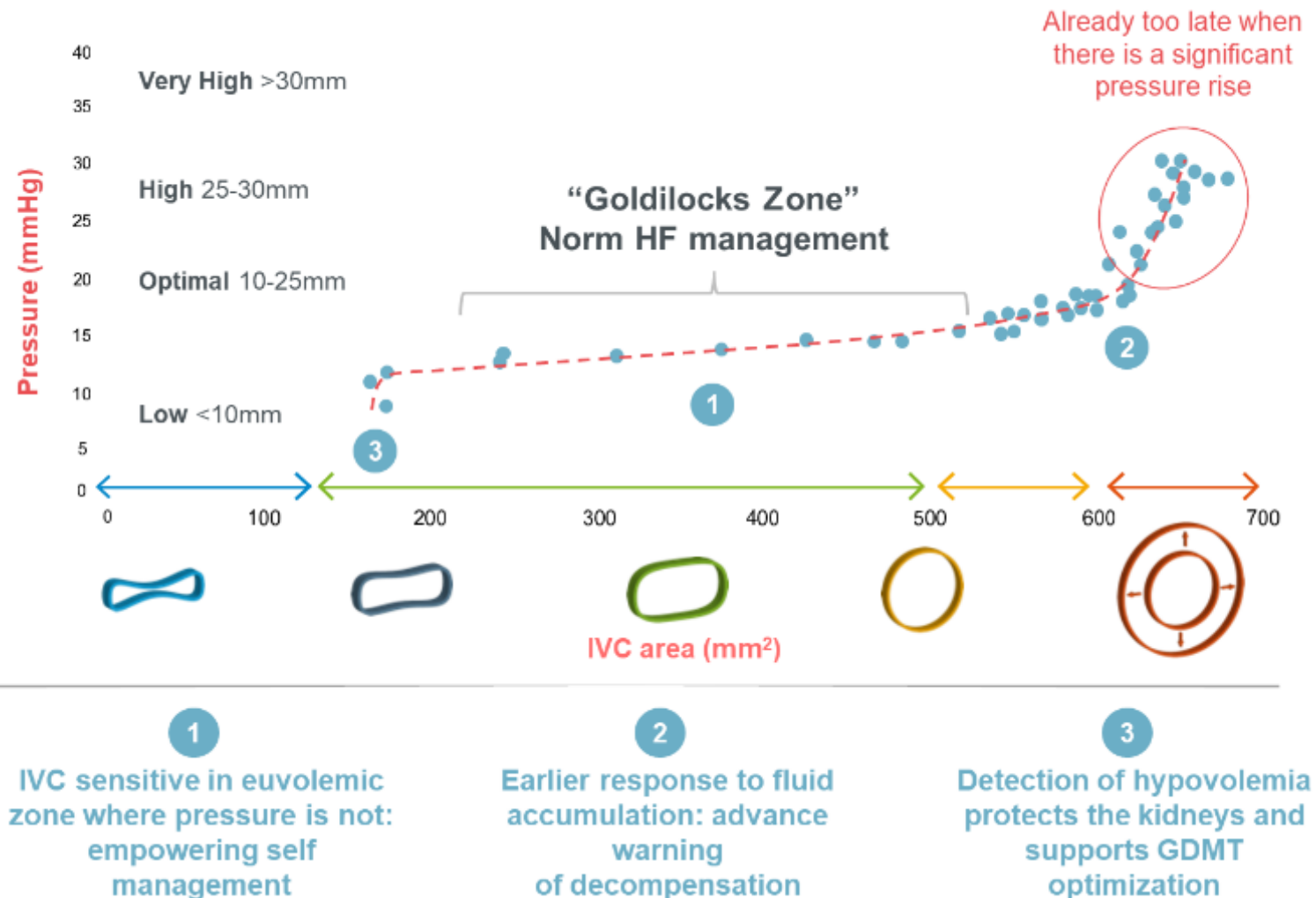
Implant procedure performed outside the heart

Broad range of physicians who can implant

Allows other interventions



Ambulatory measurements = unique insights e.g., HFpEF



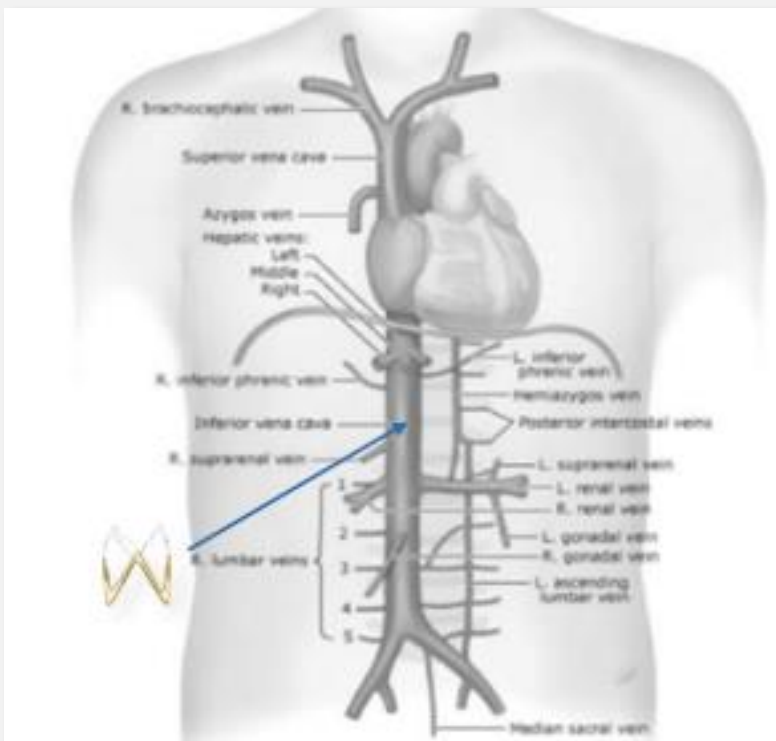


Patient empowerment

The world's first direct measure of intravascular volume status



reddot winner 2024



The sensor is deployed in
the Inferior Vena Cava (IVC)

Our software applications
empower the patient and
enable Clinician-Directed
Patient Self Management

Our algorithms identify clinically
relevant trends and escalate to
the Clinical Teams only when
necessary

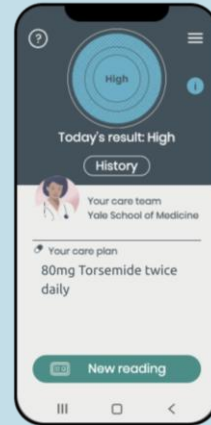
NORM™ patient-centric workflow

Wireless belt and patient self management

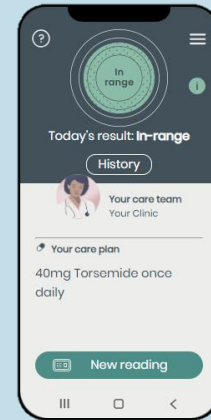
Patient Takes Daily Reading



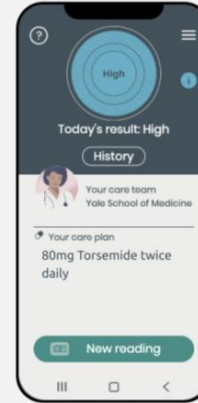
Patient receives elevated dose message



Patient receives standard dose message



If NORM™ signal remains high
Management escalates to HF care team



Reading returns to within range

Significant
clinician
workload
reduction as
patient self
manages

Exciting Results:

Growing Clinical Experience

OUS: 50 Patients
US: 18 Patients

>1600 patient months
follow up without
sequelae

>35,000 days home
Readings

>382 follow up visits

Longest follow up
period > 5 years

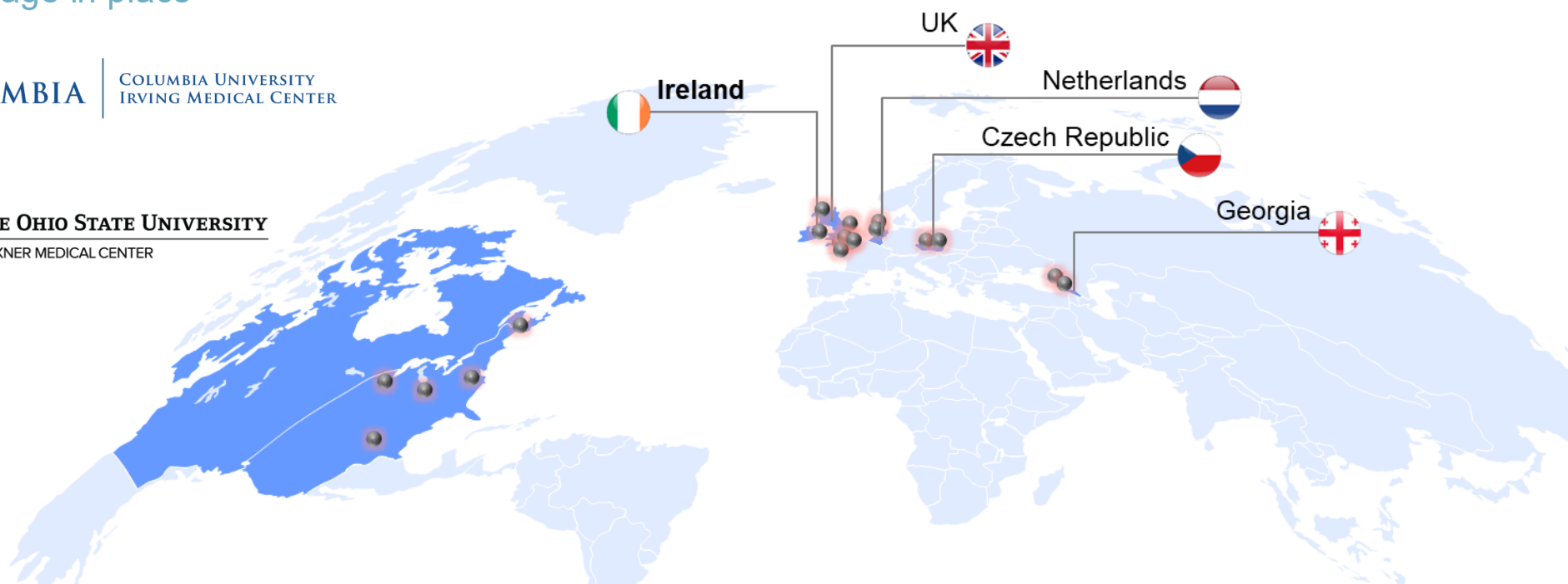
FUTURE HF2 (US EFS)

NCT05763407 Category B coverage in place



FUTURE HF (EU FIH)

NCT04203576



Backed by leading clinicians

Growing Clinical Experience



Mandeep Mehra, MD- Senior Medical Advisor

William Harvey Distinguished Chair in Advanced Cardiovascular Medicine and a professor of medicine at Harvard Medical School and medical director of the Brigham Heart and Vascular Center in Boston, Massachusetts.



Nir Uriel, MD- National PI FUTURE HF 2

Professor of Medicine at Columbia University Irving Medical Center and Weill Cornell Medicine, and the Director of the New York Presbyterian Heart Failure, Heart Transplant and Mechanical Circulatory Support (MCS) Programs.



Jeffery Testani, MD- Clinical Advisor

Professor of Medicine and director of Heart Failure Research at Yale University. He is trained as an advanced heart failure and cardiac transplantation cardiologist. Dr. Testani runs a large research program focusing on cardio-renal interactions and diuretic resistance in heart failure.



Publications

US EFS STUDY(n=15):

Safety and Feasibility of an Implanted Inferior Vena Cava Sensor for Accurate Volume Assessment: FUTURE-HF2 Trial URIEL, NIR et al. Journal of Cardiac Failure, Volume 31, Issue 2, 369 - 376

<https://doi.org/10.1016/j.cardfail.2024.09.003>

EU FIH Study (n= 50):

Kalra, P, Gogorishvili, I, Khabeishvili, G. et al. First-in-Human Implantable Inferior Vena Cava Sensor for Remote Care in Heart Failure: FUTURE-HF. J Am Coll Cardiol HF. <https://doi.org/10.1016/j.jchf.2025.01.019>

Preclinical data

[Safety and Accuracy EJHF](#)

[Sensitivity vs Pressure EJHF](#)

Case Studies and Editorials

[Case Study](#)

[Editorial 1](#)

[Editorial 2](#)



Recent publications

US EFS STUDY(n=15):


Safety and Feasibility of an Implanted Inferior Vena Cava Sensor for Accurate Volume Assessment: FUTURE-HF2 Trial URIEL, NIR et al. Journal of Cardiac Failure, Volume 31, Issue 2, 369 - 376

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Pivotal Trial Design

Target start date Q1 2026

80 sites

(Majority US, some in key European markets)

800 Patients – strong evidence

Prospective, multicenter, randomized controlled trial with blinded adjudication of endpoints

Treatment arm

Physician directed self-management based on NORM readings

Control arm as SOC

- Minimizes interactions
- Reduces placebo effect
- Maximizes effect size

Primary Efficacy Endpoint

- Composite of
- CV MORTALITY
 - HFH

(hard endpoints for FDA, clinical adoption, payors)