www.gasgonmedical.com

#### CLINICAL EVALUATION STUDY





Gasgon Medical is an award winning Irish startup company based in Cork and was founded by Vincent Forde in 2018, Gasgon is motivated to tackle the challenges of making IV infusions better for patients and clinicians and strives towards a future where all IV medicine can be infused with confidence. Working directly with doctors, nurses and caregivers, learning through their frontline experience, they are developing specific tools to improve patient experience and clinical outcomes. Gasgon has recently raised €2.25m in funding to launch its AirVault technology.



# About Health Innovation Hub Ireland

Health Innovation Hub Ireland (HIHI) was established by the Department of Business, Enterprise and Innovation and the Department of Health and is supported by Enterprise Ireland (EI) and the Health Service Executive (HSE) to drive collaboration between the health service and enterprise. We offer companies the opportunity for pilot and clinical evaluation studies and we provide the health service access to innovative products, services and devices that they may not otherwise be exposed to. HIHI is built on the recognition that collaboration with enterprise can benefit patient care, patient pathways and outcomes.

We assess all concepts for healthcare innovation from those on the frontline – from clinician to porter. We encourage healthcare professionals to get in touch with HIHI if they have an idea or solution to how something in your job might work better.



## The Healthcare Challenge

Intravenous (IV) infusion of fluids and medicines is the most common invasive medical procedure, with over 80% of hospital inpatients receiving one and billions performed globally every year. Air bubbles in IV infusion lines can carry serious risk to both patients and healthcare workers.

Air is foreign to our vascular system and if air bubbles enter a patient's vein it could result in serious health complications. The removal of air bubbles in chemotherapy IV lines can also expose healthcare workers to harmful drugs which can lead to fertility issues and cancer.



## The Healthcare Solution

Gasgon has developed a novel closed-system air trap, the AirVault. As a single-use device, AirVault is designed to provide a safe, easy and effective technology to prevent the impact of Air-in-Line, a common disruptor of infusion therapy, which will result in improved safety for patients and healthcare staff. Gasgon has just frozen its design so that it can focus on a multi-centre study designed to capture clinical evidence and contribute towards CE mark and FDA accreditation.



### HIHI Role

Gasgon Medical approached HIHI to get feedback on its AirVault medical device from clinical experts to ensure it will meet the needs of healthcare professionals and their patients. Through its clinical network, HIHI identified suitable clinicians to attend five focus groups in three different hospitals in Cork and Dublin. HIHI facilitated the focus groups, advised on the key questions which were addressed by over 35 experts in nurse practice

development, nursing management, infection control, oncology, pharmacy, quality risk management and biomedical engineering. The company received valuable feedback and suggestions, which assisted them in the final design of the AirVault. The clinical feedback also highlighted other use-cases for this technology which HIHI is currently helping the company to explore.

## **Outcome Report**

The outcomes of this clinical evaluation study were:

- Extremely valuable clinical feedback on the working
  AirVault prototype which confirmed that the device
  addresses the needs of patients and healthcare staff and
  gave Gasgon insights on how to optimise the design
  for end-users, with further development leading to a
  freeze of the product design. With confidence in the final
  product Gasgon was able to proceed with manufacturing,
  regulatory tasks and clinical trials.
- The proposal of two sites in Cork and Dublin to pilot the AirVault once it has been awarded its CE mark.
- The identification of additional use-case for the AirVault technology. HIHI is supporting Gasgon Medical with a follow-on focus group with clinical experts with other expertise to explore this opportunity.



#### **Testimonial**

HIHI has been a significant contributor to our product development by facilitation of access to targeted clinical end users. This action has fast-tracked our AirVault product development and resulted in necessary and important design improvements. From our clinical engagement sessions across multiple sites, the benefit of having so many voices was invaluable and appropriate actions were then possible to improve the overall design, positioning and market approach of the company. I can honestly state that this support from HIHI has been fundamental in our company's success, leading to a more effective product and subsequent investor confidence. The HIHI team have proven to be effective, reliable and enthusiastic in their support for Gasgon Medical, with the ability to connect us into the desired contact points in the Irish healthcare system, while acting with an impeccable level of professionalism. We look forward to continuing to work with HIHI in our planned pilot studies in Irish hospitals in 2023.

Vincent Forde,



HIHI (UCC)