



# Bell Potter Healthcare Conference Investor Presentation

ASX:4DX

9 November 2021

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# Executive summary

**4DMedical is a software company creating a step change in the capacity of physicians to diagnose and manage patients with lung disease via its four-dimensional lung imaging platform - XV Technology™**

- Focused on commercialising our flagship XV Lung Ventilation Analysis Software (XV LVAS™), which utilises mathematical models and algorithms to convert X-ray images into quantitative scan data
- Clinically validated to provide non-invasive analysis of regional lung motion and airflow in real-time

**Global respiratory diagnostic market represents a ~US\$31 billion per annum opportunity**

- Approximately 377 million respiratory diagnostics tests performed per annum globally
- Existing lung diagnostics are decades out of date, not fit for purpose and ripe for displacement
- Initial focus on the U.S. respiratory diagnostic market worth US\$13.7 billion per annum

**Company is well funded to execute on commercialisation strategy**

- Offering is focused on improving hospital and patient outcomes with limited capex requirements
- Capital light business model with rapid SaaS deployment – expected >90% gross margin
- Significant barriers to entry: first mover, strong IP portfolio and advanced product pipeline
- Strong balance sheet, with A\$72.2m cash in bank as at 30 September 2021

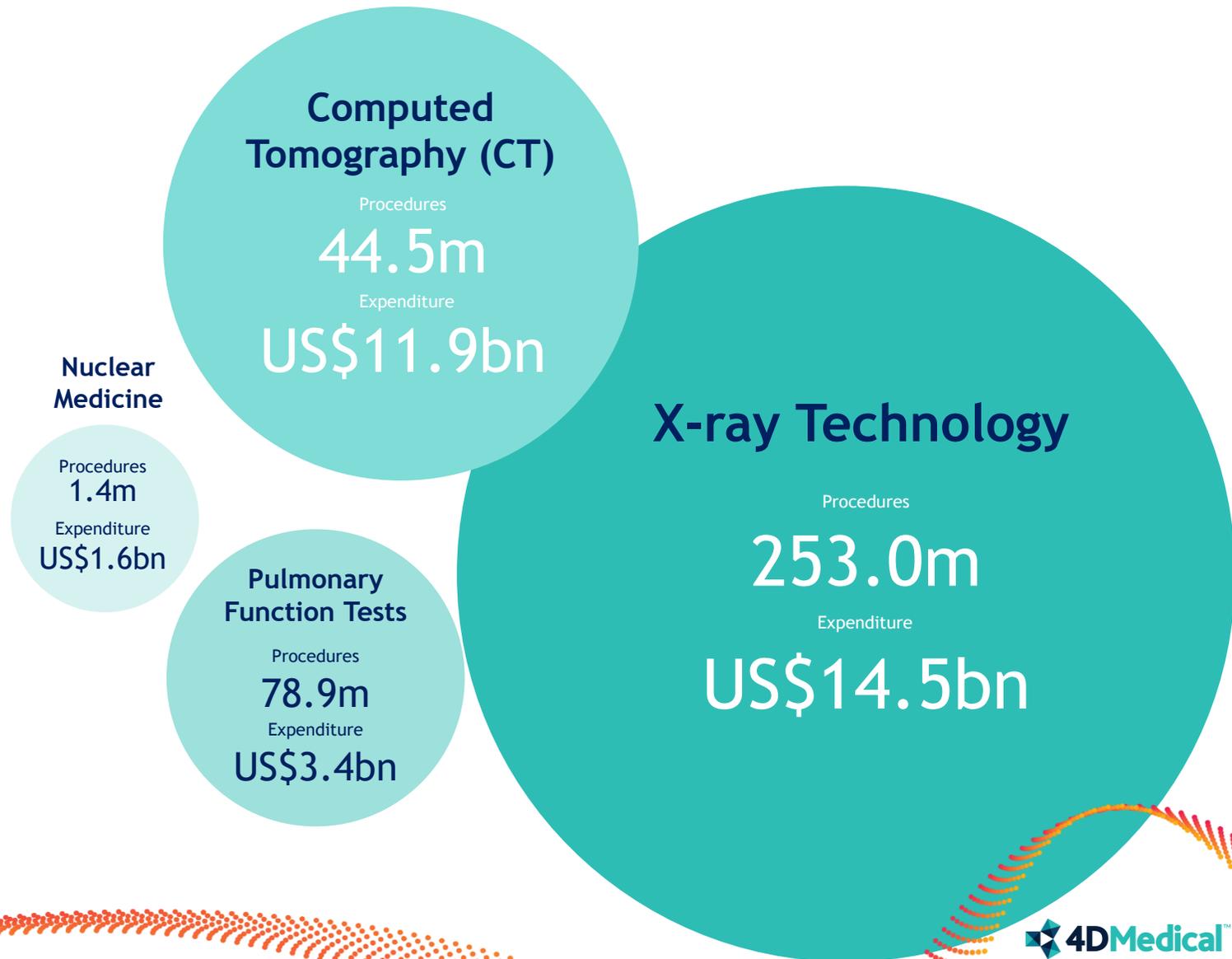


# Respiratory Diagnostics Market Overview

# Global lung diagnostics market

## ~US\$31 billion global lung diagnostics market opportunity ripe for disruption

- Initial focus is on penetrating the U.S. and Australian markets representing a US\$13.7bn and US\$285m opportunity respectively
- Given the large market size, even low market penetration could lead to substantial revenue generation with high gross margin
- Respiratory diagnostic technologies are out of date having made insignificant advancements over the last 50 years
- Approximately 99% of all lung diagnostics are made up of thoracic X-ray, thoracic CT, PFTs and nuclear medicine
- Current diagnostics trade off accuracy, sensitivity, cost and radiation exposure, while failing to provide a comprehensive insight into the form and function of the patient's lungs

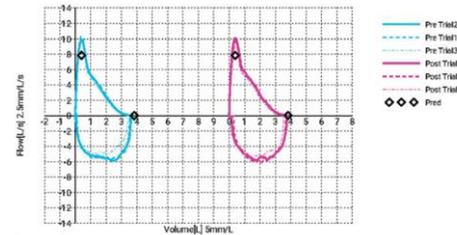


# Spirometry & PFT

## Accurate but insensitive

### Overview

- Invented in 1846
- 1-dimensional technology
- Current benchmark in lung diagnostics
- #2 lung diagnostic in U.S. with ~12.2m tests performed in 2019 (~17% of all lung diagnostic procedures)



### Average estimated cost\*

- Spirometry: US\$72
- Complete PFT: US\$750

### Advantages

- Functional
- Accurate
- Zero dose
- Non-invasive
- Low cost (Spirometry)

### Limitations

- Insensitive (quantifies the whole of lung as one averaged measure)
- Non-specific: requires 20% variance to be clinically significant resulting in late diagnosis
- Complete PFT expensive and time consuming
- Effort dependent (repeatability issues)
- Not applicable to all patient cohorts

# X-ray technology

## Inexpensive, but tells us very little about airflow

### Overview

- Invented in 1895
- 2-dimensional technology
- Widely used in clinics to determine changes in lung structure
- #1 lung diagnostic in U.S. with ~49.6m tests performed in 2019 (~67% of all lung diagnostic procedures)



### Average estimated cost\*

- US\$120

### Advantages

- 2-dimensional scan
- Ubiquitous
- Relatively inexpensive
- Low radiation dosage (0.1 mSv)

### Limitations

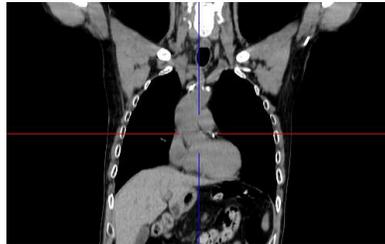
- Measures structure rather than function
- Limited clinical value
- Overlapping anatomy means features can be hidden and be missed
- Poor record in screening applications (e.g. lung cancer, and occupational diseases)

# Computed Tomography (CT)

Sensitive, but expensive and high radiation dose

## Overview

- Invented in 1971
- Considered the current gold standard in lung diagnostic testing
- #3 lung diagnostic in U.S. with ~10.9m tests performed in 2019 (~15% of all lung diagnostic procedures)



## Average estimated cost\*

- US\$525

## Advantages

- 3-dimensional scan (can't miss features)
- Sensitive
- High-resolution detail of images

## Limitations

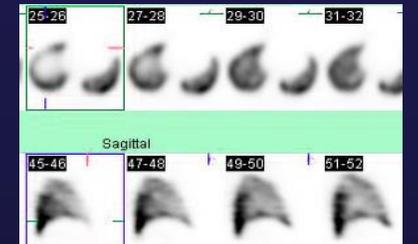
- Expensive: 4 times the cost of an X-ray
- High radiation dose: 70 times an X-ray (7 mSv); cancer risk for recurring exposure
- High rate of false positives (~95% in NLCST vs 3% mortality for surgery)
- Measures structure rather than function (requires skilled radiologist to infer function)
- Very high rate of utilisation based on availability

# Nuclear medicine

Capability to measure both ventilation and perfusion, but has significant limitations

## Overview

- Invented in 1963
- Ventilation-perfusion (VQ) scan uses dual radioactive agents to examine airflow and blood flow in the lungs
- #4 lung diagnostic in U.S. with ~780k tests performed in 2019 (~1.1% of all lung diagnostic procedures).



## Average estimated cost\*

- VQ Scan: US\$1,503

## Advantages

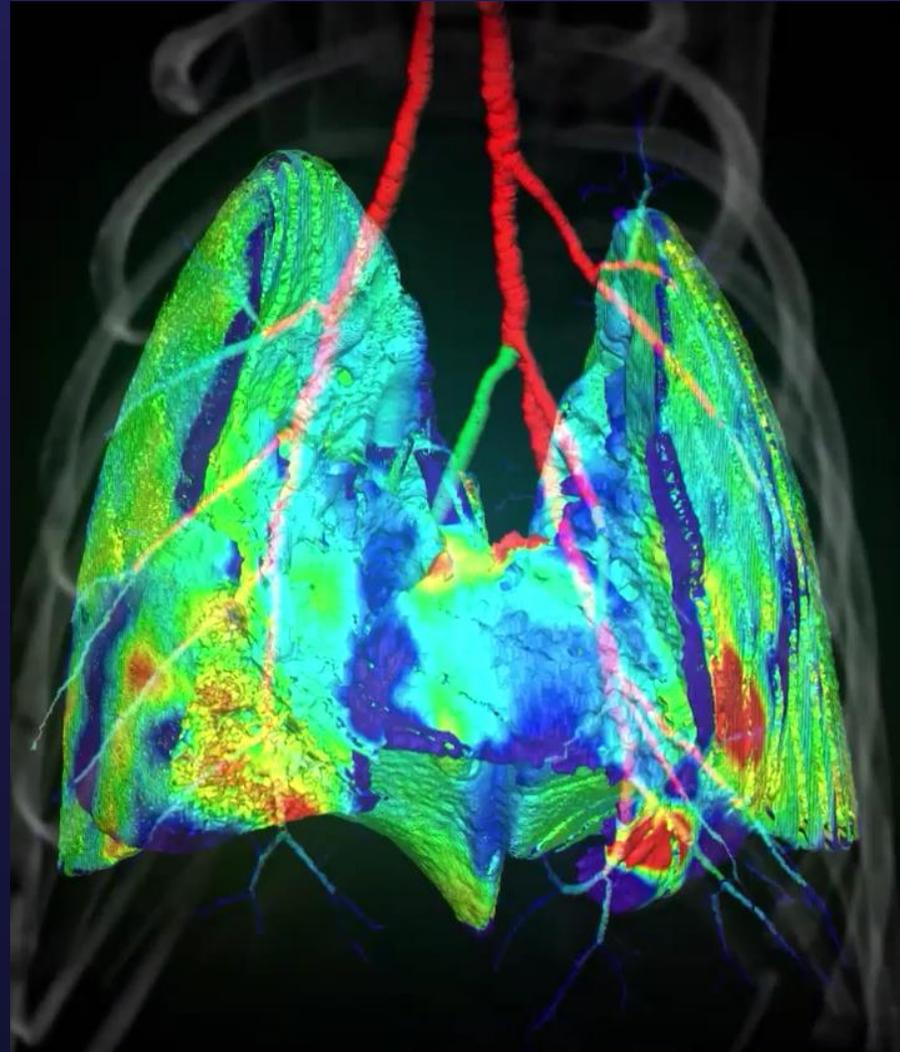
- Perfusion analysis capability
- Only modality that can identify ventilation-perfusion mismatch
- Importance in treating pulmonary embolism & hypertension

## Limitations

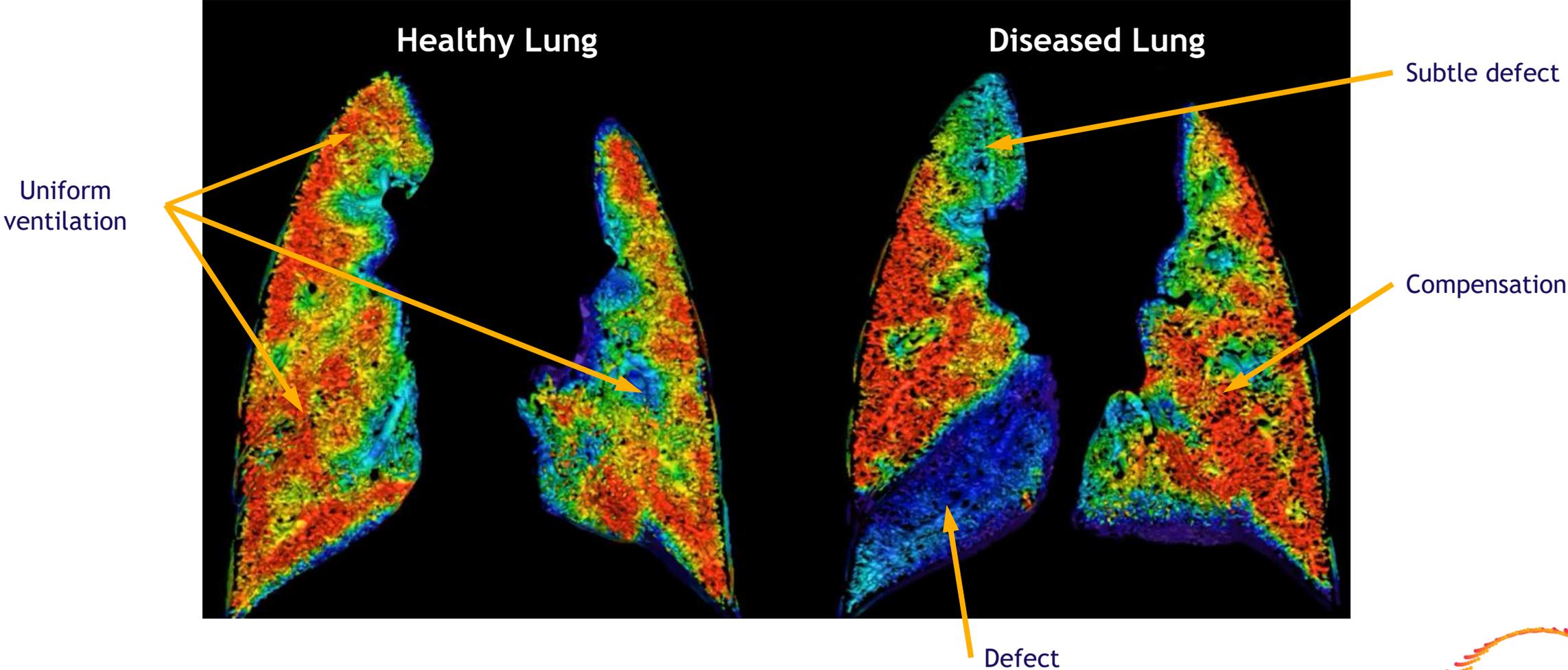
- High cost, poor resolution of outputs
- Time consuming (1 hour to complete)
- Use of dual radioactive particulate contrast agents raises toxicity concerns, particularly for those with pulmonary hypertension
- Expensive testing equipment needed
- Complex to administer, requires expert analysis, onerous safety precautions

# Introducing XV Technology™

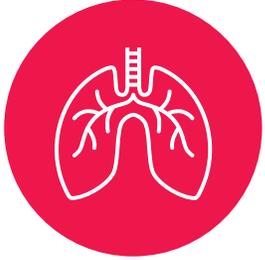
# Overview of XV Technology™



# XV Technology™ demonstration



# XV Technology™ value proposition



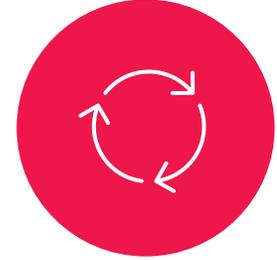
Superior lung health analysis to existing modalities



Non-invasive and fast imaging protocol (~5 mins)



Earlier diagnosis provides improved patient outcomes



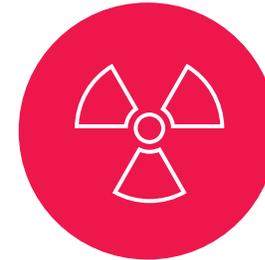
Seamless integration with radiology workstreams



Rapid integration (~5 days) leveraging existing hospital equipment



Cost effective for hospital with no additional capex



Low radiation dose and no contrast agents

# Support from key opinion leaders



“4DMedical lung imaging technology **provides a rare and exciting opportunity to improve lung health outcomes** for patients globally.”

**Professor Greg Snell**  
Head of Lung Transplant Service, Alfred Hospital



“Overall pulmonary airflow measurements do not provide information on regional airflow... **[4DMedical’s] technology will help physicians monitor the specific airways involved in asthma accurately**, enabling us to understand and treat disease in a more targeted manner.”

**Kewal Asosingh Ph.D.**  
Associate Professor of Pathobiology, Cleveland Clinic



“[4DMedical’s technology] is a breakthrough in understanding how the lungs work... **For the first time ever, we can look at lung structure and lung function together** by visualising and measuring airflow at tiny levels in the lungs.”

**Professor Adam Jaffe**  
Professor of Pediatrics, University of New South Wales



“There are many advantages to 4DMedical’s technology over existing diagnostic techniques, including the **ability to estimate regional ventilation, the high-level resolution image outputs, reduced image acquisition time and significant reduction in radiation exposure** and no use of contrast agents.”

**Naresh Punjabi M.D. Ph.D.**  
Chief of Pulmonary, Critical and Sleep, University of Miami School of Medicine

# Company Overview

# Recent milestones & announcements

4DMedical has achieved several important commercial milestones in the last 12 months

## August 2020

Successful Initial Public Offering (IPO) on the ASX, raising \$50 million

## October 2020

AusIndustry approved finding to receive tax credits for up to 43.5% of eligible overseas R&D expenditure

## December 2020

First commercial use of XV LVAS to a patient based in Victoria, Australia

## February 2021

ALHI awarded \$28.9m of funding under MRFF Frontiers initiative.  
Completed \$46 million Placement & SPP

## May 2021

Commenced first clinical trial for its contrast-free Ventilation Perfusion (VQ) product

## September 2020

Received TGA approval for XV LVAS for all respiratory indications

## November 2020

Secured research partnership with University of Miami in the U.S.

## January 2021

Secured first clinical pilot for XV LVAS at St. Joseph Hospital in the U.S.

## March 2021

Streamlined access to U.S. Department of Defense & Veterans Affairs contracts

## June 2021

Commenced XV LVAS clinical trial at Johns Hopkins, bringing the total number of active trials to eight

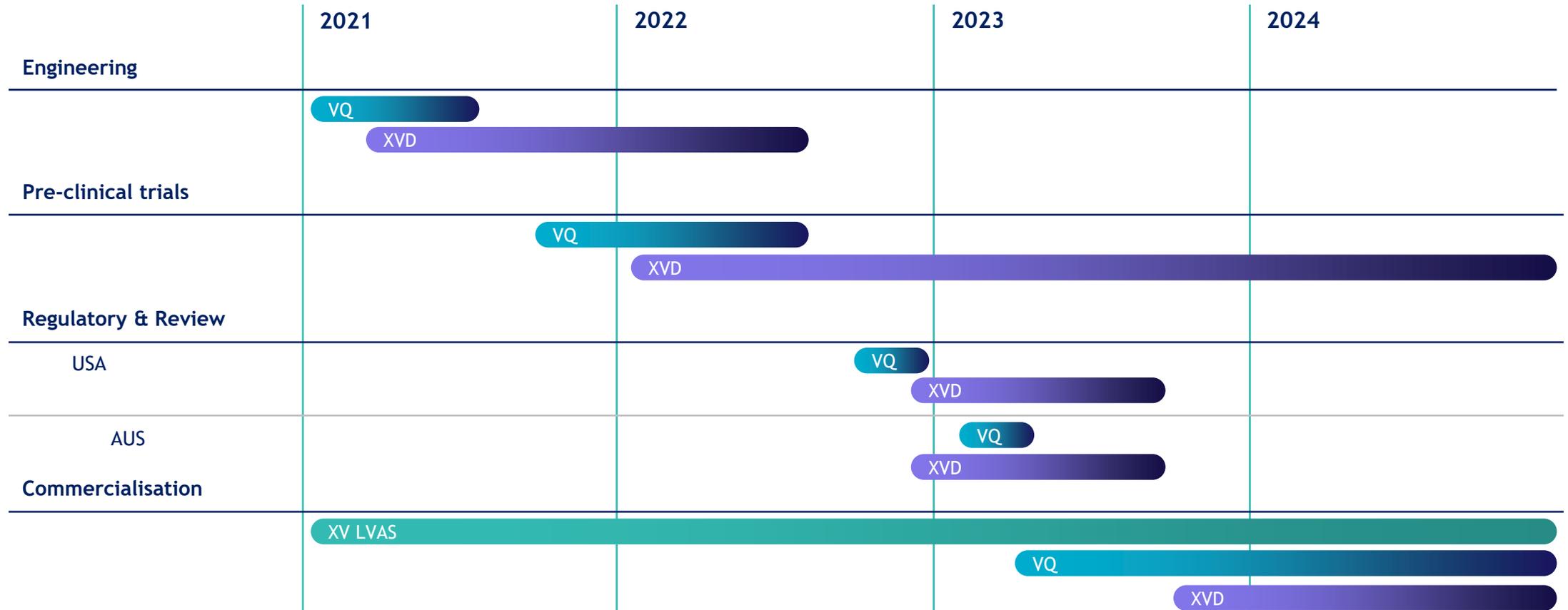
# Product pipeline

4DMedical's products are designed to improve patient outcomes for lung disease sufferers

	1 XV LVAS XV Lung Ventilation Analysis Software	2 VQ Ventilation Perfusion	3 XVD Scanner XV Dedicated Lung Scanner
Overview	<ul style="list-style-type: none"> <li>Quantifies regional lung function at all locations in the lungs during active breathing</li> <li>FDA-cleared and TGA approved</li> </ul>	<ul style="list-style-type: none"> <li>Evaluates airflow and blood flow in the lungs without the use of radioactive or contrast agents</li> </ul>	<ul style="list-style-type: none"> <li>The world's first dedicated lung function scanner enabling both XV LVAS and VQ outputs</li> </ul>
Benefits	<ul style="list-style-type: none"> <li>Low barrier to market entry, utilising existing fluoroscopy equipment</li> <li>Low dose, high-sensitivity data</li> </ul>	<ul style="list-style-type: none"> <li>Easy to administer, faster &amp; simpler than existing diagnostic technology</li> <li>No contrast agent reduces patient harm</li> </ul>	<ul style="list-style-type: none"> <li>Leverages existing market take-up of XV Technology</li> <li>Reduced radiation dose, increased scanning throughput and broadened patient cohort</li> </ul>
Use cases	<ul style="list-style-type: none"> <li>Asthma</li> <li>Cystic fibrosis</li> <li>Chronic obstructive pulmonary disease</li> <li>Chronic bronchitis</li> <li>Lung transplant</li> <li>Constrictive bronchiolitis</li> </ul>	<ul style="list-style-type: none"> <li>Pulmonary embolism</li> <li>Pulmonary hypertension</li> </ul>	<ul style="list-style-type: none"> <li>Both XV LVAS and VQ indications in both adults and children</li> </ul>
Competing technologies	<ul style="list-style-type: none"> <li>X-ray</li> <li>Computed Tomography (CT)</li> <li>Pulmonary Function Tests (PFTs)</li> </ul>	<ul style="list-style-type: none"> <li>Nuclear V/Q scan</li> <li>CT Pulmonary Angiogram (CTPA)</li> </ul>	<ul style="list-style-type: none"> <li>X-ray</li> <li>CT</li> <li>PFTs</li> <li>Nuclear V/Q scan</li> <li>CTPA</li> </ul>

# Product milestones

Strategically planned to build upon the previous products target indications and market opportunity



**Notes:**

- XVD Scanner (Gen 1) milestones; and
- VQ product line includes CFPA capabilities.

# Commercialisation Strategy

# Commercialisation strategy

Two pillars of 4DMedical's commercialisation strategy to secure market share and scale

## Clinical trials



Research partners delivering the body of scientific evidence for clinical use

### Who

Eminent researchers & leading medical institutes

### Why

Diagnostics, treatment efficacy, monitoring, disease progression & more

### Outcome:

- Scientific investigation into case applications
- Publishing medical manuscripts and presenting research to industry

Study design: Full scientific method per researcher

## Clinical pilots



Physicians gaining familiarity with XV Technology and insights for patient care

### Who

GPs, respiratory specialists, imaging centres & hospitals

### Why

Assess regional lung function for patient management

### Outcome:

- Clinical familiarisation with XV Technology
- Feasible new use of existing X-ray equipment (imaging centres)

Pilot design: Tiered per facility & physician interest

# Commercialisation roadmap

Each strategy supports broad market adoption and uptake of XV Technology



# Clinical trial pipeline

Each trial is conducted to the highest scientific standards under ethics oversight by Institutional Review Boards (IRB)

Steps in each clinical trial:

- 1 Collaboration Agreement Executed
- 2 Study Design Approved
- 3 Budget Approved
- 4 IRB Approved
- 5 Patient Recruitment
- 6 First Imaging
- 7 Final Imaging
- 8 Study Complete

PH

Cleveland Clinic

VQ

Patient Recruitment

1 2 3 4 5 6 7 8

Lung Transplant

Duke University

XV LVAS

First Imaging

1 2 3 4 5 6 7 8

CB (Veterans)

Vanderbilt University

XV LVAS

First Imaging

1 2 3 4 5 6 7 8

COPD

Johns Hopkins

XV LVAS

First Imaging

1 2 3 4 5 6 7 8

COPD

Oregon Health & Science University

XV LVAS

First Imaging

1 2 3 4 5 6 7 8

COPD

University of Miami

VQ

First Imaging

1 2 3 4 5 6 7 8

Bronchoscopic

University of Miami

XV LVAS

First Imaging

1 2 3 4 5 6 7 8

Pediatric CF

Johns Hopkins

XV LVAS

Patient Recruitment

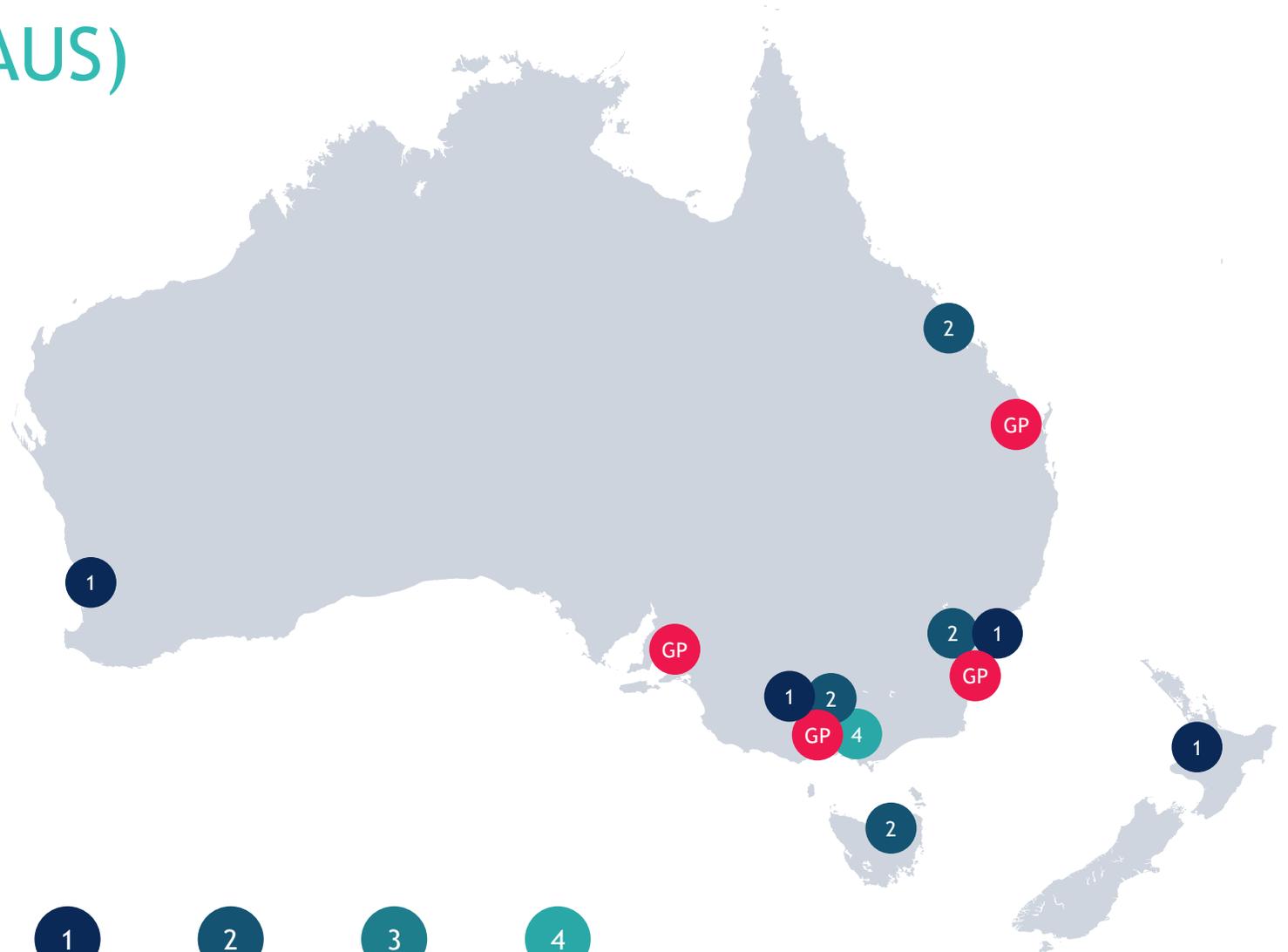
1 2 3 4 5 6 7 8

# Clinical pilot pipeline (AUS)

Since expanding the sales team we have rapidly built a strong pipeline of clinical pilot demand

## Types of pilot partners:

- Capital city hospitals
- Major regional hospitals
- National imaging centre
- Respiratory specialist health services
- GP practitioners



Primary care project



Pilot in development



Pre-pilot agreement



Pilot agreement executed/active



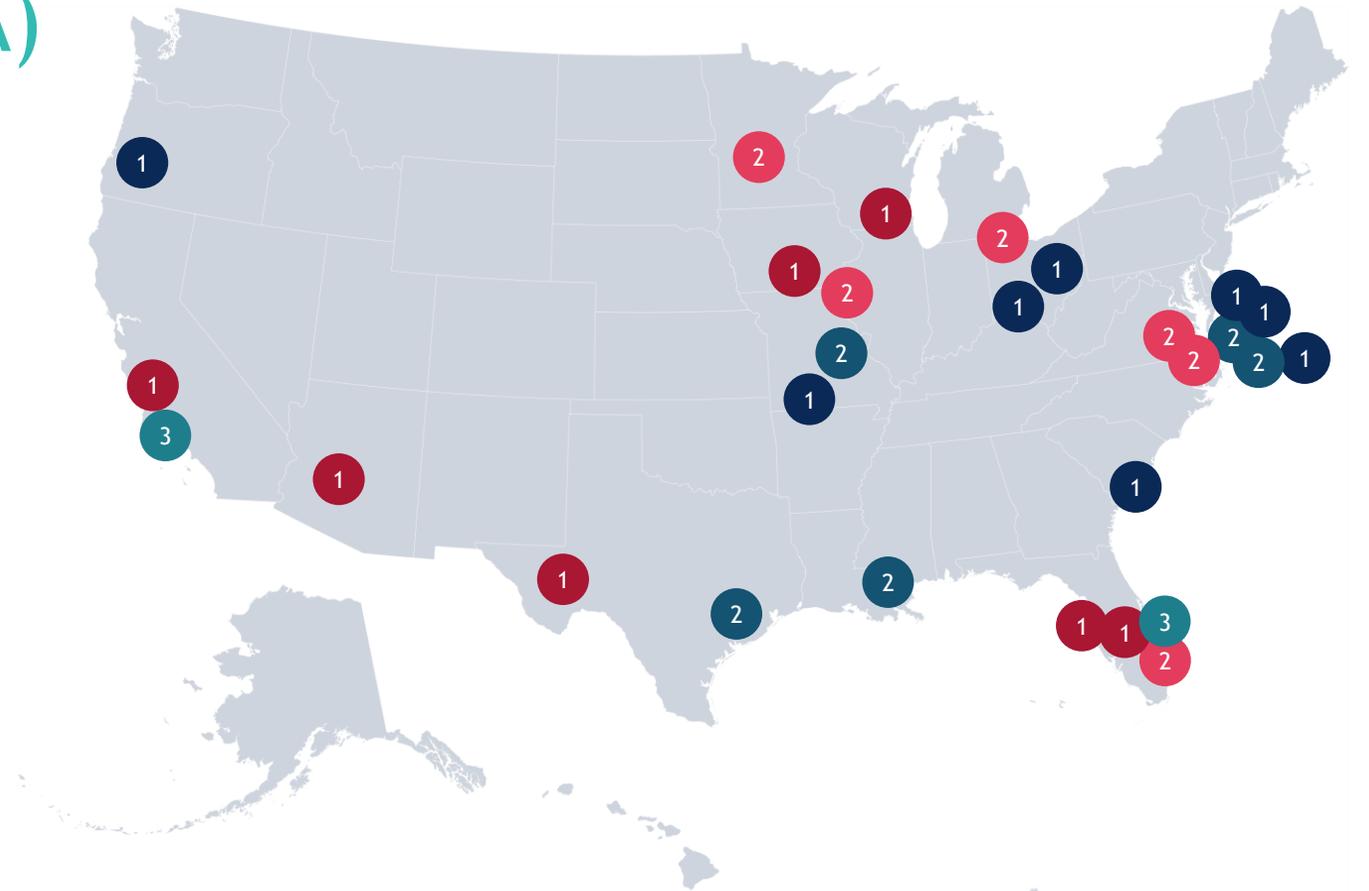
Post pilot reporting

# Clinical pilot pipeline (USA)

Since expanding the sales team we have rapidly built a strong pipeline of clinical pilot demand

## Types of pilot partners:

- Capital city hospitals
- Major regional hospitals
- National imaging centre
- Respiratory specialist health services
- GP practitioners



## Acute Hospital Network

1

Pilot in development

2

Pre-pilot agreement

3

Pilot agreement executed/active

## Veterans Affairs Hospital Network

1

Pilot in development

2

Pre-pilot agreement

3

Pilot agreement executed/active

# Example case study (1)

## Summary

Patient unable to complete spirometry. Strong pain on the right side. XV LVAS demonstrated an unexpected, dramatic loss of ventilation function in the right lung. Physician was then able to prescribe appropriate treatment.

## Age

45

## Indications

- Biopsy-proven silicosis
- Ex-smoker
- Right-sided chest discomfort with breathing

## Sex



## Clinical observations

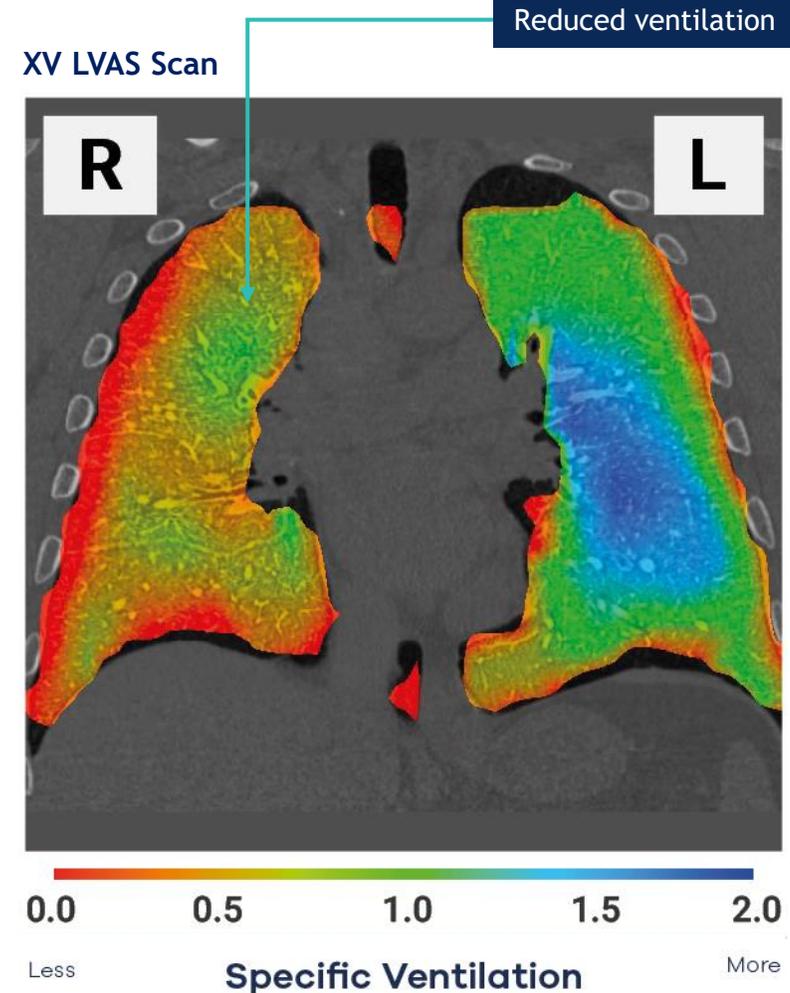
### XV LVAS:

Asymmetry in regional lung ventilation, with relative reduction in peri-hilar hyper-ventilation on right side.

### Ventilation heterogeneity

32.6	<b>66.4</b>	42.7
Small scale	Total	Large scale

VDP:	Tidal volume:
20.2%	0.41L



# Example case study (2)

## Summary

CT imaging indicated a large hiatus hernia. XV LVAS demonstrated a greater functional reduction in ventilation than expected from CT changes.

Age 69

## Indications

- Past history of COVID-19
- Gastric Oesophageal Reflux Disease
- Recurrent chest infections

Sex



## Clinical observations

### XV LVAS:

Relative reduced ventilation in left lower zone due to mass-effect from hernia (non-obstructive atelectasis). Not fully appreciated on CT scan.

### Ventilation heterogeneity

46.6	<b>91.9</b>	54.0
Small scale	Total	Large scale

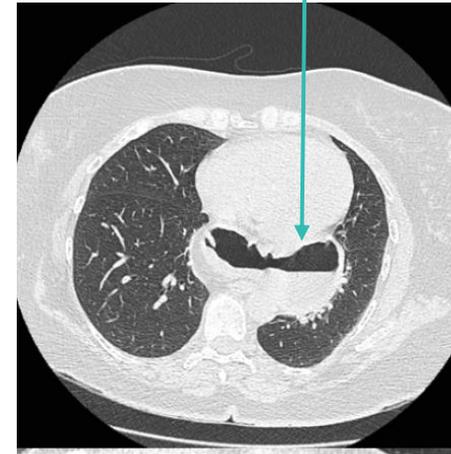
VDP:

26.9%

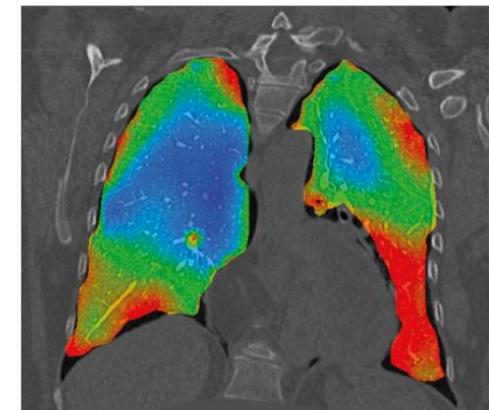
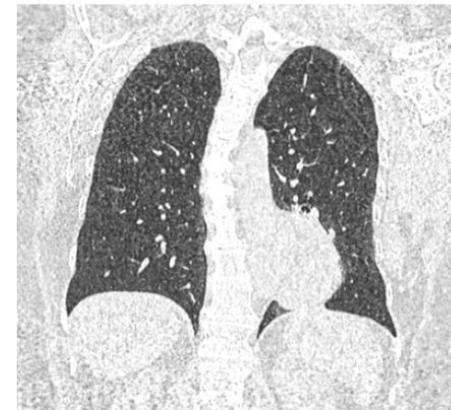
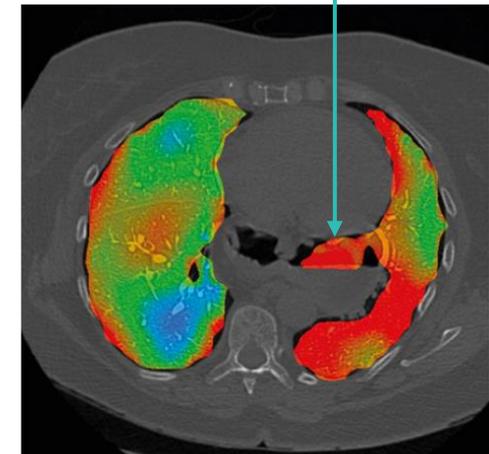
Tidal volume:

0.38L

CT Scan



XV LVAS Scan



# Summary

Strong product pipeline

XV Technology™ commercialisation maturing

FY21 delivered significant milestones at fantastic pace

Our foundations for commercialisation, and focus for FY22:

1. Clinical trials, and
2. Commercial pilots,

providing support for a solid sales pipeline (and conversion of paying customers)

Questions?