Bell Potter Healthcare Conference Investor Presentation

ASX: 4DX

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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- Existing lung diagnostics are decades out of date, not fit for purpose and ripe for displacement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

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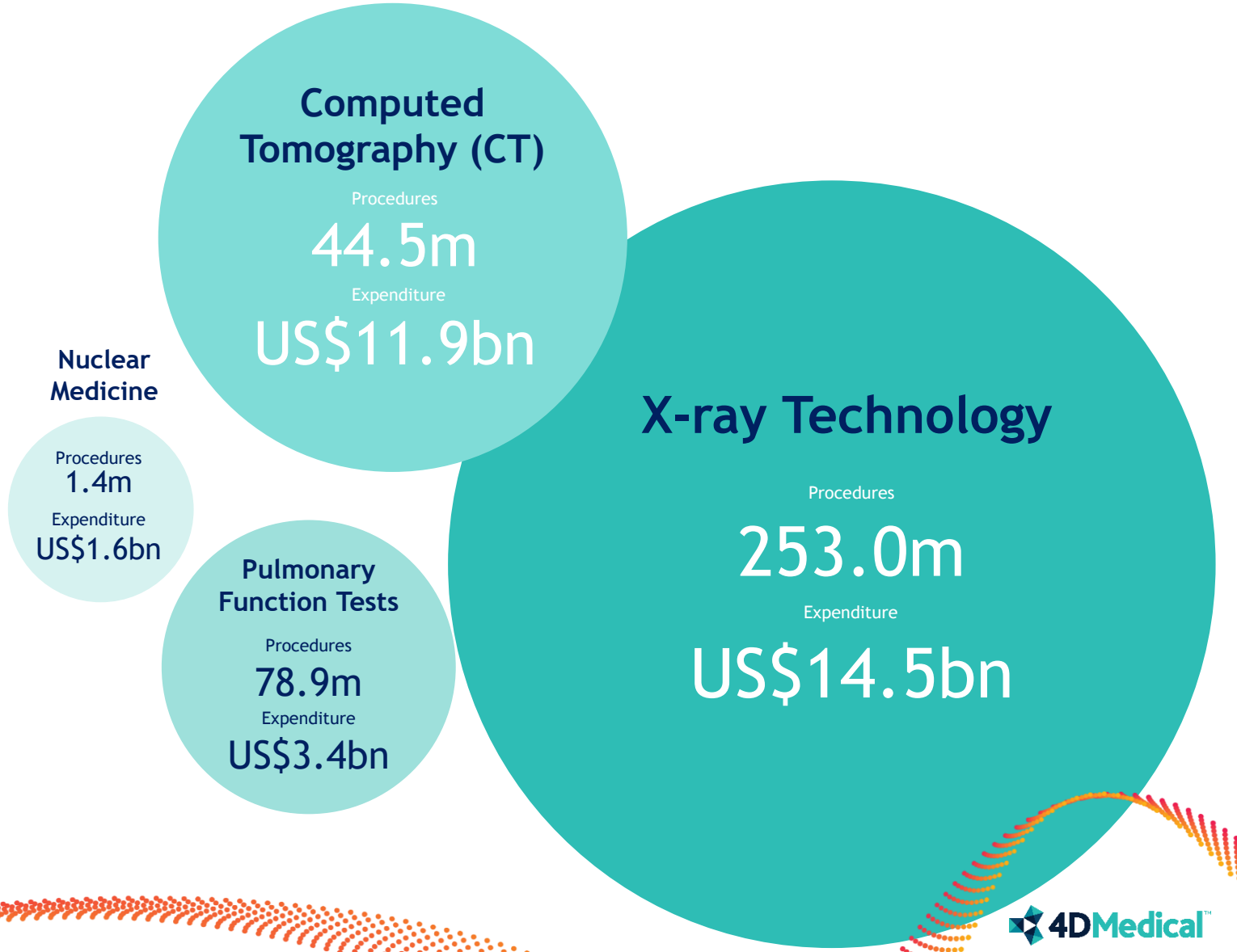
Respiratory Diagnostics Market Overview

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- Respiratory diagnostic technologies are out of date having made insignificant advancements over the last 50 years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

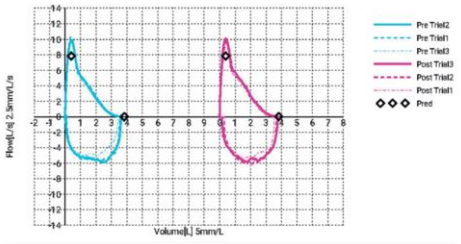


Frost & Sullivan 2020 (per annum)

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

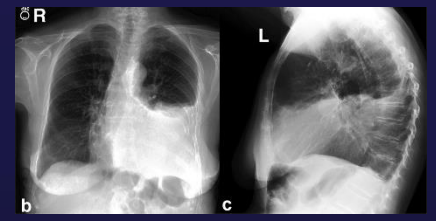
Advantages
- Functional
- Accurate
- Zero dose
- Non-invasive
- Low cost (Spirometry)

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)

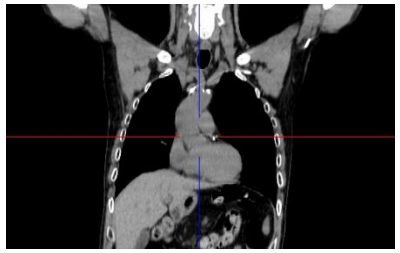
*Frost & Sullivan 2020

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

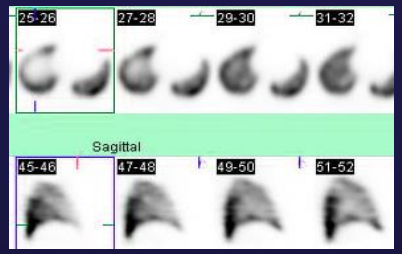
- Expensive: 4 times the cost of an X-ray
- High radiation dose: 70 times an X-ray (7 mSv); cancer risk for recuring exposure
- High rate of false positives (~95% in NLCST vs 3% mortality for surgery)
- Measures structure rather than function (requires skilled radiologist to infer function)
- Very high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

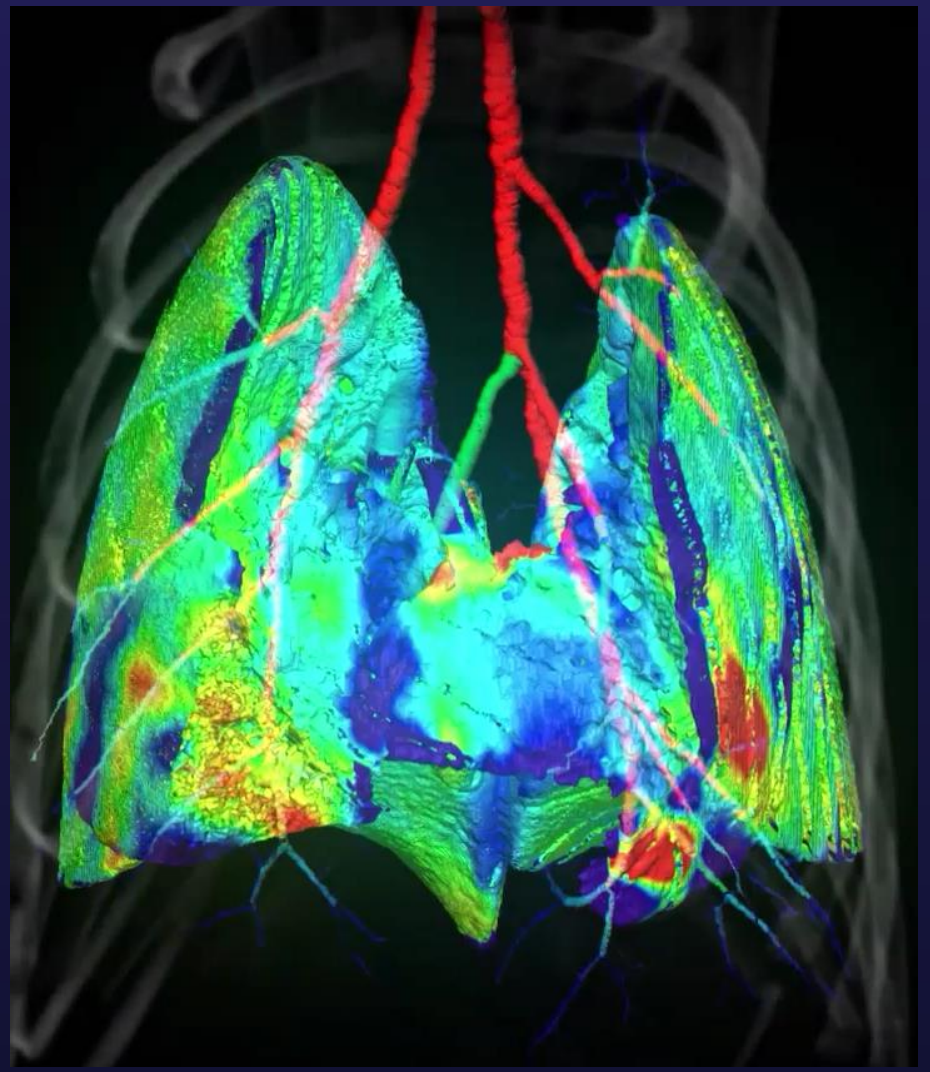
Limitations

- 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

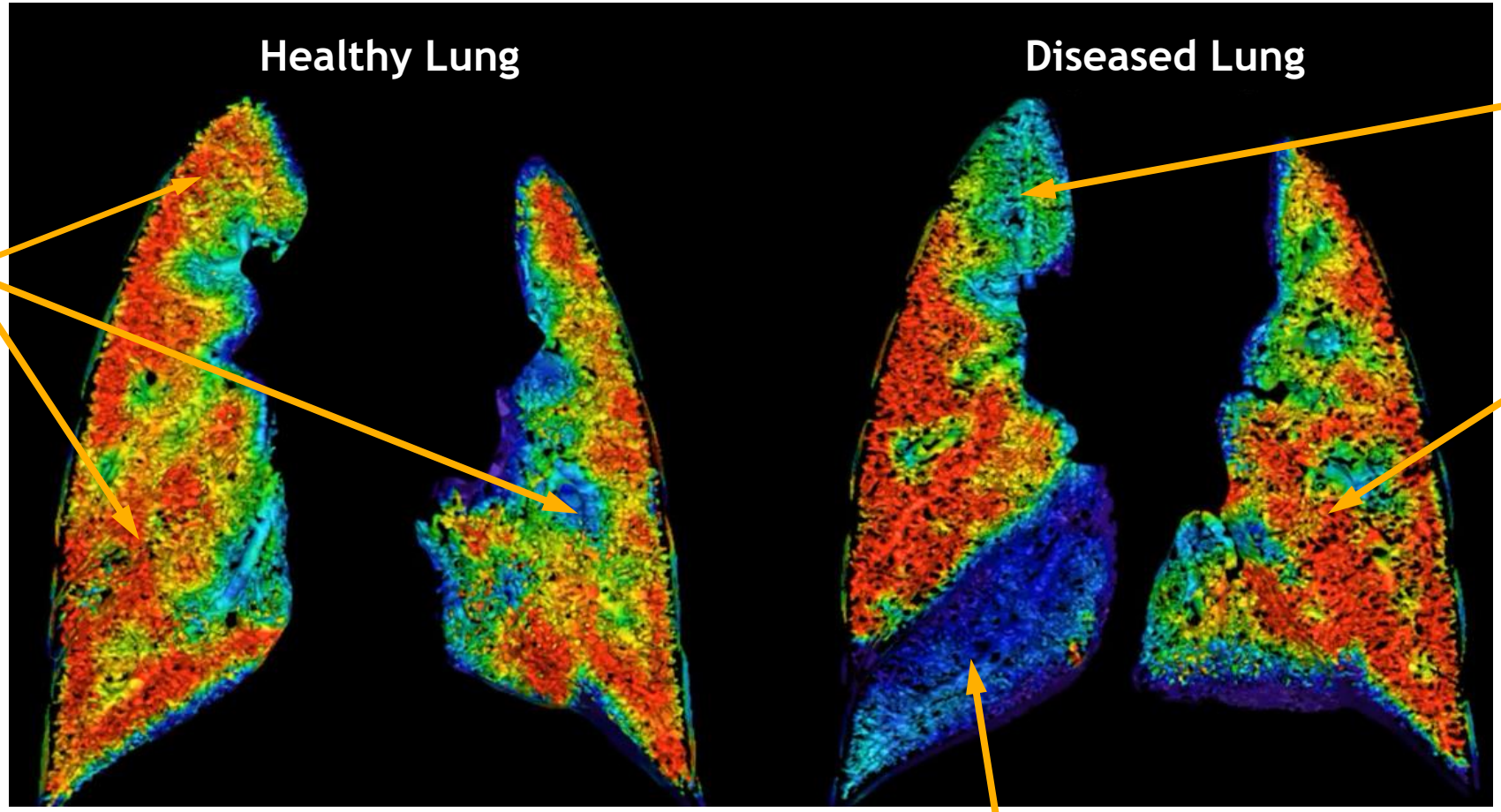
*Frost & Sullivan 2020

Introducing XV Technology™

Overview of XV Technology™



XV Technology™ demonstration



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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

September 2020

Received TGA approval for XV LVAS for all respiratory indications

October 2020

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

November 2020

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

December 2020

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

January 2021

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

February 2021

ALHI awarded $28.9m of funding under MRFF Frontiers initiative.

Completed $46 million Placement & SPP

March 2021

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

May 2021

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

June 2021

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

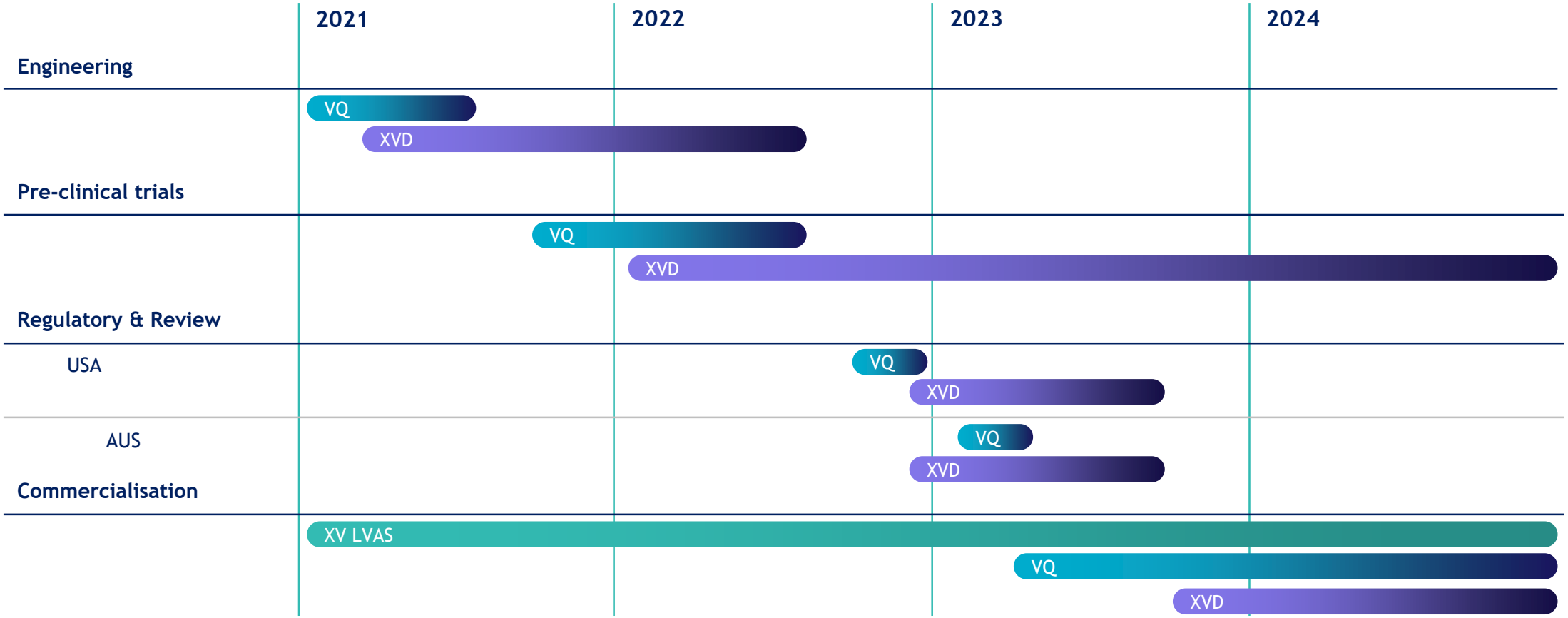
Product pipeline

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	• Quantifies regional lung function at all locations in the lungs during active breathing • FDA-cleared and TGA approved	• Evaluates airflow and blood flow in the lungs without the use of radioactive or contrast agents	• The world's first dedicated lung function scanner enabling both XV LVAS and VQ outputs
Benefits	• Low barrier to market entry, utilising existing fluoroscopy equipment • Lose dose, high-sensitivity data	• Easy to administer, faster & simpler than existing diagnostic technology • No contrast agent reduces patient harm	• Leverages existing market take-up of XV Technology • Reduced radiation dose, increased scanning throughput and broadened patient cohort
Use cases	• Asthma • Cystic fibrosis • Chronic obstructive pulmonary disease • Chronic bronchitis • Lung transplant • Constrictive bronchiolitis	• Pulmonary embolism • Pulmonary hypertension	• Both XV LVAS and VQ indications in both adults and children
Competing technologies	• X-ray • Computed Tomography (CT) • Pulmonary Function Tests (PFTs)	• Nuclear V/Q scan • CT Pulmonary Angiogram (CTPA)	• X-ray • CT • PFTs • Nuclear V/Q scan • CTPA

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 trials

1. Build relationships with eminent KOLs in specific indications
2. Commence clinical trials at eminent medical institution
3. Researcher presents at medical conferences
4. Results published in peer reviewed medical journals
5. Builds greater awareness & confidence in the technology

6 Months +

Clinical pilots

1. Sales team identify medical practice with strong interest in XV Technology
2. Clinical pilot agreement executed
3. Active pilot phase: scanning, report interpretation & patient consultation
4. Post pilot report: operational, clinical, patient & financial benefits
5. Medical practice onboarding & commercial service agreement go-live

3 weeks - 3 months

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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

Lung Transplant

Duke University

XV LVAS

First Imaging

1 2 3 4 5 6

CB (Veterans)

Vanderbilt University

XV LVAS

First Imaging

1 2 3 4 5 6

COPD

Johns Hopkins

XV LVAS

First Imaging

1 2 3 4 5 6

COPD

Oregon Health & Science University

XV LVAS

First Imaging

1 2 3 4 5 6

COPD

University of Miami

VQ

First Imaging

1 2 3 4 5 6

Bronchoscopic

University of Miami

XV LVAS

First Imaging

1 2 3 4 5 6

Pediatric CF

Johns Hopkins

XV LVAS

Patient Recruitment

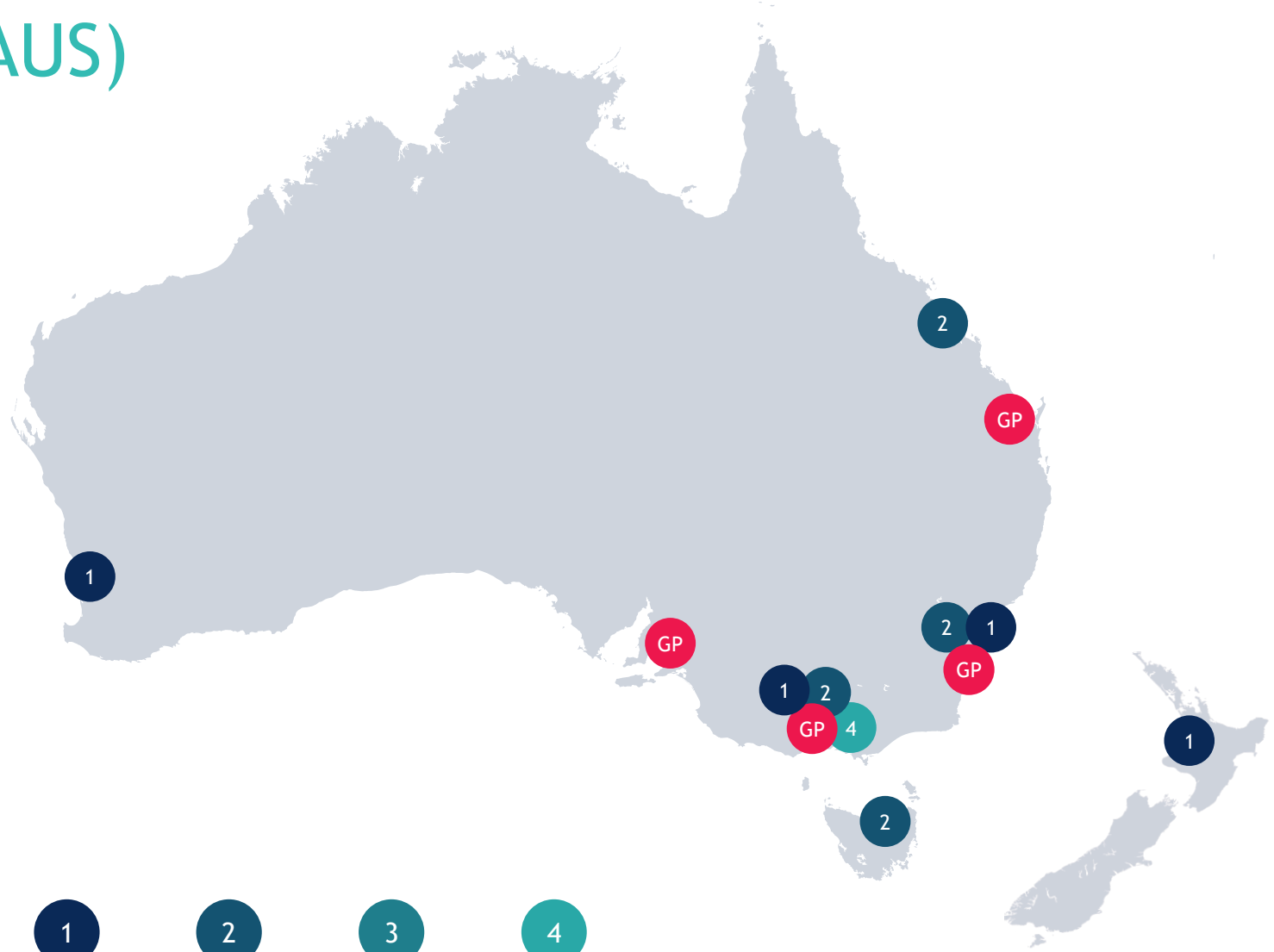
1 2 3 4 5

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



GP — Primary care project

1 — Pilot in development

2 — Pre-pilot agreement

3 — Pilot agreement executed/ active

4 — Post pilot reporting

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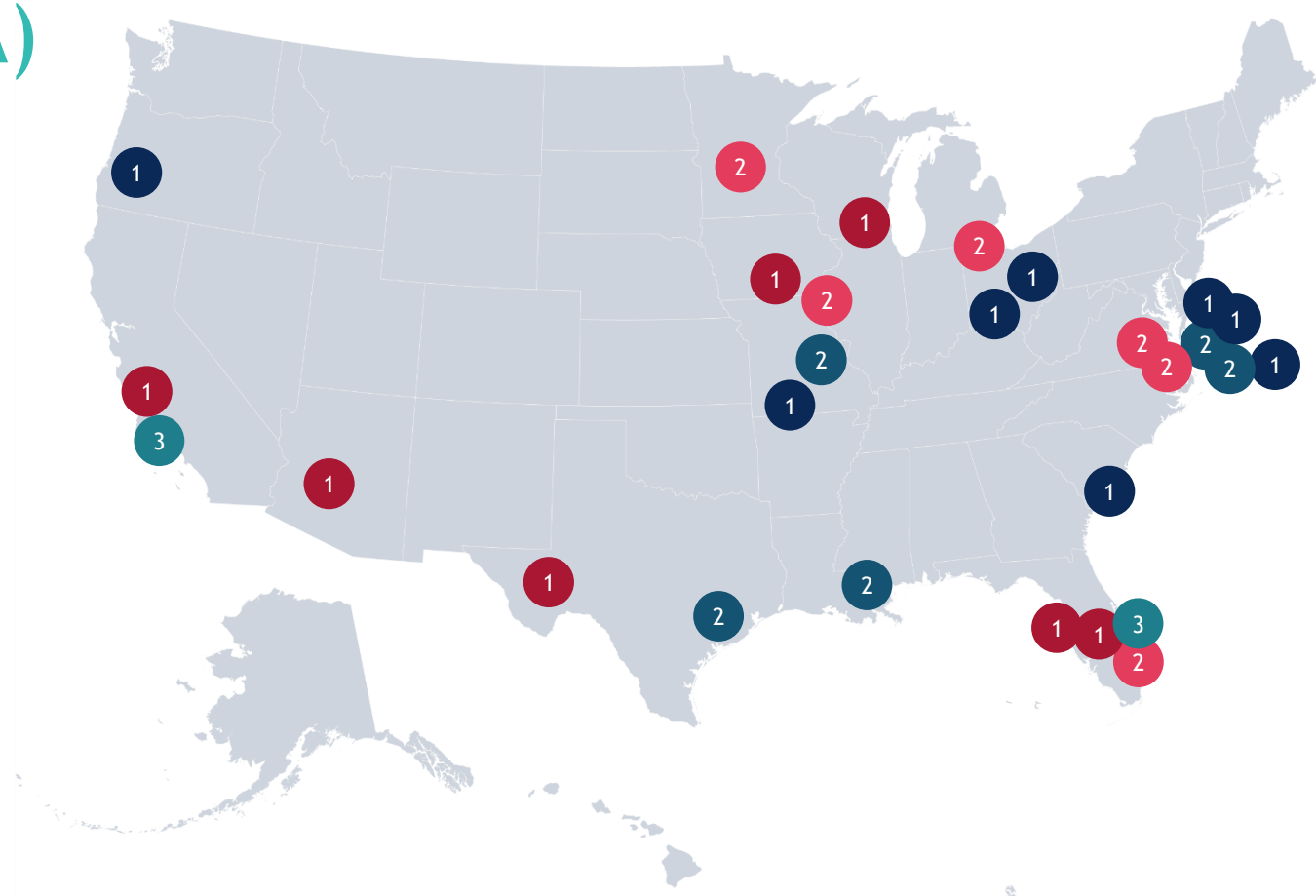
Clinical pilot pipeline (USA)

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	2	3
Pilot in development	Pre-pilot agreement	Pilot agreement executed/ active

Veterans Affairs Hospital Network

1	2	3
Pilot in development	Pre-pilot agreement	Pilot agreement executed/ active

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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

Sex

Indications

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

Clinical observations

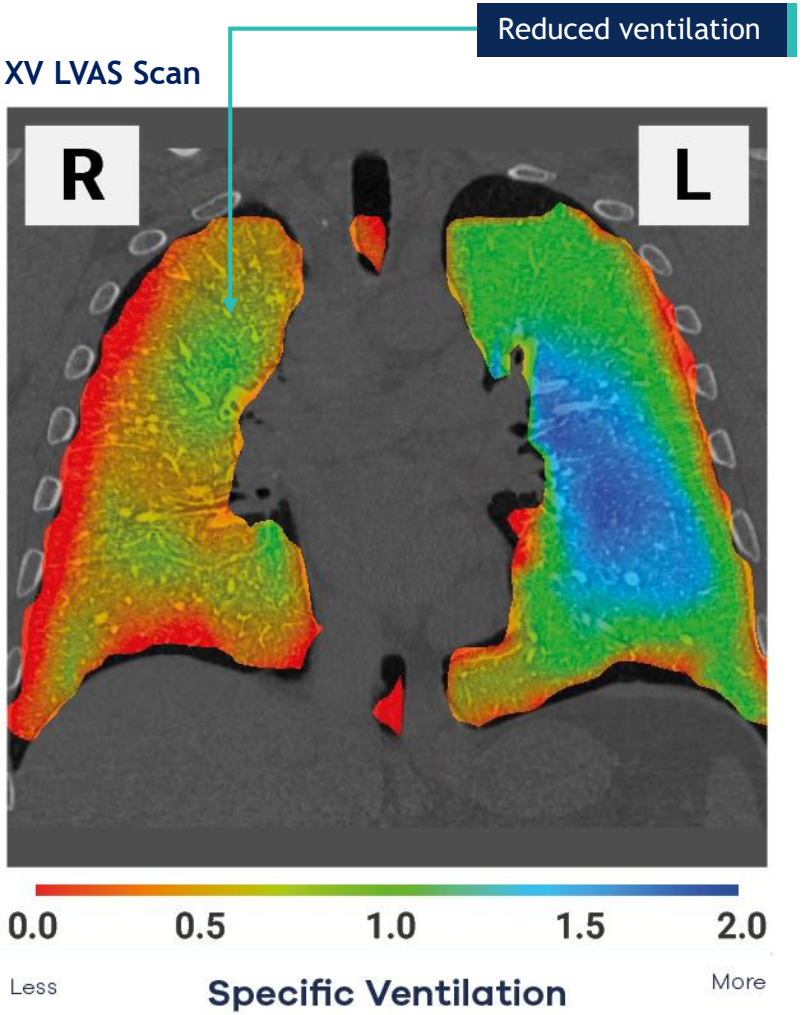
XV LVAS:

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

Ventilation heterogeneity

Small scale	Total	Large scale
32.6	66.4	42.7

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

Sex

Indications

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

Clinical observations

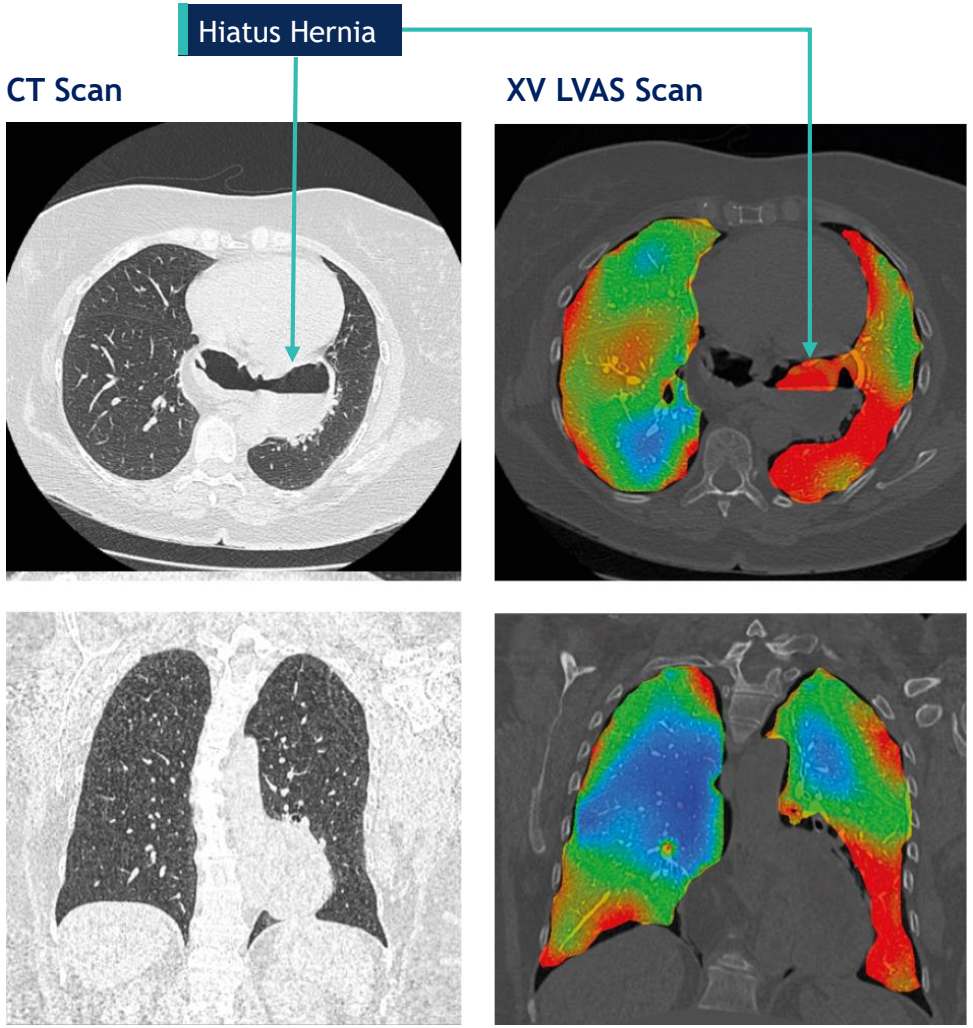
XV LVAS:

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

Ventilation heterogeneity

Small scale	Total	Large scale
46.6	91.9	54.0

VDP:	Tidal volume:
26.9%	0.38L



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Questions?