

MEDIWALES  
**connects**  
NHS COLLABORATION CONFERENCE

29 Jun 2023

**Dr Emma Rees**

Associate Professor of  
Healthcare Science



Swansea University  
Prifysgol Abertawe

**Annamarie Saarinen, MA**

Health Economics  
CEO, Bloom Standard



**BLOOM**  
STANDARD







# Late, missed or misdiagnosis of heart and lung conditions are the leading causes of:

- ✓ newborn + infant death (28% of mortality)
- ✓ poorer health outcomes
- ✓ more (and longer) hospitalizations
- ✓ more costly medical interventions





**1M** babies

die each year from heart defects and lung conditions

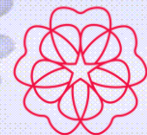
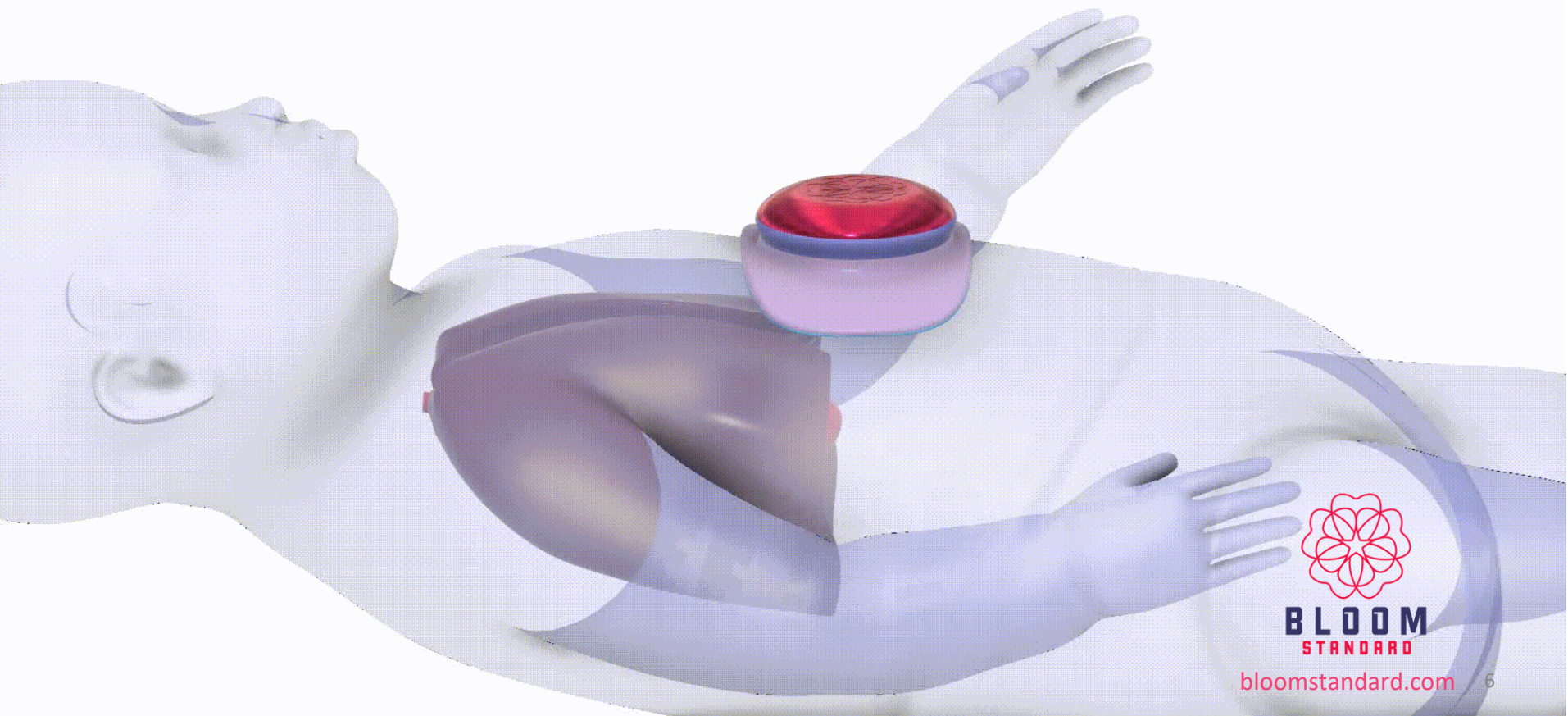
---

**Ultrasound**

can detect them...yet,

**95%** lack access

# Self Driving Ultrasound



**BLOOM**  
STANDARD

[bloomstandard.com](http://bloomstandard.com)

# Autonomous Imaging

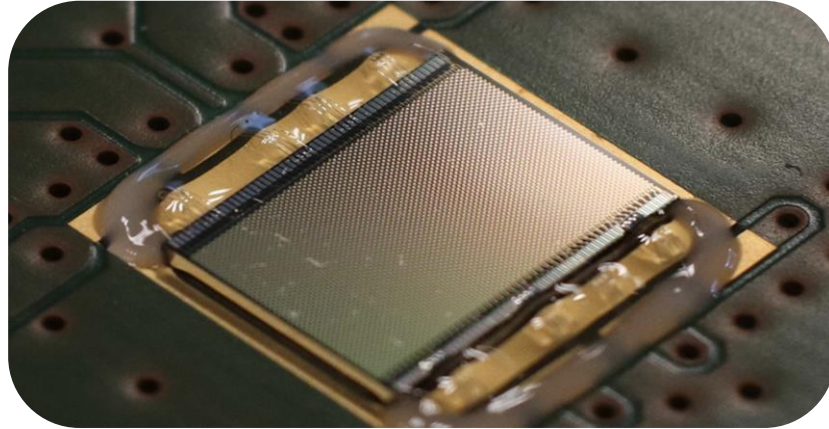
4000 microsensors

## Frequency Range

Flexible frequency range | pediatric penetration depth

## High Resolution

Broad bandwidth + beam steering



## Energy Efficient

Low power operation

## Small Patients Small Form Factor

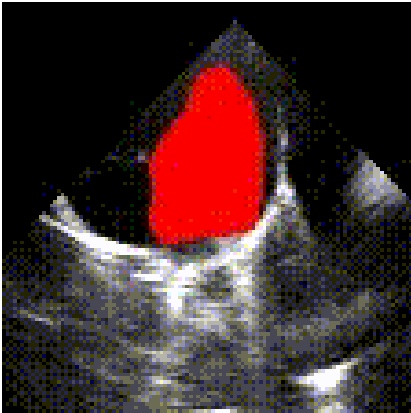
High density sensors spanning just a few micrometers

## Low Cost

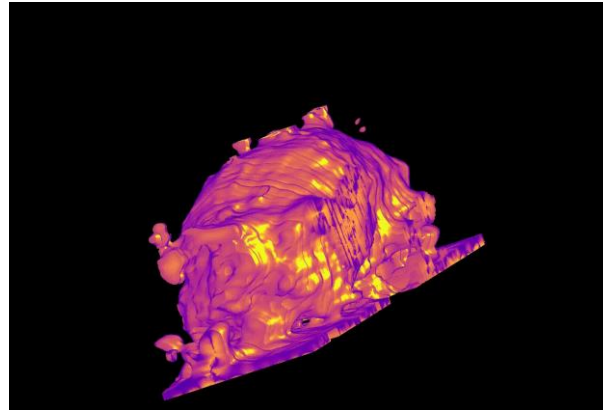
High volume  
Batch manufacturing

# Clinical Decision Support

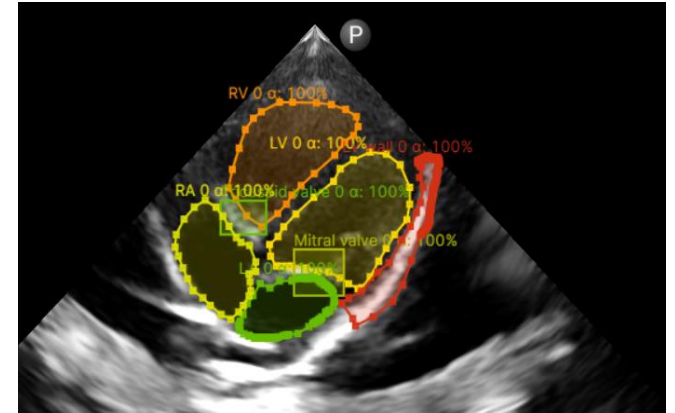
Fine tuning machine learning parameters and establishing first convolutional neural network predictions



Left Ventricle volume and ejection fraction (Bloom V3)



Bloom 3D visualisation [of small heart]



Right and left ventricle diameter and septum wall thickness (Bloom V3 Image)



# Users

**ANYONE, ANYWHERE**  
3-minute, self-driving scans



## Newborn Screening

Follow up testing for routine newborn screening pre-discharge

## Researchers

Consented + de-identified data capture - for R&D, image libraries, QI

## Primary Care Screening

Autonomous Ultrasound  
Primary Care + Retail Clinics, Rural  
Medicine, Guided Referrals

## Telemedicine

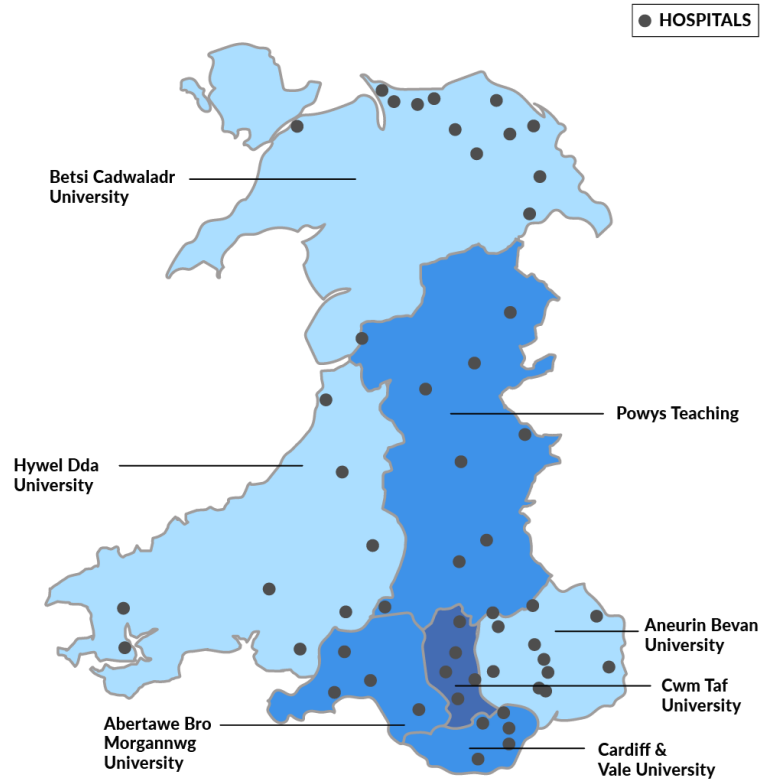
Remote patient scanning |  
telemedicine, interoperable

## Emergency + Transport | Triage Med

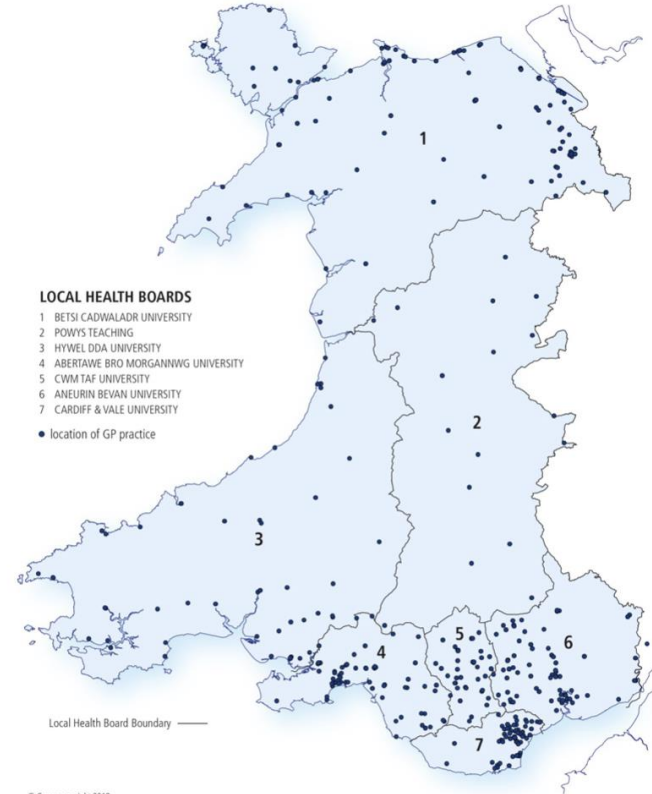
Front Line POCUS:  
(COVID + post-COVID)



# Hospitals + Delivery Sites (2018)



# GP + Peds Practices (2018)



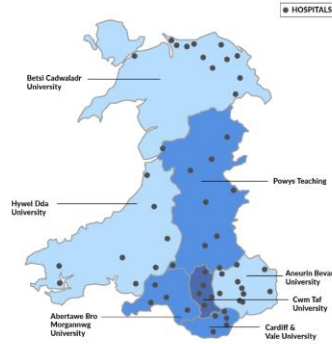


Royal College of  
Paediatrics and Child Health  
Wales

*Leading the way in Children's Health*

Welsh  
Parliamentary  
Election 2021

Hospitals + Delivery Sites  
(2018)



GP + Peds Practices  
(2018)



# Our manifesto for child health in Wales

From the Royal College of Paediatrics and  
Child Health - Wales

- Reduce child health inequalities.
- Prioritise public health, prevention and early intervention.
- Build and strengthen children's services.





# FDA + Clinical Pathway (2023)

FDA CLEARANCE  
2024 Q2

UK CA | EU MDR  
2024 Q4

	Q1	Q2	Q3	Q4
FDA	<ul style="list-style-type: none"> <li>Follow up FDA Meetings - CDRH Pediatric Devices</li> <li>Safety Testing completed Q4 2022 (Int'l Standard)</li> </ul>	<ul style="list-style-type: none"> <li>FDA Breakthrough Submission (system)</li> <li>3X prototypes, data collection</li> <li>Regulatory + QMS (US, UK, EU, APAC)</li> </ul>	<ul style="list-style-type: none"> <li>Ongoing clinical data collection (UK/NHS) NICE MHRA Notification, Class 2A</li> <li>Cost Effectiveness + Study Published</li> </ul>	<ul style="list-style-type: none"> <li>Ongoing clinical data collection</li> <li>Field test merged hardware + AI</li> <li>FDA + MX submissions (hardware)</li> </ul>
CLINICAL SITES	3	4	3	
PATIENTS	100		200 300	
\$NEEDED +USE	\$295K Engineering + ML Hires, Safety Testing	\$387K FDA Breakthrough Submission, 3X Prototypes	\$454K Interim Study Findings @WCPCCS + AAP	\$483K FDA 510K Submission

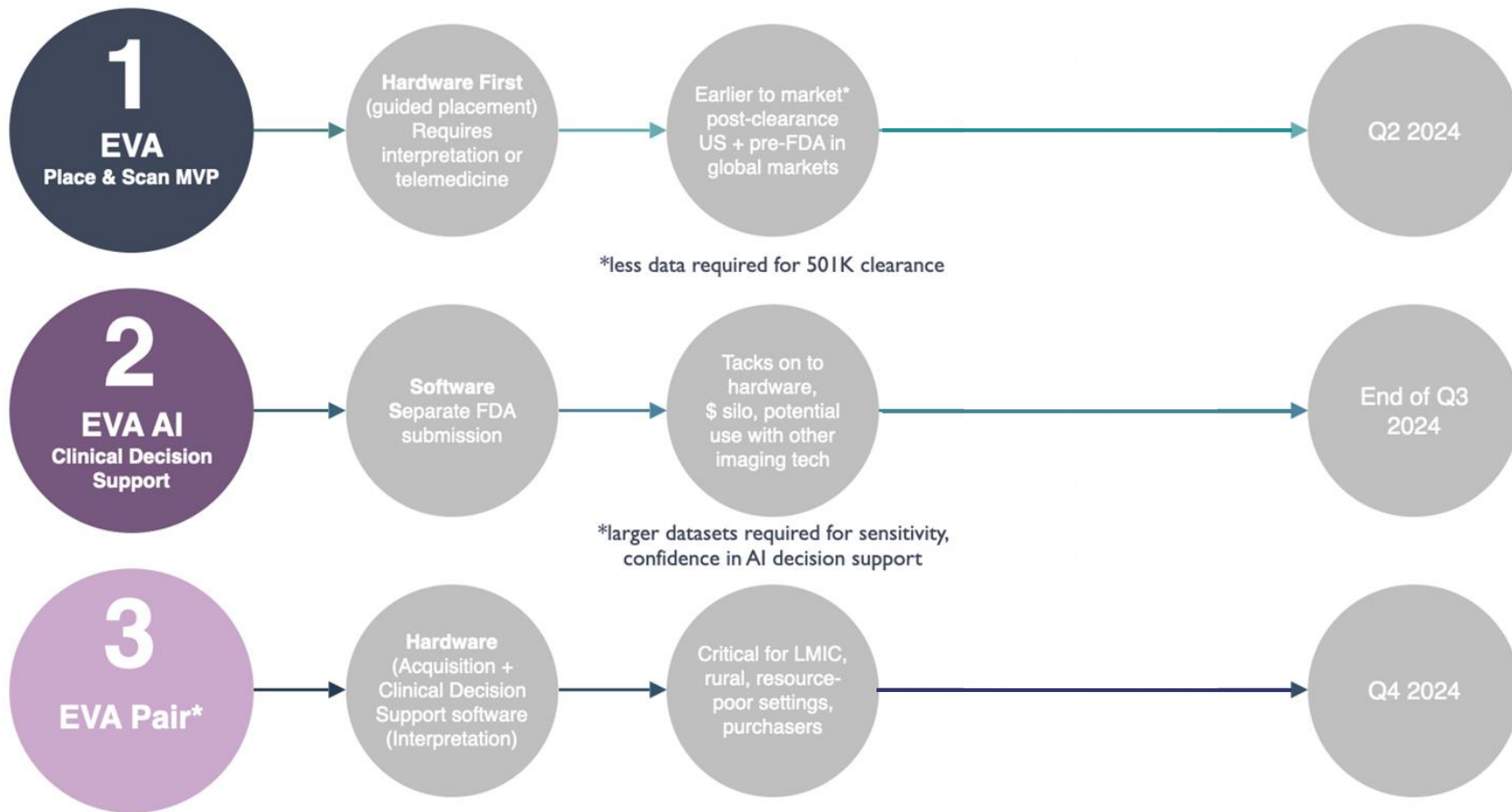
\$5M Seed  
\* Value inflection point

MVP PATHWAYS

STRATEGY

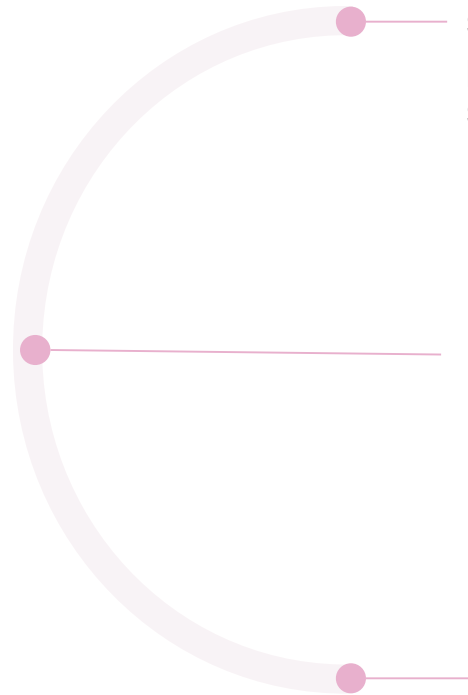
RATIONALE

GTM TIMING



\*ongoing dev while EVA MVP launches

Healthcare providers,  
health systems +  
patients benefits by  
knowing sooner ▶



### **DETECT**

telemedicine + clinical decision support algorithms - flag problems in time to do something about it

### **DIFFERENTIATE**

between benign or dangerous cardiac or respiratory conditions

### **TRACK**

Simple spot-check ultrasound scans to track trajectory, ensure timely care, better outcomes, cost savings





Govt  
Julie Russell  
Lynda Jones

R1D

Emma Pess  
Matthew  
Natalie  
Sion Charles  
Prof. Chris Hopkins  
Prof. Keith Lloyd

Funding

NIHR

SBR1 (due July 25) / NHS

Accelerated Access Collaborative  
AHSN Network

Dev Bank Wales  
Welsh Govt Innovation (Simon)

engels invest Wales  
Steve Hall

Alicia Dublin  
LSC groups

Health Boards  
1. Swansea Bay  
2. Ceredigion  
3. Hywel Dda

Univ  
Dr Naomi Jayce  
US  
Swansea: Lab

Regulatory  
MHRA  
NHS/NICE  
SBR1  
HSTW



Swansea Uni  
Bloom

US

Health Technology Wales  
Susan Nyles  
Zoe Aiken  
Mark Briggs - CVHB  
Accelerate ATC  
(Welsh Govt / EU Funds)

Phil Welsh R1D

Heathey Payne MD  
Uzair MB  
Chris Gale MD (ICL)  
Najib Rahman (Res. Oxford)  
Hantao Liu (Cardiff)

Welsh Ambulance Service

IP Review Audit

- WATER PROOFING?
- ELECTRICALLY INSULATED

T.T. electronics  
• elec  
• thermal  
• biomat comp

Swansea  
UCL  
UoM

• BIO COMPATIBILITY MATERIALS

focus tech  
(avoiding capitation)

1. mechanical index M1
2. thermal index (not heating) T1

Benefit emit  
bias voltage  
better control of ring tone  
15% noise, better performance

ATC  
Assistive Tech  
Innovation Centre

Life Science  
Hub Wales

NIHR  
(Nat'l Inst. Health Research)  
Digital Health Ecosystem  
Wales

NIHR Kolls

Nat'l Imaging  
Academy

Del. gov't

Centre for Digital Health  
CBMW  
Made Simple  
Short Supply  
Health  
Innovation

Contract

Clinical  
Innovation  
Accelerator

Tritech Link

Chris Hopkins  
Matt L.

Area of Excellence  
Welsh Univ

Dr. Richard James  
Dr. Paul Kober  
+ colleagues  
philosophy

SBR1  
Centre of Excellence

Home > Postgraduate > Postgraduate scholarships and bursaries > **Research Scholarships**



**Swansea University**  
Prifysgol Abertawe

## **RESEARCH SCHOLARSHIPS**

### **HEALTH SCIENCE: FULLY FUNDED SWANSEA UNIVERSITY PHD: NOVEL ULTRASOUND TECHNOLOGY AND COMMUNITY PATHWAY INTERVENTIONS TO IMPROVE HEALTHCARE OUTCOMES (RS375)**

Closing date: 12 July 2023

#### **Key Information**

**Fully Funded Swansea University PhD: Novel ultrasound technology and community pathway interventions to improve healthcare outcomes in remote and low resource settings**

# Pipeline

Tiny hearts and lungs are just the beginning...

## ALGORITHMS CURRENTLY IN DEVELOPMENT:

### Cardiac:

Comparative Atrial Size in newborns |  
Infants | older pediatric populations  
Comparative Ventricular Size in  
newborns | Infants | pediatric populations

### Lung:

A + B-Lines (confirm/rule out)  
Lung Pleural Effusion  
Lung Consolidation

## OTHER DATA COLLECTION + ALGORITHMS IN EARLY DEVELOPMENT

### Cardiac:

Velocity | Pressure Gradient (infants)  
Fluid Volumes (infants)

### Brain:

Ventricle size (infants)  
Cerebral blood flow (infants)  
(for Hypoxic Ischemic Encephalopathy, (HIE) +  
Intraventricular Hemorrhage (IVH)

# Q1 Progress: Bloom Mexico + Bolivia Newborn Screening Highlighted in WHO Global Quality Rounds



UNIVERSIDAD  
AUTÓNOMA DE  
QUERÉTARO



Annamarie Saarinen  
Co Founder  
The BORN Project  
Newborn Foundation



Dr. Oscar San Roman  
Coordinator of Born LatAm  
Universidad Autonoma de Querétaro, Mexico



Dr. Isidro Gutierrez  
Professor at UAQ  
Director Born Mexico



World Health  
Organization



Dr. Alexandra Heath  
Pediatric Cardiologist  
Kardiozentrum, La Paz, Bolivia



MSc. Pablo Freudenthal  
Project Manager Ajayu  
Research Assistant  
University of Witten Herdecke, Germany

## WHO Global Quality Rounds

Universal Neonatal Cardiac Screenings  
can reduce newborn and infant mortality

Best practices from a Mexican-Bolivian Partnership





# Diolch yn fawr

am@bloomstandard.com

US +1 (612) 964 6728

HK +852 6770 6502

UK +44 7747 111 398

bloomstandard.com



**BLOOM**  
STANDARD

