Imperial College London

Breath testing for pancreatic cancer: the <u>VAPOR</u> study

Volatile organic compound assessment in pancreatic ductal adenocarcinoma

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PANCREATIC CANCER – THE SCALE OF THE PROBLEM



Non-specific signs & symptoms makes early diagnosis a challenge



Late diagnosis is common:47% patients present withStage 4, incurable disease



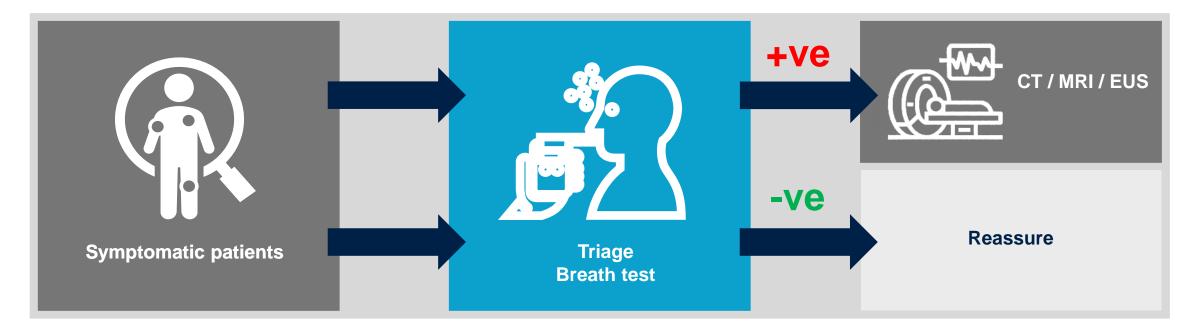
Current lack of **biomarkers** with sufficient sensitivity or specificity and **no screening programme**



5-year survival just **7.3%** makes pancreatic cancer the **fifth** commonest cause of cancer death



OUR PROPOSED SOLUTION – NON-INVASIVE BREATH TEST



Solution: Breath Test	 Triage test Non-invasive, highly acceptable in primary care MAGIC trial Detects volatile organic compounds (VOCs) released from the tumour and its environment at early stage
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Potential for earlier diagnosis, improved survival, and cost savings to the NHS

OUR PROPOSED SOLUTION – NON-INVASIVE BREATH TEST

Breath collection system



Less than 30 seconds breathing into bag

• Good utility

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- Low level of contamination
- Low cost



Breath analysis

Breath transfer



- Stainless steel
- 89 mm long
- 64 mm outer diameter
- No VOC loss for 3 months



- Automated system
- Quality management
- Standard operating
 procedures

HIGH-THROUGHPUT AUTOMATED SYSTEM

Conditioning tubes



80 tubes every 3 hours

Robot for addition of standards in tubes



>300 tube per day

Autosampler per analytical instrument



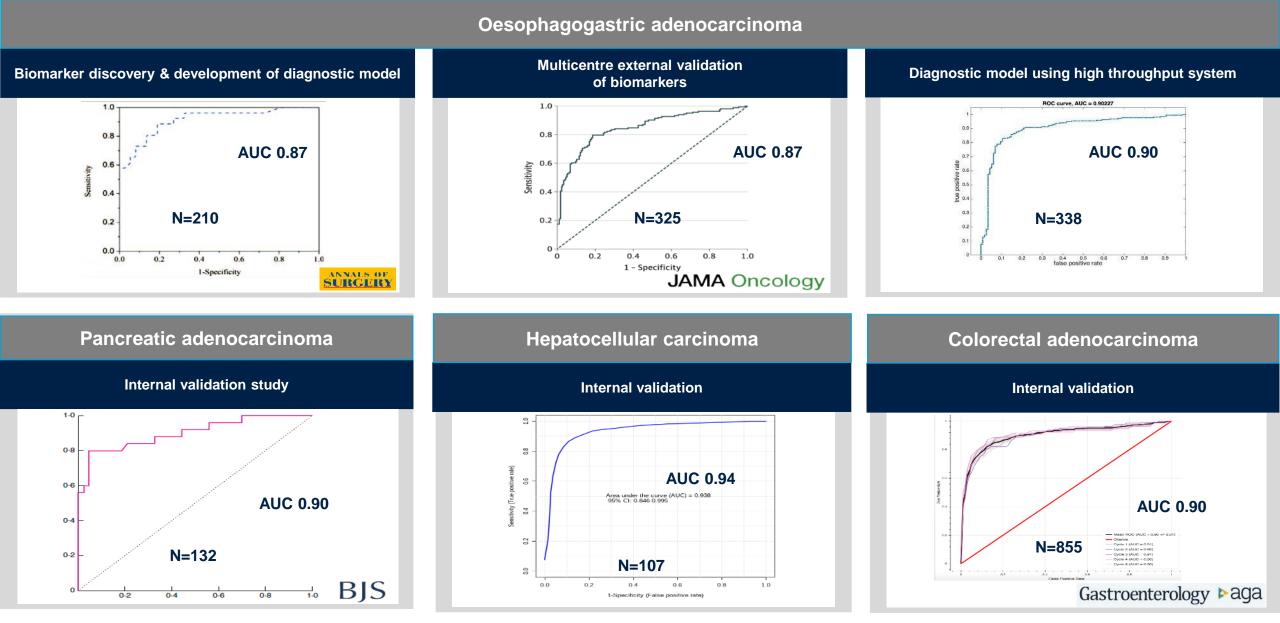
100 tube position instrument

Nine GC-TOF-MS replica instruments



In dedicated VOC laboratory

PROFILING CLINICAL STUDIES



VALIDATION STUDIES

Model optimisation multicentre studies

Oesophagogastric cancer	Pancreatic cancer	Colorectal cancer	Liver cancer			
AROMA CANCER RESEARCH	VAPOR Pancrea Cancer	tic COBRA: 720 patients	VOCAL			
678 patients	771 patients K	NIHR National Institute for Health and Care Research	750 patients			
Triple-blind validation multicentre studies						

Patient, breath sampler, VOC analyst, cancer classifier are unaware of disease status

AROMA	VAPOR	COBRA	VOCAL
6648 patients	6079 patients	6850 patients	8334 patients
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Dedicated validation multicentre studies for sub-groups

T1 oesophageal cancer and

high-grade dysplasia

NEED

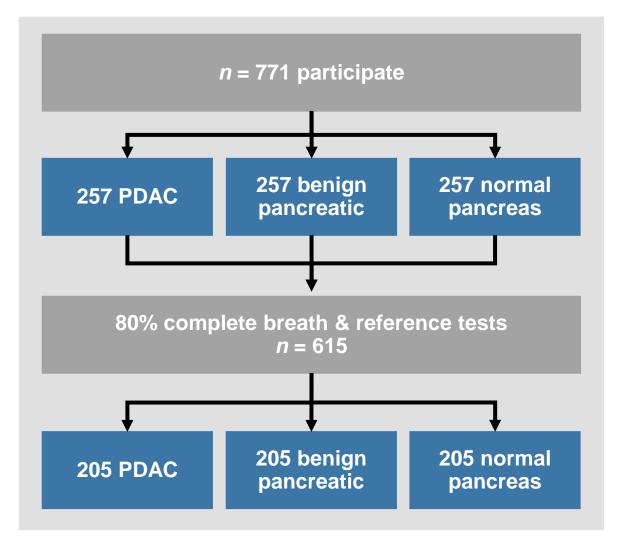
288 patients

guts UK! **Oesophageal squamous cell cancer**

VISON 518 patients NIHR National Institute for Health and Care Research

Pancreatic Cancer U K

VAPOR 1 CLINICAL STUDY





NHS Foundation Trust

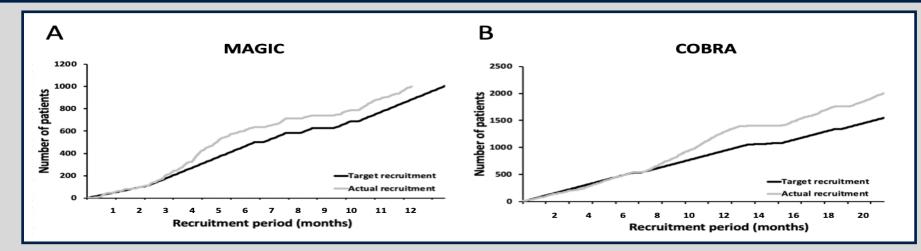
Imperial College Healthcare University Hospitals Birmingham Royal Surrey The Newcastle upon Tyne Hospitals Manchester University University Hospital Southampton Sheffield Teaching Hospitals Liverpool University Hospitals North Tees and Hartlepool



Bwrdd Iechyd Prifysgol Bae Abertawe Swansea Bay University Health Board

SCALING UP TO CLINICAL PRACTICE

Acceptability testing



99% very easy / easy & very comfortable / comfortable to use

Usability and regulatory

- Real world human factors studies: triage test in primary care
- Economic modelling: £155M annual cost-saving for the NHS in upper GI pathway
- Laboratory ISO-17025 accreditation in progress
- Registering AROMA, VAPOR and COBRA with MHRA [Medicines and Healthcare products Regulatory Agency]

NEXT STEPS: Completion of validation clinical studies & regulatory approvals

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> CANCER RESEARCH

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