Innovate UK

**Results of Competition:** Phase 2 SBRI Stratified Medicines - Connecting the UK Healthcare
**Competition Code:** 1701_SBRI_HEAL_SMIP6_PH2

**Total available funding for Phase 2 is £7.1m**

**Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.**

| Participant organisation names | Project title | Proposed project costs | Proposed project grant |
|---|---|---|---|
| **Sarissa Biomedical Ltd** | Purines for Rapid Identifcation of Stroke MImics (PRISM) | £1,998,604 | £1,998,604 |

## Project description - provided by applicants

Stroke is the 2nd leading cause of death worldwide and the commonest cause of adult disability in the western world. It is responsible for a huge health and social care burden which exceeds heart disease, including £5.5bn/year for treatment (5% of the NHS budget) and £5bn/year economic impact for care costs and lost earnings. Powerful evidence exists that even small improvements in the accuracy of diagnosis and the speed of treatment produce large gains for population health and greatly reduced care costs. The impact is greatest when stroke is caused by an arterial blockage (85%), as the chance of a faster, better recovery is directly related to how quickly patients are treated with a clot busting drug (thrombolysis within 4.5 hours) or surgical clot removal (thrombectomy within 6 hours for large arteries). Even when unsuitable for one of these treatments, all patients benefit from admission to a centralised specialist Hyperacute Stroke Unit (HASU), which often involves bypassing a local A&E. Ambulance services are responsible for the initial recognition of symptoms that might be due to stroke. However, it is a challenging condition for non-specialists to diagnose correctly in the first few critical hours, and a number of other conditions have the same symptoms as stroke, resulting in mimics patients entering the stroke treatment pathway. As a result, there is a high degree of misdiagnosis: 30% of stroke patients go unrecognised in A&E; 50% of suspected stroke patients identified by paramedics turn out to have mimic conditionss; and up to 17% of patients receiving thrombolysis (an expensive and potentially hazardous treatment) have not had a stroke. Mimic conditionss are also a major burden on limited resources; around 13,500 mimic patientss annually are treated by NHS HASUs at an additional cost of £31m compared to a standard hospital bed. Accurate identification of stroke and mimic patients in ambulances and A&E departments would lead to improved patient outcomes and better use of limited specialist resources. Sarissa Biomedical is working with researchers and NHS services to develop a simple Point of Care Diagnostic blood test (SMARTChip) which measures blood purine levels. Studies in hospital have shown that these are an extremely early indicator of stroke. As the majority of referrals to HASU are via ambulance, developing SMARTChip for paramedic use would assist in the correct diganosis of stroke and significantly reduce the number of patients being inappropriately directed to HASUs. This would ensure that specialist resources are reserved for stroke and enable mimics patients to be assessed in a more appropriate local setting. The purine levels correlate with stroke severity and rapidly provides clinicians with additional information to optimise treatment decisions (i.e. to follow a thrombolysis and/or thrombectomy pathway). Phase 1 of this project confirmed that SMARTChip would be valued by clinicians and could be deployed in NHS services with a projected saving of over £25 million annually. Phase 2 will seek regulatory approval and commissioning support for routine clinical use by generating evidence of patient and service benefits, operational feasibility and positive economic impact.

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| **Mologic Ltd** | COPD Exacerbation Alert for patient stratification | £2,000,000 | £2,000,000 |

## Project description - provided by applicants

COPD is the second most common cause of emergency admissions in the UK, responsible for one in eight (130,000) acute adult medical admissions. It is a global problem, with 210 million sufferers and 3 million deaths annually (WHO, 2009). There are 1.2M COPD patients in the UK. Patients with COPD have daily symptoms, a poorer health status, reduced exercise capacity, and impairment in lung function. The symptoms can deteriorate rapidly in response to infection or pollution. The acute and sustained worsening of the symptoms is termed an acute exacerbation of COPD. In the UK COPD exacerbations account for 15% of all medical admissions, 1 million bed days and an annual NHS expenditure of £500M [NICE 2010]. Mologic has developed two products for patient stratification. These are simple urine based tests similar to the familiar home pregnancy test kits. The first test Headstart will clearly identify or confirm the first signs of exacerbation with sufficient reliability and clarity for the patient to know when to take medication and when to seek medical attention. The second product is Rightstart, for use at home or in primary care to identify whether to use antibiotics or corticosteroids. Early identification of COPD exacerbation has the potential to reduce the severity of exacerbations by allowing faster treatment and reducing the need for GP and emergency visits to A&E. Use of Rightstart to identify the cause of the exacerbation helps ensure the correct treatment is given and also has the potential to reduce unnecessary antibiotic treatment which supports the UK governments strategies for Antimicrobial Stewardship. This project will conduct clinical trials of the Rightstart and Headstart products in conjunction with clinical experts from the Respiratory groups at Leicester Hospital and Prince Philip Hospital. The design of these trials and analysis of the results is being assisted by the Diagnostic Evidence Cooperatives (DEC) and Academic Health Science Networks (AHSN) at Oxford and Newcastle. They have developed healthcare economic models to assess the potential benefits and costs savings to the NHS from the use of Headstart and Rightstart and will use the results of the trials to further update and refine their models. In addition, they will also work throughout the project to help identify the best ways to integrate these products into existing care pathways within the NHS. Because COPD patients have multiple points of contact with the NHS including their GPs, respiratory specialists in hospital based clinics, Out of Hours Services and A&E it is important to be able to integrate and provide education on the product across a broad range of clinicians and locations with the NHS. To gain support for the product's use requires the ability to demonstrate the patient value and cost saving potential to both Clinical Commissioning Groups (CCGs) who make decisions on the Care pathways for COPD and the Prescription Pricing Agency which decides which diagnostic tests are available for prescription by GPs. The AHSN and DEC groups at Oxford and Newcastle will be providing the expertise and analysis required to support the adoption of the product by both CCGs and clinicians. In addition, patient support groups including the British Lung Foundation and Breathe Easy will be engaged to provide ongoing patient perspective and support the education and training on the products.

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|---|---|---|---|
| **Atlas Genetics Ltd** | A stratified medicine diagnostic test for STI patients at the point-of-care | £1,998,984 | £1,998,984 |

| Project description - provided by applicants |
| --- |
| A rapid stratified medicine diagnostic test for STI patients at the point-of-care. Atlas Genetics are developing a rapid, multi-pathogen, point-of-care (POC) diagnostic test for patients presenting at sexual health clinics, to enable the stratification of these patients, allowing sexual health professionals to direct immediate and effective treatment based on these test results. Current sexual health clinical pathways rely on large central laboratory analysers to provide the test result to aid diagnosis. The logistics associated with the use of these systems means the test results are not available at the initial patient visit, resulting in either delayed treatment or the clinician presumptively treating the patient, often incorrectly or unnecessarily. The Atlas Genetics io® (POC) platform provides laboratory quality results in 30 minutes from the clinical sample (swab or urine) and the development of the multi-pathogen sexually transmitted infection test (MSTI) will give clinicians a definitive diagnosis on these key STI pathogens whilst the patient waits. Concurrent to MSTI test development, the successful collaboration in SBRI Phase 1 between Atlas Genetics and the Applied Diagnostic Research and Evaluation Unit (ADREU) at St George's University of London (SGUL) and Public Health England (PHE) and Aquarius Population Health (APH) will continue, developing an enabling infrastructure and guidance for effective adoption of this product. This will be based on acquiring knowledge on the facilitators and barriers to adoption of the Atlas Genetics io® Instrument with Atlas CT/NG stratified medicine diagnostic cartridges deployed in, and evaluated for, clinical use in exemplar sexual clinics across the UK. The programme will include a proactive phase of garnering the necessary local knowledge of process, decision making, acceptability and economic impacts to inform the development and submission of strong and locally relevant business cases for adopting the technology beyond Innovate funding and lead to paving the way for adopting the io® MSTI product in sexual health services, once commercially available. |

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