Antimicrobial Resistance

Phase 1 Funding Competition



Health Innovation Network





Contents

- **1** Executive Summary
- **2** SBRI Healthcare: Phase 1 funding competition
 - Programme ambitions
 - Accelerated Access Collaborative's priorities
- **3** Antimicrobial Resistance
 - Background and introduction
 - Challenges
- **4** Useful Information for Applicants
 - Eligibility
 - Innovations excluded from the competition
 - Desirable exit points
 - Additional considerations
 - The SBRI Healthcare Programme
 - SBRI Healthcare application process
 - Key dates

Executive Summary

The UK has great pride in the NHS, and the shared social commitment it represents. However, work remains to be done to meet the challenges set out in the NHS Long Term Plan, such as funding, staffing and increasing inequalities.

SBRI Healthcare provides a mechanism to signal the challenges that the NHS and the wider system face and invites entrepreneurs to deploy innovative solutions to deliver improved outcomes of care and efficiencies. Our individual competition themes are scoped by working in close collaboration with the Health Innovation Network and frontline NHS and social care staff.

At early stage, the SBRI Healthcare programme offers a two-phased development approach; projects start with initial feasibility and subject to funding can then move on to more detailed product development. Phase 1 contracts for technical and commercial feasibility testing are valued at up to £100,000 (NET) and last for six months. Phase 2 contracts for prototype development and early clinical evidence are worth up to £800,000 (NET), subject to budget availability, over one year.

The SBRI Healthcare Competition 25 Phase 1 funding competition invites breakthrough technologies to address challenges in **antimicrobial resistance** and aims to identify innovative solutions which have the potential to enter the NHS, social care and the wider market, tackling:

- 1. Point of care diagnostics, monitoring, and susceptibility testing
- 2. Prescribing decision support and risk stratification
- 3. Novel care delivery methods
- 4. Infection prevention and control (IPC)

Applicants are asked to consider the impact of their innovation on the whole system and to be aware of the competitive environment, even considering working together with other companies and organisations to bring forward solutions that can make a real difference. Health inequality and equity of access to care should be a central pillar of any successful innovation as well as a commitment to contribute to NHS net zero ambitions.

SBRI Healthcare: Phase 1 funding competition

Programme ambitions

The SBRI Healthcare Phase 1 funding competition invites outstanding entrepreneurs to put forward breakthrough innovations which address a clearly articulated challenge faced by the NHS and/or the social care community. The aim of the open tender is to facilitate the development and validation of such innovations and build on the value proposition required by commissioners and regulators for NHS adoption and wider commercialisation.

Phase 1 proposals concentrate on activities which will significantly contribute to proving the technical and commercial feasibility of the proposed innovation. If successful at Phase 1, and subject to budget availability, projects are eligible to apply for further funding at Phase 2, which will allow teams to undertake prototype development and generate clinical evidence. At the end of Phase 2, it is intended that the proposed solution will be ready for the next stage of development (e.g., manufacturing, regulatory approvals, etc), NHS adoption and/or wider commercialisation.

Accelerated Access Collaborative's priorities

The <u>Accelerated Access Collaborative</u> (AAC) funds the SBRI Healthcare Programme and brings together industry, government, regulators, patients and the NHS. Its ambition is to help the NHS become stronger in supporting clinicians and patients to access new innovations at pace and scale. It does so by removing barriers and accelerating the introduction of groundbreaking innovations which will transform care and support the NHS to more quickly adopt clinically and cost-effective innovations, to ensure patients get access to the best new treatments and technologies. Innovations include medicines, diagnostics, devices and digital products.

The AAC ensures that research and innovation meet the needs of the public, patients and the NHS. This includes ensuring that all innovations that are adopted into the NHS can support the following targets:

- Reducing health inequalities and enhancing equity of access to care through the Core20PLUS5 initiative
- Supporting NHS ambitions to be a net zero health service through the 'Delivering a Net Zero NHS' initiative

Core20PLUS5

NHS England launched the <u>Core20PLUS5</u> initiative in 2021 and a bespoke <u>Children and young</u> <u>people Core20PLUS5 in 2022</u> to reduce health inequalities at both the national and system level. The approach defines a target population cohort and five focus clinical areas requiring accelerated improvement. The Core20 are the most deprived 20% of the national population as identified by the national index of multiple deprivation while PLUS are population groups experiencing poorer than average health access, experience or outcomes which are not captured in the Core20 alone.

Delivering a net zero NHS

The NHS strategy also includes ambitions to become the world's first net zero national health service. The "<u>Delivering a Net Zero Health Service</u>" report sets out the ambition and two evidence-based targets:

- To reduce direct emissions (NHS Carbon Footprint) and reach net zero by 2040, with an ambition to reach an 80% reduction by 2028 to 2032
- To reduce influenced emissions (NHS Carbon Footprint Plus) and reach net zero by 2045, with an ambition to reach an 80% reduction by 2036 to 2039.

As outlined in the NHS Long Term Plan (LTP), sustainability commitments range from reducing single-use plastics and water consumption, through to improving air quality. The Greener NHS National Programme was formed to drive this transformation, while delivering against broader environmental health priorities.

Antimicrobial Resistance

Background and introduction

Antimicrobials are used to treat a broad range of diseases and are also used routinely prior to carrying out surgical procedures to prevent infection at the surgical site. Antimicrobial resistance (AMR) occurs when the microorganisms that cause disease (including bacteria, viruses, fungi and parasites) are no longer killed by the antimicrobial medicines (such as antibiotics, antivirals, antifungals and antiparasitics) that we use to prevent or treat the disease.

With an increase in AMR, <u>more people will suffer for longer</u> as infections become more difficult to treat, hospital stays will lengthen, routine surgical procedures will become more dangerous, and diseases previously controlled with antimicrobials will increasingly result in death.

AMR is a significant threat to public health and has become a leading cause of death worldwide. The WHO has listed AMR as one of the <u>top global public health and development threats</u>. In 2019, the deaths of <u>4.95 million people were associated with drug-resistant bacterial infections</u>, with <u>1.27 million deaths directly caused by AMR</u>. This number is estimated to increase to up to 10 million deaths worldwide per year by 2050, alongside an additional \$1 trillion in healthcare costs if no action is taken. After a decline in antibiotic use from 2014-2020, antibiotic use increased <u>8.4% in 2022 and resistant infections rose by 4%</u>, thus there is a pressing need for novel solutions.

The <u>NHS Long Term Plan</u> identifies antimicrobial resistance as one of five priorities requiring NHS action on prevention, and reiterates the UK's <u>20-year vision for AMR</u> which outlines the aim for a world in which antimicrobial resistance is effectively contained, controlled and mitigated. With the completion of the first 5-year national action plan (NAP) <u>'Tackling</u> <u>antimicrobial resistance 2019 to2024</u>, a new 5-year NAP, building on the first, was published in May 2024, <u>'Confronting antimicrobial resistance 2024 to 2029</u>' which commits the UK to reducing its use of antimicrobials to progress towards the 20-year vision.

AMR can be addressed by both reducing the overall use of antimicrobials, developing alternatives to current antimicrobials, as well as reducing inappropriate use of antimicrobials through the following:

- prevention of infections
- timely, accurate diagnosis
- appropriate prescribing and use of antimicrobials only when there is an infection for which they are the most appropriate treatment
- effective management of infections
- development of alternatives to current antimicrobials.

AMR affects all, but not equally. Incidence rates across all infections were higher in the most deprived areas of England. Infections requiring antibiotics particularly affect older adults and young children. Antibiotic exposure in children can adversely affect the normal development of the immune system increasing susceptibility to infections later in life.

Age-standardised rates of infections have been shown to be greater in Asian and black ethnic groups than mixed, white or other ethnic groups for all infections, other than MSSA bacteraemia which was highest in the white population. (Annual epidemiological commentary: Gram-negative, MRSA, MSSA bacteraemia and C. difficile infections, up to and including financial year 2022 to 2023 - GOV.UK (www.gov.uk). The highest percentage of antibiotic resistant infections was noted in Asian or Asian British ethnic group with 35% of blood stream infections in this population in 2022 showing resistance to at least one of the key antibiotics compared to 19% in the white ethnic group [https://ukhsa.blog.gov.uk/2023/11/15/the-fight-against-antimicrobial-resistance-progress-and-challenges/].

Improving access to medicines and vaccines is essential for limiting the spread of antimicrobial resistance. Early access to appropriate medicine can prevent infection and manage its spread. Barriers to seeking healthcare support, particularly in communities known not to engage, need to be addressed to save lives and prevent resistance arising and spreading.

Challenges

Under the overall theme of "Antimicrobial resistance (AMR)", 4 sub-challenges have been identified *via* consultation with clinicians and other stakeholders working in provision of care across the spectrum.

Applicants are expected to respond to one or more of the categories and should consider if their solution is specific to or can be tailored to one of the categories, whilst being mindful of the broader impact.

Emphasis should be placed on how the technology/solution will address any challenges associated with health inequalities, such as demographic and geographic disparities, and it is expected that applicants provide details on how they will address these e.g. provide details on the care pathway the intervention will affect and how it can improve this.

Challenge 1 – Point of care diagnostics, monitoring, and susceptibility testing

Diagnosis remains challenging in many diseases (such as sepsis, urinary tract infection) due to generalised symptoms or high incidence in populations with complex needs (i.e. elderly with memory problems or confusion). Early identification is critical for timely administration of appropriate treatment to optimise patient outcomes and prevent administration of antibiotics when not needed. Accurate diagnosis and coding is also required to support improved decision support tools and contribute to appropriate decision making. Following initial diagnosis, understanding the severity of disease and the prognosis can help guide optimal treatment strategy, including treating early when needed as well as de-escalation.

Pathogen identification and susceptibility to antimicrobials is typically determined through culture which can take days. A broad-spectrum antibiotic may be prescribed initially to ensure

a potential severe infection is treated and the patient does not deteriorate. However, there is strong evidence that use of broad-spectrum antibiotics (more than narrow-spectrum) selects for resistance as well as exposing patients to risk of unnecessary adverse drug effects, therefore, a targeted approach for prescribing antibiotics is needed. Rapid diagnosis of the disease, the disease-causing pathogen, and the antimicrobial susceptibility could accelerate administration of the correct treatment (antimicrobial or not), minimising potential for AMR and optimising patient care.

NHS England AMR Board identified four clinical pathways as priority areas of focus as they present the greatest opportunities to reduce inappropriate antimicrobial prescribing through more innovative, accurate and rapid diagnosis. The four pathways are:

- Lower respiratory tract infections (LRTIs)
- Urinary tract infections (UTIs)
- Sepsis
- Surgical site infections (SSIs)

Potential solutions include (but are not limited to):

- Solutions to support appropriate use of diagnostics (for quality, choice of test etc.).
- Rapid, point-of-care (home, primary care, secondary care and/or community) diagnostic technologies that can confirm bacterial vs viral/fungal infection (and differentiate from colonisation) and/or the pathogen involved. Where biomarkers are used for diagnosis, including multiple biomarkers rather than using a single biomarker is preferable for greater accuracy.
- Tests for LRTIs that can more accurately and rapidly identify bacterial or viral infections (and differentiate from colonisation) and/or determine antimicrobial susceptibility for bacterial infections.
- Tests for LRTIs that can more accurately and rapidly identify patients at risk of deterioration.
- Diagnostics for UTIs particularly suitable for use in the elderly population within a care home and/or community setting, and/or solutions to determine antimicrobial susceptibility (with or without pathogen identification).
- Solutions that can provide an early diagnosis of sepsis, the cause of the infection, and/or antimicrobial susceptibility to allow a more rapid identification of specific antibiotic to be administered.
- Technologies suitable for neonates with suspected sepsis (noting the low blood culture sensitivity in this population).
- Solutions addressing early detection of surgical site infections in hospitals, primary care and community settings.
- Diagnostics to guide alternatives to antimicrobials (i.e. probiotics for Helicobacter Pylori infection).

• Solutions to address monitoring the progression of infection for early identification of sepsis and to ensure appropriate treatment regimen including de-escalation (cease treatment, amend antimicrobial, refer to non ward-based treatment, extend antimicrobial prescription, switch from intravenous to oral antimicrobial treatment).

Challenge 2 – Prescribing decision support and risk stratification

In 2018, Public Health England suggested that at least <u>20% of the antibiotics prescribed in UK</u> <u>primary care were inappropriate</u>, with up to 8-times the recommended amount prescribed for some diseases. When deciding what treatment to provide, healthcare professionals follow guidelines but existing decision support systems rarely contain sufficient useful information on the natural history of infection illness, the prognosis of untreated infection, the benefits and risks of antimicrobials, alternatives to antimicrobials, or consider variation between individuals, dose optimisation, and physician/patient engagement.

<u>Responses to antimicrobial drugs vary between patients</u> as well as in the same patient over time. Standard dosing schemes do not account for this variability and the suboptimal use of antimicrobial drugs can increase the chance of antimicrobial resistance and may lead to therapeutic failure in the patient. With consideration of polypharmacy and co-morbidities, personalised dosing involves tailoring drug dose to a particular individual, while dynamic dosing tailors the dose based on the current state of the patient. Clinical decision support for personalised and dynamic dosing presents an opportunity to optimise antimicrobial drug use and improve patient outcomes.

Risk stratification tools can also support decisions on when to prescribe, and when to stop, antimicrobial medication. Tools should consider both individual risk as well as population risk.

Potential solutions include (but are not limited to):

- Clinical decision support tools that incorporate real-time information from patient (including physiological and pharmacological), hospital, and population data to guide clinicians and patients on treatment decisions (including dosing schemes, when it is safe and effective to use non-pharmaceutical methods, and de-escalation) with particular consideration of how to present outcomes for ease of understanding by healthcare professionals and patients for shared decision-making.
- Risk stratification solutions to identify high-risk populations or settings and ensure targeted dosage of antimicrobials in different patient groups, including when such solutions should be used.
- Tools that support clinicians in identifying the "threshold for treatment" reducing unnecessary prescriptions.

Challenge 3 – Novel care delivery methods

Infection care can often present in silos. Joining up infection management to combine AMR, IPC and clinical care through novel clinical care delivery methods such as <u>acute respiratory</u> <u>infection (ARI) hubs</u> or <u>virtual wards</u> aims to achieve a smoother interface between primary, secondary and community care. Design should build on existing infrastructure and match local need reducing health inequalities by providing an accessible and equitable service.

Data management systems exist within healthcare settings, or are in development, and can be used to share information across settings. These may be adapted and repurposed for infection management and to combat AMR. A system-wide infection management approach should deliver optimal outcomes for patients, as well as improving the use of antimicrobials.

Potential solutions include (but are not limited to):

- Novel models of care developed through co-design with clinicians, patients, carers and service-users.
- Solutions for information/data sharing across care settings involved in pathways that can contribute to antimicrobial stewardship (particularly re-purposing technology already integrated in/interoperable with existing health and care systems).
- Solutions for virtual patient monitoring to support infection management.
- Solutions particularly targeted at areas of high antimicrobial prescribing for greatest impact (i.e. primary care, care homes).
- Solutions to facilitate equitable patient access to appropriate healthcare services for timely infection diagnosis and management support as an outpatient, inpatient and/or under remote care.

Challenge 4 – Infection prevention and control (IPC)

Reducing infections reduces the amount of antimicrobials used and therefore lowers the chance of resistance. Although the majority of infections start in the community, healthcare associated infections, contribute a significant number. With <u>hospital-onset infection rates</u> <u>remaining high</u>, infection prevention and control (IPC) measures require optimisation to improve patient safety and combat AMR.

The <u>2024-29 NAP</u> identifies the need for informed interventions, IPC within the built environment, and targeted action to prevent spread. It also outlines design considerations ensuring the design of new, or redevelopment of old facilities includes consideration of IPC. Effective protection of surfaces and efficient decontamination of medical devices and/or healthcare linen can also contribute to preventing the spread of infection.

Potential solutions include (but are not limited to):

• Cost-effective evidence-based clinical decision support tools, including appropriate diagnostics and interventions for infection outbreak management across healthcare

settings where there are competing priorities and limited resources (including community care facilities), that create risk-stratified solutions for the populations involved.

- Design-led sustainable solutions & interventions to mitigate spread within healthcare facilities (including antimicrobial coatings, novel decontamination methods,) that are cost-effective across healthcare.
- Evaluating, using human behavioural methods, which IPC interventions work best to make it easy to do the right thing every time and where further work is needed, in healthcare, community, and social care settings.
- Solutions to engage communities less likely to attend healthcare settings to improve access to diagnostics, medicines and vaccines when needed to ensure early treatment to save lives and prevent resistance arising and spreading.
- Guidance on culturally appropriate patient-to-healthcare professional interactions that influence patient expectations and awareness of antibiotics, risks of AMR and use of self-care covering interactions across different settings such as remote consultations, e-consults, urgent care settings, acute respiratory infection (ARI) hubs, community pharmacies and so on.

Useful Information for Applicants

Eligibility

The competition is open to single organisations (contracts are executed with individual legal entities) based in the UK or EU from the private, public, and third sectors, including companies (large corporates and small and medium enterprises), charities, universities and NHS providers, as long as a strong commercial strategy is provided. Organisations based outside the UK or EU with innovations in remit for this call can apply as subcontractors of a lead UK/EU based organisation or via a UK or EU subsidiary.

Collaborations are encouraged in the form of subcontracted services as appropriate.

Innovations excluded from this competition

There are a number of technologies or types of solutions which are already available or will not make a significant impact on the challenges addressed in this brief. These are listed below.

- Any technologies that negatively impact staff workloads and do not support the workforce pressure, and that require high upfront capital investment by clinical services will be excluded.
- Systems and solutions that will not easily integrate or communicate with NHS/community setting systems.
- Technologies that will exacerbate health inequalities (including digital exclusion or data inequalities) and inequity of access to care e.g., digital technologies that are inaccessible to certain communities that experience digital poverty.
- Public awareness campaigns (including for education settings).

Desirable exit points

At the end of Phase 1, projects are expected to have established the technical merit, feasibility, and commercial potential of the proposed technology.

Examples of exit points include:

- Feasibility technical study
- Market validation
- Business plan developed
- · Clinical and/or social care partners identified
- Evidence generation plan for adoption
- Development of patient and public involvement and engagement (PPIE) strategy
- Development of net zero strategy to demonstrate environmental impact

Health inequalities impact assessment

Following successful completion of Phase 1, projects can apply for further funding at Phase 2 to continue development, subject to budget availability. It is expected that at the end of Phase 2, some of the following will be achieved:

- Minimum viable product developed
- Early clinical evidence gathered to demonstrate safety and accuracy
- Developed commercialisation strategy
- Health economics
- Evidence gathered towards regulatory approval
- Implementation plan for adoption
- Strong involvement and engagement with patients and the public
- Projected carbon savings of the proposed innovation and methodology used to estimate the carbon impact
- Timeline and strategy to comply with the requirement set out in the NHS Supply Roadmap, including the development of a Carbon Reduction Plan
- Next stream of funding identified / investment readiness.

Additional considerations

Please consult the <u>Guidance for Applicants</u> for more details.

Those submitting applications are also asked to consider:

- The programme supports innovations that plan to meet relevant regulatory standards, compliances and generate a strong evidence base. These may include CE marking, UKCA, relevant ISO certifications, etc.
- Where relevant, the <u>NICE Digital Health Technology Framework</u> and the <u>Digital</u> <u>Technology Assessment Criteria (DTAC)</u> should be consulted and your application should evidence your plan to meet the appropriate evidence guidelines.
- How will the proposed solution impact the care system and how will the system need to be changed (including people, processes and culture) in order to deliver system-wide benefits?
- How will you ensure that the innovation will be acceptable to patients (and their families and wider support network) and to health and social care workers? How could these groups be involved in the design of a solution and its development? There are expectations that individual bids show a strong element of co-creation with children and young people, their families and their carers.
- How will it be ensured that the innovation is affordable to the NHS and wider systems such as Integrated Care Systems (ICSs) both immediately and throughout the life of the

product? What evidence, both health economic and delivery of true impact will the NHS and wider system require before the technology can be adopted?

- How will the innovation support the NHS's commitment to reach net zero carbon? Applicants will be asked to provide information on the steps they have taken to identify the carbon pathway and the consequences of the proposed solution on carbon emissions.
- All proposed technologies should take into consideration appropriate integration with electronic patient records (EPR).

SBRI Healthcare Programme

This SBRI Healthcare competition is funded by the Accelerated Access Collaborative (AAC) in partnership with the Health Innovation Network to identify innovative new products and services. The projects will be selected primarily on their potential value to the health service and social care system and on the improved outcomes delivered for those in receipt of care.

The competition runs in two phases (subject to availability of budget in 2025/26):

- Phase 1 is intended to show the technical and commercial feasibility of the proposed concept. The development contracts will be for a maximum of 6 months and up to £100,000 (excl. VAT) per project.
- Phase 2 contracts are intended to develop and evaluate prototypes or demonstration units over a maximum of 12 months with up to £800,000 (excl. VAT). Only those projects that have successfully completed Phase 1 will be eligible for Phase 2.

Projects will be 100% funded and suppliers for each project will be selected by an open competition process and retain the intellectual property rights (IPR) generated from the project, with certain rights of use retained by the NHS.

SBRI Healthcare application process

This competition is part of the Innovate UK Contracts for Innovation, formerly known as Small Business Research Initiative (SBRI) programme, which offers innovative organisations the chance to work directly with the public sector to solve complex challenges:

- It enables Government departments and public sector agencies to procure new technologies faster and with managed risk;
- It provides vital funding for a critical stage of technology development through demonstration and trial especially for early-stage companies.

The scheme is particularly suited to small and medium-sized businesses, as the contracts are of relatively small value and operate on short timescales for Government departments. Thus, it is an opportunity for new companies to engage a public sector customer pre-procurement.

For more information about Contracts for Innovation, visit: <u>Contracts for Innovation - Innovate</u> <u>UK Business Connect (ktn-uk.org)</u>.

SBRI Healthcare is managed on behalf of NHS England by LGC Group. All applications should be made using the application portal which can be accessed through the <u>Research Management</u> <u>System</u>. Applicants are invited to consult the <u>Invitation to Tender</u>, and the <u>Guidance for</u> <u>Applicants</u>, the <u>RMS portal guidance</u> and <u>FAQ</u> pages on the SBRI Healthcare website to help prepare their proposal, along with attending supporting webinars and Q&A sessions.

A briefing event for organisations interested in finding out more about the competition and a webinar event to respond to potential applicants' questions will be held. Please check the <u>SBRI</u> <u>Healthcare website</u> and/or <u>SBRI Healthcare LinkedIn</u> page for confirmation of dates, information on how to register, and details of the competition, along with attending supporting webinars and Q&A sessions.

Key dates

Competition launch	17 July 2024
Deadline for applications	28 August 2024 (13:00 BST)
Selection Panel	November 2024
Project start	January 2025

More information

For more information on this competition, visit: SBRI Healthcare website

For any enquiries email: sbri@LGCGroup.com









