**Title:** Prior information Notice of Market engagement with Clinical Research Organisations for a contract to deliver Clinical Evaluations (LSRS321)

Prior Information Notice (PIN)

Objectives of this PIN:

The UK Health Security Agency (UKHSA) wishes to inform the market of their intention to undertake preliminary market engagement in advance of any potential future procurement to source one or more Clinical Research Organisations (CRO) or equivalent organisations who have the capability and experience of operational delivery of evaluation studies relating to In Vitro Diagnostic devices (IVDs) or pathogen characterisation.

This will include amongst other things protocol development, re-kitting and distribution of diagnostic devices, study design, participant recruitment, data management and analysis, report writing and dissemination of findings to support the UK’s diagnostic testing and infectious disease surveillance capabilities.

This procurement will allow UKHSA to rapidly initiate evaluation studies in a range of settings including but not limited to primary care, NHS Trusts, organisations, and community.

It is UKHSA’s understanding that this activity is not widely carried out across the Public Sector, so UKHSA therefore wishes to explore the market, identify interest and potential solutions from suitably qualified suppliers and interested parties. The scope of our market engagement may be influenced by the responses we receive.

Request for Information

To refine our requirements and help shape our proposal for a potential formal tender process, we are inviting initial expressions of interest regarding involvement in the market engagement.

We are intending to publish a Request for Information (RFI) next week (week commencing the February 5th) which we encourage interested parties to complete. We may choose to follow up on submitted RFI's with selected respondents.

Meet the Buyer event

We will also be hosting an on-line Meet the Buyer event where members of the Clinical and Public Health team will share their initial requirements and desired outcomes of the forthcoming sourcing project.

The TEAMS meeting for the online Meet the Buyer event, which will take place on February 12th at 2pm and can be accessed via this link [Click here to join the meeting](https://teams.microsoft.com/l/meetup-join/19%3Ameeting_NDA1ZDZiZjctYTdhMy00OGE3LTllZjItOWU2YWFhMjc3MGMx%40thread.v2/0?context=%7b%22Tid%22%3a%22ee4e1499-4a35-4b2e-ad47-5f3cf9de8666%22%2c%22Oid%22%3a%22da83948a-95dc-4fec-b965-371c9bd58914%22%7d)

At this stage we are merely undertaking preliminary market engagement. This will not be defined as negotiation and any future tender process will remain an open competitive process. These preliminary market consultations are being carried out under the provisions of Regulation 40 of the Public Contracts Regulations 2015 (SI

2015/102). Responding to the RFI, attendance at the Meet the Buyer event or involvement in early market engagement will not preclude a participant from participating in any future tender process.

If you would like to:

* Express an interest in any forthcoming related procurement
* Be kept informed about future events relating to this procurement
* Contribute to our market information gathering,

then please follow the link in the PIN to our e-sourcing platform Atamis and it would be helpful if you register your interest by 2nd February 12 noon.

[Link to Health Family Atamis Access](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fhealth-family.force.com%2Fs%2FWelcome&data=04%7C01%7CTTResearchCommercial%40dhsc.gov.uk%7C1cf694eef1064c83305008d9c3adb19a%7C61278c3091a84c318c1fef4de8973a1c%7C1%7C0%7C637755973050334801%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=UQ7qtsgfaPEHzwtHPRnUdK9ZuI57QSiyPoa4%2BsCr5UQ%3D&reserved=0)

You will be asked to agree to treat the information in the RFI as commercial in confidence to access the RFI.

Please note that any forthcoming procurement will also be advertised with a Contract Notice posted in FTS and Contract Finder.

**Background:**

UKHSA undertook an open market procurement in 2021 with a single award to a Clinical Research Organisation. The Public Health and Clinical Oversight directorate within UKHSA has championed and overseen multiple research studies that have been undertaken throughout the pandemic in different settings. Over the past year this has expanded beyond COVID-19 to include IVD evaluations for other pathogens of interest to UKHSA. The current contract is due expire within the next financial year.

**Our vision for the future:**

Empower all UKHSA directorates with seamless access to a cutting-edge Clinical Research Organisation. Enabling facilitation and the swift initiation of evaluation studies across diverse health and care settings, encompassing primary care, NHS Trusts, Adult Social Care (ASC), and potentially other settings if required. In addition to this, our vision is to secure a provider equipped with the surge capacity essential for UKHSA to rapidly deliver studies in an emergency scenario, ensuring agility and excellence in research endeavours that advance public health and well-being.

**Potential scope of the forthcoming procurement:**

As UKHSA transitions from a COVID-19-centric focus to encompass a broader spectrum of diseases, we envision a strategic evolution in our approach. By conducting evaluation studies across all healthcare settings in England, UKHSA is contemplating a dynamic shift towards specialisation. Our vision is to organise healthcare into three distinct and specialised areas: Primary, Secondary & Tertiary, and Organisations & Community.

To optimise this transition and ensure excellence in each specialised domain, UKHSA is considering a procurement strategy based on care setting specialisms. We feel this approach would allow us to engage providers with specialised expertise in specific areas. Through procurement based on care setting specialisms we seek partners who not only possess deep knowledge in their respective domains but also demonstrate a commitment to delivering high-quality and efficient services.

Crucially, these providers will be equipped to maintain surge capacity, ensuring resilience and responsiveness in the face of evolving healthcare challenges. We hope to position UKHSA at the forefront of research delivery fostering expertise, innovation, and collaboration across diverse healthcare landscapes for the benefit of public health in England.