**Service Specification**

**Acute drug harms surveillance and early warning system in UK emergency departments**

**Purpose**

Public Health England (PHE) is seeking to commission an external partner with an existing system and / or capability to deliver an opioid and new psychoactive substances (NPS) clinical harms surveillance programme. The programme will:

* rapidly detect any incident involving synthetic opioids in the heroin or cocaine markets;
* monitor the emergence of a synthetic opioid market as seen in North America;
* identify health harms associated with toxicity from emerging/new NPS, such as synthetic cannabinoids.

The programme will involve laboratory testing of biological samples from A&E patients around the UK who have been treated for adverse reactions to illicit drugs. Participating A&E departments will take and submit biological samples from suitable patients. These samples will be toxicologically analysed and assessed, alongside other intelligence sources. Any emerging trends and signals of interest will be reported to PHE to ensure that drug health harms are identified and acted upon promptly.

**Background**

**About PHE**

PHE is the expert national public health agency which fulfils the Secretary of State for Health’s statutory duty to protect health and address inequalities, and executes his power to promote the health and wellbeing of the nation.

PHE supports local authorities, and through them clinical commissioning groups, by providing evidence and knowledge on local health needs, alongside practical and professional advice on what to do to improve health, and by taking action nationally where it makes sense to do so.

**Why are we commissioning this work?**

This drugs market can and does change rapidly: new substances emerge with specific harms and unknown to users and clinicians; adulterated batches of traditional drugs (such as fentanyl in heroin) can put local drug using populations at heightened risk; and emerging patterns of use can also require different clinical and policy responses. This system will be an important component of PHE’s drugs surveillance and early warning capability and will enhance our ability to detect and respond to a range of scenarios that pose a threat to public health. Along with other concerns, the scale of the opioids problem hitting North America in particular, underlines the need for a robust early warning system in the UK.

PHE has been funding the Identification of Novel Psychoactive Substances (IONA) research project currently operating from ~30 emergency depts across England, Wales and Scotland; and is seeking proposals from organisations with existing capability to deliver a similar surveillance programme as articulated in this service specification.

**Outline of Work**

The provider will deliver an opioid and NPS clinical harms surveillance programme.

The successful provider will:

* develop or adapt existing project planning and governance documentation, such as standard operating procedures, protocol, consent forms etc for sign off by PHE. This will include agreement as to the mix of analytical methods for looking at compounds of interest (e.g. fentanyls) and submitting selected samples of particular interest for discovery analysis;

* recruit and manage the on-going relationships with participating NHS trusts, ensuring a good geographical spread, including sites in Scotland;
* coordinate with participating A&E departments to take and submit biological samples from suitable patients;
* collate submitted samples;
* ensure the capacity to undertake toxicological analysis for samples using absolute/targeted detection techniques and samples using mass spectrometry and report to PHE on results within one month of samples being received;
* produce monthly, quarterly and ad hoc/as required data and written reports for PHE on toxicological results and emerging trends/signals of interest;
* attend quarterly contract review meetings with PHE to review progress against agreed performance measures.

**Deliverables**

The delivery partner would be expected to be able to collect and test samples from 200-250 individuals per quarter presenting to emergency departments with suspected drug toxicity. The analytical technique used to detect substances in most samples would only need to be able to identify drugs from an agreed panel of previously identified substances (i.e. absolute/targeted detection). However, the delivery partner would need to have the capability to test samples using mass spectrometry where absolute/targeted detection does not adequately identify substances likely to have caused the clinical features of the case.

Any proposals below this range should indicate what actions will be taken to reach these levels, with likely timescales.

**Dissemination of findings**

The delivery partner will contribute to a PHE-led dissemination plan which will encourage key stakeholders (both national and local) across England to access the findings of the programme. The main route for sharing findings will be via PHE’s Drug Harms Assessment and Response Team (DHART), a multidisciplinary group meeting quarterly to share and review the latest intelligence on the drug market and clinical harms from a wide range of sources. The DHART group agrees a quarterly ‘dashboard’ of emerging drug health harms for dissemination to professionals.

**Reporting arrangements**

The delivery partner will work closely with PHE to plan, implement and report on the project.

The dissemination process will be inclusive of local and national stakeholders via the DHART and other relevant channels.

The evaluation and review process will be transparent and will include sharing information on objectives, plan and timetable and reports with providers, stakeholders, commissioners and policymakers as appropriate.

The delivery partner will provide:

* alerts to PHE wherever a signal or potential pattern of emerging harm in order for PHE to assess the appropriate course of action locally, regionally or nationally;
* monthly data in an agreed template;
* quarterly data and written reports using agreed templates at least one week ahead of the DHART. These reports will be reviewed in a quarterly contract review meeting;
* ad hoc data and written reports/presentations as directed by PHE (i.e. where other intelligence sources are giving a signal of interest, PHE may ask the delivery partner to report on any relevant information from the programme).

**Data Handling and Provision**

All personal data (as defined within the General Data Protection Regulation (GDPR)), collected, stored, analysed or shared must be carried out in compliance with the Data Protection Act 2018, GDPR and must conform with the policy statements specified in the PHE Information Governance Policy framework.

The successful provider must adhere to the Freedom of Information Act (2000).

**Risk Management**

Applicants should submit, as part of their application, a summary explaining what they believe will be the key risks to delivering this project, and what contingencies they will put in place to deal with them.

A risk is defined as any factor which may delay, disrupt or prevent the full achievement of a project objective. All risks should be identified. The summary should include an assessment of each risk, together with a rating of the risks’ likelihood and its impact on a project objective (using a high, medium or low classification for both). The risk assessment should also identify appropriate actions that would reduce or eliminate each risk, or its impact.

**Stakeholder and Public Involvement**

The provider will be undertaking direct engagement with stakeholders as appropriate. The provider will be expected to submit as part of their application their mechanism for engaging with key stakeholders from a range of sectors and engagement with the public (where necessary).

**Delivery Timescale**

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| --- | --- |
| **Date** | **Action or deliverable** |
| **August 2021** | Delivery partner develops or adapts existing project planning and governance documentation, such as standard operating procedures, protocol, consent forms etc for sign off by PHE. This will include agreement as to the mix of analytical methods for looking at compounds of interest (e.g. fentanyls), and submitting selected samples of particular interest for discovery analysis  Evidence of ethical assurance and data management provided to PHE  Reporting templates signed off by PHE  Sample collection on-going |
| **September 2021** | First monthly data report to PHE |
| **November 2021** | First quarterly data and written report to PHE (covering 1st August 2021-31st October 2021) at least one week ahead of the DHART meeting and first quarterly contract review meeting |
| **On-going** | Monthly data reports and quarterly data and written reports/contract review meetings. This is likely to include presenting findings to the DHART and other relevant groups. |

**Contract Period**

The contract is expected to run from 1st August 2021 until 30th July 2022 as per the commissioning timetable below.

Standard break clauses for each contract will be enforced prior to the contract renewal.

**Contact Point(s)**

It is expected that the supplier will appoint a named, suitably qualified project lead manager who will be the main point of contact with PHE.

The key contact point at PHE will be Craig Wright (Senior Programme Manager). All members of PHE staff will be available for telephone or face-to-face advice throughout the project lifetime. PHE can facilitate discussions with other topics experts from within PHE and other key partners where required.

**Costs**

The provider will need to give a detailed breakdown of their costs. Please note that applicants will need to demonstrate value for money.

The contract value will be a maximum of £100,000 (excluding VAT) with an expected start date of 1st August 2021 and end date of 31st July 2022.

In the interests of continuous improvement PHE invites suppliers to outline proposed deliverables or improvements in addition to the core requirements above and beyond the indicated contract value of £100,000 (excluding VAT).

Please outline the following clearly separated from proposals to deliver the core requirements:

1. the proposed additional deliverables with costs (shown separately for each element); and
2. delivery timescales.

Should funds become available during the contract period, the opportunity may arise for expanding the scope of this work.

**Application Process**

Applications should be submitted electronically and include the following documentation:

* + Supporting statement setting out and establishing suitability to undertake the project (see selection criteria below), including evidence of carrying out work of a similar nature
  + Project plan
  + Budget (including detailed breakdown of spend)
  + Risk mapping and associated risk register, including any potential conflicts of interest

Brief biography of all project team members and their expertise in this area. Word count (excluding biographies) is a maximum of 2,000 words per document.

Applications will be reviewed by an internal PHE panel and candidates will be informed electronically of the result.

If two applications are scored identically then both applicants may be invited to an interview to decide the outcome.

**Selection Criteria**

Criteria used by members of the PHE panel to assess applications for funding from the project include:

1. **RELEVANCE** of the proposed project plan and methodology to the aims and objectives of the project;
2. **QUALITY** of the work plan and proposed management arrangements;
3. **STRENGTH** of the project team;
4. **IMPACT** of the proposed work;
5. **VALUE** for money (justification of the proposed costs);
6. **INVOLVEMENT** of key partners and the public.

**Commissioning Timetable**

It is anticipated that commissioning of this project will occur to the following approximate timetable:

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| --- | --- |
| **Date** | **Action** |
| **7th June 2021** | Issue of invitation to tender via BRAVO |
| **28th June 2021** | Deadline for receipt of applications |
| **12th July 2021** | Notification of outcome of applications review |
| **19th July 2021** | Award of contract |
| **1st August – 1st September 2021 /** | Contract begins |
| **31st July – 31st August 2022** | Project completion |