Department of Health

INVITATION TO TENDER FOR THE PROVISION OF:

Review of the Early Access to Medicines Scheme (EAMS).

Deadline: **27/08/2015 –14:00**

ITT Reference: **59959**

PART B – Tender Schedules
(To be returned by Tenderers)

Schedule One (a): Tenderer Response

SECTION A Organisation details

Tenderer name

Please confirm the name of the Tenderer*:

Tenderer Name:	PwC LLP

- Full name of organisation tendering (or of organisation acting as the lead contact where a consortium bid is being submitted)

Contact details*

Tenderers must provide contact details for this tender.

Contact Name*	*Information redacted in line with Section 40 of the FOIA*
Telephone number	*Information redacted in line with Section 40 of the FOIA*
Email address:	*Information redacted in line with Section 40 of the FOIA*
Address:	7 More London Riverside, London SE1 2RT

- Contact is the person responsible for any queries relating to this proposal

Organisational status

Please confirm whether (or not) the Tenderer is a Small & Medium Enterprise[1] (**SME**).

The Tenderer is an SME (Yes / No)	No

[1] To be considered an SME, an organisation must have a headcount less than 250 Annual Work Units (anyone that has worked full-time within the enterprise, or on its behalf, during the reference year counts as one unit. Part-time staff, seasonal workers and those who did not work the full year are treated as fractions of one unit) **AND** a turnover less than €50 million **OR** annual balance sheet of €48 million.

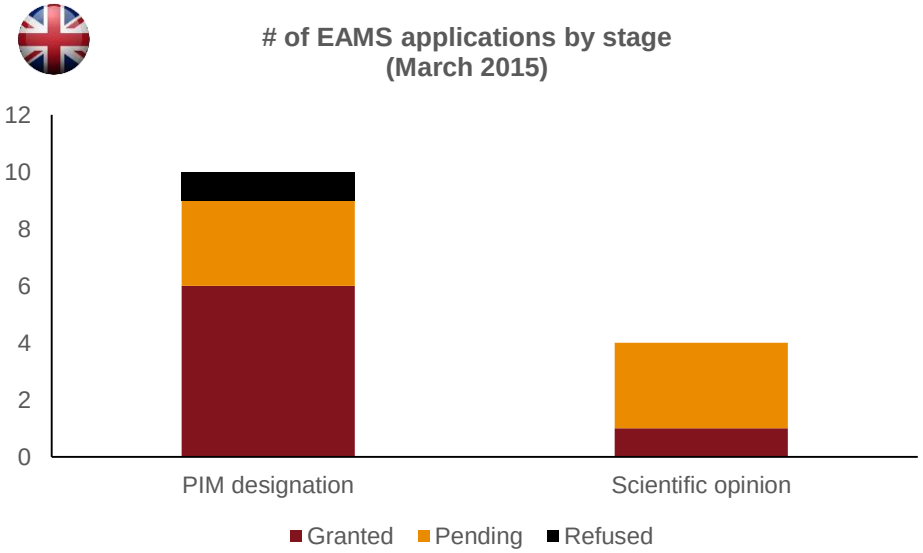
SECTION B Solution Proposal - refer to table 2, Part A for evaluation intention and evaluation criteria.

- **Overview**

Tenderers must provide a concise summary highlighting the key aspects of the proposal.

(This response is not evaluated and should be used to contextualise the Tenderer's response.)

Response (maximum 500 words)
Since its launch in April 2014, the Early Access to Medicines (EAMS) scheme has achieved a modest success as the MHRA has awarded **7 PIM designations and 3 Scientific Opinions**. These numbers are far lower than the number of applications to comparable schemes in France and Japan.



Source: MHRA

More than **400 product applications** to **ATU** scheme between 1994 and 2001, i.e. an average of approx. 57 per year
Source: ANSM

About **60 products** put forward as candidates for **Sakigake Designation** between April and June 2015
Source: PharmaJapan

We have initial hypotheses based on a preliminary analysis of publicly available information. We will be testing these during the project, once agreed with you:

- As per the above graph[2], out of the 6 PIM designations awarded until March 2015, only 1 company was successful in obtaining a positive scientific opinion. We think this limited throughput is related to the lack of

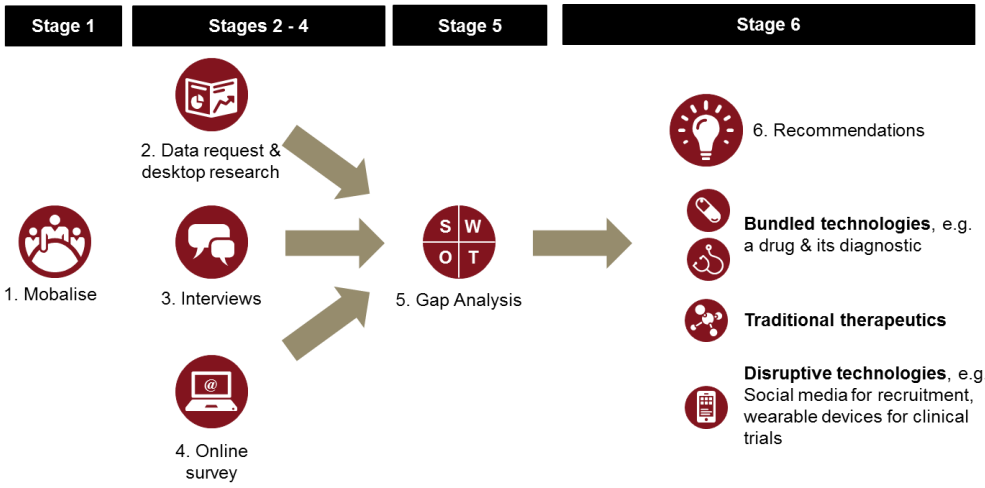
[2] The data in the graph (6 PIM designations and 1 positive scientific opinion) do not reflect the current status of 7 PIM designations and 3 positive scientific opinions, as the latest data published by MHRA date from March 2015. Since then, there have been 2 additional positive scientific opinions, both for Bristol-Myers Squibb's *Nivolumab*.

Response (maximum 500 words)

central funding for EAMS to reimburse companies for the cost of unlicensed drugs.

- Moreover, all 3 positive scientific opinions granted to date are highly similar; they are all for last-resort oncology drugs, implying varying success rates of the EAMS scheme across product groups.

The current review aims to look analyse the current EAMS process, evidence for the above observations and develop recommendations to improve EAMS. The focus will be to investigate how EAMS can move beyond pharmaceuticals to **promote the development of stratified medicines and their partner diagnostics, convergent and combinatorial technologies and new therapeutic technologies**. As part of our review, we will also **develop new product archetypes** under the categories of bundled technologies, traditional therapies and disruptive technologies; we will categorise our review findings and recommendations by product archetype to ensure EAMS is able to accommodate these products in future. If we are also assigned the



adaptive pathways review project (workstream 2), we will leverage these to develop and analyse options per archetype.

Our suggested method is as follows:

- **Step 1: Mobilise**

- **Steps 2-4: a**n **in-depth as-is assessment** with **desktop research** into the data MHRA has available, RAND review, international schemes similar to EAMS and the market landscape over the next decade. We will also hold **interviews** with all relevant stakeholders and send out an **online survey** to gives us input from a larger set of players, including those who were deterred from completing EAMS applications.

- **Step 5:** A **gap analysis** will be developed, to identify strengths and weaknesses in the current EAMS process and make it fit for future needs.

Response (maximum 500 words)
• **Step 6:** The final stage of the project will deal with the **development of the evidence-based recommendations** to feed into the final report. A significant element of the third stage will be to ensure that the EAMS programme is agile and future proofed to accommodate new types of products into the scheme, such as medical devices and diagnostics likely to come to market in the next decade. Throughout the project, we be using the **crowdsourcing platform** to engage key stakeholders, test and refine our ideas with practitioners. The **outputs** will include a detailed report and PowerPoint summary outlining: (1) our methodology, (2) gap analysis supported by factual evidence and clear weighting process and (3) our recommendations, which will be prioritised according to a commonly agreed mechanism.

- **Leadership (10%)**

Provide details of the qualifications and skills of the individual whose responsibility will be to ensure that the requirement is delivered.

Response (maximum 500 words)
Information redacted in line with Section 40 of the FOIA, Director • *Information redacted in line with Section 40 of the FOIA*

- **Method statement (35%)**

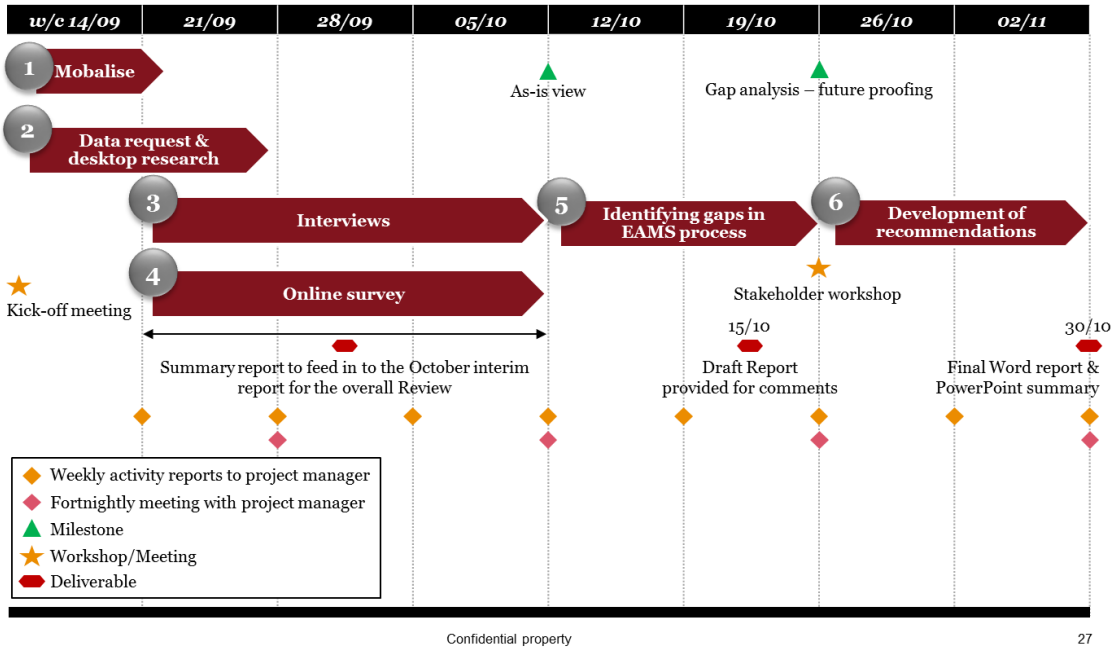
Describe (with specific reference to the elements of the requirements and the outcomes expected) how it is intended to deliver the requirements of the specification.

Response (maximum 1000 words)
We propose a project length of 8 weeks, with the draft report scheduled to be complete by 30 September and final deliverable by 6 November. **1. Stage 1: Mobilise** We will start with a **kick-off meeting** w/c 14 September, where we will prepare the following to discuss and agree with you: • Hypotheses on potential strengths, weaknesses and lessons learned from the EAMS scheme to validate and tailor with you to inform our research • A data request having consolidated what information is publicly available and what we have in-house • Recommendations for stakeholder interviews from our broad

Response (maximum 1000 words)

network

- A proposed governance and ways of working approach



2. Stage 2: Data Request & Desktop Research

We will begin with a thorough information review consisting of the below elements:

- A **data request** will be made to the workstream 2 team to obtain all the relevant data (e.g. overview of companies applying for PIM designation), prior research (including RAND's *Insights on Earlier Adoption of Medical Innovations*). This will give a good understanding of the existing EAMS processes, key decision points, stakeholders involved and the information flow of between them.

- Through **desktop research,** we will fill the remaining data gaps, leveraging reports such as that from RAND. We will do this by:
  - bringing in our international experience to take on board best practices from other countries, such as Italy and Germany, and leverage our network of local PwC experts
  - explore the pharmaceuticals landscape for the next 10 years, to help us develop archetypes in traditional therapeutics, bundled technologies and disruptive technologies

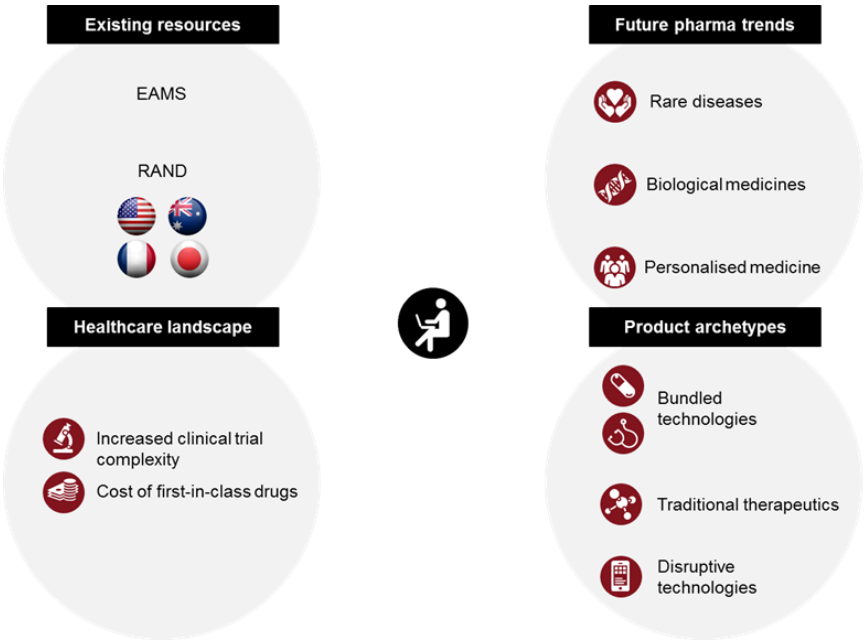
Information redacted in line with Section 40 of the FOIA.

  - consider future trends such as new modalities for biological medicines, higher investment in personalised medicine, and pharma's focus on rare diseases with high unmet need

Response (maximum 1000 words)

- look into how the wider healthcare environment will cope with the pipeline of first-in-class drugs and greater clinical trial complexity

With these evolutions in mind, we will assess EAMS in its current shape and whether it is future-proof.



- At the end of this research phase we aim to **adjust the hypotheses** we formed at kick-off. We propose to share these initial insights with stakeholders through the AAR's **crowdsourcing platform** to test our ideas with practitioners and refine them as required.

3. Stage 3: Interviews

Overall we will hold 15 to 20 **interviews** with **academic institutions**, **public sector** partners and **industry** (including medical technology, diagnostics, devices, digital innovation, and pharma).

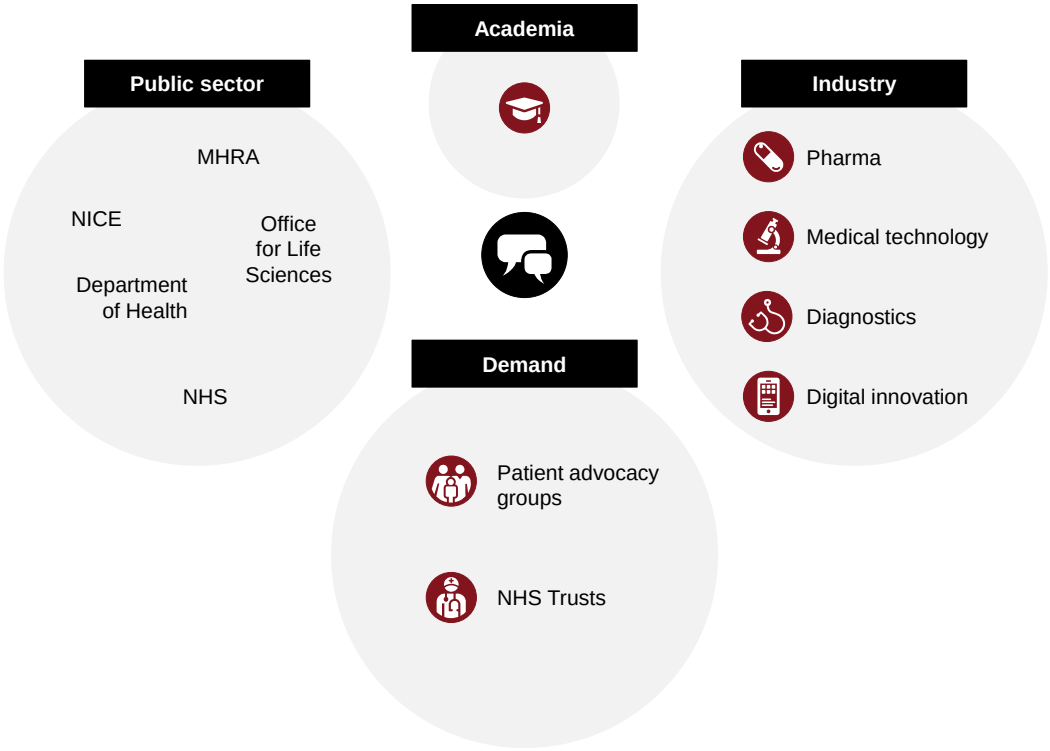
We will involve global and SME pharma companies with varying EAMS experiences as per the categories below:

- The 2 companies whose products have been granted scientific opinion
- Companies who chose not to pursue a scientific opinion after being given PIM status.
- Companies unsuccessful at either stage

This will give us a view of what works well and what could be improved in the current EAMS process – for example, poor link with NICE or poor awareness of the scheme amongst the general public. We will also meet players involved on the **EAMS demand side**, i.e. patient advocacy

Response (maximum 1000 words)

groups and practitioners from NHS Trusts.



4. **Stage 4: Online survey**

   To get as wide a perspective as possible, we will launch an **online survey**. The survey will provide insight into the reasons why some companies were deterred from applying for EAMS. We will involve players of different size and therapy area of focus.

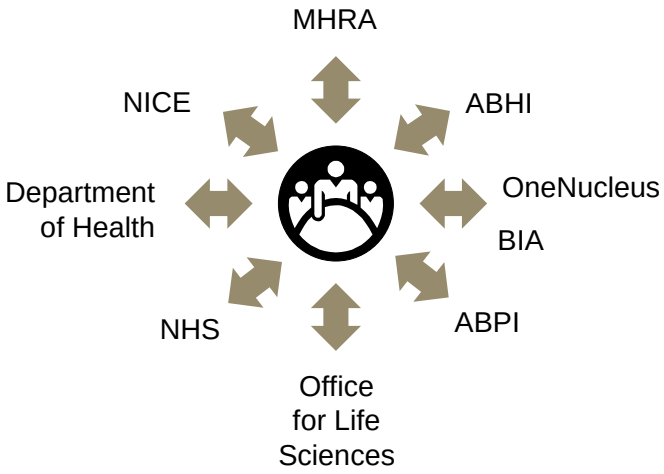
5. **Stage 5: Identify gaps in EAMS process**

   The results of the first three activities will inform the gap analysis of **strengths and weaknesses and priority areas for change in the EAMS process**. This analysis will be shared on the crowdsourcing platform to seek opinions from practitioners. The conclusions will be used to show how the critical and best-performing elements of EAMS can serve as basis for a new pathway and include medical devices, diagnostics, digital solutions and other future trends.

Response (maximum 1000 words)

These preliminary conclusions will be tested in a **workshop** to increase buy-in from EAMS stakeholders and invite their initial feedback.

Proposed workshop attendees



6. Stage 6: Development of recommendations

Finally, the **recommendations** will be refined for the final report. The report will focus on new types of products that will come to market in future, particularly around stratified medicine and their partner diagnostics, convergent and combinatorial technologies and new therapeutic technologies and how these relate to the product archetypes. The final recommendations will be posted on the crowdsourcing platform to stimulate ongoing discussions.

Ongoing: We have a **rigorous project management framework**, the 12 Elements of Delivery Excellence, which allows us to flex our approach to meet the project's critical success factors:

- Timely access to the **right data** to deliver to **agreed deadlines**
- **Feasible and practical recommendations** based on discussions with practitioners in the field
- **Access to a broad network of stakeholders**
- Transfer of **ownership of the deliverables** to the workstream 2 team

We will manage the **scope** of the project to keep the focus on the intended deliverables and we will also resource a **high-performing team** that is well networked and has experience with similar work.

Information redacted in line with Section 40 of the FOIA.

Together with you, we will set up appropriate **governance** structures and decide on a frequency and format for reporting. We will deal with any **risks** by openly discussing these with you and proposing mitigating strategies in a timely manner.

Response (maximum 1000 words)
One of our key strengths is our ability to **manage stakeholders**, even in challenging circumstances. Our approach is tried and tested in complex engagements such as our role in assisting Vanguard sites towards delivering the Five Year Forward view, and our work in constructively managing the input on PwC's strategy of our Health Industries Oversight Board, *Information redacted in line with Section 40 of the FOIA*. Our approach to **benefits management** means we work towards delivering the benefits you require from this project, as well as **embedding** the **lessons learned** in your organisation as described in the Exit Strategy section. We work with you to create a plan for **quality management** around the different deliverables and events scheduled for this project. This means that we agree the expectations together with the approach, process, acceptance criteria and roles and responsibilities for delivering on the quality.

- **Resource Plan (20%)**

Provide a complete resource plan for the delivery of the Specification including details of the team involved, what these individuals will be doing and why these individuals are suitable for this requirement.

Response (maximum 1000 words)
We have assembled a team which we propose to work across both bids. The overall resource plan is indicated here and focuses senior resources on hypothesis development upfront, stakeholder engagement, participation to key interviews/discussions, deliverable review and workshop facilitation. All our team members are familiar with the UK environment, strategic option analysis, hypothesis driven approaches and have experience working with Pharma clients. Below is a plan of how we intent to resource the project: *Information redacted in line with Section 40 of the FOIA* *Information redacted in line with Section 40 of the FOIA* • *Information redacted in line with Section 40 of the FOIA* **responsibilities** include: o Keeping oversight of the project o Challenging hypothesis generation and bringing her industry and UK environment insight o Participating at the fortnightly reviews to provide direction and challenge

Response (maximum 1000 words)
○ Facilitating the workshops ○ Reviewing all draft deliverables and challenging thinking to achieve the highest quality ○ Presenting the final deliverables ○ Engaging senior stakeholders in 1:1 discussions as needed to get buy-in into recommendations ○ Acting as the point of escalation in case of any concerns or feedback from stakeholders • *Information redacted in line with Section 40 of the FOIA* • *Information redacted in line with Section 40 of the FOIA* • She has worked with a **broad range of industry clients**. She has led projects for a variety of pharmaceutical clients, ranging from global pharma clients to generic, OTC and biotechnology players. She has also worked on strategy and capability development for medical devices companies • *Information redacted in line with Section 40 of the FOIA* *Information redacted in line with Section 40 of the FOIA*, Director and Project Lead • *Information redacted in line with Section 40 of the FOIA* **responsibilities** include: ○ Driving hypothesis generation and structure of the final deliverable(s) ○ Directing the team on a day-to-day basis and troubleshooting, as needed ○ Identifying, highlighting and proposing mitigating actions for relevant issues ○ Directing the research, analysis and recommendation development ○ Co-facilitating the workshops with *Information redacted in line with Section 40 of the FOIA* ○ Supporting the team in interviews as needed, particularly with key stakeholders ○ Reviewing all draft deliverables before a final review is conducted by *Information redacted in line with Section 40 of the FOIA* ○ Co-presenting the final deliverables with *Information redacted in line with Section 40 of the FOIA* ○ Participating at the fortnightly reviews to provide direction ○ Supporting *Information redacted in line with Section 40 of the FOIA* with engagement of senior stakeholders via 1:1 discussions as needed to get buy-in into recommendations

Response (maximum 1000 words)

• The details of *Information redacted in line with Section 40 of the FOIA* experience are outlined in the Leadership section as she is the responsible employee for this project.
 	
Information redacted in line with Section 40 of the FOIA, Consultant
• Information redacted in line with section 40 of the FOIA responsibilities include:
  ○ Managing the delivery team
  ○ Delivering project status updates and tracking project KPIs
  ○ Structuring the hypotheses and coordinating the research and analysis
  ○ Development of interview guides per stakeholder
  ○ Leading interviews
  ○ Attending the regular updates and fortnightly reviews
  ○ Working closely with you to get feedback on content and deliverables
  ○ Supporting workshop facilitation and final deliverable presentation
• *Information redacted in line with Section 40 of the FOIA*.
• Recent relevant strategic project experience which will enable *Information redacted in line with Section 40 of the FOIA* to quickly develop hypothesis and structure the research analysis include:
  ○ *Information redacted in line with Section 40 of the FOIA*. This work involved an analysis of local access schemes and reimbursement criteria, as well as a holistic review of global market access trends.
  ○ *Information redacted in line with Section 40 of the FOIA*.
  ○ *Information redacted in line with Section 40 of the FOIA*, covering an end-to-end mapping of activities and identification of new opportunities for collaboration between the client and industrial partners.
  ○ *Information redacted in line with Section 40 of the FOIA*
 	
Information redacted in line with Section 40 of the FOIA, Subcontractor
• *Information redacted in line with Section 40 of the FOIA* **responsibilities** include:
  ○ Engaging his network for interviews
  ○ Providing challenge to hypotheses
  ○ Providing the AHSN/academic perspective on challenges and that of an ex-GSK R&D leader
• *Information redacted in line with Section 40 of the FOIA*

- **Exit Strategy & Skills Transfer (5%)**

Describe the processes and deliverables of the exit phase of the service and how skills will be retained within the Authority.

Response (maximum 500 words)
During the kick off as we discuss ways of working we will also agree with you how knowledge and skills transfer happens throughout the project to minimise the impact on our exit. We will strive to give the workstream 2 team **total ownership of the deliverables** by the end of the project. In order to achieve this we will: • Share points of views from different stakeholders as we go during our update meetings and engage you as we discuss with key stakeholders so you retain that knowledge • Create our final deliverables to be **stand-alone documents** that contain all the necessary sources of information and appendices. • Be clear in the way we structure deliverables so the reasoning can be followed at a later time • Provide all other data files and annexes with calculations • Discuss the content of all the information and answer any questions at the time • Remain at your disposal to answer any questions you might have once the final deliverables have been transferred, and follow-up meetings can be scheduled. So that the lessons from this project have a lasting impact and are embedded within the DH organisation, we aim to **maximise interaction** with all key **DH stakeholders** involved in workstream 2. This will be achieved through the weekly progress updates and bi-weekly meetings set out in the project management structure. During these sessions we will allow sufficient time for Q&A, and opportunities to bring up any other matters the DH project team wishes to raise. We would like you to challenge our thinking so that you feel ownership of the final recommendations and can justify them to senior DH stakeholders as if they were your own. In addition, we will engage in a process of co-creation with DH and its stakeholders during the **collaborative workshop** so that you can understand and endorse the evidence base of the recommendations and rationale for the prioritisation. In our experience where we engage our clients throughout the project then the knowledge transfer is happening throughout the project rather than at the end where it may be difficult to follow the progression and retain the information. This achieves lasting buying in and allows your teams' skills and knowledge to be developed gradually taking into account how they prefer to work and capture the knowledge. We also aim to engage the broader community of stakeholders and transfer

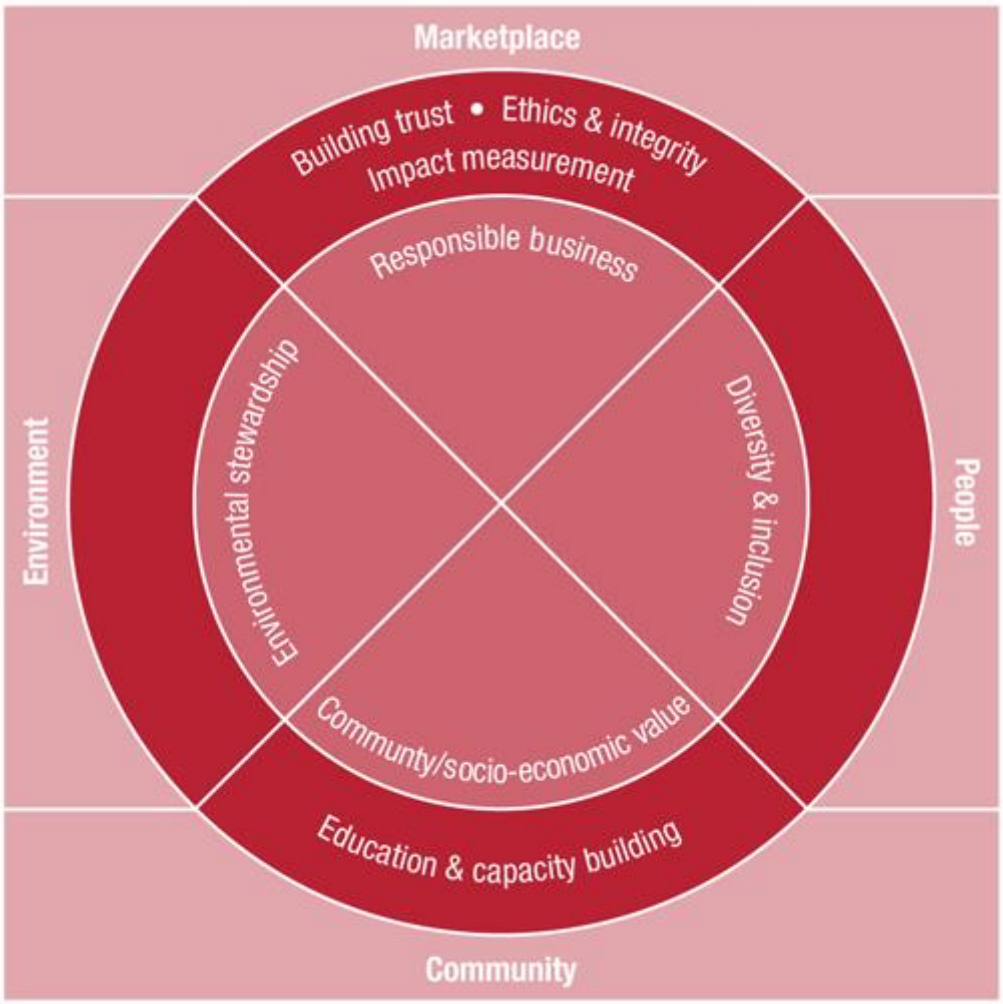
Response (maximum 500 words)
lessons learnt on a wide scale, by keeping them informed via the **crowdsourcing platform**, and invite their comments and suggestions for improvement throughout the entirety of the project.

- **SME and sustainability outcome reporting (This question is not weighted)**

Briefly describe how you are able to satisfy / commit to the Government initiatives on SME expenditure and sustainability outcome reporting

Response (maximum 200 words)
PwC shares the government's goal of providing fair opportunities will engage *Information redacted in line with Section 40 of the FOIA*. He will contribute his experience as an academic and start-up entrepreneur in working within the UK Life Sciences environment. PwC's **sustainability** strategy comprises four areas: responsible business; workplace and diversity; community engagement; and environmental stewardship.

Response (maximum 200 words)



With regards to environmental stewardship, our policy focuses on:

- **Carbon emissions**: we have reduced our carbon emissions by 26% since 2007
- **Travel**: We are currently 16% below 2007 levels of emissions from business travel
- **Energy**: Since 2007 we have reduced our energy consumption by 37%
- **Waste**: We have reduced our total waste by 50% since 2007
- **Water & paper**: Since 2007, we have reduced our paper and water consumption by 51% and 32% respectively

We are also one of only a handful of organisations to achieve the Chartered Institute of Purchasing & Supply (CIPS) **Platinum accreditation**, in recognition of world class supply chain management. In addition, we have developed a framework to give organisations a holistic view of their impacts on society: **Total Impact Measurement & Management** (TIMM). We have carried out TIMM reporting for ourselves and various clients.

Schedule One: Pricing Schedule

1. General Instructions

1.1. The rates contained within the Pricing Schedule are, unless otherwise expressly agreed between the parties, firm.

1.2. The rates entered shall be deemed to include complete provision for full compliance with the requirements of the Contract.

1.3. **The rates exclude VAT**.

1.4. The rates entered in the Pricing Schedule shall include all travel and subsistence costs. Expenses will only be approved if supported by original receipts. The Authority will only pay for expenses claimed that are in line with the Department's guidelines for expenses. Original receipts will need to be provided.

1.5. The Authority will only make payment for overnight stays that have been authorised beforehand in writing by the Authority's Representative.

1.6. Any extra expenses other than travel and subsistence must be priced separately in the Pricing Schedule. The Department will only pay for expenses claimed that are included in this pricing schedule and are deemed to be reasonable for delivery of the requirement.

1.7. Tenderers must include in the pricing schedules any discounts or any reduced pricing they are proposing to offer to the Authority in delivery of this requirement.

DESCRIPTION OF SERVICE			**FIRM PRICE**
Management & staff and respective man-days:			
Name & Position	Cost per day	No of days	
Information redacted in line with Section 40 of the FOIA	Information redacted in line with Section 43 of the FOIA		
Sub-total/total consultancy cost			£ 19,505
Production of reports *(or any other output)*			£ 0
Any other costs (please describe what these costs are)			£ 0
Discount **Note:** We would like to offer you an unconditional discount of £4,505 for this piece of work in order to comply with your £15,000 budget requirement. A discount of £5,000 will be applied to ITT 59941 if the work relating to both ITTs is won. This is because we expect synergies to arise between the two projects in the form of project management & knowledge transfer.			£4,505
Total Contract Price (Evaluation Price)			£ **15,000**

Schedule three: Contract Monitoring

1 General Instructions

1.1. Tenderers must provide all the information requested in the following section as part of their tender proposal. Supporting documents may be submitted but must be clearly referenced back to the appropriate section.

2. Representatives

2.1 Name of Authority's Representative(s): To be confirmed at Contract award

2.2. Name of Contractor's Representative(s): *Information redacted in line with Section 40 of the FOIA*

3. Deliverables

3.1 The final deliverable will be a concise Word report, setting out the strengths and weaknesses of the current EAMS processes, whether EAMS is future-proofed to cope with new product types and environment expected in the next ten years, and any priority areas for change.

3.2 The final version of the final deliverable is due on 30 October 2015, and will be accompanied by a PowerPoint summary and supporting documentation. A draft version of the final deliverable is due for comments on 15 October 2015.

Key performance indicators

Indicator	Due date
Regular progress updates to project manager and wider team	Weekly
Regular meetings with the project manager and wider team	Minimum fortnightly
Broad stakeholder engagement: • List of individuals and organisations approached and who commented provided to review team • Good diversity of stakeholders at workshops to test and validate emerging findings	Lists to be shared in regular updates and the draft and final reports.
Summary report to feed in to the October interim report for the overall Review	September (date tbc)
Draft report provided for comment	15 October
Final Word report and PowerPoint summary including clear evidence of the impact of EAMS, incorporating: • strengths and weaknesses of the current EAMS process; • an assessment of the degree to which EAMS is future-proofed	30 October

• assessment of any priority areas for change. Supporting evidence and data supplied in Annexes.	
Close off meeting	November

4. MEETINGS

4.1 Frequency of contract management meetings: Fortnightly

4.2 Location of contract management meetings: Face to face in London or telephone/video conference as agreed as appropriate

4.3 Checking performance against anticipated plan: Weekly status reports will be expected and used to inform the contract management meetings

5. REMEDIES

5.1 Where the Authority through contract management meetings identifies issues of below expected performance the contractor shall work with the Authority to ensure that such performance is addressed and the delivery outputs and timescales are adhered to. Where performance issues arise the Supplier shall address with the Authority immediately to resolve, with the supplier setting out how such matters will be dealt with to ensure continued delivery to the required standard.

Schedule Four: Confidential & Commercially Sensitive Information

1. General

1.1. All the information that the Authority supplies as part of this Contract may be regarded as Confidential Information as defined in Condition 1 (Definitions) of Section Three – Conditions of Contract.

1.2. The Contractor considers that the type of information listed in paragraph 2.1 below is Confidential Information.

1.3. The Contractor considers that the type of information listed in paragraph 2.2 below is Commercially Sensitive Information.

2. Types of Information that the Contractor Considers to be Confidential

2.1. Type 1: Confidential information:

Information considered confidential	Reason for FoIA exemption (include paragraph reference)	Period exemption is sought (months)
None		

2.2. Type 2: Commercially sensitive information:

Information considered commercially sensitive	Reason for FoIA exemption (include paragraph reference)	Period exemption is sought (months)
None		

Schedule Five: Administrative Instructions

1. AUTHORISATION

1.1. The person shown below person shall act as the Authority's Representative on all matters relating to the Contract:

NAME	**To be confirmed at Contract Award**
CONTACT DETAILS	**To be confirmed at Contract Award**

1.2. The Department's Representative may authorise other officers to act on their behalf.

2. NOTICES

2.1. Any notice the Contractor wishes to send the Authority shall be sent in writing to the Authority's Representative at the address shown in paragraph 1.1 above.

2.2. Any notice the Authority wishes to send the Contractor shall be sent in writing to the Contractor's Representative at the address shown in paragraph 4.2 below.

3. ADDRESS FOR INVOICES

3.1. It is preferred that invoices are sent electronically to:

MB-PaymentQueries@dh.gsi.gov.uk

3.2. Alternatively invoices can be sent to the Department addressed to:

Department of Health
Accounts Payable
Room 530
Richmond House
79 Whitehall
London
SW1A 2NS

3.3. Invoices must not be sent to the Authority's Representative.

4. CORRESPONDENCE

4.1. All correspondence to the Authority except that for or relating to invoices shall be sent to the following address: *To be confirmed at contract award stage*

4.2. All correspondence to the Contractor shall be sent to the following address:

Tenderer to provide Address

Schedule Five: Appendix A: Variation to Contract

(FOR INFORMATION ONLY – NOT FOR COMPLETION AT TENDER STAGE)

CONTRACT TITLE:	

FOR THE PROVISION OF:	

CONTRACT REF:		**VARIATION NO:**		**DATE:**	

BETWEEN:

The Secretary of State for Health (hereinafter called the Department) and [INSERT NAME OF CONTRACTOR] (hereinafter called the Contractor) having his main or registered office at [DN:INSERT ADDRESS]:

The Contract is varied as follows:

(DN:INSERT DETAILS OF VARIATION)

Words and expressions in this Variation shall have the meanings given to them in the Contract.

The Contract, including any previous Variations, shall remain effective and unaltered except as amended by this Variation.

SIGNED:

FOR: THE AUTHORITY	**FOR THE CONTRACTOR**
By	**BY**
Full name	**FULL NAME**
GRADE / PAY BAND	**TITLE**
DATE	**DATE**

Schedule Five: Appendix B: Novation Agreement

(FOR INFORMATION ONLY – NOT FOR COMPLETION AT TENDER STAGE)

THIS DEED (THIS AGREEMENT is made on the [dd] day of [month & year] BETWEEN

(1) THE SECRETARY OF STATE FOR HEALTH (the **Secretary of State**) whose principal place of business is at Richmond House, 79 Whitehall, London, SW1A 2NS,

(2) THE [CONTRACTOR] of [address]

(3) THE [NEW PARTY] of [address]

WHEREAS

(A) This Agreement is supplemental to an agreement dated [dd Month Year] between the Secretary of State and the Contractor (the **Contract**) under which the Contractor agreed to provide services to the Secretary of State.

(B) The Secretary of State has authorised the New Party to replace the Secretary of State as the contracting Department under the Contract on the terms of this Agreement and the Contractor is willing to accept the New Party in place of the Secretary of State on those terms.

IT IS HEREBY AGREED AS FOLLOWS:

1. Subject to the following Clauses of this Agreement –
   a) The Contract shall continue in full force and effect as if the New Party were named as a party to the Contract in place of the Secretary of State for Health.
   b) All rights, obligations and liabilities arising under the Contract from the date of this Agreement shall be rights, obligations and liabilities between the New Party and the Contractor.
   c) Any existing rights, obligations or liabilities of the Secretary of State relating to the performance of the Contract up to the date of this Agreement shall pass to the New Party and shall be enforceable between the Contractor and the New Party in place of the Secretary of State.
2. The rights, obligations and liabilities of the Contract shall be exercisable and enforceable as the rights of the New Party under this Agreement.
3. This Agreement shall be governed by and interpreted in accordance with English law and shall be subject to the jurisdiction of the courts of England.

Signed by .....for and on behalf of the
Secretary of State for Health in the presence of:

Signed by .....for and on behalf of the
Contractor in the presence of:

Signed by .....for and on behalf of the
New Party in the presence of:

Schedule Five: Appendix C: Sub-Contractors

All suppliers to the Department of Health are asked to provide details of all sub-contractors that will be used to perform the contract.

NAME & ADDRESS OF SUB-CONTRACTOR		SERVICE PERFORMED FOR CONTRACTOR	PROVIDE DETAILS OF STAFF NUMBERS[3]	PROVIDE LATEST YEAR'S TURNOVER
NAME: ADDRESS:	*Information redacted in line with Section 40 of the FOIA* *Information redacted in line with Section 40 of the FOIA*	Strategic advice, connecting with potential interviewees, stakeholder engagement, active workshop participation	2	Approx. £40,000
NAME: ADDRESS:				
NAME: ADDRESS:				

[3] This is the average annual numbers of both staff and managerial staff employed over the last trading year

Schedule Six: Form of Tender

Declaration

PROPOSAL FOR THE PROVISION OF Review of the Early Access to Medicines Scheme (EAMS).

Having examined the proposed Contract comprising of:

(a) Part A – Section Two, (Conditions of Contract);

(b) Part B – Schedules One, One (a), Two and Six (mandatory); and

(c) Part B – Schedules Three to Five inclusive (as amended).

As enclosed in the ITT response dated (20 August 2015). We do hereby tender against the requirements, and terms and conditions of the proposed Contract.

There are a number of areas in the terms and conditions which we would like to discuss the application of, in practical terms, in the context of the services to be provided.

We undertake to keep the tender open for acceptance by the Authority for a period of ninety (90) days from the deadline for receipt of tenders.

We declare that this is a bona fide tender, intended to be genuinely competitive, and that we have not fixed or adjusted the amount of the tender by, or under, or in accordance with, any agreement or arrangement with any other person. We further declare that we have not done, and we undertake that we will not do, any of the following acts prior to award of this Contract:

(a) Collude with any third party to fix the price of any number of tenders for this Contract;

(b) Offer, pay, or agree to pay any sum of money or consideration directly or indirectly to any person for doing, having done, or promising to be done, any act or thing of the sort described herein and above.

Unless and until the Tenderer and the Authority have executed a formal agreement, the Authority's acceptance of this tender with all its enclosures shall not constitute a binding contract between us. We understand that you are not bound to accept the lowest price, or any, tender.

Name of person duly authorised to sign tenders:

Date: 27 August 2015

Name: *Information redacted in line with Section 40 of the FOIA*

in the capacity of: Partner

duly authorised to sign tenders for and on behalf of:

PwC LLP

By completing this Declaration and submitting your tender you have agreed that the statements in this Form of Tender are correct.