Order Form - Confidential When Complete

Call-off Contract Details	
Title of Framework Agreement:	Consultancy and Advisory Services for Health
Framework Agreement Reference:	SBS10197
Lot number:	Lot 3 - Commercialisation, Innovation & Transformation
Call-off procedure used: [Further Competition/Direct Award]	Further Competition
Total Call-off Contract Value:	£500,000
Order Form Reference No:	C362058/CASH_321
Authority Contact Details:	
Name:	Medicines and Healthcare Products Regulatory Agency
Category Generic Email Address:	commercial@mhra.gov.uk

Order Form Details

This Order Form sets out the agreement between the following Parties and in accordance with the Terms and Conditions of the Framework Agreement and the Call-off Terms and Conditions.

Period of the Agreement			
Commencement Date:	**10/07/2025**	Expiry Date:	**09/07/2026**
Extension Period(s): [Optional]	N/A		
Maximum Permissible Term	12 months		

Unless otherwise agreed by both Parties, this Order Form will remain in force until the expiry date agreed above. If no extension/renewal is agreed and the Approved Organisation continues to access the Supplier's Goods and/or Services, the terms of this Contract shall apply on a rolling basis until the overarching Framework Agreement expiry date.

In circumstances where the Framework Agreement had already expired and the Approved Organisation continues to access the Supplier's Goods and/or Services, then the terms of this Contract shall apply on a rolling basis until the expiry of the Call-off Terms and Conditions' maximum permissible term (as set out above).

Any capitalised terms shall have the meaning given to such terms in the Call-off Terms and Conditions.

Supplier Order Form Signature Panel

The "Supplier"	
Name of Supplier:	Deloitte LLP
Name of Supplier Authorised Signatory:	Redacted
Job Title of Supplier Authorised Signatory:	Partner
Contact Details Email Address:	Redacted
Contact Details Phone Number:	Redacted
Address of Supplier:	1 New Street Square, London, EC4A 3HQ

Signature of Authorised Signatory:	Redacted	Date of Signature:	09/07/2025

Approved Organisation Order Form Signature Panel

The "Approved Organisation"	
Name of Approved Organisation:	Medicines and Healthcare Products Regulatory Agency
Name of Approved Organisation Authorised Signatory:	Redacted
Job Title of Approved Organisation Authorised Signatory:	Chief Finance Officer
Contact Details Email Address:	Redacted
Contact Details Phone Number:	Redacted
Address of Approved Organisation:	10 South Colonnade, Canary Wharf, London, E14 4PU

Signature of Approved Organisation Authorised Signatory:	Redacted	Date of Signature:	

Please Note: Each Party's respective Authorised Signatory above shall also be that Party's authorised representative for the purposes of Clause 21.2 of Schedule 2 of the Call-off Terms and Conditions in respect of any variations to the Call-off Contract during its Term.

Subject to the Parties complying with Clause 28 (Assignment, novation and Sub-contracting) of Schedule 2 of the Call-off Terms and Conditions, this Order Form shall remain in force regardless of any change of organisational structure to the above-named Approved Organisation or Supplier and shall be applicable to any successor organisations as agreed by both Parties.

As per the Framework Agreement, the Supplier shall forward a copy of the jointly signed Order Form to the Authority by no later than 5 (five) Business Days of it being executed.

Agreement

1. Agreement Overview

This Order Form represents an agreement between the Parties listed above pursuant to the Framework Agreement listed above for the provision of Goods and/or Services as outlined below. This Order Form in conjunction with the Call-off Terms and Conditions outlines the parameters for the provision of Goods and/or Services as they are mutually understood by the Parties.
The Framework Agreement terms and conditions (including the Specification) will apply in all instances, unless specifically agreed otherwise by both Parties within this Order Form.

2. Stakeholders

The primary stakeholders from the Supplier and the Approved Organisation will be responsible for the day-to-day management of the Call-off Terms and Conditions, this Order Form and the delivery of the Goods and/or Services. If different from the Authorised Signatory details listed on page 1 of this Order Form, please provide the names of the Contract Managers associated with this Order Form.

Supplier Call-off Contract Manager Details:	
Supplier Call-off Contract Manager:	Redacted
Supplier Call-off Contract Manager contact details:	Redacted
Approved Organisation Contract Manager Details:	
Approved Organisation Call-off Contract Manager:	Redacted Head of Strategic Programme Management
Approved Organisation Call-off Contract Manager contact details:	Redacted

3. Periodic Review

In accordance with Clause 15.1 of the Call-off Terms and Conditions, this Order Form is valid from the **Commencement Date** outlined herein and is valid until the **Expiry Date** (as set out above) as agreed. This Order Form should be reviewed as a minimum once per financial year; however, in lieu of a review during any period specified, the current Call-off Terms and Conditions and Order Form will remain in effect.

4. Requirements

A. Services to be Provided

Please detail the Services, where applicable, that will be provided, where and by when, by the Supplier to the Approved Organisation or include an attachment with full details.

Stage 1: initiation, discovery and recommendations

- **Information gathering**: Collecting data on existing activities, performance reporting, and monitoring through the internal project team. This is likely to involve interviewing subject matter experts, organizing workshops, and distributing questionnaires.

- **Current process**: produce a high level E2E 'as is' process map across the lifecycle of the products we regulate. This process map should highlight significant interdependencies and key points for measurement across all operational areas, including Science Research & Innovation, Safety & Surveillance, and Healthcare Quality & Access.

- **Review and challenge**: Conduct a review and analysis of our end-to-end process, current activities, operational metrics and KPI performance reporting. This includes challenging existing KPIs, governance structures, and accountability levels, ensuring consistency and interconnectivity between performance metrics aligned with our strategic priorities. Focus should be on how we track meaningful outcomes, rather than outputs, and integrate pipeline reporting to effectively allocate resources and respond to future demands.

- **Benchmarking and improvement opportunities:** Identify the key operational performance metrics and KPIs that should be measured to establish MHRA as a world-leading regulator. This may involve conducting comparative analyses against other relevant organisations, international regulators, health bodies, and the pharmaceutical industry. The analysis should consider the uniqueness of MHRA's offerings (e.g. innovative research undertaken) and provide recommendations on how to enhance our operational performance metrics and KPIs.

- **Consistency and constraints:** Ensure consistent interpretation and application of relevant legislation across teams, including the application of 'clock-stop' in KPI measurement, and identify constraining factors such as the availability of current data and/or need for resource-intensive collation.

- **Summarising initial findings / recommendations**: A report should be delivered to the internal project team by the end of Week 4, so it can be presented to senior stakeholders for a decision on the way forward. The report should summarise the work undertaken, provide a high level E2E 'as is' process map and include a well-supported recommendation / project roadmap for the proposed course of action. This should cover (i) proposed KPIs and underpinning performance metrics, and (ii) cross-cutting dashboard for real-time oversight, considering existing and upcoming MHRA technology solutions. The latter should be supplemented with a pros and cons analysis underpinning the recommendation to build or buy the new dashboard.

Stage 2: Planning, mapping, and design

Pending feedback on the initial report, work with the internal project team to implement agreed course of action:

- **Planning:** Define the problem the new activity and performance reporting model aims to address, setting key objectives, deliverables, and overall approach to ensure the model is aligned with organisational priorities and delivers the desired outcomes.

- **Future Process**: Building on high level current ‘as is’ E2E process map, collaborate with subject matter experts to map future ('to be') E2E performance reporting process across the product lifecycle. This should highlight key activities, measurements and inter-connections across all operational areas.

- **Developing refreshed KPIs**: Develop new Agency KPIs and underpinning performance metrics – identifying relevant leading and lagging indicators to flag early warning signals of potential performance issues – to provide single 'source of truth' data and enhance real-time operational decision making.

- **Designing activity and performance reporting structure**: Design an appropriate reporting structure for three tiers of accountability: Operational Group level, Delivery and Performance Committee (DPC), and Executive Committee (ExCo) / MHRA Board. This proposal should set out proposed data / information for decision-making at each accountability level to ensure appropriate governance and discharge of assurance function.

- **Performance Dashboard Design**: Plan and design a cross-cutting performance dashboard to be owned, maintained, and run on MHRA systems. Aim is for the system to utilise real-time data for activity and performance reporting for three-tiered governance structure; incorporate early warning indicators; and support supply and demand forecasting and workforce planning. Potentially, the system should be designed following a low-code approach, to enable iterative improvements as new MHRA systems are implemented.

- **Progress summary**: A progress report should be delivered to internal project team around Week 9 to confirm project on track to be delivered in line with agreed timescales, specification and budget.

Stage 3: Delivery and Implementation

The delivery and implementation plan expected to include:

- **Prioritised Implementation Plan**: Delivering a prioritised implementation plan in collaboration with the internal project team and subject matter experts.

- **Integrated solution:** The cross-cutting dashboard system should be designed for automated streamlined data analysis against three-tiered governance structure, enable appropriate level of granularity for each area and take into account current and future MHRA technology solutions.

- **Resource Planning and Transition**: Supporting resource planning to ensure a smooth handover and transition into Business as Usual (BaU). This includes enabling business owners to iteratively improve the new system as needed, along with any necessary upskilling and training.

- **Audit Process**: Establishing a process to audit the new activity and performance reporting model post-project closure, ensuring alignment with quality assurance drivers.

Closure

A closure report should be delivered to the internal project team around Week 16.

Throughout: collaborative partnership

The external supplier will work in collaboration with identified Agency resources and stakeholders in a blended team to deliver the required activities.

The MHRA cross-agency project team will share background information, facilitate connections, and support the development of a fit-for-purpose solution.

The supplier will propose what should be measured and how these measurements should be integrated across the end-to-end lifecycle. This includes designing the cross-cutting performance dashboard and proposing a hierarchy of reporting.

See Schedule 5 - Bid Response for full details of services to be provided

B. Goods to be Provided

Please detail the Goods to be provided or include an attachment with full details.

The Supplier is not providing Goods to the Approved Organisation pursuant to this Order Form and the Call-off Terms and Conditions and on that basis the terms in relating to the supply of Goods set out in this Order Form and the Call-off Terms and Conditions shall not apply.

C. Goods Delivery Schedule/Services Implementation Plan

Please provide a delivery schedule/Implementation Plan, where applicable, outlining how and when the Goods and/or Services will be provided by the Supplier to the Approved Organisation or include an attachment with full details.

Stage	Deliverables	Expected Timeframes
1 - Initiation, discovery and recommendations	A report should be delivered to internal project team, which includes: • summary of work undertaken. • high level E2E 'as is' process map, including key operational interdependencies. • well-supported recommendation / project roadmap for proposed course of action on:	By the end of Week 4 [once mobilisation activities are complete)

	(i) proposed KPIs and underpinning performance metrics; and (ii) cross-cutting dashboard for real-time oversight.	
2 - Planning, mapping, and design	A report should be delivered to internal project team, which includes summary of work undertaken on: • Planning and overall project approach • Future ('to be') E2E performance reporting process across the product lifecycle • New Agency KPIs and underpinning performance metrics • New activity and performance reporting structure for three tiers of accountability • Proposed Activity & Performance Reporting Dashboard Design	By the end of Week 9
3 – Delivery and implementation	The delivery and implementation plan expected to include: • Prioritised Implementation Plan • Delivery of integrated solution • Supporting resource planning and transition into Business as Usual (BaU). • Establishing future audit process which aligns with quality assurance drivers.	Weeks 10 - 16
4 – Closure	A closure report should be delivered to the internal project team	By the end of Week 16

See Schedule 5 for full details of services to be provided including assumptions and dependencies.

Within two weeks of the contract commencement, the Supplier should produce a comprehensive delivery schedule and implementation plan for agreement by the Approved Organisation.

D. Key Personnel

Please set out key personnel required for the supply of Goods and/or the provision of Services.

Redacted

E. Sub-contracting and Personnel

Where the Approved Organisation permits sub-contracting of the supply of Goods and/or the provision of Services by Suppliers, the following information is required. If the Supplier Sub-contracts any of its obligations under this Order Form and Call-Off Contract, every act or omission of the Sub-contractor shall for the purposes of this this Order Form and Call-Off Contract be

deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Approved Organisation as if such act or omission had been committed or omitted by the Supplier itself.

- Not Applicable

F. Policies

Please list and provide links to/copies of all policies with which the Supplier is required to comply.

Offsite and remote working shall be in compliance with the Agency's Information Security policies.
Supplier staff working on any MHRA site is required to have completed baseline personnel security standard (BPSS) screening.

G. Leases or Licences

Where applicable, please detail any leases or licences to be provided by either Party to the other.

We are not expecting any leases to be provided by either party. However, the supplier will be required to visit and attend MHRA offices as part of the engagement. If any licenses are needed to access IT software or databases, MHRA will arrange for the relevant supplier team members to have the necessary access.

H. Special Terms

The Parties hereby acknowledge that Special Terms:

- may only be proposed for inclusion by the Approved Organisation;
- can be applied solely to enhance or augment existing provisions within the Call-off Terms and Conditions; and
- must not substantially alter or vary the Call-off Terms and Conditions, in order for this Order Form and Call-off Contract to remain compliant with the Public Contracts Regulations 2015.

Please insert any applicable Special Terms below.

Notwithstanding anything contrary in the Call-Off Terms and Conditions, the following Special Terms apply to this Order Form and take precedence over the same:

1. If the scope of Services, assumptions, dependencies, content of the ITT, and/or Approved Organisation responsibilities prove to be inaccurate, the Parties will address this as a change as per clause 23 of the Call-Off Terms and Conditions.

2. The deliverables provided pursuant to the Services are for the Approved Organisation's exclusive use and provided for the purposes described in this Contract. No person other than the Approved Organisation may rely on these deliverables and/or information derived from them.
3. The Supplier is not an intermediary to which any of the conditions in s61N Income Tax (Earning and Pensions) Act 2003 apply. The Supplier may use equity partners, who are self-employed for tax, in the delivery of the Services.
4. The Parties will discuss and agree the content of statements of work or work packages in good faith on award taking into account the actual scope of the Services and nature of the projects as required by the Approved Organisation.
5. Intellectual Property Rights of the Supplier include enhancements and/or modifications developed in the course of providing the Services.
6. A Deed of Guarantee is not required.
7. Supplier will only be accountable for failures to meet service levels, KPIs and/or milestones where due to its own act or omission.
8. Approved Organisation will supply Supplier with any internal policies, codes, standards, Guidance or procedures that Approved Organisation requires Supplier complies with prior to the start of the Services (and when the same are updated). Supplier must only comply with such policies, codes, standards, Guidance or procedures if they do not increase the costs of the Supplier; increase the scope of the Services; or conflict with any policy or regulatory obligation of the Supplier.
9. Supplier will not update, upgrade, maintain or provide new versions of any Deliverable after the date on which the final Deliverable is delivered or signed.
10. Supplier will provide any necessary sub-license(s) to Approved Organisation on the relevant software vendor's standard licence terms and it provides no warranty in relation to such software.
11. The Approved Organisation will ensure that it has the rights to allow the Supplier to use software, products or services of its third-party vendor(s) if required.
12. Unless otherwise agreed in writing, all processing of Approved Organisation data will be conducted on Approved Organisation assets.
13. Each party shall comply with its respective obligations with regard to Personal Data and the Data Protection Legislation. The Authority will not send any Personal Data to the Supplier without its consent.
14. Supplier Staff will be entitled to any absence(s) as agreed between the Parties.
15. All rights of audit/access under the Call-Off Contract are subject to the Supplier's obligations of confidentiality to its other clients and/or third parties. Supplier will, on reasonable notice, permit the Relevant Authority and/or Auditor such access as is reasonably and strictly necessary to conduct the audit, during Supplier's normal business hours.

I. Charges

Standard Supplier pricing and rates (the Contract Price) are included within the Commercial Schedule and represents the maximum that can be charged. Please detail all discounts, volume arrangements or variations in relation to the standard rates. The Contract Price of the Goods and/or Services are to be included below, or detailed as a separated attachment.

Is the Contract Price agreed to be subject to indexation?	**No**

See Schedule 6 – Commercial Schedule

Rate Card shall be used for any future requirements and subsequent Statement of Works agreed by the parties to call-off up to contract value of £500,000:

Role	Day Rate
Partner / Director	Redact
Managing Consultant / Associate Director	Redact
Subject Matter Expert / Principal Consultant	Redact
Senior Consultant	Redact
Consultant	Reda
Junior Consultant	Reda
Support and Administrative Staff	Red

To note as per schedule 6 of the Call Off the discount offered is not on the stated day rate and is based on free days and investment of time from Deloitte on the estimate for the initial scope of work tendered. For future requirements the underlying day rates remain as above. We estimate the work package to be delivered for the price stated at schedule 6 assuming delivery milestones and assumptions remain the same.

J. Confidential Information

Please detail all information relevant to this Order Form and the Call-off Terms and Conditions which either Party considers to be treated as Confidential Information.

MHRA: Any data or material that is designated as confidential, or that should reasonably be considered as confidential, as well as any personal data. We will primarily share management information for the purpose of contract delivery. This includes data captured through Appian and Sentinel as well as any local systems and spreadsheets which relates to Agency work on Scientific Advice, Clinical Trials, Licensing, Inspections, and wider operations.

Deloitte: Any information relating to: personal information (CV's, contact details etc.); pricing and details of Supplier's cost base; insurance arrangements; proprietary information; and/or approach and/or methodologies, is commercially sensitive/confidential and exempt from disclosure under the Freedom of Information Act 2000 ("FOIA") and as management information to Third Party Bodies. If a request to disclose such information is received, the Parties will work together and consider the applicability of any FOIA exemptions.

K. Complaints/Escalation Procedure

As per the Framework Agreement, the Supplier shall inform the Authority of all complaints. Please detail the Approved Organisation's additional requirements regarding complaints.

The Supplier shall have in place robust and auditable procedures for logging, investigating, managing, escalating and resolving complaints or issues.
Acknowledgement of a complaint (by email) is required within 1 Working Day of receipt (a remedial/resolution timetable shall be agreed).

L. Limit of Liability

Please populate the limit of liability values

Notwithstanding clause 14.2 of the Call-Off Terms and Conditions, the total liability of each Party to the other under or in connection with this Contract whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall be limited in aggregate to one hundred and twenty five percent (125%) of the total Contact Price paid or payable during the Term by the Approved Organisation to the Supplier for the Goods and/or Services.

M. Management Information (MI)

In addition to the management information required by the Authority under the Framework Agreement, the Supplier shall provide to the Approved Organisation the following Management Information at the frequency outlined.

We would like the format of a weekly update report to be agreed upon within two weeks of the contract commencement.

This report is likely to cover the following areas:

1. Performance against Milestones
2. Performance against Budget
3. Key Risks/Issues and Mitigations

Additionally, it would be helpful to include the hours worked per week along with a high-level summary of key areas of focus.

N. Invoicing

Please detail all specific invoicing requirements here.

The Approved Organisation shall provide the Supplier with a Purchase Order (PO) that includes a reference to the Call-Off Contract and the Framework Agreement to which this Order Form relates.

All invoices must be submitted electronically in arrears to accounts.payable@mhra.gov.uk in accordance with the payment terms/invoicing milestones agreed for the project during mobilisation meetings.

The Buyer shall pay the Supplier the Charges within 30 days of receipt of a valid, undisputed invoice. Each invoice must include a supporting breakdown of the work that has been completed and the associated values. Payment shall only be made following the satisfactory delivery of the agreed Services and deliverables.

The Buyer has a "no purchase order no pay policy" in place. Any work or expense the Supplier undertakes prior to receipt of a purchase order shall be undertaken solely at their risk. Any invoice submitted must display a valid purchase order number and the invoice value must not exceed the value of the purchase order. Invoices not meeting these requirements could be rejected and therefore payment may be delayed.

The supplier may use equity partners, who are self-employed for tax, in the delivery of the Services.

O. Exit Requirements

Please include details of any exit requirements with which the Supplier is required to comply.

- Return of any MHRA equipment provided for delivery of the contract
- Knowledge transfer and handover to technical teams

P. Termination

Please detail specific termination provisions here.

Persistent failure by the Supplier to meet the agreed service levels as specified within the Order Form may lead to the Contract being terminated or alternative supplier(s) being appointed by the Approved Organisation to maintain levels of service to service users.

Prior to termination the complaints and escalation procedure should be followed to attempt to resolve any issue. Should suitable resolution not be achieved, the Approved Organisation will be allowed to terminate the Call-Off Contract immediately.

Either party can terminate for material breach which is not capable of remedy or where is remediable has not been remedied in accordance with the Remedial Proposal. If a material breach occurs, either remedial proposal is required or termination is permitted if breach is not remediable. Note that the timeframe for a remediation proposal is 5 days under the Framework Agreement, but 10 days under a Contract.

Supplier may terminate the Contract upon written notice to Approved Organisation if the performance of any part of the Services would conflict with law, professional rules or Supplier's independence. Supplier agrees to provide as much notice to Approved Organisation as is reasonably possible and will work with Approved Organisation to seek to mitigate any impact on the Services and/or the project.

6. Other Specific Requirements

Detailed Requirements

Please list all detailed requirements or include an attachment with full details.

No specific business continuity requirements apply to these Services. Supplier assumes that Approved Organisation accepts Supplier's BCDR policy and IS022301 certification – copies of which can shared with Approved Organisation if requested. The provision of an exit plan will not be required for the Services unless otherwise agreed in writing between the Supplier and the Approved Organisation.

PLEASE NOTE:

In accordance with Clause 3.1 of Schedule 2 of the Framework Agreement, by no later than five (5) Business Days following the execution of an Order Form by the Approved Organisation and the Supplier, the Supplier shall send a copy of the executed version of the Order Form to the Authority's Contract Manager.

All Goods and/or Services provided by the Supplier without an Approved Organisation's jointly signed Order Form is entirely at the Supplier's risk.

Appendix 1 – Data Protection Protocol

DATA PROTECTION PROTOCOL

Additional Data Protection Obligations

1. The Supplier shall immediately inform the Approved Organisation if, in its opinion, an instruction infringes Data Protection Legislation.
2. The Supplier shall not engage another processor without the prior written authorisation of the Approved Organisation.
3. The Supplier shall not transfer Personal Data to a third country without the prior written authorisation of the Approved Organisation.

Table A – Processing, Personal Data and Data Subjects

Description	Details
Subject matter of the Processing	The supplier will be processing data on Key Performance Indicators including activities that underpin these, as set out in the authorities' statutory obligations and corporate responsibilities.
Duration of the Processing	From award until contract end. (Current statement of work expected to end late October 2025 but could continue as late as 30 June 2026.)
Nature and purposes of the Processing	The supplier will be processing activity data and key performance metrics. This processing includes but is not limited to collection, recording, organising, structuring, sorting, adapting, altering, retrieving, consulting, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of data. The purpose of the data processing is to manage and deliver a range of project outputs which includes but is not limited to: • Reviewing and challenging existing key performance indicators and activities that underpin these. • Reviewing and challenging governance and reporting requirements on authority statutory obligations. • Design and implementation of new data analysis platform. • Integrating pipeline reporting, tracking flow of E2E activities to support authority in resource planning.

	• Ensuring compliance with the MHRA's corporate and statutory obligations. The data will be processed on existing MHRA systems, with aggregated, non-personal outputs of this used on the Supplier's own systems. The Supplier's systems must be secure to store/hold such data with robust data handling and processing procedures practised by the Supplier to safeguard the confidentiality and integrity of such Data from unauthorised access, loss and/or disclosure. The Supplier should only share information with relevant Supplier Staff necessary to provide support.
Type of Personal Data	**All Data Subjects**
Categories of Data Subject	Data Subjects may include but is not limited to: • Staff (including volunteers, contractors, agents, and temporary workers) • Patients • Members of the public • Healthcare professionals • Industry stakeholder staff including representatives from pharmaceutical companies, manufacturers, distributors, suppliers • Customers • Members of expert committees and other 3rd party experts/ professional advisers • Clinical trials participants, sponsors and representatives
Plan for return and destruction of the data once the Processing is complete UNLESS requirement under union or member state law to preserve that type of data	The Personal Data shall be retained until the relevant Processing has been completed, or at the latest within 90 days of the completion of a research project. Where the Personal Data needs to be retained longer under applicable Data Protection, for statutory compliance purposes and/or as required by Law, this Data must be securely stored and managed and deleted as soon as possible. The Supplier shall return or erase Personal Data from any computers, storage devices and storage media, as soon as practicable after it has ceased to be necessary for them to retain such Personal Data.