

WORK ORDER

GENERAL

This Work Order takes effect as of 1st February 2024 (the “Effective Date”) by and between:

The “Parties”:	“NDA”	and	“Client”
Company name:	NDA Regulatory Science Ltd.		Medicines & Healthcare products Regulatory Agency (MHRA)
Reg. No.:	3711905		N/A government agency
VAT No.:	GB 730 8097 36		GB888849726
Incorporated under the laws of:	UK		UK
Office Address:	Grove House Guildford Road Leatherhead Surrey, KT22 9DF, United Kingdom		10 S Colonnade London E14 4PU United Kingdom

The Work Order is entered into pursuant to the Main Agreement with effective date 26th January 2024 between the Client and NDA Group AB and covers the following services:

Project Title:

Support for the clinical assessment of applications

Services Description:

- Assessment of initial clinical trial applications/substantial amendments
- Mentoring and supporting for Junior Assessors

Work order duration and project completion:

This Work Order is valid until 31st March 2024

COMPENSATION

Charges for Services are on an hourly rate basis for defined Services, plus Value added Tax at the rates prevailing at the time of invoice.

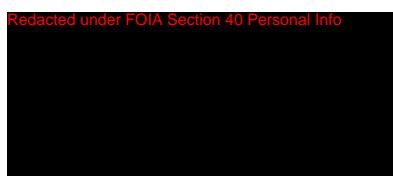
The total cost for this Work Order shall not exceed £67,200.

The rates charged by NDA for such Services are presented in Exhibit B.

PROJECT CONTACTS

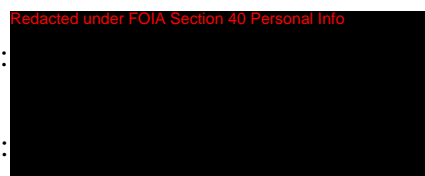
For NDA:

Name:
Tel:
Email:



For the Client:

Name:
Tel:
Email:



INVOICING

Schedule

- The services are invoiced monthly, usually around the 20th of the month.

Payment terms

- 30 days net and interest for late payment will be charged at 2% per month.
- To the following bank account:

Redacted under FOIA Sect 43(2) Commercial Interests

Finance contact for NDA:

Name:
Tel:
Email:

Redacted under FOIA Section 40 Personal Info

Finance contact for the Client:

Name: N/A
Tel: N/A
Email: Accounts.Payable@mhra.gov.uk

Note: Invoices to be sent to the Client for the attention of:

Purchase Order Numbers:

PO number is the Client's responsibility. The Client understands that the issue of the PO number should not impact the invoicing schedule defined in this Work Order.

SIGNATURES

For and on behalf of NDA:

Name:
Title:

Email:
Date: 5-Feb-2024

Redacted under FOIA Section 40 Personal Info

For and on behalf of the Client:

Name:
Title:

Email:
Date: 05.02.2024

Redacted under FOIA Section 40 Personal Info

Signature:

Redacted under FOIA Section 40 Personal Info

Signature:

Exhibit A

SERVICES DEFINITION:

Activity	Estimated cost (GBP)	Comments/Assumptions
Medical Advisor support		
Provision of a Medical Advisor <small>Redacted under FOIA Section 40 Personal Info</small> <ul style="list-style-type: none"> – Up to a 8-week duration to provide input into the assessment of initial clinical trial applications and/or substantial amendments – Provide mentoring and supporting for Junior Assessors 		<small>Redacted under FOIA Sect 43(2) Commercial Interests</small>

SERVICE TIMELINES

- The outlined support shall commence upon approval of the MSA and Work Order. This Work Order shall terminate on 31st March 2024

ASSUMPTIONS

General project assumptions

- That the Client designates a contact person with whom NDA can liaise in order to plan the project and report on progress as well as to ensure that all questions and communications are answered quickly and completely in order to meet the desired timelines.
- NDA has access to all documents and materials required to undertake and complete the Services in due time. The Client is responsible for the completeness and accuracy of all information supplied to NDA.
- The documentation will be of high quality, complete, in the English language and available electronically as Word or PDF files.
- Timings are dependent upon availability of supporting data and will be planned in conjunction with the Client.
- Project oversight required includes set-up, planning and coordination of all project related activities, expert identification, background research and project familiarisation, internal progress meetings, short clarifying calls and e-mails on an ongoing basis, meetings with the client team as needed, a strategic kick-off meeting, a project finalisation meeting, and planning and coordination of all QC activities.
- NDA will carry out QC checking of all documents generated by NDA.
- Final medical and regulatory responsibility always remains with the Client.

- This offer is valid, and planned project experts will be reserved up to, one month after date of issue.

Cost estimate assumptions

Redacted under FOIA Sect 43(2) Commercial Interests

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PERSONAL DATA PROCESSING DETAILS

Services related to processing

- As per the service description.

Duration of processing

- Processing of Personal Data will be carried out during the delivery of the services outlined in this Work Order. After processing is complete, and if there are no subsequent activities planned, NDA shall destroy all Personal Data except for protected backup(s) and shall not retain Personal Data other than one copy thereof as required for NDA to live up to its statutory and regulatory requirements.

Nature and purpose of processing

- Personal Data will be processed by NDA and its partner companies/collaborators on behalf of the client as required for the performance of the Services under this Work Order.

Personal Data

- Pseudonymised (“key coded”) demographic and medical data relating to subjects/patients participating in clinical trials or other forms of medical research.
- Name, contact details of healthcare professionals, support staff and consumers of pharmaceutical products (applicable if requested by regulatory agency) requesting information on pharmaceutical products and/or reporting adverse events and safety events, and other information relating to use of pharmaceutical products, related to details of potential adverse and safety events.

Data subjects

- Patients, clinical trial subjects, healthcare professionals, support staff.

Exhibit B

Redacted under FOIA Sect 43(2) Commercial Interests

