Planning

Investigational Medicinal Product Trial -Metformin

Sheffield Teaching Hospitals NHS Foundation Trust

F01: Prior information notice
Prior information only
Notice identifier: 2024/S 000-018100
Procurement identifier (OCID): ocds-h6vhtk-046f3b
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Section I: Contracting authority

I.1) Name and addresses

Sheffield Teaching Hospitals NHS Foundation Trust

Herries Road,

Sheffield

S5 7AU

Contact

Andrew Duffield

Email

a.duffield1@nhs.net

Telephone

+44 7790363970

Country

United Kingdom

Region code

UKE3 - South Yorkshire

Internet address(es)

Main address

https://www.sth.nhs.uk/

Buyer's address

https://www.atamis.co.uk/registration

I.3) Communication

Additional information can be obtained from the above-mentioned address

Electronic communication requires the use of tools and devices that are not generally available. Unrestricted and full direct access to these tools and devices is possible, free of charge, at

https://health-family.force.com/s/Welcome

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

Investigational Medicinal Product Trial -Metformin

Reference number

W137575

II.1.2) Main CPV code

- 33600000 - Pharmaceutical products

II.1.3) Type of contract

Supplies

II.1.4) Short description

We would like to engage with Suppliers who have the capability to purchase or manufacture Metformin 500mg extended release tablets and an identical placebo for a clinical trial, to package and label them to our requirements and distribute to 35-40 NHS Trusts across the UK. This Prior information Notice will allow us to gain a better understanding of the market and help inform our Procurement Strategy prior to any Tendering exercise. Any procurement would also be dependent on regulatory approval from MHRA. Please note this is not a call for competition but for Market engagement purposes only.

II.1.5) Estimated total value

Value excluding VAT: £400,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKE32 - Sheffield

Main site or place of performance

Sheffield Teaching Hospitals
Northern General
Sheffield
S5 7AU

II.2.4) Description of the procurement

We would like to assess Suppliers technical capability to Prepare, Package and label Metformin 500mg extended- release tablets and an identical Placebo and distribute drugs according to specification below.

• Treatment length for each participant:24 months (End of Treatment, last patient c. 31/10/2028)
• Dispensing frequency: six monthly.
• Pack size: 128 tablet bottles packed into kits of three bottles per kit. Each participant will need eight kits in total (24 bottles).
• Number of participants in the UK: 300 randomised.
• Recruitment period: 24 months.
• 1200 kits of placebo and 1200 kits of Metformin = 2400 kits plus necessary overage.
• 921,600 tablets – 460,800 each of Metformin 500mg extended-release and equivalent Placebo, plus necessary overage.
• Suggest overage of 25% for each production run, this is stated as a % as number of runs are not known at this stage and will depend on shelf life.
• Number of sites: 35-40 UK sites proposed. Deliveries to be made direct to site pharmacies and to be covered by relevant temperature monitoring as appropriate for the product. Estimate two deliveries per site per production run.
• Blinding: Full blinding of IMP packs required. Packs to be identified with pack-specific IDs to allow pack allocation by an external globally managed IWRS system.
• Simplified IMPD(s) and IMP labels required for regulatory submission during trial set up period.
• Expected initial purchase of approximately 20% of the total quantity of Metformin and matching placebo. Future purchases to be made when the outcome of the internal pilot study is known and in consultation with Sheffield Teaching Hospitals NHS Foundation Trust (STH) & Norwich Clinical Trials Unit (NCTU), but we assume 3-4 more purchases are to be made, up to the total quantity.
• Placebo shelf life must be at least matching that of the active substance and ideally be 2+ years.

II.2.14) Additional information

• The contractor must be able to accept and store bulk shipments of active drugs from raw material manufacturers. There may be up to five bulk deliveries of the IMP.

• Trial stock must be stored in line with the requirement of each product.
• Trial stock must be stored in a facility with appropriate environmental and temperature monitoring covering a period up to 31/10/2028, with the ability to accommodate any agreed extension if required.
• Maximum lead time for campaigns will be between 2 and 3 months.
• Tablets must be counted into child-resistant, tamper-evident bottles for each of the IMPs.
• Bottle size will be 128 tablets per bottle. Bottles to be packed in to kits of three bottles per kit.
• All bottles from the same packaging and labelling campaign must be labelled with the same expiry date i.e. using the expiry date from the product with the earliest expiry date.
• The contractor must retain a sample of bottles for each IMP in accordance with current regulations and make these available to STH/NCTU upon request to enable product identity confirmation testing if required.
• The contractor must keep a record of batch numbers and expiry dates used for each bottle and will supply this in an agreed format to STH/NCTU.
• The contractor must prepare a packaging and labelling batch record for each batch of the product.
• The contractor must keep all original packaging and labelling batch records documentation for a minimum of 25 years or as agreed in the Technical Agreement and current regulatory requirements.
• The contractor must provide Sheffield Teaching Hospitals NHS Foundation Trust STH) & Norwich Clinical Trials Unit (NCTU) with any corresponding batch documentation as agreed in the technical agreement.
• The contractor must provide a simplified Investigational Medicinal Product Dossier (sIMPD) to support placebo manufacture and stability of active drugs and matching placebo within 4 weeks of the contract being signed.
• The contractor must create an Annex 13 compliant label (English language only) for primary packaging as agreed by both parties with text provided by STH/NCTU within 4 weeks of the contract being signed.
• The contractor must apply the agreed Annex 13 compliant label with a product identifier to each bottle, upon agreement from STH/NCTU that labelling may commence -this will usually be after regulatory approval of the label.
• The contractor must have the capacity to re-label for expiry date extensions throughout the contract period if required.
• The contractor must have capacity for Qualified Person (QP) certification of packaged and labelled trial drug in line with UK requirements.
• The contractor must provide QP certification to NCTU for the finished products in line with UK requirements prior to distribution.
• The contractor must have previous experience of delivering trial drug supplies to NHS sites.
• The contractor must have the ability and capacity to distribute IMP to approx. 35-40 NHS Trust sites within the UK over a 48 month period according to recruitment rate and in coordination with NCTU. The number of sites may increase or decrease depending on the

needs of the trial.
• The contractor must provide temperature controlled shipping to NHS sites using the most cost-effective method.
• The contractor must have appropriate distribution systems and agreements in place to be able to distribute drug to site.
• The contractor must be able to make approximately eight deliveries per site in total. The number of deliveries may increase or decrease depending on the needs of the trial.
• Should the need to recall trial treatment arise from advice from the manufacturer, contractor or the Sponsor, the contractor must assist STH in determining all bottles affected and assist with recall in a timely manner.
• The contractor must be able to provide recent qualitative evidence of successful management of IMP labelling, packaging and distribution for a multicentre study by providing contact details for two references for similar systems that the contractor has previously supplied.
• The contractor must hold and provide copies of specific licences for the manufacture of investigational medicinal products.
• The contractor must hold and provide copies of specific licences as required for the import of licenced medicinal products from the EEA (if applicable).
• The contractor must work in accordance with Good Manufacturing Practice (GMP) derived from “the rules governing medicinal products in the European Community, Good Manufacturing practice for Medicinal Products”.
• The contractor must work in accordance with Good Distribution Practice (GDP).
• The contractor must work in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments and future relevant revisions, guidelines on Good Manufacture Practices (Volume 4) and Good Distribution Practice.
• The contractor must maintain an appropriate Quality Management System (QMS) and have appropriate SOPs in place.
• The contractor must have an appropriate storage and archiving facility for study documentation for a minimum retention time of 25 years after study closure.

II.3) Estimated date of publication of contract notice

5 July 2024

Section IV. Procedure

IV.1) Description

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: Yes