

Order Schedule 20 (Order Specification)
 Order Ref: **710354450**
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This Schedule sets out the characteristics of the Deliverables that the Supplier will be required to make to the Buyers under this Order Contract

Purpose

The Army Health and Performance Research (AHPR) team are undertaking work to determine the validity of innovative methods to predict ovulation and monitor menstrual health in servicewomen. The EMPOWER trial will investigate the validity of these innovative methods for detecting ovulatory / anovulatory cycles, and the end-user acceptability of these methods in military training.

Background

[REDACTED] Ovulation (the release of an egg) is a key event of the menstrual cycle and is associated with a healthy hormonal environment *protective* of musculoskeletal health. Oestrogens are known to directly affect bone, muscle, and tendons, and changes in their production can influence injury risk and physical performance. Women can stop ovulating but continue to have periods, so methods of detecting ovulation, independent of changes in bleeding frequency, will help them monitor their own menstrual health and seek early intervention. AHPR have identified three possible innovative candidate methods to predict ovulation [REDACTED]

- i) wearable technology;
- ii) hormone measurement in finger-tip blood samples, and
- iii) hormone measurement in saliva.

These methods need to be validated against the gold-standard measure of ovulation from urinary metabolites of female hormones.

Objectives

The objective of this requirement is to validate the data from the innovative methods against ovulation determined from serial measurements of urinary progesterone.

Scope

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Urine samples are being collected as part of a human research trial. These samples need to be analysed in a laboratory to determine the concentrations of female hormones.

Requirements

This requirement seeks to measure female hormones in urine analysed by an accredited laboratory, using non clinically routine methods, to detect and validate ovulation in servicewomen during arduous military training. The urine has been collected as part of an Army research trial.

SPECIFIC REQUIREMENTS

- Analysis of urine samples for urinary metabolites of oestradiol (e.g., estrone glucuronide), progesterone (e.g., P4 or pregnanediol 3 glucuronide), and luteinising hormone, and creatinine for up to 13,500 samples in an accredited laboratory.
- Confirm ovulation using established and reliable methods and thresholds (e.g., a rise in urine PDG above 5µg/mL).
- Provide technical advice to the research team on sample analysis and interpretation.
- Provide reference ranges to enable interpretation of the findings.

Outputs/deliverables/milestones

Deliverables	Date
Final raw data set within 90 days of receipt of samples.	Within 90 days of receipt of samples

Acceptance

Acceptance will be upon the final delivery of raw data.

Evaluation

The outcome of this work will be evaluated by the AHPR project team.

Intellectual Property (IP) Rights (Known as IPR)

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All new IP generated from the research studies will remain with the MoD as per the T&Cs of this call off contract.

Government Furnished Supplies

- MOD will provide Urine samples

Payment

Payment will be made at the end of the trial, on completion of all deliverables. Payment will be made within 30 days of a valid and undisputed invoice. Payment will be made through CP&F/Exostar. The supplier must be willing to join these platforms if not already on them.

Contract management arrangements

Contract Management for this requirement will be ad hoc.

End of contract/Exit strategy

The end of contract milestone will be when all data have been delivered to the MOD. At the end of the trial, all data should be transferred over to MOD, and any data the supplier holds should be disposed of.

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