RCloud Tasking Form – Part B: Statement of Requirement (SoR)

Title of Requirement	**705569450 - Project Cayenne – Clinical Trial for Non-Freezing Cold Injury (NFCI)**
Requisition No.	**0061406553**
SoR Version	**0.2**

1.	**Statement of Requirements**
1.1	**Summary and Background Information**

Acronyms

- MODREC – MOD research ethics committee
- CA – Contract Award
- NFCI – non-freezing cold injury
- GDPR – General Data Protection Regulation 2016
- MHRA – Medicines and Healthcare products Regulatory Agency
- SP – service personnel
- PI – principal investigator

Summary

The Authority requires analysis from a 3-year clinical trial that will assess the impact of a novel medical treatment for service personnel suffering from a chronic medical condition, non-freezing cold injury (NFCI). The trial shall use a licensed medical patch containing Capsaicin. The trial should involve military patients (50 in total across both placebo control patch and capsaicin patch treatment groups) and analyse the effect of the specific medication on improving their condition.

Background

The condition, now termed Non-freezing cold injury (NFCI), was previously called Trench Foot, and it has been known since World Wars I and II to be a vaso-neuropathy. NFCI and the associated chronic neuropathic pain are both a health burden to military personnel and a financial burden for the Ministry of Defence.

[redacted]

From 2006 there was a notable change particularly in Army personnel with over 600 referrals per year to the Cold Injury Clinic. Of those medically discharged from the military over 50% have Armed Forces Compensation Scheme (AFCS) awards.

Research in the past has focused on the underlying issues causing NFCI and several research departments with links to the MOD have looked at this There is now a better understanding of the underlying insult and damage at the time of the cold injury. This has allowed progress toward therapeutic targets, much due to Nobel Prize winning research in California and the implication of the capsaicin receptor. Current management of affected individuals relies of cold avoidance, personal protective equipment (PPE) and prescribed oral analgesic type treatments targeting

	nerve receptors to manage the neuropathic pain. There is limited evidence demonstrating significant benefit and medication used is burdened with multiple side effects. Further, there are no treatments that can modify the underlying condition toward cure. Occupational relevance; NFCI leads to a downgrading of military functional status and may prompt early discharge from the armed services. In addition, by virtue of current medical management, there are iatrogenic effects impacting on other aspects of the service person's (SP) life and carried into their civilian roles. The clinical trial proposed should build on the academic knowledge gained during the published pilot trial in NFCI (2018-2021). [1] Caterina et al., The capsaicin receptor: a heat-activated ion channel in the pain pathway. *Nature* 1997 Oct 23; 389(6653):816-24 2 Anand et al., Capsaicin 8% Patch Treatment in Non-freezing Cold Injury: Evidence for Pain Relief and Nerve Regeneration; Front. Neurol. 19 Aug 21; https://doi.org/10.3389/fneur.2021.722875
1.2	**Requirement**
	Project Requirement The Supplier is required to conduct a clinical trial and provide a final report to assess the impact of repeated applications of a Capsaicin patch to service personnel suffering NFCI. Elements of Clinical Trial The Supplier will be able to define the day-to-day clinical and research aspects of running the trial and thus this has not been defined as a deliverable; however, the Supplier is required to deliver the following aspects: Participant recruitment – The Supplier is responsible for recruiting trial participants in a 1:1 Ratio with 25 patients using the capsaicin patch and 25 matched controls using a placebo patch (this number was determined by statistical calculations for power of the trial and agreed by Ministry of Defence Research Ethics Committee (MODREC)). The trial participants will either be serving personnel or Veterans. Any participant identifiable data should be anonymised by the Supplier in accordance with the MODREC protocol. The Supplier shall be responsible for obtaining both the capsaicin and equivalent placebo patches in support of the trial. The placebo patch is used to ensure the participants are not aware of which patch they receive (blinded and randomised). This is important to reduce bias in the study and produce an academically perceived higher quality of trial. The Supplier is required to work with the Authority's appropriate Defence Medical Consultant during the trial who will provide any support and provide a Military liaison as needed for the trial. However, the Authority, or any other entity, will have no input into the recruitment process. MODREC is commissioned to review research projects involving human participants. It safeguards the rights, dignity and welfare of the individuals volunteering to participate in research studies. The Committee is an independent body comprising of non-MOD (expert and lay) members and is supported by appropriate MOD advisers. Prior to final review by MODREC, scientific and technical rigour is assured through assessment by a Scientific Advisory Committee (SAC). In accordance with Milestone 1 and pre-commencement of the trial, the supplier is required to apply for and satisfy:

- the MODREC regarding any clinical trial protocol to be used on SP, by completing the MODREC application form
- the Medicines and Health Regulatory Agency (MHRA)

Contract Kick Off Meeting – D1
The Supplier shall arrange and deliver a Contract Kick Off Meeting with the Authority, to be held via Microsoft Teams, during which both parties shall introduce its key stakeholders and discuss the Suppliers approach and planned schedule for delivering the requirement. The Supplier shall ensure the meeting takes place within 20 working days of Contract Award and ensure sufficient notice is given to the Authority. The Supplier shall ensure it has the appropriate representation to meet the aims of the meeting and shall record, and distribute to the Authority, minutes, and any RODs (Record of Decisions) within 5 working days of the meeting.

Quarterly Progress Reports - D2

The Supplier shall deliver to the Authority a Progress Report at quarterly intervals. The Progress Report should as a minimum:

- Update the Authority on the Suppliers progress against the requirement milestones and deliverables.
- Update the Authority on the Suppliers performance against the Key Performance Indicators.
- Identify any risks to the delivery of the requirement and outline mitigation activity.

The Supplier shall deliver each Quarterly Progress Report within 10 working days of the end of the Quarter for which the report relates. The Supplier shall also ensure the Quarterly Progress Report is delivered no later than 5 working days before the related Quarterly Review Meeting. The provision of a written report prior to the meeting allows the Authority to review and formulate any questions.

The Authority shall confirm whether it deems the Quarterly Progress Report to meet the requirement during the related Quarterly Review Meeting.

Quarterly Review Meetings - D3

The Supplier shall update the Authority at quarterly intervals to ensure progress as expected following on from receipt of the Quarterly Progress Report. The Supplier shall arrange and deliver Quarterly Review Meetings, to be held via Microsoft Teams, ensuring it has the appropriate representation to:

- Update the Authority on its progress against the requirement milestones and deliverables
- Update the Authority on its performance against the Key Performance Indicators.
- Identify any risks to the delivery of the requirement and outline mitigation activity.
- Answer any questions the Authority may have regarding the requirement.

The Supplier shall deliver each Quarterly Review Meeting within 10 working days of the end of the quarter for which the review relates.

The Supplier shall record and distribute ROD's and minutes from the meeting within 5 working days of the meeting taking place.

Final Report – D4

The Supplier shall analyse all data gathered and produce a report which should as a minimum:

- Detail the findings of the trial and assess the impact of the Capsaicin patches on NFCI.
- Provide details of the trial methodology and how the trial was conducted
- Provide details of all results, including those where participants may have been lost to follow-up
- Provide details relating to any significant events or side-effects as part of the medication or placebo patches and how these were managed and/or reported
- Provide details of how results impact the current management of NFCI and how use of capsaicin patches in sufferers of NFCI may contribute, or not, to a change in management or treatment.
- Conclusion – recommendation to either use or not use capsaicin patches on patients to improve NFCI symptoms

The Supplier shall provide the Final Report to the Authority via email within 36 months of Contract Award. Upon receipt of the Final Pilot Report the Authority shall review the document and either confirm acceptance or suggest any required amendments in accordance with the above guidelines. If required by the Authority the Supplier shall make good any suggested amendments within 10 working days before resubmitting the Report. The Authority is aware that it shall have no ability to change the results/outcomes of the trial.

1.3 Options or follow on work *(if none, write 'Not applicable')*

Not applicable

1.4 Contract Management Activities

Key Performance Indicators

Ser	Category	Description	Performance target	% Reduction
1	Quarterly Progress Report	The Supplier shall deliver a Quarterly Progress Report in accordance with 'Project Requirement – Quarterly Progress Report'.	The Supplier shall deliver Quarterly Progress Reports to the Authority within 10 working days of the end of the quarter for which the report relates and no later than 5 working days ahead of the related Quarterly Review Meeting.	Green – no reduction Amber – 5% reduction to the Payment associated with the quarter to

				Green – The Supplier delivers the Quarterly Progress Report within 10 working days of the end of the quarter for which the report relates and no later than five working days ahead of the related Quarterly Review Meeting. Amber - The Supplier delivers the Quarterly Progress Report more than 10 but less than 20 working days from the end of the quarter for which the report relates and/or more than five but less than 10 working days before the related Quarterly Review Meeting. Red – The Supplier delivers the Quarterly Progress Report 20 or more working days from the end of the quarter for which the report relates and/or does not meet the deadline of before the related Quarterly Review Meeting.	which the Quarterly Report relates. Red - 10% reduction on the Payment associated with the quarter to which the Quarterly Progress Report relates.
	2	Quarterly Review Meeting	The Supplier shall deliver Quarterly progress meetings in accordance with 'Project Requirement – Quarterly Review Meeting'	The Supplier shall deliver each Quarterly Review Meeting within 10 working days of the end of the quarter for which the review relates. Green – The Supplier delivers the Quarterly Review Meeting within 10 working days of the end of the quarter for which the meeting relates.	Green – no reduction Amber – 5% reduction to the Payment associated with the quarter to which the Quarterly Report relates.

			Amber - The Supplier delivers the Quarterly Review meeting more than 10 but less than 20 working days from the end of the quarter for which the meeting relates. Red – The Supplier delivers the Quarterly Review Meeting 20 or more working days from the end of the quarter for which the meeting relates	Red - 10% reduction on the Payment associated with the quarter to which the Quarterly Progress Report relates.
3	Final report	The Supplier shall deliver a final report in accordance with 'Project Requirement - Final Report'	Green – The Supplier delivers the Final Report no later than Contract Award + 36 months Amber - The Supplier delivers the Final Report 1 or more but less than 10 working days after the Contract end date (CA + 36 months) Red – The Supplier delivers the Final Report 10 or more working days after the Contract end date (CA + 36 months)	Green – no reduction to the Final Report milestone payment Amber – 5% reduction to the Final Report milestone payment Red – 10% reduction to the Final Report milestone payment

Project Milestones

Milestone	Milestone Detail	Due Date	Acceptance Criteria
M1 - Appropriate medical authority to commence a clinical trial	The Supplier shall obtain approval to commence the trial via MoDREC. The Supplier shall obtain MHRA approval.	Contract Award (CA) + 20 working days	The Supplier shall provide evidence to the Authority of both MoDREC and MHRA approval. Once content with the provided evidence, the Authority shall provide email confirmation to the Supplier, to confirm that the trial can commence

	M2 - Completion of Trial	The Supplier shall conduct and complete the clinical trial in accordance with 'Project Requirement – Elements of Clinical Trial'.	Contract award (CA) + 36 months	The Supplier shall provide the Authority with regular updates regarding trial progress via the quarterly reports and during the quarterly review meetings.

1.5	**Health & Safety, Environmental, Social, Ethical, Regulatory or Legislative aspects of the requirement**
	All requirements are covered within the Ministry of Defence Ethics Committee (MODREC) application form.

1.6	Deliverables & Intellectual Property Rights (IPR)					
Ref.	**Title**	**Due by**	**Format**	**Expected classification (subject to change)**	**What information is required in the deliverable**	**IPR Condition**
D1 -	Contract Kick Off Meeting	Frequency: Once - Within 20 working days of contract award	Via Microsoft Teams - The Supplier shall arrange and attend the Kick-Off Meeting within 20 working days of Contract Award. The Supplier shall record and distribute RODs and minutes to the Authority within 5 working days of the meeting.	Official	The Supplier shall arrange and deliver a Contract Kick Off Meeting to key stakeholders to discuss the approach and planned schedule for delivering the requirement. Further detail of the required content of the Contract Kick Off Meeting can be found in 'Project Requirement – Contract Kick Off Meeting'	Default RCloud Agreement Terms and Conditions shall apply
D2	Quarterly Progress Report	Frequency: Quarterly	The Supplier shall deliver, via email, a Quarterly Progress Report to the Authority within 10 working days of the end of the quarter for which the report relates and no later than 5 working days before the related Quarterly Review Meeting. The Authority shall confirm whether it deems the Monthly Progress Report to meet the requirement and thus is accepted during the	Official	The Supplier shall deliver a Quarterly Progress Report which updates the Authority on its progress against the requirement. Further detail of the required content can be found in 'Project Requirement – Quarterly Progress Report'.	Default RCloud Agreement Terms and Conditions shall apply

			related Quarterly Progress Meeting.			
D3	Quarterly Review Meeting	Frequency: Quarterly	The Supplier shall arrange and deliver Quarterly Review Meetings within 10 working days of the end of the quarter for which the review relates. The Supplier shall record and distribute to the Authority minutes and any ROD's from the meeting within 5 working days. The Authority shall confirm via email, whether it is content with contents of Quarterly Review Meeting and the minutes and ROD's provided by the Supplier.	Official	The Supplier shall arrange and deliver Quarterly Progress Review Meetings with the Authority during which the Supplier shall update the Authority on its progress against the requirement. Further detail of the required content can be found in 'Project Requirement – Quarterly Review Meeting'	Default RCloud Agreement Terms and Conditions shall apply
D4	Final Report	Frequency: Once – By Contract award + 36 months	The Supplier shall deliver, via email , the final report to the Authority in accordance with 'Project Requirement - Final Report' and no later than Contract Award + 36 months.	Official	The Supplier shall deliver a final report to the Authority, as detailed in 'Project Requirement - Final Report'	Default RCloud Agreement Terms and Conditions shall apply In accordance with RCloud Agreement Terms and Conditions, paragraph 12(g), the Authority shall have the right to publish any and all material contained in a Full Rights Version of this Deliverable (Final Report)

1.7	**Deliverable Acceptance Criteria**
	Please refer to “format” column in the Deliverables table

2	**Evaluation Criteria -** **Direct Award**
2.1	Method Explanation
	The Supplier is to provide a Statement of Work detailing how it will deliver a solution to the Authority’s Statement of Requirement (RCloud Tasking Form – Part B). The Supplier should include any assumptions and dependencies and detail any identified risks including how the Supplier intends to mitigate against these.
2.2	Technical Evaluation Criteria
	The Authority shall review the Suppliers technical response to the Authority’s Statement of Requirement including any risks, assumptions and dependencies to confirm compliance.
2.3	Commercial Evaluation Criteria (Mandatory Criteria)
	1. Supplier to provide completed R-Cloud Tasking Form – Part C: Task Response Form including Statement Relating to Good Standing, as per Annex A of the R-Cloud Tasking Response Form (Part C), and Notification of Intellectual Property Rights (IPR) Restrictions, as per Annex B of the R-Cloud Tasking Response Form (Part C). 2. Supplier to provide completed Proposed Payment plan in accordance with Annex A to this Statement of Requirement and aligned to its response to R-Cloud Tasking Form – Part C: Task Response Form. 3. Supplier to confirm its proposed solution can be delivered within the timeframes outlined in this Statement of Requirement. 4. Supplier to provide unconditional acceptance of all Terms and Conditions in relation to this tasking. 5. Supplier to review and confirm acceptance of Schedule 5 – Personal Data Particulars. 6. Supplier to provide all additional information requested within the Supporting Documentation.