# Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

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| **Acronym study title** | **OVCA-1 (OVACT)** |
| **Study Details** | **Trial title:** A Phase I/Ib, Multi-centre, Open-label Study to Evaluate the Safety, Tolerability, and Immunogenicity of Cryptivax-1001, a mRNA Lipid Nanoparticle Therapeutic Cancer Vaccine, in Participants with FIGO Stage III–IV High-Grade Serous or Predominantly Serous Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Following Optimal Primary/Interval Debulking Surgery and First-Line Platinum-Based Chemotherapy (OVACT Study)<br><br>**Brief lay title:** OVACT: Phase I/Ib Study of Cryptivax-1001 in Maintenance Setting for Advanced Serous Ovarian, Fallopian Tube, or Primary Peritoneal Cancer<br><br>**Trial phase:** I/Ib<br><br>**Indication:** Maintenance Ovarian/Fallopian/Primary Peritoneal Cancer after surgery and chemotherapy<br><br>**Investigational medicinal product (IMP):** Cryptivax-1001 vaccine |
| **Principal Investigator PI Sub PI's** | Principal Investigator: Professor Dennis Yiannakis (Dennis.Hadjiyiannakis@lthtr.nhs.uk)<br><br>**Consultant Sub-Investigators:**<br>Professor Pierre Martin-Hirsch (Pierre.Martin-Hirsch@lthtr.nhs.uk)<br><br>Sub-investigator: Dr David Cameron (David.Cameron@lthtr.nhs.uk)<br>Tel: 01772 522031 (Working hours) |
| **Research Nurse Team** | Lead nurse: Elizabeth Coates (Elizabeth.Coates@lthtr.nhs.uk)<br>Tel: 01772 522031 (Working hours) |
| **Drug therapy** | This open-label trial involves treating patients who have had surgery and completed adjuvant chemotherapy without recurrence. During the maintenance phase they are dosed with the IMP, an IM vaccine Cryptivax-1001.<br><br>Cryptivax-1001 is an mRNA vaccine with a lipid envelope. The envelope has been previously used in previous trials into Covid-2019.<br><br>As the mRNA is unique, the exact adverse event profile is unknown. However based on previous mRNA vaccines and previous work involving the lipid envelope, known potential adverse events can be expected |

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| | **Potential Lipid nanoparticle associated AEs:** Injection site pain, Swelling, Headache, Fatigue, Myalgia, Arthralgia, Redness, Fever, Chills. These may be managed symptomatically.<br><br>**Cytokine mediated AEs:** In case of Cytokine Release Syndrome (CRS), Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS), Haemophagocytic Lymphohistiocytosis (HLH), the use of anti-cytokine agents (eg Tocilizumab), Corticosteroids, fluids, antipyretics, vasopressors etc are permitted. |
| **In the event that a patient calls this hotline for advice** | Emergency contact:<br>PI Professor Dennis Yiannakis who can be contacted via RH switchboard if required.<br>If not available, please contact Sub-I Professor Martin-Hirsch as above.<br><br>Advise patient to seek medical assistance via nearest available healthcare provider depending upon severity of symptoms. In an emergency they are to seek emergency medical attention through 999.<br><br>Advise patient to keep all relevant trial paperwork with them for review by treating clinician.<br><br>Patients requiring admission may be reviewed by the on-call Oncology SpR/Consultant.<br><br>Daytime contact number of the trials unit is 01772 522031.<br><br>Treatment interruption/modification may be required (Dose modification or interruption guidance is contained in the study protocol). The principal Investigator and Sub-Investigators should have access to this via the NHS EDGE system. |
| **Dose Escalation** | This trial involves a dose-escalation phase. As such, patients may be exposed to new, higher, doses of IMP than previous patients. Adverse events must be collected and reported as soon as possible to maintain overall safety management of the trial. |