Clinical Trials Summary for out of hours Important Reference

Acronym study title	**MOBILIZE (MODERNA) mRNA-4359-P101**
Study Details	**Trial title:** Phase 1/2 Study of mRNA-4359 Administered Alone and in Combination with Immune Checkpoint Blockade in Participants with Advanced Solid Tumours **Indication:** NSCLC and Melanoma **Investigational medicinal product (IMP):** mRNA-4359
Principal Investigator PI Sub PI's	Principal Investigator: Professor R. Board (Ruth.Board@lthtr.nhs.uk) Sub-Investigator: Professor Dennis Yiannakis Sub-Investigator: Dr Kellati Prasad Sub-investigator: Dr David Cameron (David.Cameron@lthtr.nhs.uk) Tel: 01772 522031 (in hours)
Research Nurse Team	Lead nurse: Allan Brown (Allan.Brown@lthtr.nhs.uk) Tel: 01772 522031 (in hours)
Drug therapy	This trial involves treating patients with the investigational product (IMP) mRNA-4359 in combination with Pembrolizumab. mRNA-4359 is an mRNA vaccine delivered within a lipid-nanoparticle covering. This vaccine is designed to stimulate an immune response to PD-L1 and IDO1, and tumour destruction. The hypothesized mechanism of action for mRNA-4359 is based on the theory that IDO1- and PD-L1-specific T cells, following vaccine-mediated activation, will kill the immunosuppressive and/or regulatory immune cells and cancer cells within the tumor microenvironment that overexpress IDO1 and/or PD-L1. Potential risks for mRNA-4359 include localized injection site reactions, injection-related reactions, immune-related reactions, and hypersensitivity reactions. Common (>10%) potential adverse events that have been seen earlier in this trial are: Injection site pain

	Fatigue Pyrexia Headache Decreased appetite Influenza-like illness Vomiting
In the event that a patient calls this hotline for advice	Refer to SoC protocol for additional information regarding Pembrolizumab treatment. mRNA-4359 toxicity should be managed according to clinical practice guideline on immune checkpoint inhibitor-related adverse events. Injection site reactions are any experiences that occur at the injection site for mRNA-4359. Consultation with a dermatologist may occur for participants who have an injection site reaction of Grade 3 or higher for injection site pain/tenderness, erythema/redness, induration/swelling, pruritus; or is clinically significant and persists for more than 14 days. For persistent Grade 3 injection site reactions, mRNA-4359 should be held. 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. Advise patient to keep all relevant trial paperwork with them for review by treating clinician. Patients requiring admission may be reviewed by the on-call Oncology SpR/Consultant. **Beyond this, further advice can be obtained via the PI Professor Ruth Board, or Sub-Investigators Professor D.Yiannakis, Dr A.Ali, Dr TC Lam or Dr D.Devleena, contactable via switchboard.** Daytime contact number of the trials unit is 01772 522031. Treatment interruption/modification may be required (Dose modification or interruption guidance is contained in the study protocol).