Clinical Trials Summary for out of hours Important Reference

NHS
Lancashire Teaching Hospitals
NHS Foundation Trust

Acronym study title	**BNT 122 - BioNTech**
Study Details	A multi-site, open-label, Phase II, randomized, controlled trial to compare the efficacy of RO7198457 versus watchful waiting in resected, Stage II (high risk) and Stage III colorectal cancer patients who are ctDNA positive following resection
Principal Investigator PI Sub PI's	**Dr Deborah Williamson** **Dr Sin Lau** **Dr Kellati Prasad** **Dr David Cameron**
Research Nurse Team	**Oncology Research Nurse Team – Rashmi Madan – 01772 524656** **LCRF Research Nurse Team, Elizabeth Coates – 01772 522031**
Drug therapy	*Experimental Arm – ARM B* *25 Ug RO7198457 15 doses* *(6x q1w, 2x q2w, 7x q6w)* *6 weekly doses of RO7198457, followed by 2 doses with 2 wk intervals, followed by 7 "booster" doses every 6 wks, to receive a total of 15 doses over the course of trial treatment, or until disease recurrence or unacceptable toxicity, whichever occurs first.* The investigational medicinal product (IMP) RO198457 is an intravenous (i.v.) liposomally formulated messenger RNA (mRNA) (RNA lipoplex, RNA-LPX) that systemically delivers mRNA encoding up to 20 tumor neoantigens (identified from surgically removed tumor tissue) to antigen-presenting cells (APCs) resident in secondary lymphoid tissues. RO7198457 is an individualized neoantigen-specific immunotherapy (iNeST) that is designed to mount an immune response against tumor-specific antigens, arising due to the unique mutational landscape of each patient's tumor. We hypothesize that RO7198457 has the potential to prolong RFS in this early-stage CRC patient population, as RO7198457 provides both immuno-stimulatory signals and expression of cancer-specific neoantigens sufficient to induce an immune response.

In the event that a patient calls this hotline for advice	***07523 804 742*** ***24hr emergency mobile held by Dr Deborah Williamson in the event of an emergency***