Dear RAMPART Investigator,

The Schedule of Events for the RAMPART study has been prepared by the MRC CTU at UCL in collaboration with the South London CRN, who have reviewed and agreed the activities and attribution of all costs associated with the study.

The attribution of costs has been carefully considered and is based on the guidance provided by AcoRD. A justification has been provided below to explain why specific activities have been allocated to NHS Support Costs, Treatment Costs or Excess Treatment Costs.

It should be noted that there are significant differences between the activities required for control (A) and active treatment arms (B and C). As a result, there are multiple lines for some activities within the Schedule of Events to clarify the differences.

Activity	Justification
NHS Support Costs	
Identify potential participants Approach potential participant to discuss study Take informed consent	All activities relating to the identification and consent of potential patients have been attributed as NHS Support Costs, as per the guidance in AcoRD Annex A: "The processing of the patient record to identify NHS patients who may be suitable to approach to ask if they wish to participate in a research project." "Obtaining informed consent from patients where the study is a health research study, taking place within the NHS." Any tests and checks to confirm eligibility have been allocated as Research Costs.
WHO Performance Status Review/reporting of patient AEs/SAEs Concomitant medication check Vital Signs (safety visits – week 2 and 6 only) Physical Exam (safety visits – week 2 and 6 only)	All patients in arms B and C will be required to have the listed checks completed at each treatment visit to ensure that it is safe to go ahead with the infusion. These checks will also be performed at the additional safety visits (weeks 2, 6, 52 and month 15) specified in the protocol. The tests are being performed for safety purposes only and so have been attributed as NHS Support Costs, as per the guidance in AcoRD Annex A: "Additional investigations, assessments and tests where the results are required by the patient's care team to ensure patient safety and where arrangements are in place to feed the results back to the clinician."
Pregnancy test (urine)	All female patients of childbearing potential in arms B and C will be required to have pregnancy test prior to each infusion. This is necessary to ensure that a pregnant mother and unborn foetus are not exposed to the trial medications which may have unknown effects. The tests are being performed for safety purposes only and so have been attributed as NHS Support Costs, as per the guidance in AcoRD Annex A.

Activity	Justification
Biochemistry A (amylase, magnesium, uric acid) Biochemistry B (creatinine clearance) Biochemistry Profile – Full Gamma glutamyltransferase (GGT) Random cortisol Full Blood Count	All patients in arms B and C will be required to have the listed blood tests completed at each treatment visit to ensure that it is safe to go ahead with the infusion. These checks will also be performed at the additional safety visits (weeks 2, 6, 52 and month 15) specified in the protocol. As these tests are being performed for safety purposes only, they have been attributed as NHS Support Costs, as per the guidance in AcoRD Annex A.
ECG no report	All patients in arms B and C will be required to have an ECG at their first treatment visit ensure that it is safe to go ahead with the infusion. This test is being performed for safety purposes only and so has been attributed as NHS Support Costs, as per the guidance in AcoRD Annex A.
Treatment Costs	
CT scan with contrast	The radiology assessments outlined in the trial protocol have been designed to follow the standard of care at participating sites as closely as possible, and as such have been attributed as Treatment Costs in most incidences. The only exceptions to this are a baseline scan to assess eligibility and an additional scan in the first year (not routinely done at some centres), which have both been attributed as Research Costs.
Excess Treatment Costs	
Prescription for study Administer study drug in clinic Aseptic dispensing agent time Individual patient drug accountability time	At present, there is no proven adjuvant treatment for renal cancer patients so there are no costs associated with the preparation and administration of treatments. If either treatment arm in RAMPART became standard of care, the costs of the listed activities would continue to be incurred by the NHS and have therefore been attributed as excess treatment costs.
Vital Signs (treatment visits) Physical Exam (treatment visits)	All patients in arms B and C will be required to have their vital signs checked before, during and after administration of each infusion. These safety checks are part of routine care for advanced RCC patients receiving nivolumab treatment. It is expected that they would form part of routine care for adjuvant treatment if either arm in RAMPART became routine care. The costs of the listed activities would continue to be incurred by the NHS and have therefore been attributed as excess treatment costs.

All other costings within the Schedule of Events have been attributed to Research Costs (A or B) and are expected to be covered in full by site payments from the Sponsor, which will total £2,000 per patient randomised into the study.

Kind Regards,

Mr Ben Smith
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