

List of Activities

This section provides definitions of / more information on activities given in the drop-down lists in the general activities and participant activities tabs. This is not an exhaustive list of all possible activities associated with a research project and applicants may enter additional activities by free-text in the general activities and/or participant activities tabs. Applicants are invited to use the User Feedback tab to comment on the usefulness of the activities given and to suggest the inclusion of additional activities in future versions of this tool.

Activities relating to the study in general

Area of Activity	Specific Activity	Definition or description
Study Set-Up	Attendance at training	
	Site Initiation Visit	
	OTHER - Please specify by over-writing	
Study Monitoring	Attend monitoring visit (PI)	
	Attend monitoring visit (Research Nurse)	
	Completion of remote monitoring form	
	OTHER - Please specify by over-writing	
Study Close-Down	Archiving	
	Return of Study Equipment	
	OTHER - Please specify by over-writing	

Activities Relating to each participant

Area of Activity	Specific Activity	Definition or description
Consent Procedures	Approach potential participant to discuss study	
	Consent for Genetic Sample	
	Database search	
	Eligibility check (exclusions)	
	Identify potential participant	
	Mailout	
	Take informed consent	
	OTHER - Please specify by over-writing	
Laboratory Tests and Investigations	Biochemistry A	ALT, Amylase, Chloride, CRP, Creatinine Kinase, Glucose, Iron, Magnesium, Oestradiol, Osmolality, Triglycerides, Uric Acid
	Biochemistry B	Bicarbonate (Total CO2), CA125, Ca15-3, CA19-9, CEA, Cholesterol, Creatinine Clearance, CRP, Direct Bilirubin, Electrophoresis (EPS), Faecal occult blood, Free T4, hCG, HDL-Cholesterol, Human Growth Hormone (HGH), LH, T3, T4, U&E, UFC
	Biochemistry C	beta 2 microglobulin, BNP, Serum Electrophoresis (EPS), FSH, IGF-1, Immunofixation - serum or urine, Immunoglobulins (A,G,M), Paraprotein measurement (Densitometry), Progesterone, PSA, Prolactin, Testosterone, TGB, Thyroglobulin/TG auto Ab, Total T3, Transferin/TIBC, TSH
	Biochemistry Profile - Basic	Basic Biochemistry Profile: Includes ALT, Alkaline phosphatase, Bilirubin (Total), Calcium, Carbon dioxide, Chloride, Creatinine, Glucose, Potassium, Phosphate, Sodium, Urea, Nitrogen (BUN)
	Biochemistry Profile - Full	Full Biochemistry Profile: Includes Albumin, Bilirubin (total), Calcium, Carbon Dioxide (bicarbonate), Chloride, Creatinine, Glucose, Alkaline Phosphatase, Potassium, Protein, Sodium, Alanine Amino Transferase, (ALT) (SGPT), Aspartate AminoTransferase, (AST) (SGOT), Urea, Nitrogen (BUN)
	Biochemistry Profile - Lipid Panel	Biochemistry Lipid Panel: Includes Total Cholesterol, Lipoprotein, high density cholesterol, cholesterol (HDL cholesterol), Triglycerides
	Biochemistry Profile - Liver Function Test	Biochemistry Liver Function Test: Includes Albumin, Bilirubin, Phosphatase, Alkaline, Protein, total, Transferase, Alanine amino Transferase (ALT) (SGPT), Aspartate amino transferase (AST) (SGOT)
	Biochemistry Profile - Thyroid Function Tests	Biochemistry Thyroid panel, thyroid function tests - Includes triiodothyronine (T3), thyroxine (T4), thyroid stimulating hormone (TSH)
	Biopsy of Bone marrow	Biopsy of Bone marrow, by trocar or needle: Includes preoperative care (including a medical history and physical examination), anaesthesia and typical postoperative care and reporting.
	Biopsy of muscle	Biopsy of muscle: Includes preoperative care (including a medical history and physical examination), anaesthesia and typical postoperative care.
	Biopsy of skin	Biopsy of skin, subcutaneous tissue and/or mucous membrane, skin tumour: Includes preoperative care (including a medical history and physical examination), anaesthesia and typical postoperative care.
	Full Blood Count	Blood count; haemogram and platelet count, haematocrit, haemoglobin, automated and manual differential WBC count (CBC), haematology, Red blood indices: Mean corpuscular volume (MCV), Mean corpuscular haemoglobin (MCH), Mean corpuscular haemoglobin concentration (MCHC), Red blood cell distribution width (RDW).
	GTT, OGTT	Glucose tolerance test (GTT) (OGTT)
	Haematology A	D Dimer, aPTT, Coombs test, Differential (manual), ESR, Fibrinogen, Iron stain, Prothrombin Time, Reticulocyte, TCT
	Haematology B	CD20, CD4, Clotting screen for line insertion, T Cell Count, TTC Code: Prothrombin time (PT) and Thromboplastin time, partial (PTT) (aPTT) combined.
	Hepatitis C antibody	Hepatitis C antibody (HCvab) (anti-HCV).
	INR	International Normalised Ratio (INR)
	Microbiology A	Microbiology A, Chlamydia serology, Genital swab, Hep B vaccine Ab status, Legionella Ab, Rubella clinical, serology non-viral (syphilis), throat swab, Toxoplasma Ab, Urine culture (incl germ tube test), Viral Ab screen.
	Microbiology B	ASO, Cl. Difficile, Hep A, Hep C screen, HIV, other bacteriology (incl mycology), Wound swab.
	Microbiology C	Antibiotic assay, Blood culture, Chlamydia detection, Faeces, Sputum, TB Culture.
	Pregnancy test (blood)	Serum pregnancy, chorionic gonadotropin (hCG) (BetahCG); quantitative.
	Pregnancy test (urine)	Urine pregnancy, chorionic gonadotropin (hCG) (BetahCG); qualitative.
	OTHER - Please specify by over-writing	
Area of Activity	Specific Activity	Definition or description
Medical Exposure / Imaging Tests and Investigations	Bone and/or joint imaging	Bone and/or joint imaging, bone scan, bone scintigraphy, whole body: Includes the technical and professional components (reading)
	Copy of imaging investigation	Copy of imaging investigation on CD/DVD/Film
	CT Scan complex with contrast	Computerized axial tomography, (Cat Scan) (CT Scan); Complex, multi area with contrast material : Includes the technical and professional components (reading) .
	CT Scan with contrast	Computerized axial tomography, (Cat Scan) (CT Scan); with contrast material. Includes the technical and professional components (reading) .
	CT Scan without contrast	Computerized axial tomography, (Cat Scan) (CT Scan); without contrast material. Includes the technical and professional components (reading) .
	DEXA, BM, DXA	Dual energy x-ray absorptiometry (DEXA) (BMD) (DXA) bone density study: Includes the technical and professional components (reading).
	ECG no report	Electrocardiogram, routine 12 lead ECG, Tracing only
	ECG with report	Electrocardiogram, routine 12 lead ECG includes tracing, interpretation and report.

	IVUS	Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention (IVUS)
	MRI more than one area with contrast	Magnetic resonance imaging, (MRI); with contrast material(s) more than one area (e.g. chest & abdo, abdo & pelvis). Includes the technical and professional components (reading)
	MRI single area with contrast	Magnetic resonance imaging, (MRI); with contrast material(s) single area (e.g. extremities, joints, chest, brain, orbit, face). Includes the technical and professional components (reading).
	MRI single area, no contrast	Magnetic resonance imaging (MRI); single area e.g. extremities, joints, chest, brain without contrast material(s): Includes the technical and professional components (reading).
	MUGA RNV	Cardiac blood pool imaging, radionuclide ventriculography, left ventricular ejection fraction (LVEF) (RNV) (MUGA), single study at rest or stress: Includes the technical and professional components (reading).
	RECIST Premium on Standard (per scan)	Response Evaluation Criteria in Solid Tumours (RECIST) applicable criteria for measuring tumour response using X-ray, CT and MRI using this technique.
	Transthoracic ECHO	Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording.
	UDS	Urine Drug screen (UDS)
	Ultrasound 1with report	Ultrasound, (echography) (uls); B-scan: chest, extremities, non-vascular, soft tissues (head & neck). Includes the technical and professional components (reading)
	Ultrasound 2 with report	Ultrasound, retroperitoneal (e.g., renal, aorta, kidney, spleen, gallbladder) (echography) (uls); peripheral vascular system real time with image documentation. Includes the technical and professional components (reading).
	Ultrasound 3 with report	Ultrasound, transrectal, prostate (echography) (uls). Includes the technical and professional components (reading)
	Ultrasound 4 with report	Ultrasound, transvaginal, vaginal probe ultrasonography (TVUS) (echography) (uls): Includes the technical and professional components (reading)
	Urinalysis	
	X-ray multiple views with report	Radiologic examination, (X-Ray); multiple views. Includes the technical and professional components (reading)
	X-ray single view with report	Radiologic examination, (X-Ray); single view. Includes the technical and professional components (reading)
	X-ray -spine or bone with report	Radiologic examination (X-Ray); spine or bone survey. Includes the technical and professional components (reading)
	OTHER - Please specify by over-writing	
Pharmacy	Aseptic dispensing agent time	
	Controlled drug - additional dispensing time	
	Dispensing for standard agent or IMP/NIMP (excluding use of IVR/IWR)	
	Individual patient drug accountability time	
	Pharmacy arrangement of IMP delivery or posting preparation time to the patient	
	Prescription charge	
	Use of IVR/IWR system for dispensing by Pharmacy (additional time)	
	OTHER - Please specify by over-writing	
Other Tests and Investigations	24 hour Cardio memo/ cardio diary	Electrocardiographic monitoring for 24 hours by continuous computerized monitoring and non-continuous recording, and real-time data analysis utilizing a device capable of producing intermittent full-sized waveform tracings, possibly patient activated; includes monitoring and real-time data analysis with report, physician review and interpretation
	24 hour Holter monitoring with interpretation	Electrocardiographic monitoring for 24 hours by continuous original ECG waveform recording and storage, holter monitoring; Includes hook-up, recording, scanning analysis with report, physician review and interpretation, each 24 hours
	24 hour Holter monitoring without interpretation	Electrocardiographic monitoring for 24 hours by continuous original ECG waveform recording and storage, holter monitoring; recording which includes hook-up, recording, and disconnection, each 24 hours
	Cardiac Troponin	Troponin, quantitative; Cardiac Troponin I (cTnI), Cardiac Troponin T (cTnT)
	Central I.V. Line	Central I.V. Line
	Endoscopy - no biopsy	Upper gastrointestinal endoscopy diagnostic including oesophagus, stomach, and either the duodenum and/or jejunum as appropriate
	Endoscopy - simple - no biopsy	Upper gastrointestinal endoscopy including oesophagus, stomach, and either the duodenum and/or jejunum as appropriate; simple primary examination
	Endoscopy with biopsy	Upper gastrointestinal endoscopy including oesophagus, oesophagus, stomach, and either the duodenum and/or jejunum as appropriate; with biopsy
	Glucose test - Finger Stick	Glucose; blood, serum, reagent strip, finger stick test
	OTHER - Please specify by over-writing	
Interventions (clinical)	Administer study drug in clinic	
	Blood pressure (only)	
	Blood sample - collection only	
	Blood sample - collection processing	
	Concomitant medication check (at screening)	
	Concomitant medication check (on study)	
	Medical history	
	Physical examination	
	Prescription for study	
	Spirometry	
	Urinalysis - Urine collection only (at clinic)	
	Urinalysis - Urine processing (dipstick or sample preparation)	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose haemoglobin, ketones, leukocytes, nitrite gravity, urobilinogen (urine analysis) (UA); without microscopy
	Vital Signs measurements (Temp, BP, Pulse and respiration)	
	Waist and Hip Circumference	
	Weight & Height (including BMI if required)	
	OTHER - Please specify by over-writing	
Area of Activity	Specific Activity	Definition or description
Interventions (non-clinical)	Collect and review diaries	
	Dispense diaries and instruct	
	Interview of Participant	
	Observe meeting, clinical practice, etc.	
	Review Questionnaire	
	Subject Questionnaire	
	OTHER - Please specify by over-writing	
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Other Procedures / Activities	CRF/eCRF completion including data transfer and query resolution	
	Device calibration / alteration of mechanical device settings and monitoring	
	Dissemination of study results to participants	
	Drug accountability and compliance	
	Follow-up phone call	
	Handover to routine care (End of Trial)	
	IMP/NIMP related task	
	Instructions/education for patient and/or care giver	
	Monitoring visits	
	Overnight stay	Overnight stay at clinical research site. Includes periodic monitoring and attendance by health care professionals
	Randomisation (manual, IVRS or IWRS)	
	Review/reporting of patient AEs/SAEs	
	Specimen Dispatch by post/courier	
	OTHER - Please specify by over-writing	