Gold Coast University Hospital (GCUH) - Cardiovascular

Location:
-27.959214 - 153.38179
Local Services Offered:
Clinical trials site;Investigator Initiated Trials;Satellite Site;Trial Patient Recruitment;Treatment of patients;Completion of study documentation as per ICH GCP and contract
Details: In addition to the information contained within csv generated by this website, this PDF provides additional site information

Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions?	Yes
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	Yes
Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions?	No
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	Yes
Is your Facility affiliated with a government agency or part of a government funded health service?	Yes
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Does your Facility have computers that are dedicated to research studies?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes
Does the Facility have the ability to handle radio-labelled Investigational Products?	Yes

Is your Facility capable of administering infusions?	Yes
What browser does your facility use?	Edge
Does the Facility have access to local IT support?	Yes
Does your Facility limit or prohibit access and use of external web-based tools or sites for clinical research (E.g. web portals to submit documents to sponsors or CROs)?	Yes, CRA have read-only access
Does your Facility have the ability to manage on-site or off-site destruction of the Investigational Product?	Yes
Other facility details	N/A
Do you have Affiliated Research Sites or Satellite Sites/Clinics?	N/A
Does your Facility have patient record archiving on-site?	Yes
Provide Location name and address of any offsite archives.	Grace
Can your Facility support in-patient admissions for research studies?	Yes
Does your Facility have the ability to collect and store PK/PD specimens?	Yes
Facility written sop during transportation to satellite site	N/A
Does your Facility have an SOP or process that ensures routine calibration and maintenance of general equipment? Examples of general equipment include: scale, pulse oximeter, stadiometer, sphygmomanometer, etc.?	Yes

Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	Yes
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	Yes
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Can your Facility support patient visits on weekends?	Yes
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Yes
Other Meeting Frequency	Yes
Can your Facility support patient visits on weekends?	Yes
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Yes
Meeting frequency	Monthly
Other Meeting Frequency	2 per week with NMA
Does the course content include GCP?	Yes
Lab Name	Pathology Queensland-Gold Coast
Local Lab Usage	Yes
Committee street name and number	1 Hospital Boulevard
Committee City	Southport
Committee Country	Australia
HREC Committee Name	Gold Coast HHS
Registration No.	EC00160
Committee State/Province/Region	Queensland
Committee Zipcode	4032
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
Life Sciences Queensland (LSQ) Member	No

Does your Facility have a written SOP/Policy/Procedure for Minor Assent for paediatric populations?	Yes
Does your Facility have a written SOP/Policy/Procedure for Other vulnerable populations?	Yes
Please provide program course/s name	IQVIA
Street name and number of IP recipient	LG, Block B, 1 Hospital Boulevard
City	Southport
Country	A
IP Recipient Name	Gold Coast University Hospital Pharmacy
State/Province/Region	Queensland
Zip/Postal Code	4032
Does the HREC Committee require payment prior to the release of final approval documents?	Yes
Does your Facility have other review boards that need to approve the study prior to HREC (IRB/ERB/Ethics) Committee submission?	No
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	Yes
Conducting research training	Yes
Does your institution and/or local regulation mandate the distribution of safety reports e.g., Development Safety Update Report (DSUR), Suspected Unexpected Serious Adverse Reaction (SUSAR) to a local review only HREC (IRB/ERB/ETHICS) Committee?	Yes

Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Yes
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
Does your Facility have a training program for the research staff?	Yes
Training program for the research staff	Yes
Storage Room Backup Power	Yes
Is the Investigational Product Storage Room secured with controlled access?	Yes
Storage area securely constructed	Yes
SOP for Calibration	Yes
Is your Facility able to initiate study activities prior to HREC (IRB/ERB/ETHICS) Committee protocol approval?	No
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
Types of HREC (IRB/ERB/ETHICS) Committee that are used	Local;Central Acting as Local
Therapeutic area	Cardiovascular Diseases
Other areas of expertise	Adult Coronary Syndrome, Anaemia, Anaemic Infarcts, Angina,Aortic, Arteriosclerosis, Atherosclerosis, Atrial Fibrillation, Atypical Haemolytic, Brain Ischemia,Chronic Heart Failure, Congestive Heart Failure, Coronary Artery Disease, Endocrinology, Hypotension, Infection and Inflammation, Interventional Cardiology and Cardiothoratics, Ischemic Heart Disease,Medical Devices, Mitral Valve Prolapse, Pericarditis, Phlebitis, Stroke,Thromboembolic Disease, Uremic Syndrome,Vascular Disease, Venous Thromboembolism
Location Information	Grace

EDC Systems Description	iMedidata; RedCap; IVRS/IWRS
EDC Systems	Oracle Inform;Medidate Rave;Oracle Remote Data Capture (RDC); Auslab
Additional equipment	Ultrasound, PSMA-PET, FET PET
Please indicate all equipment that will be available to Monitors	Phone;Copy Machines;Internet Access
Has your Clinical Trial site been audited?	Yes
If your Clinical Trial Site has been audited, please select all relevant types.	Sponsor, TGA
Facility Department	Medicine
Does your Clinical Trial site undertake any patient recruitment?	Yes
Additional General information	Recent opening of the Day Medical and Clinical Trials Unit. Dedicated clinical space - infusion chairs; inpatient beds and consultation rooms.