Gympie Hospital

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: This PDF complements the information found in the CSV generated by this website with additional site information.

Facility Details:	
Facility ID	68
Please provide your Facility Website.	https://www.sunshinecoast.health.qld.gov.au/hospitals-and-health-centres/gympie-hospital
What Department is your Trial Site? (Queensland Health HHS- See List of Services and Levels-Clinical Services Capability Framework)	Medicine
Is your Facility affiliated with a government agency or part of a government funded health service?	Yes
Do you have Affiliated Research Sites or Satellite Sites/Clinics? *A Satellite Site is a secondary location where the investigator sees clinical trial subjects. Usually this is the same investigator who sees subjects at the primary site location.*	Yes
Please provide other facility details.	SCUH
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Please provide other areas of expertise for your Facility.	Renal
Provide the list of Sub-Therapeutic Areas for your Facility.	Renal
Has your Clinical Trial Site been accredited?	Yes
If your Clinical Trial Site has been accredited, please select all relevant types.	Internal
Does your Clinical Trial site undertake any patient recruitment?	Yes
IRB/ERB/Ethics Committee:	
Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions?	No

Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions?	No
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	Three meetings per week in NMA
Does your Facility have other review boards that need to approve the study prior to HREC (IRB/ERB/Ethics) Committee submission? For example, scientific, radiation safety committees, or others	Yes
Does the HREC require contract/budget approval prior to release of final approval documents?	Yes
Does the HREC Committee require payment prior to the release of final approval documents?	Yes
Consent:	
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	Yes
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
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	Yes
Training:	
Does your Facility have a training program for the research staff?	Yes
Does your Facility training course content include GCP?	Yes
If your facility uses external program course/s. Please provide the program course/s name.	Caledonian; ARCS and Syneos online
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes

Does the study staff that prepares or transports dangerous goods have training that meets the IATA International Air Transport Association (US) or other countries hazardous training requirements for shipping dangerous goods?	Yes
Facility And Equipment:	
Facility Capabilities:	
Is your Facility capable of administering infusions?	No
Can your Facility support in-patient admissions for research studies?	Yes
Does your Facility have the ability to collect and store PK/PD specimens?	No
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	No
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 typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	No
Equipment:	
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	No
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.?	No
Please list any additional equipment that your Facility uses for Clinical Trials.	Specialised Imaging at SCUH
IT Capabilities:	

Does your Facility have computers that are dedicated to research studies?	Yes
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
What browser does your facility use?	Edge
Does the Facility have access to local IT support?	Yes
Please indicate all equipment that will be available to Monitors	Phone;Copy Machines;Internet Access
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
Labs:	
Is your Facility using a local lab?	Yes
Please provide local lab details.	Pathology Queensland-Gympie
IP Storage Details:	
IP Recipient Name	Sunshine Coast University Hospital
Does the Investigational Product Storage Room have back-up power?	Yes
Is the Investigational Product Storage Room secured with controlled access?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of the Investigational Product?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes
Does your Facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	Yes
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Yes
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Yes
Source Documents:	

Secure Storage Records	Yes
Does your Facility have patient record archiving on-site?	Yes
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	None
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No