

# Princess Alexandra Hospital- Medical Gastrology Hepatology

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?	Chrome

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
Does your Facility have the ability to manage on-site or off-site destruction of the Investigational Product?	Yes
Does your Facility have patient record archiving on-site?	Yes
Secure Storage Records	Yes
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	Yes
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

Lab Name	Pathology Queensland-PAH
Local Lab Usage	Yes
Committee Country	Australia
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
IP Recipient Name	PA Clinical Trials Pharmacy Department
Does the HREC Committee require payment prior to the release of final approval documents?	Yes
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	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	Caledonian; ARCS; Syneos online
Storage Room Backup Power	Yes
Is the Investigational Product Storage Room secured with controlled access?	Yes
Storage area securely constructed	Yes

What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
Sub-Therapeutic areas	Gastroenterology Hepatology; Crohn's Disease; Diverticulitis; GERD; Hypochlorhydria; Irritable Bowel Syndrome; NASH; Pancreatitis; Ulcerative Colitis; Upper GI Disorders
Please indicate all equipment that will be available to Monitors	Phone; Copy Machines; Internet Access
Has your Clinical Trial Site been accredited?	Not Applicable
Has your Clinical Trial site been audited?	Not Applicable
If your Clinical Trial Site has been audited, please select all relevant types.	Other
Does your Clinical Trial site undertake any patient recruitment?	Yes
What percentage of Clinical trials undertaken on your site do you meet or exceed the recruitment target?	80-90%
EMR/EHR systems	In-house system
Does the HREC require contract/budget approval prior to release of final approval documents?	Yes
Any Additional Process	No