Austrials

Local Services Offered: Clinical trials CRO
Details: This PDF complements the information found in the CSV generated by this website with additional site information.

Facility Details:

Is your Facility affiliated with a government agency or part of a government funded health service?	No
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	Yes
Provide the list of Sub-Therapeutic Areas for your Facility	Endometriosis;depression and anxiety.
Has your Clinical Trial Site been accredited?	No
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%
Additional General information	We provide a coordinating investigator to support our network at multiple sites
IRB/ERB/Ethics Committee	
Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions?	Yes
Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions?	Yes
Does the HREC Committee require payment prior to the release of final approval documents?	Yes
Does the HREC require contract/budget approval prior to release of final approval documents?	No
Does your Facility have other review boards that need to approve the study prior to IRB/ERB/Ethics Committee submission? For example, scientific, radiation safety committees, or others.	No
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 provide language translations for consents?	No
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 other external training program course/s. Please provide the program course/s name.	IATA; IQVIA and Whitehall
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
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
Facility And Equipment:	
Facility Capabilities:	
Can your Facility support in-patient admissions for research studies?	No
Can your Facility support patient visits on weekends?	No
Is your Facility capable of administering infusions?	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 your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	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 the Investigational Product?	Not Applicable
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Does your Facility have the ability to collect and store PK/PD specimens?	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
Equipment:	
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	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
IT Capabilities:	
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
Does your Facility have computers that are dedicated to research studies?	Yes
Which internet browser does your facility use?	Internet Explorer
Does the Facility have access to local IT support?	Yes
Please indicate all equipment that will be available to Monitors	Phone;Fax;Copy Machines;Internet Access
What is your facility's Internet download speed?	100/100
What is your facility's internet upload speed?	Fibre 100/100
Lab:	
Is your Facility using a local pathology lab?	No
Does your Facility use private laboratory services?	Yes

IP Storage Details:	
Please provide the IP Recipient Name.	Westside Hospital-Jemimah Sguena
Is the Investigational Product Storage Room secured with controlled access?	Yes
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Yes
Source Documents:	
Does your Facility have patient record archiving on-site?	No
If your Facility stores patient records offsite. Please provide the location name and address of any offsite archives.	Grace
For Facilities with satellite sites, where is the monitor required to access source documents, please details the location of the monitor?	At site
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No
What Electronic Data Capture (EDC) systems does your Facility use for clinical trials?	CLIMCAL INK
Please provide other EDC Systems that your facility uses?	Oracle Inform;Medidate Rave;Oracle Remote Data Capture (RDC);Others
Please list any access limitations/requirements for the Electronic Medical Records	No CRA access to eHR - print off a paper source