Gallipoli Medical Research Foundation

Local Services Offered:
Early Phase, Clinical trials site, Phase 1 unit, Bench research, 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:	
Please provide your Facility Website.	www.gallipoliresearch.com.au
What Department is your Trial Site? (**Queensland Health HHS**- *See List of Services and Levels- Clinical Services Capability Framework*)	Medicine
Please provide contact person phone number.	0733947297
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
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.	Ramsay Clinical Trials Network
Please provide other areas of expertise for your Facility.	Respiratory Non tuberculosis mycobacterium
Provide the list of Sub-Therapeutic Areas for your Facility.	NASH, Solid Tumours
Does your Clinical Trial site or Service undertake any recruitment?	Yes
What percentage of Clinical trials undertaken on your site do you meet or exceed the recruitment target?	90%
Has your Clinical Trial Site or Service been accredited?	No
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
Any Additional Process	Yes

Details of other steps for HREC (IRB/ERB/Ethics)Committee review and submission	Choice of Ramsay Queensland HREC and lead to Bellberry
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?	Yes
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
If other review boards, please provide details of the process.	Governance process to be determined
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?	No
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
If your facility uses external program course/s. Please provide the external program course/s name.	Yes
If your facility uses external program course/s. Please provide the program course/s name.	Praxis, ACRP
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:	
Can your Facility support patient visits on weekends?	No
Can your Facility support in-patient admissions for research studies?	Yes
Is your Facility capable of administering infusions?	Yes
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	Yes
Does your Facility have the ability to collect and store PK/PD specimens?	Yes
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	Yes
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	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
Please provide details of any additional equipment.	Fibroscan for NASH studies
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?	Safari

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 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
IP Storage Details:	
IP Recipient Name	Ramsay Oncology Pharmacy (Greenslopes Private)
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 the Facility have the ability to handle radio-labelled Investigational Products?	No
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Not Applicable
Source Documents:	
Provide Location name and address of any offsite archives.	Grace
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	Oracle Inform, Medidata Rave, Oracle Remote Data Capture (RDC), IBM merge, VIADOCS,