Paratus Clinical Research

Local Services Offered:
Clinical trials site, GP trials, Trial Patient Recruitment
Details: In addition to the information contained within csv generated by this website, this PDF provides additional site information

Facility Details:	
Please provide your Facility Website.	https://paratusclinical.com/brisbane
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?	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.*	No
Has your Clinical Trial Site or Service been accredited?	No
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 %
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
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	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?	No
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	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 external program course/s. Please provide the program course/s name.	Tanya Simmons GCP
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 in-patient admissions for research studies?	No
Can your Facility support patient visits on weekends?	No
Is your Facility capable of administering infusions?	No
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	No
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?	No

Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Does your Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs?	Yes
If yes, which of the following? (chose all that apply)	DNA vaccines
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 list any additional equipment that your Facility uses for Clinical Trials.	ECG/EKG Electrocardiogram
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?	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)?	No
Please indicate all equipment that will be available to Monitors	Copy Machines, Internet Access
Labs:	
Is your Facility using a local lab?	No
Does your Facility use private laboratory services?	Yes

Please provide private laboratory services name.	4Cyte Pathology
IP Storage Details:	
IP Recipient Name	Paratus Clinical
Storage Room Backup Power	No
Does the Facility have the ability to handle radio-labelled Investigational Products?	No
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	No
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?	No
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Not Applicable
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Yes
Source Documents:	
Does your Facility have secure storage for patient records?	Yes
Provide Location name and address of any offsite archives.	Iron Mountain
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	RealTime CTMS
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
What EMR/EHR system do you use?	In-house