

Question	Answer
Enter the name of the Clinical Trial Site- Organisation Name	Queensland Health
Enter the contact name for this Clinical Trial Site- Contact Person	HeIDI Research Coordinator
If you selected Queensland Health as the Organisation name, please provide your QH Facility ID	00201
If you selected Queensland Health as the Organisation name, please select your Hospital and Health Service (HHS).	Metro North
Services Offered by your site	Clinical trials site, Investigator Initiated Trials, Trial Patient Recruitment
Please provide the short promotional description of your Clinical Trial Site for marketing purposes.	
Clinical Trial Site person - Title	
Clinical Trial Site contact person - First Name	Herston Infectious Diseases Institute
Clinical Trial Site contact person - Last Name	Research Coordinator
Contact person email address	heidi-research@health.qld.gov.au
Contact person phone number	07 3647 1045
Your Clinical Trial Site website address	
Building/Floor/Room/Suite	Royal Brisbane and Women's Hospital
Street name and number	1 Butterfield Street
Additional address information	
City	Herston
State	QLD
Postcode	4029
Country	Australia
Life Sciences Queensland (LSQ) Member	No
GPS location of your Clinical Trial Site- GPS Location 1	
GPS location of your Clinical Trial Site- GPS Location 2	
Please select the Clinical Trial Site Facility's department	Medicine
Please provide the list of Therapeutic Areas for your Clinical Trial Site Facility: (Select all relevant)	Bacterial Infections and Mycoses, Parasitic Diseases, Respiratory Tract Diseases, Virus Diseases
Please list any sub-therapeutic areas.	
Any other areas of expertise?	
Please indicate the Study phase capabilities of your Clinical Trial Site.	Phase II, Phase III, Phase IV
Does your Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs?	No
If yes, which of the following? (choose all that apply)	
If you selected other in the previous question, please specify which other types of GMOs .	
Do you have Affiliated Research Sites or Satellite Sites/Clinics?	No

If you selected Yes for the previous question, please list where	
What study types does your Facility have experience with?	Academic, Industry, Investigator
If Other was selected, please indicate which study types.	
Is your Facility affiliated with a government agency or part of a government funded health service?	Don't know
Patient Population Demographics: (Select all that apply)	Adults 18 and onwards
Are there any notable factors relating to your Patient Population (e.g. First Nations populations)	
What is the average time (in calendar days) to start a study once you have received the regulatory package? E.g. the completed Clinical Trials Notification (CTN) Form	Less than 30
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?	No
Department contact name	
Department phone number	
Department email address	
Is your Facility able to initiate study activities prior to HREC (IRB/ERB/ETHICS) Committee protocol approval?	No
What types of HREC (IRB/ERB/ETHICS) Committee does your Facility use? Select all that apply. If QH choose Central Acting as Local-For National Mutual Acceptance (NMA)	Central Acting as Local
Does your institution and/or local regulation mandate the distribution of safety reports e.g., Development Safety Update Report (DSUR), Suspected Unexpected Serious Adverse Reaction (SUSAR) to a local review only HREC (IRB/ERB/ETHICS) Committee?	Yes
Are there any other steps that the Sponsor should be aware of for your HREC (IRB/ERB/ETHICS) Committee review and submission?	No
If Yes, provide details about the role various committees play in your site's review and submission process. If you have multiple local HREC (IRB), explain what drives the decision on which HREC to use.	
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?	
Has your Clinical Trial site been audited?	Yes
If your Clinical Trial Site has been audited, please select all relevant types.	TGA (Therapeutics Drug Administration)
If you selected Other types of Audit, please list here.	
Has your Clinical Trial Site been accredited?	Yes
If your Clinical Trial Site has been accredited, please select all relevant types.	
If you selected Other type of Accreditation, please list here.	
Which is your Local HREC (IRB/ERB/Ethics) Committee?	Metro North HHS - Royal Brisbane and Women's Hospital
If Other was selected for the HREC Committee Name, please name here.	
Local HREC Committee Street Name and Number	
Local HREC Committee Building/Floor/Room/Suite	
Additional address information for the Committee	
Local HREC Committee State/Province/Region	
Local HREC Committee City	
Local HREC postcode	
Local HREC Committee Country	
Local HREC Committee Registration No.	
What is the meeting frequency of your Local HREC Committee?	Other
If Other was selected, please indicate the frequency:	Second monthly
How long prior to HREC meeting does the application need to be submitted?	Greater than 2 weeks
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 HREC (IRB/ERB/Ethics) Committee submission?	No
If other review boards, please name.	
Is your Facility using a local pathology lab?	Yes
Select local Pathology Queensland laboratory	Central
Does your Facility use private laboratory services?	No
If you selected 'Yes' on the previous question, please specify here which services.	
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	No

Does your Facility have a written SOP/Policy/Procedure for Other vulnerable populations?	No
Does your Facility have a written SOP/Policy/Procedure for Minor Assent for paediatric populations?	No
Will your Facility require language translations for consents?	No
Does your Facility have a training program for the research staff?	No
Does the course content include GCP?	
Please provide program course/s name	
Do you have a process or program in place to retrain research staff when a protocol is amended?	No
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
Can your Facility support patient visits on weekends?	No
Can your Facility support in-patient admissions for research studies?	Yes
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	Yes
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 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
Identify the Diagnostic Equipment available at or near the Facility to support Research studies? (Check all that apply.)	CT Scan Computerized Tomography Scan, ECG/EKG Electrocardiogram, FLRO Fluoroscopy, MRI Magnetic Resonance Imaging, MRA Magnetic Resonance Angiography, MRS Magnetic Resonance Spectroscopy, NMED Nuclear medicine (e.g. Bone scan, thyroid scan, thallium cardiac stress test), PET Positron Emission Tomography Scan, X-Ray
Describe any additional equipment relevant to Clinical Trials:	
Does your Facility have an SOP or process that ensures routine calibration and maintenance of general equipment? Examples of general	Yes

equipment include: scale, pulse oximeter, stadiometer, sphygmomanometer, etc.?	
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	Yes
Do you have centrifuge available at the Facility to support Research studies?	Yes
Do you have refrigerated centrifuge available at the Facility to support Research studies?	Yes
Do you have a refrigerator (2 to 8 Degrees C) available at the Facility to support Research studies?	Yes
Refrigerator 2 to 8 Degrees C Do you have the ability to generate a temperature monitoring log for this equipment?	Yes
Refrigerator 2 to 8 Degrees C Does this equipment provide Min/Max Temperature Monitoring?	Yes
Refrigerator 2 to 8 Degrees C How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	
Refrigerator 2 to 8 Degrees C Does this equipment have back-up power?	
Refrigerator 2 to 8 Degrees C Does this equipment have a temperature alarm?	
Refrigerator 2 to 8 Degrees C Do you have an SOP that supports the calibration of this equipment?	
Do you have a freezer (-20 to -30 Degrees C) available at the Facility to support Research studies?	Yes
Freezer -20 to -30 degrees C Do you have the ability to generate a temperature monitoring log for this equipment?	Yes
Freezer -20 to -30 degrees C Does this equipment provide Min/Max Temperature Monitoring?	Yes
Freezer -20 to -30 degrees C How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	
Freezer -20 to -30 degrees C Does this equipment have back-up power?	
Freezer -20 to -30 degrees C Does this equipment have a temperature alarm?	
Freezer -20 to -30 degrees C Do you have an SOP that supports the calibration of this equipment?	Yes
Do you have a freezer (-70 to -80 Degrees C)	Yes

available at the Facility to support Research studies?	
Freezer -70 to -80 degrees C Do you have the ability to generate a temperature monitoring log for this equipment?	Yes
Freezer -70 to -80 degrees C Does this equipment provide Min/Max Temperature Monitoring?	Yes
Freezer -70 to -80 degrees C How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	
Freezer -70 to -80 degrees C Does this equipment have back-up power?	
Freezer -70 to -80 degrees C Does this equipment have a temperature alarm?	
Freezer -70 to -80 degrees C Do you have an SOP that supports the calibration of this equipment?	Yes
Do you have a freezer (-Liquid Nitrogen -135 Degrees C) available at the Facility to support Research studies?	
Freezer (Liquid Nitrogen -135 degrees C) Do you have the ability to generate a temperature monitoring log for this equipment?	
Freezer (Liquid Nitrogen -135 degrees C) Does this equipment provide Min/Max Temperature Monitoring?	
Freezer (Liquid Nitrogen -135 degrees C) How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	
Freezer (Liquid Nitrogen -135 degrees C) Does this equipment have back-up power?	
Freezer (Liquid Nitrogen -135 degrees C) Does this equipment have a temperature alarm?	
Freezer (Liquid Nitrogen -135 degrees C) Do you have an SOP that supports the calibration of this equipment?	
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)
If in the previous question you stated 'Other', please indicate which OS that is.	
What is your facility's internet upload speed?	
What is your facility's Internet download speed?	
What browser does your facility use?	Internet Explorer/Edge
Does your Facility limit or prohibit access and use of external web-based tools or sites for	No

clinical research (E.g. web portals to submit documents to sponsors or CROs)?	
Does the Facility have access to local IT support?	Yes
Investigational Product and Controlled Substances (e.g. drugs, devices or gases, etc.) Recipient Name:Product and Controlled Substances (e.g. drugs, devices or gases, etc.) Recipient Name:	
IP Recipient Street Name and Number	
IP Recipient Building/Floor/Room/Suite	
IP Recipient Additional Address Info	
IP Recipient Country	
IP Recipient State/Territory	
IP Recipient City	
IP Recipient Postcode	
IP Recipient Phone number	
IP Recipient Fax number	
IP Recipient email	
IP Storage Location Name	The Royal Brisbane and Women's Hospital
If you selected 'Other' for the IP Storage Location Name, please fill in the information here.	
Location of Investigational Product storage Street name and number	
Location of Investigational Product storage Building/Floor/Room/Suite	
Location of Investigational Product storage Additional address information	
Location of Investigational Product storage Country	
Location of Investigational Product storage State / Territory	
Location of Investigational Product storage Postcode	
Location of Investigational Product storage Phone number	
Location of Investigational Product storage Fax number	
Location of Investigational Product storage email address	
Investigational Product Storage Equipment at your Facility Refrigerator (2-8 degrees C)	Yes
Identify the Investigational Product Storage Equipment at your Facility Freezer (-20 to -30 Degrees C)	
Identify the Investigational Product Storage Equipment at your Facility Freezer (-70 to -80 Degree C)	
Identify the Investigational Product Storage	

Equipment at your Facility Freezer (Liquid Nitrogen -135 Degrees C)	
Is the Investigational Product Storage Room secured with controlled access?	Yes
Do you have the ability to generate a temperature monitoring log for this Investigational Product Storage Room?	Yes
Does the Investigational Product Storage Room have back-up power?	
Does the Investigational Product Storage Room have a temperature alarm?	Yes
Do you have an SOP that supports the calibration of the temperature monitoring equipment in the Investigational Product Storage Room?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of the Investigational Product?	Yes
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Yes
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	
Does your facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	
Please describe additional Investigational Product Storage and Handling Capabilities.	
Please identify the Investigational Product preparation capabilities at your Facility	
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 the Facility have the required licenses or registrations to receive, store, dispense and return controlled substances as required by local law?	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?	
What type of source documents will be used? (Select all that apply):	Paper and Electronic
Does your Facility have patient record archiving on-site?	Yes

Provide Location name and address of any offsite archives.	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
What EMR/EHR system do you use? Electronic Medical Records (EMR) /Electronic Health Records	In-house system
For Facilities with satellite sites, where is the monitor required to access source documents, please details the location of the monitor?	
Please list any access limitations/requirements for the Electronic Medical Records	
Please indicate all equipment that will be available to Monitors	Phone, Fax, Copy Machines, Internet Access
Please describe Other EDC Systems:	
Please provide additional information not captured in other sections of the Facility Profile that you feel is important for Sponsors to know about your Facility. Please reference the section name, if applicable.	
Do you agree to the information you have provided to be published on the Queensland Clinical Trials Portal? qldclinicaltrials.com.au	Yes