Question	Answer
Enter the name of the Clinical Trial Site-	The Prince Charles Hospital Clinical Trials
Organisation Name	Centre
Enter the contact name for this Clinical Trial Site-	Jenny Peek
Contact Person	
If you selected Queensland Health as the	Queensland Health
Organisation name, please provide your QH	
Facility ID	
If you selected Queensland Health as the	Metro North
Organisation name, please select your Hospital	
and Health Service (HHS).	
Services Offered by your site	Early Phase, Clinical trials site, Phase 1 unit,
	Investigator Initiated Trials, Trial Patient
	Recruitment, Treatment of patients
Please provide the short promotional description	The TPCH Clinical Trials Centre is a phase
of your Clinical Trial Site for marketing purposes.	I–capable, mRNA-enabled facility dedicated to
of your Chillean That Site for marketing purposes.	,
	bringing the latest research to the bedside. We
	partner with established Clinical Research
	Groups (CRGs), universities and industry to
	deliver safe, ethical and efficient trials that
	improve outcomes for Queenslanders.
Clinical Trial Site person - Title	Assistant Nursing Director Clinical Trials
Clinical Trial Site contact person - First Name	Jenny
Clinical Trial Site contact person - Last Name	Peek
Contact person email address	tpch-ctc@health.qld.gov.au
Contact person phone number	3139 6219
Your Clinical Trial Site website address	https://metronorth.health.qld.gov.au/tpch/researc
	h/clinical-trials-centre
Building/Floor/Room/Suite	Main Building, Level 1
Street name and number	624 Rode Rd
Additional address information	The Prince Charles Hospital
City	Chermside
State	Queensland
Postcode	4032
Country	Australia
Life Sciences Queensland (LSQ) Member	No
GPS location of your Clinical Trial Site- GPS	J25F+W4 Chermside, Queensland
Location 1	, , , , , , , , , , , , , , , , , , , ,
GPS location of your Clinical Trial Site- GPS	
Location 2	
Please select the Clinical Trial Site Facility's	Medicine
department	
Please provide the list of Therapeutic Areas for	Bacterial Infections and Mycoses,
your Clinical Trial Site Facility: (Select all	Cardiovascular Diseases, Digestive System
relevant)	Diseases, Occupational Diseases, Respiratory
Tolovality	Tract Diseases, Virus Diseases, General
Places list any sub therapoutic areas	Tract Discases, Vilus Discases, Gelleral
Please list any sub-therapeutic areas.	The Prince Charles Hespital (TDCU) is
Any other areas of expertise?	The Prince Charles Hospital (TPCH) is
	internationally recognised as Queensland's
	leading heart and lung facility, with established
	I and the second se

excellence in cardiology, thoracic medicine, cardiac surgery, transplantation, and critical care. The hospital combines clinical expertise with a strong research culture, positioning it at the forefront of innovation in cardiovascular and respiratory medicine. Located only a few kilometres from Brisbane Airport, TPCH offers exceptional accessibility for national and international collaborators, making it an ideal environment for conduct Clinical Trial Site. Please indicate the Study phase capabilities of your Clinical Trial Site have the capacity to conduct Clinical Trial Site have the capacity to conduct Clinical Trial is involving GMOs? 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? If you selected Yes for the previous question, please list where What study types does your Facility have experience with? 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? Patient Population Demographics: (Select all that apply) 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 Does your Facility perform HREC (IRB/ERB/ETHICS) Committee submissions? Does your Facility perform HREC (IRB/ERB/ETHICS) Committee submissions? Department contact name Department phone number Department phone number Department email address Is your Facility able to initiate study activities prior to HREC (IRB/ERB/ETHICS) Committee protocol approval?		·
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prior to HREC (IRB/ERB/ETHICS) Committee	·	
	prior to HREC (IRB/ERB/ETHICS) Committee	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) 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? Are there any other steps that the Sponsor should be aware of for your HREC (IRB/ERB/ETHICS) Committee review and submission? 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? What percentage of Clinical trials undertaken on your site do you meet or exceed the recruitment target? Has your Clinical Trial site been audited, please select all relevant types. If you selected Other types of Audit, please list here. If your Clinical Trial Site been accredited, please select all relevant types. If you selected Other type of Accreditation, please select all relevant types. If you selected Other type of Accreditation, please select all relevant types. If your selected Other type of Accreditation, please select all relevant types. If your selected Other type of Accreditation, please select all relevant types. If your selected Other type of Accreditation, please select all relevant types. If your selected Other type of Accreditation, please select all relevant types. If your selected Other type of Accreditation, please select all relevant types. If your selected Other type of Accreditation, please select all relevant types. If your clinical Trial Site has been accredited, please select all relevant types. If your selected Other type of Accreditation, please select all relevant types. If your clinical Trial Site has been accredited, please select clinical Trial Site has been secredited, please select c		
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Additional address information for the Committee Local HREC Committee State/Province/Region	Building/Floor/Room/Suite	
	Local HREC Committee State/Province/Region	
	Local HREC Committee City	

Local HREC Committee Country Local HREC Committee Registration No. What is the meeting frequency of your Local HREC Committee? If Other was selected, please indicate the frequency: How long prior to HREC meeting does the application need to be submitted? Does the HREC Committee require payment prior to the release of final approval documents? Does the HREC require contract/budget approval prior to release of final approval documents? Does your Facility have other review boards that need to approve the study prior to HREC (IRB/ERB/Ethics) Committee submission? If other review boards, please name. Is your Facility using a local pathology lab? Select local Pathology Queensland laboratory Does your Facility use private laboratory services? 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? Does your Facility have a written SOP/Policy/Procedure for Other vulnerable populations? Does your Facility have a written SOP/Policy/Procedure for Minor Assent for paediatric populations? Will your Facility require language translations for consents? Does your Facility have a training program for the research staff? 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? Does the study staff that prepares or transports dangerous goods have training that meets the ATA International Air Transport Association (US) or other countries hazardous training requirements for shipping dangerous goods? Can your Facility support patient visits on weekends? Can your Facility support patient visits on weekends? Can your Facility support patient includents on the program of the program of the program of the research studies?	Lacel LIDEC pastoods	
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Does your Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)? Does your Facility have the ability to collect and store PK/PD specimens? Does your Facility have the ability to collect and store PK/PD specimens? Does your Facility have the ability to collect spring to the property of th		
Does the Facility have the ability to collect and store PK/PD samples beyond normal business hours? Does your Facility have the ability to collect and store PK/PD samples beyond normal business hours? Does your Facility have the ability to collect PK/PD samples beyond normal business hours? Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes? Identify the Diagnostic Equipment available at or near the Facility to support Research studies? (Check all that apply.) 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 include: scale, pulse oximeter, stadiometer, shygmomanometer, etc.? Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)? Do you have centrifuge available at the Facility to support Research studies? Do you have refrigerated centrifuge available at the Facility to support Research studies? Do you have refrigerated centrifuge available at the Facility to support Research studies? Do you have refrigerated centrifuge available at the Facility to support Research studies? Do you have refrigerator (2 to 8 Degrees C) pose this equipment provide Min/Max Temperature Monitoring? Refrigerator 2 to 8 Degrees C Does this equipment nave back-up power? Refrigerator 2 to 8 Degrees C Does this equipment have a temperature alarm? Yes Yes Yes	and translation support for study conduct (e.g.	Yes
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equipment have a temperature alarm?	,	Yes
Refrigerator 2 to 8 Degrees C Do you have an Yes	equipment have a temperature alarm?	
	Refrigerator 2 to 8 Degrees C Do you have an	Yes

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.	Daily
Freezer -20 to -30 degrees C Does this equipment have back-up power?	Yes
Freezer -20 to -30 degrees C Does this equipment have a temperature alarm?	Yes
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) available at the Facility to support Research studies?	Yes
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.	Daily
Freezer -70 to -80 degrees C Does this equipment have back-up power?	Yes
Freezer -70 to -80 degrees C Does this equipment have a temperature alarm?	Yes
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?	No
Freezer (Liquid Nitrogen -135 degrees C) Do you have the ability to generate a temperature monitoring log for this equipment?	No
Freezer (Liquid Nitrogen -135 degrees C) Does this equipment provide Min/Max Temperature	No

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? What type of computer operating system(s) does your institution use to support studies? Windows (Window your institution use to support studies?	
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dedicated to research studies? What type of computer operating system(s) does Windows (Window	
What type of computer operating system(s) does Windows (Window	
vour institution use to support studios?	ws XP, Windows 7, Windows
, ,	
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/I	Edge, Firefox
Does your Facility limit or prohibit access and No	
use of external web-based tools or sites for	
clinical research (E.g. web portals to submit	
documents to sponsors or CROs)?	
Does the Facility have access to local IT Yes	
support?	
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 Prince Charle	es 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	Yes
your Facility Refrigerator (2-8 degrees C)	
Identify the Investigational Product Storage	Yes
Equipment at your Facility Freezer (-20 to -30	
Degrees C)	
Identify the Investigational Product Storage	Yes
Equipment at your Facility Freezer (-70 to -80	
Degree C)	
Identify the Investigational Product Storage	No
Equipment at your Facility Freezer (Liquid	
Nitrogen -135 Degrees C)	
Is the Investigational Product Storage Room	Yes
secured with controlled access?	
Do you have the ability to generate a	Yes
temperature monitoring log for this	
Investigational Product Storage Room?	
Does the Investigational Product Storage Room	Yes
have back-up power?	
Does the Investigational Product Storage Room	Yes
have a temperature alarm?	
Do you have an SOP that supports the	Yes
calibration of the temperature monitoring	
equipment in the Investigational Product Storage	
Room?	
Does your Facility have the ability to manage on-	Yes
site or off-site destruction of the Investigational	1 00
Product?	
	Yes
Does your facility have a written	। ८०
SOP/Policy/Procedure for the destruction of	
Investigational Product?	Voc
Do you provide your Satellite Site(s) with a	Yes
dedicated inventory of Investigational Product?	Voc
Does your facility have a written	Yes
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	Vertical laminar flow hood (chemo/hazardous
preparation capabilities at your Facility	drugs)
Is your Facility capable of administering	Yes
infusions?	
Is your Facility adequately staffed to support	Yes
studies with both blinded and unblinded	103
Investigational Product?	
Does the Facility have the required licenses or	Yes
	165
registrations to receive, store, dispense and	
return controlled substances as required by local	
law?	Voc
Does your Facility have the ability to manage on- site or off-site destruction of controlled	1 52
substances when appropriate?	No
Does the Facility have the ability to handle radio-	INU
labelled Investigational Products?	Den an and Elastrania
What type of source documents will be used?	Paper and Electronic
(Select all that apply):	\ <u>\</u>
Does your Facility have patient record archiving	Yes
on-site?	
Provide Location name and address of any	
offsite archives.	
Do you have Electronic Health Records (EHR)/	No
Electronic Medical Records (EMR)?	
What EMR/EHR system do you use? Electronic	
Medical Records (EMR) /Electronic Health	
Records	
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	Phone, Copy Machines, Internet Access
available to Monitors	
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	Yes
provided to be published on the Queensland	
Clinical Trials Portal? qldclinicaltrials.com.au	
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