Question	Answer
Enter the name of the Clinical Trial Site- Organisation Name	UniSC Clinical Trials – Sippy Downs
Enter the contact name for this Clinical Trial Site- Contact Person	Tom Nott
If you selected Queensland Health as the Organisation name, please provide your QH Facility ID	
If you selected Queensland Health as the Organisation name, please select your Hospital and Health Service (HHS).	
Services Offered by your site	Clinical trials site, Trial Patient Recruitment
Please provide the short promotional description of your Clinical Trial Site for marketing purposes.	Our Sippy Downs clinic, located at Ochre Health, is within walking distance of the University of the Sunshine Coast's main campus. We partner with various institutions across the Sunshine Coast to provide a range of clinical trials.
Clinical Trial Site person - Title	Mr
Clinical Trial Site contact person - First Name	Tom
Clinical Trial Site contact person - Last Name	Nott
Contact person email address	BDTrials@usc.edu.au
Contact person phone number	+61754098623
Your Clinical Trial Site website address	https://www.unisc.edu.au/community/unisc-clinical-trials-clinical-trial-site-network
Building/Floor/Room/Suite	Level 1
Street name and number	9 Ochre Way
Additional address information	
City	Sippy Downs
State	QLD
Postcode	4556
Country	Australia
Life Sciences Queensland (LSQ) Member	Yes
GPS location of your Clinical Trial Site- GPS Location 1	-26.712671420328437, 153.06435066790715
GPS location of your Clinical Trial Site- GPS Location 2	
Please select the Clinical Trial Site Facility's department	
Please provide the list of Therapeutic Areas for your Clinical Trial Site Facility: (Select all relevant)	Bacterial Infections and Mycoses, Cardiovascular Diseases, Digestive System Diseases, Endocrine System Diseases, Eye Diseases, Female Urogenital Diseases and Pregnancy Complications, Hemic and Lymphatic Diseases, Immune System Diseases, Male Urogenital Diseases, Mental Disorders, Musculoskeletal Diseases, Nervous System Diseases, Nutritional and Metabolic Diseases, Otorhinolaryngologic Diseases, Parasitic Diseases, Pathological Conditions, Signs and Symptoms, Respiratory Tract Diseases, Skin

	and Connective Tissue Diseases, Stomatognathic Diseases, Virus Diseases, Wounds and Injuries, General
Please list any sub-therapeutic areas.	
Any other areas of expertise?	Healthy volunteers Obesity and metabolic health Cardiovascular disease Neurology Women's health Infectious diseases and vaccines Orthopedics Rheumatology Ophthalmology Gastroenterology and hepatology Respiratory and sleep medicine Dermatology Nephrology Endocrinology
Please indicate the Study phase capabilities of your Clinical Trial Site.	Phase I, Phase II, Phase III, Phase IV, Device Pilot, Device Pivotal, Device Post Approval
Does your Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs?	Yes
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?	Yes
If you selected Yes for the previous question, please list where	With sites across South East Queensland, UniSC Clinical Trials is conveniently located in Maroochydore, Sippy Downs, Morayfield, Birtinya, Brisbane, and Meadowbrook.
What study types does your Facility have experience with?	Industry
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?	No
Patient Population Demographics: (Select all that apply)	Adults 18 and onwards, Geriatrics 65 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	30-60
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
Department contact name	
Department phone number	
Department email address	
Is your Facility able to initiate study activities	No

prior to HREC (IRB/ERB/ETHICS) Committee protocol approval?	
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?	
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?	Yes
What percentage of Clinical trials undertaken on your site do you meet or exceed the recruitment target?	97.87% of target patient enrolment achieved
Has your Clinical Trial site been audited?	Yes
If your Clinical Trial Site has been audited, please select all relevant types.	FDA (Food Drug Administration), TGA (Therapeutics Drug Administration), CRO (Clinical Research Organisation), Sponsor, Other
If you selected Other types of Audit, please list here.	Internal
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?	Other
If Other was selected for the HREC Committee Name, please name here.	Bellberry Limited
Local HREC Committee Street Name and Number	196 Greenhill Road
Local HREC Committee Building/Floor/Room/Suite	Level 1
Additional address information for the Committee	
Local HREC Committee State/Province/Region	South Australia
Local HREC Committee City	Eastwood
Local HREC postcode	5063
Local HREC Committee Country	Australia

Local HREC Committee Registration No.	https://bellberry.com.au/about-us/hrec/hrec-certification-registration/
What is the meeting frequency of your Local HREC Committee?	Weekly
If Other was selected, please indicate the frequency:	
How long prior to HREC meeting does the application need to be submitted?	2 weeks
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?	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	
Does your Facility use private laboratory services?	Yes
If you selected 'Yes' on the previous question, please specify here which services.	Sullivan Nicolaides Pathology
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	Yes
Does your Facility have a written SOP/Policy/Procedure for Other vulnerable populations?	Yes
Does your Facility have a written SOP/Policy/Procedure for Minor Assent for paediatric populations?	
Will your Facility require language translations for consents?	No
Does your Facility have a training program for the research staff?	Yes
Does the course content include GCP?	Yes
Please provide program course/s name	External training delivered by the Australian Clinical Trials Education Centre (A-CTEC).
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
Can your Facility support patient visits on weekends?	Yes
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?	Yes
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, DXA Dual-Energy X-ray Absorptiometry or Bone Densitometry, ECG/EKG Electrocardiogram, FLRO Fluoroscopy, MRI Magnetic Resonance Imaging, MRA Magnetic Resonance Angiography, MRS Magnetic Resonance Spectroscopy, MAMMO Mammography, NMED Nuclear medicine (e.g. Bone scan, thyroid scan, thallium cardiac stress test), PET Positron Emission Tomography Scan, X-Ray, SPECT, Perfusion CT, Other
Describe any additional equipment relevant to Clinical Trials:	Our local providers offer a comprehensive range of specialist imaging services.
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
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	Daily

support.	
Refrigerator 2 to 8 Degrees C | Does this equipment have back-up power?	Yes
Refrigerator 2 to 8 Degrees C | Does this equipment have a temperature alarm?	Yes
Refrigerator 2 to 8 Degrees C | Do you have an SOP that supports the calibration of this equipment?	Yes
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?	
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?	
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?	
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
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	
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)	Yes
Identify the Investigational Product Storage Equipment at your Facility | Freezer (-70 to -80 Degree C)	Yes
Identify the Investigational Product Storage Equipment at your Facility | Freezer (Liquid Nitrogen -135 Degrees C)	No
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?	Yes
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?	Not Applicable
Does your facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	Not Applicable
Please describe additional Investigational Product Storage and Handling Capabilities.	
Please identify the Investigational Product preparation capabilities at your Facility	Vertical laminar flow hood (chemo/hazardous drugs)
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):	Electronic
Does your Facility have patient record archiving on-site?	No
Provide Location name and address of any offsite archives.	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	No
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 available to Monitors	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	Yes

provided to be published on the Queensland Clinical Trials Portal? qldclinicaltrials.com.au	