

Question	Answer
Enter the name of the Clinical Trial Site- Organisation Name	Veracity Clinical Research Pty Ltd.
Enter the contact name for this Clinical Trial Site- Contact Person	Dr Lynda Spelman
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, Investigator Initiated Trials
Please provide the short promotional description of your Clinical Trial Site for marketing purposes.	Veracity Clinical Research is a dermatology clinical research company that conducts clinical research trials in the field of inflammatory skin conditions. Lead by Dermatologist - Dr Lynda Spelman, Veracity Clinical Research is a dedicated private research facility with experienced investigators and study coordinators. Dr Spelman has over 30 years experience in clinical trials having participated in over 210 clinical research studies.
Clinical Trial Site person - Title	Principal Investigator
Clinical Trial Site contact person - First Name	Lynda
Clinical Trial Site contact person - Last Name	Spelman
Contact person email address	trials@veracityclinicalresearch.com.au
Contact person phone number	+617 3039 1311
Your Clinical Trial Site website address	www.veracityclinicalresearch.com.au
Building/Floor/Room/Suite	Suite 18, Level 1
Street name and number	250 Ipswich Road
Additional address information	Woolloongabba
City	Brisbane
State	Queensland
Postcode	4102
Country	
Life Sciences Queensland (LSQ) Member	Yes
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	Paediatric Medicine
Please provide the list of Therapeutic Areas for your Clinical Trial Site Facility: (Select all relevant)	Immune System Diseases, Occupational Diseases, Pathological Conditions, Signs and Symptoms, Skin and Connective Tissue Diseases, Wounds and Injuries
Please list any sub-therapeutic areas.	Dermatology
Any other areas of expertise?	We have experience conducting clinical trials for inflammatory skin conditions, and some related immune system diseases. This includes: Atopic

	Dermatitis (Eczema), Hand Dermatitis, Psoriasis, Psoriatic Arthritis, Lupus (CSLE/ SLE), Hidradenitis Suppurativa, Alopecia Areata, Rosacea, Ulcerative Pyoderma Gangrenosum?, Lupus (CSU/CINDU), Prurigo Nodularis, Ichthyosis, Vitiligo, Sebaceous Hyperplasia, non-melanoma skin cancers.
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)	GM products that do not contain live GMOs
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?	No
Patient Population Demographics: (Select all that apply)	Paediatrics, Adolescents/Adults 16 and onwards, Adults 18 and onwards, Geriatrics 65 and onwards
Are there any notable factors relating to your Patient Population (e.g. First Nations populations)	Veracity Clinical Research is happy to accomodate any patient population for opinion and management of their skin condition. This includes First Nations Populations, non-medicare card holders, low income groups, citizens or non Australian citizens.
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?	No
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?	Yes

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)	Sponsor Provided Central
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?	No
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.	FDA (Food Drug Administration)
If you selected Other types of Audit, please list here.	
Has your Clinical Trial Site been accredited?	not applicable
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.	
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?	Twice a Month

If Other was selected, please indicate the frequency:	
How long prior to HREC meeting does the application need to be submitted?	1 week
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?	No
Select local Pathology Queensland laboratory	
Does your Facility use private laboratory services?	No
If you selected 'Yes' on the previous question, please specify here which services.	Site can use local Laboratory if required for sample collection and testing
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?	Yes
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?	Yes
Please provide program course/s name	
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?	No
Can your Facility support in-patient admissions for research studies?	No
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	Yes

Materials, etc.)?	
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, ECG/EKG Electrocardiogram, MRI Magnetic Resonance Imaging, 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 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 support.	Daily
Refrigerator 2 to 8 Degrees C Does this equipment have back-up power?	No
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	Yes

for this equipment?	
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?	No
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?	No
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?	Yes
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 Monitoring?	No
Freezer (Liquid Nitrogen -135 degrees C) How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Daily
Freezer (Liquid Nitrogen -135 degrees C) Does this equipment have back-up power?	No

Freezer (Liquid Nitrogen -135 degrees C) Does this equipment have a temperature alarm?	No
Freezer (Liquid Nitrogen -135 degrees C) Do you have an SOP that supports the calibration of this equipment?	No
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), Apple/Mac (OS X Snow Leopard, Mountain Lion, El Captain, etc)
If in the previous question you stated 'Other', please indicate which OS that is.	
What is your facility's internet upload speed?	Standard
What is your facility's Internet download speed?	Standard
What browser does your facility use?	Internet Explorer/Edge, Safari, Firefox, Chrome
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
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:	Site has on site pharmacy. This information will be provided upon request.
IP Recipient Street Name and Number	250 Ipswich Road
IP Recipient Building/Floor/Room/Suite	Suite 18, Level 1
IP Recipient Additional Address Info	Woolloongabba
IP Recipient Country	Australia
IP Recipient State/Territory	Queensland
IP Recipient City	Brisbane
IP Recipient Postcode	4102
IP Recipient Phone number	+617 3039 1311
IP Recipient Fax number	Provided upon request
IP Recipient email	trials@veracityclinicalresearch.com.au
IP Storage Location Name	Other
If you selected 'Other' for the IP Storage Location Name, please fill in the information here.	Site has on site pharmacy. This information will be provided upon request.
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)	
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?	No
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?	No
Does your facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	Yes
Please describe additional Investigational Product Storage and Handling Capabilities.	This information can be provided upon request.
Please identify the Investigational Product preparation capabilities at your Facility	
Is your Facility capable of administering	Yes

infusions?	
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?	No
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
What type of source documents will be used? (Select all that apply):	Paper
Does your Facility have patient record archiving on-site?	Yes
Provide Location name and address of any offsite archives.	This information can be provided upon request.
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?	N/A
Please list any access limitations/requirements for the Electronic Medical Records	This information can be provided upon request.
Please indicate all equipment that will be available to Monitors	None
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