Princess Alexandra Hospital - Diabetes and **Endocrine**

Local Services Offered:

Clinical trials site;Investigator Initiated Trials;Satellite Site;Trial Patient Recruitment;Treatment of patients;Completion of study documentation as per ICH GCP and contract

Details: In addition to the information contained within csv generated by this website, this PDF provides additional site information

| Does your Facility perform | Yes |
|------------------------------------|--------|
| HREC (IRB/ERB/Ethics) | |
| Committee submissions? | |
| Does your Facility have a written | Yes |
| SOP/Policy/Procedure for | |
| Informed Consent? | |
| Does your Facility have a | No |
| dedicated department or group to | |
| perform HREC | |
| (IRB/ERB/ETHICS) Committee | |
| submissions? | |
| Does your Facility have the | Yes |
| necessary equipment to treat | |
| medical emergencies (for | |
| example crash/code cart)? | |
| Is your Facility affiliated with a | Yes |
| government agency or part of a | |
| government funded health | |
| service? | |
| Does your Facility typically | Yes |
| allow the collection of | |
| Pharmacogenomic (PGX) | |
| samples for research purposes? | |
| Does your Facility have | Yes |
| computers that are dedicated to | |
| research studies? | |
| Does your Facility have the | Yes |
| ability to manage on-site or off- | |
| site destruction of controlled | |
| substances when appropriate? | |
| Does the Facility have the ability | Yes |
| to handle radio-labelled | |
| Investigational Products? | |
| Is your Facility capable of | Yes |
| administering infusions? | |
| What browser does your facility | Chrome |
| use? | |

| | T . |
|-----------------------------------|------------|
| Does the Facility have access to | Yes |
| local IT support? | |
| Does your Facility limit or | Yes |
| 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)? | |
| Does your Facility have the | Yes |
| ability to manage on-site or off- | |
| site destruction of the | |
| Investigational Product? | |
| Does your Facility have patient | Yes |
| record archiving on-site? | |
| Secure Storage Records | Yes |
| Can your Facility support in- | Yes |
| patient admissions for research | |
| studies? | |
| Does your Facility have the | Yes |
| ability to collect and store | |
| PK/PD specimens? | |
| Facility written sop during | Yes |
| transportation to satellite site | |
| Does your Facility have an SOP | Yes |
| or process that ensures routine | |
| calibration and maintenance of | |
| general equipment? Examples of | |
| general equipment include: scale, | |
| pulse oximeter, stadiometer, | |
| sphygmomanometer, etc.? | |
| | |
| Does your Facility have the | Yes |
| ability to collect PK/PD samples | |
| beyond normal business hours? | |
| Is your Facility adequately | Yes |
| staffed to support studies with | 1 65 |
| both blinded and unblinded | |
| Investigational Product? | |
| Does the Facility have storage | Yes |
| | 1 65 |
| space for Study-Related | |
| materials (e.g. Lab Kits, Patient | |
| Materials, etc.)? | Vac |
| Can your Facility support patient | Yes |
| visits on weekends? | X 7 |
| Does your facility have a written | Yes |
| SOP/Policy/Procedure for the | |
| destruction of Investigational | |
| Product? | |

| Lab Name | Pathology Queensland-PAH |
|-----------------------------------|--|
| Local Lab Usage | Yes |
| Committee Country | Australia |
| Do you have Electronic Health | Yes |
| Records (EHR)/ Electronic | |
| Medical Records (EMR)? | |
| Life Sciences Queensland (LSQ) | |
| Member | No |
| Does your Facility have a written | |
| SOP/Policy/Procedure for Minor | |
| Assent for paediatric | |
| populations? | |
| Does your Facility have a written | Yes |
| SOP/Policy/Procedure for Other | |
| vulnerable populations? | |
| | |
| IP Recipient Name | PA Clinical Trials Pharmacy Department |
| Does the HREC Committee | Yes |
| require payment prior to the | |
| release of final approval | |
| documents? | |
| Does your Facility have access to | Yes |
| translators and translation | |
| support for study conduct (e.g. | |
| consent, study-specific | |
| instruction)? | |
| Do you provide your Satellite | Yes |
| Site(s) with a dedicated | |
| inventory of Investigational | |
| Product? | |
| Do you have a process or | Yes |
| program in place to retrain | |
| research staff when a protocol is | |
| amended? | |
| Does your Facility have a | Yes |
| training program for the research | |
| staff? | |
| Training program for the | Yes |
| research staff | |
| Storage Room Backup Power | Yes |
| Is the Investigational Product | Yes |
| Storage Room secured with | |
| controlled access? | |
| Storage area securely constructed | Yes |
| | |

| VVII 4 4 C | W' 1 (W' 1 VD. W' 1 7. |
|------------------------------------|-------------------------------------|
| What type of computer operating | Windows (Windows XP; Windows 7; |
| system(s) does your institution | Windows 10; etc) |
| use to support studies? | |
| | |
| Sub-Therapeutic areas | Diabetes;Endocrine |
| Please indicate all equipment | Phone;Copy Machines;Internet Access |
| that will be available to Monitors | |
| | |
| Has your Clinical Trial Site been | Not Applicable |
| accredited? | 11 |
| Has your Clinical Trial site been | Not Applicable |
| audited? | |
| If your Clinical Trial Site has | Other |
| been audited, please select all | |
| relevant types. | |
| Does your Clinical Trial site | Yes |
| undertake any patient | |
| recruitment? | |
| What percentage of Clinical | 80-90% |
| trials undertaken on your site do | |
| you meet or exceed the | |
| recruitment target? | |
| EMR/EHR systems | In-house system |
| Does the HREC require | Yes |
| contract/budget approval prior to | |
| release of final approval | |
| documents? | |
| Any Additional Process | No |