Queensland Children's Hospital - Neurosciences

Local Services Offered:

Clinical trials site;Investigator Initiated Trials;Trial Patient Recruitment;Treatment of patients;Completion of study documentation as per ICH GCP and contract Details: This PDF complements the information found in the CSV generated by this website with additional site information.

Facility Details:	
Please provide your Facility Website.	https://www.childrens.health.qld.gov.au/
What Department is your Trial Site?	Medical Services
(Queensland Health HHS- See List of	
Services and Levels-Clinical Services	
Capability Framework).	
Provide the list of Sub-Therapeutic Areas for your Facility.	Epilepsy (including drug resistant epilepsy such as Lennox Gastaut syndrome, genetic epilepsies such as Dravet syndrome, tuberous sclerosis and metabolic epilepsy), Neuromuscular disorders (including DMD, SMA, LGMD, CMT, congenital myopathy, congenital muscular dystrophy, rhabdomyolysis), Friedreich ataxia, neuromuscular disorders, and stroke.
Does your Clinical Trial site undertake any patient recruitment?	Yes
IRB/ERB/Ethics Committee:	
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
HREC Committee Name.	Children's Health Queensland Hospital and Health Services Human Research Ethics Committee
What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	Six weekly meetings. NHMRC Accredited committee for NMA

Are there any other steps that the	Yes
Sponsor should be aware of for your	
IRB/ERB/Ethics Committee review and	
submission?	
Does the HREC Committee require	Yes
payment prior to the release of final	
approval documents?	
approvar documents:	
Consent:	
Does your Facility have a written	Yes
SOP/Policy/Procedure for	
Informed Consent?	
Does your Facility have a written	No
SOP/Policy/Procedure for Minor	
Assent for paediatric populations?	
Does your Facility have a written	No
SOP/Policy/Procedure for other	
vulnerable populations?	
	Yes
Does your Facility have access to	i es
translators and translation support for	
study conduct (e.g. consent,	
study-specific instruction)?	
Training:	
Does your Facility have a training	Yes
Does your Facility have a training program for the research staff?	Yes
program for the research staff?	Yes Yes
program for the research staff? Does your Facility training course	
program for the research staff? Does your Facility training course content include GCP?	Yes
program for the research staff? Does your Facility training course content include GCP? Do you have a process or program in	
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Is your Facility dequately staffed to support studies with both blinded and umblinded Investigational Product? Does your Facility have the ability to collect and store PK/PD specimens? Does your Facility have the ability to collect pK/PD samples beyond normal business hours? Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)? Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes? Equipment: Additional equipment Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)? 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.? IT Capabilities: What type of computer operating system(s) does your institution use to support studies? What browser does your facility use ansure calibration and maintenance of general equipment? EDGE/Chrome SEDGE/Chrome Yes Yes Yes Yes Yes Yes Yes Y	I F. :114 1.1 f	V
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use? Does the Facility have access to Yes		
Does the Facility have access to Yes		EDGE/Chrome
·	use?	
local IT support?	Does the Facility have access to	Yes
	local IT support?	

Does your Facility limit or prohibit	All access to external portals in considered on a
access and use of external web-based	case by case review
tools or sites for clinical research (E.g.	case by case leview
web portals to submit documents to	
sponsors or	
CROs)?	
<u>'</u>	M C M 1' I A
Please indicate all equipment that	Phone, Copy Machine, Internet Access
will be available to Monitors	X7
Does your Facility have computers that	Yes
are dedicated to research	
studies?	
Labs:	
Lab Name	Pathology Queensland-Children's Hospital
Local Lab Usage	Yes
IP Storage Details:	
IP Recipient Name	Queensland Children's Hospital Pharmacy
Storage Room Backup Power	Yes
Is the Investigational Product Storage	Yes
Room secured with	
controlled access?	
Storage area securely constructed	Yes
Does your Facility have the ability to	Yes
manage on-site or off-site destruction of	
controlled	
substances when appropriate?	
Does the Facility have the ability to	Yes
handle radio-labelled Investigational	
Products?	
Does your Facility have the ability to	Yes
manage on-site or off-site destruction of	
the Investigational	
Product?	
Facility written sop during	Yes
transportation to satellite site	
Does your facility have a written	Yes
SOP/Policy/Procedure for the destruction	
of Investigational	
Product?	
Source Documents:	
Does your Facility have patient	Hospital uses an electronic medical record,
<u> </u>	historical paper charts are stored off site in a
record archiving on-site?	1 1
	certified facility

Secure Storage Records	Yes	
Electronic Medical Records (EMR) /Electronic Health Records (EHR):		
Do you have Electronic Health Records	Yes	
(EHR)/ Electronic		
Medical Records (EMR)?		
EMR/EHR systems	In-house system	