NHSGGC Women & Children's Directorate:
Authorised NCIII List for Paediatrics & Neonates (RHC):
EXPEDITION Study – ETX101 for SCN1A-Positive Dravet Syndrome, Protocol No: ETX-DS-005:

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation/Preparation Required	Storage in Clinical Area Authorised	Approved * Dose Range	* Upper Limit	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
Women and children. Clinical trials - RHC Neurology department	Dr Roddy O'Kane Designated Lead and Person Administering Deputy: Dr Andreas Brunklaus	Susan Kafka Lead Clinical Pharmacist W&C Samantha Carmichael	Kirsty McLeish / Maria Nygren Sarah Casey	Patricia Clark Andrew Boag Marie Macpherson Ingrid MacNab	ETX101 2E13 VG*/ml Vials of 0.7ml solution for intracere-broventric-ular injection	Treatment of children aged 6 to 48 months with SCN1A-positive Dravet Syndrome	Investigational Medicinal Product (IMP)	Yes – will be prepared in the Aseptic Unit at the RHC.	No	Cohort A (Dose level 1) = ETX101 5.0E11 VG*/mL of estimated CSF fluid by ICV injection. Cohort B (Dose level 2) = ETX101 1.9E12 VG*/mL of estimated CSF fluid by ICV injection. Cohort C (Dose level 3) = ETX101 3.3E12 VG*/ml of estimated CSF fluid by ICV injection. Cohort D (Dose level 3) = ETX101 6.6E12 VG*/ml of estimated CSF fluid by ICV injection.	6.6E12 VG*/mL of estimated CSF fluid	Pharmacy folder and documents will be stored in both the Clinical Trials Dispensary in the CRF QEUH, and Aseptic Pharmacy RHC. Investigator folder and documents will be stored in the CRF at the QEUH. Drug will be stored in Aseptic Pharmacy RHC.	N/A

* Vector Genome