Agreement for the use of unlicensed investigational medicine Epidiolex® by Children's Health Queensland Authorised Prescribers dated 9 December, 2016

between:

GW Research Limited, incorporated in England and Wales with company number 03107561, whose registered address is Sovereign House, Vision Park, Histon, Cambridge CB24 9BZ, UK ('GW')

AND

Children's Health Queensland Hospital and Health Service ABN 62 254 746 464 of Level 7, Lady Cilento Children's Hospital, 501 Stanley Street, South Brisbane Qld 4101 ('CHQ')

RECITALS

A. On 17 June 2016, the Queensland Minister for Health and Minister for Ambulance Services entered into a Memorandum of Understanding with GW to conduct trials for the purpose of better understanding the potential for cannabinoid-based pharmaceutical products for the treatment of patients with childhood epilepsy.

B. In accordance with the goals of the Memorandum of Understanding, CHQ has agreed to conduct further research and trials into using cannabinoid-based medicines for the management of severe drug-resistant childhood epilepsy.

C. GW has agreed to provide the State of Queensland (acting through Queensland Health) (**QH**), on compassionate grounds, with a safe supply of pharmaceutical grade cannabinoid-based medicine.

D. GW will supply QH with Epidiolex® (Cannabidiol Oral Solution)—one of GW's unlicensed investigational medicines containing a highly purified cannabidiol extract— under the *Queensland Health Compassionate Access Scheme for Epidiolex®* ('CAS').

E. QH's central pharmacy will supply Epidiolex® to CHQ.

F. The clinicians listed in Appendix A to this agreement will apply to the Therapeutic Goods Administration to become an Authorised Prescriber of Epidiolex® as a way of obtaining legitimate access to the GW product under the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990* (each an 'Authorised Prescriber').

G. This agreement sets out the terms on which GW will make Epidiolex® available in order for the CHQ Authorised Prescribers to treat their patient(s).

1. Pre-conditions

A. CHQ and GW acknowledge that this agreement is conditional on GW and QH entering into a supply agreement for the supply of Epidiolex®.

B. GW will permit all CHQ Authorised Prescribers to use Epidiolex to treat their patient(s) with severe drug-resistant childhood epilepsy after CHQ delivers to GW the following documents:

(i) A copy of the correspondence with the Therapeutic Goods Administration ('TGA') approving the application of each CHQ Authorised Prescriber to act as an Authorised Prescriber;

(ii) A copy of the endorsement from the relevant Human Research Ethics Committee ('HREC') for the CHQ Authorised Prescribers to treat patients in accordance with the Conditions of Authorisation stipulated by the TGA;

(iii) A copy of the binding terms of use in which CHQ Authorised Prescribers will treat patients under the CAS ('Protocol');

(iv) Such other documentation that GW may reasonably request to demonstrate that the CHQ Authorised Prescribers possess the necessary qualifications and experience to administer Epidiolex in accordance with the Protocol.

C. If satisfied of the items in paragraph 1B, GW will issue CHQ with a letter acknowledging receipt of the documents specified in paragraph 1B and confirming that it is satisfied that each Authorised Prescriber has the necessary approvals, qualifications and experience to administer Epidiolex in accordance with the Protocol.

2. Conditions of use

D. Each CHQ Authorised Prescriber is responsible for prescribing Epidiolex to patients under their immediate care and will prescribe Epidiolex in accordance with:

(i) the *Conditions of Authorisation* stipulated by the TGA;

(ii) any conditions imposed on the endorsement by a HREC, the Protocol, and all applicable Australian state and federal laws and regulations, including but not limited to applicable TGA regulations;

(iii) institutional policies, procedures and practices regarding the Authorised Prescriber mechanism.

E. CHQ will ensure that each CHQ Authorised Prescriber receives training in relation to the obligations under this agreement and complies with these obligations.

F. CHQ will provide GW a copy of any amendments made to the Protocol.

G. CHQ will ensure that that all medical personnel involved in the CAS, including CHQ Authorised Prescribers, possess and maintain throughout the CAS, all necessary board certifications, licensure and accreditation requirements.

3. Supply of Epidiolex

A. The parties acknowledge that Epidiolex is classified as a Schedule 4 substance in the *Standard for the Uniform Scheduling of Medicines and Poisons* and its importation is controlled under the *Australian Customs (Prohibited Imports) Regulations 1956* (as amended).

B. CHQ agrees to comply with all applicable Australian federal, state and local laws relating to the receipt, security, storage, use, record-keeping, accountability and disposal of Epidiolex as a Schedule 4 controlled substance.

C. GW agrees to supply to QH for use by CHQ Authorised Prescribers certain quantities of Epidiolex subject on the following terms:

(i) GW will supply Epidiolex free of charge, until TGA registration, for no more than 30 patients at any one time in Queensland; and

(ii) CHQ must ensure that no more than 30 patients are enrolled into the CAS at any one time

D. CHQ will ensure the continuity of supplying Epidiolex to relevant patients of the CAS and will take reasonable steps to ensure that CHQ Authorised Prescribers facilitate and timely notify and respond to GW's requests for patient numbers and stocking levels.

E. CHQ understands that Epidiolex is an investigational drug and that GW cannot guarantee that this drug will be either safe or efficacious in the indication for which the CHQ Authorised Prescriber has TGA authorisation.

F. GW warrants that Epidiolex is manufactured in accordance with appropriate Good Manufacturing Practices (GMP).

G. CHQ acknowledge that the treatment of patients under the Authorised Prescriber mechanism is conducted at its own risk and that GW accepts no liability or responsibility for the use of Epidiolex by the CHQ Authorised Prescribers or any other risk arising from supply of Epidiolex by GW, except to the extent the Epidiolex supplied for use by the CHQ Authorised Prescribers fails to meet the GW's internal specifications for Epidiolex at the time it is delivered DAT to a named

terminal in Queensland and such defect is not apparent on a visual inspection of the Epidiolex and associated documentation on delivery.

4. Findings regarding safety and adverse event reporting

A. CHQ agrees to report and/or ensure that each CHQ Authorised Prescriber reports:

(i) All Serious Adverse Events (SAEs) within 24 hours of first becoming aware of the SAE to GW's Pharmacovigilance Department;

(ii) All adverse events (AEs) will be reported to GW on a monthly basis (GW will provide a spreadsheet / AE Form to assist this reporting))

(iii) Details of any actual or suspected adverse drug reactions to the TGA within 15 calendar days of first knowledge (which is a condition of TGA approval for each authorized prescriber).

(iv) CHQ agrees to report all SAE / AE information to GW's Pharmacovigilance Department (GW PV Dept. Toll Free Fax Number: 1800 454 175 or email address: pvd@gwpharm.com).

5. Treatment Progress Reporting

A. CHQ will provide a monthly report on the progress of each patient undergoing treatment with Epidiolex in a format prescribed by GW.

6. Confidential Information

A. Confidential Information of a party means information that:

(i) Is by its nature confidential;

(ii) Is designated by the Disclosing Party as confidential; or

(iii) The other party knows or ought to know is confidential. Confidential Information includes: (1) data or personal information created, collected or captured by CHQ in connection with this agreement; (2) data or information about any patients of CHQ; and (3) information concerning the business or affairs of GW or any other member of its group, including information relating to GW's operations, processes, plans, product information, market opportunities and customers but

does not include information that:

(iv) Is or becomes public knowledge, other than by breach of this agreement by the Recipient or by any other unlawful means;

(v) Is in the possession of the Recipient without restriction in relation to disclosure before the date of receipt from the Disclosing Party; or

(vi) Has been independently developed or acquired by the Recipient.

B. Subject to clause 6(c), each party ('Recipient') will ensure that it does not:

(i) Disclose Confidential Information of another party ('Disclosing Party'); or

(ii) Use Confidential Information of a Disclosing Party,

For any purpose other than the performance of this agreement without the prior approval in writing from the Disclosing party. In giving written approval the Disclosing party may impose such terms and conditions as it thinks fit.

C. The parties acknowledge that a Recipient may disclose a Disclosing Party's Confidential Information, or this Agreement itself:

(i) To the extent required by Law or by a lawful requirement of any government or governmental body, authority or agency;

(ii) If required to do so in connection with legal proceedings; or

(iii) For public accountability reasons, including a request for information by any Parliament or a Parliamentary Committee or a Minister,

Provided that the Recipient:

(i) Notifies the Disclosing Party of the intended disclosure as soon as reasonably practicable; and

(ii) Notifies the person to whom the Confidential Information is disclosed that the information is confidential to the Disclosed Party.

D. The *Right to Information Act 2009* (Qld) ('RTI Act') provides members of the public with a legally enforceable right to access documents held by Queensland Government agencies. The RTI Act requires that documents be disclosed upon request, unless documents are exempt or on balance, disclosure is contrary to the public interest. Information relating to this agreement is potentially subject to disclosure to third parties.

7. Upon receipt of a RTI application for information provided by GW in connection with this agreement, CHQ will contact GW to obtain its view on disclosure of information which may reasonably be expected to be of concern to GW, in accordance with the relevant third party provisions in 37 of the RTI Act. **Protection of Personal Information**

A. In this clause 7, 'Personal Information' means information or an opinion, including information or an opinion forming part of a database, whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

B. If GW, or subcontractor of GW, receives or has access to Personal Information in relation to the subject matter of this agreement, GW or the subcontractor must make every reasonable effort to:

(i) notify CHQ immediately upon becoming aware;

(ii) fully cooperate with CHQ to enable CHQ to respond to applications for access to, or amendment of a document containing an individual's Personal Information and to privacy complaints; and

(iii) comply with such other privacy and security measures as reasonably required from time to time.

8. Intellectual Property Rights

A. Each party to this agreement will at all times retain ownership of the party's background intellectual property. Subject to compliance with this agreement or any other terms and conditions agreed between the parties in writing, each party grants to the other a non-exclusive, royalty-free licence to use a party's background intellectual property for the purposes of fulfilling this agreement.

B. CHQ shall at all times retain ownership of all data collected by the CHQ Authorised Prescribers whilst treating patients with Epidiolex under the CAS.

C. CHQ shall disclose, or shall ensure the CHQ Authorised Prescribers shall disclose, all such data to GW (in anonymised form) as soon as they are available.

D. GW is hereby granted a worldwide royalty free license to use such data for obtaining and maintaining regulatory approvals for Epidiolex.

E. Other than required by law, or the rules of any stock exchange on which the securities of GW Pharmaceuticals plc may be listed, GW will not to make any communications, submissions or other disclosures that would impede a CHQ Authorised Prescriber's ability to publish the results arising from the treatment of patients with Epidiolex via the Authorised Prescriber mechanism in a peer-reviewed journal.

F. All and any inventions arising from the treatment of patients with Epidiolex under the terms of this agreement shall belong exclusively to GW.

G. CHQ agrees to assign, and hereby assigns to GW, all right title and interest in and to each and every invention arising from the treatment of patients with Epidiolex under the terms of this agreement.

H. CHQ agrees to execute all documents, make all applications, give all assistance and do all acts and things, at the expense of GW (as to out-of-pocket expenses only) and at any time, as may, in the reasonable opinion of GW, be necessary or desirable to give effect to the foregoing assignment and to ensure the same of each CHQ Authorised Prescriber and the institution(s) for which they work.

I. CHQ and the CHQ Authorised Prescriber shall have first right to publish, present, or use any results arising out of the CAS, provided that such publication is consistent with this paragraph 8. CHQ shall send GW a copy of such manuscript at least thirty (30) days prior to submission for publication or presentation, and agrees to allow GW thirty (30) days from the date of mailing to review the manuscript. In the event that the subject matter of the manuscript contains a patentable invention, then GW shall give written notification of such determination to CHQ prior to the expiration of such thirty (30) day period. Upon timely receipt of written notice from GW, CHQ shall delay submission of the manuscript for a period of up to sixty (60) days to permit preparation and filing of patent applications on the subject matter to be disclosed in such manuscript. After expiration of the applicable period, or the filing of a patent application on the invention, as applicable, CHQ shall be free to submit the manuscript and to publish the results disclosed therein. During the applicable period, CHQ shall make all changes to the publication reasonably requested by GW to protect GW's Confidential Information, to protect GW's intellectual property rights that might be compromised by the publication, and to correct manifest errors. The foregoing sentence shall not be interpreted to mean that the Company has editorial control over any CHQ publication or presentation.

9. Termination of permission to use Epidiolex

A. Use of Epidiolex under the terms of this agreement shall automatically terminate upon registration of Epidiolex in Australia with TGA as a therapeutic good.

B. A party may terminate this agreement by written notice to the other party if the other party:

(i) Goes into liquidation or a receiver or receiver and manager is appointed or, becomes bankrupt or enters into a scheme of arrangement with creditors or becomes the subject of any form of insolvency administration; or

(ii) Fails, within twenty (20) business days after receipt of written notice of a default in the performance of the defaulting party's obligations under this agreement, to remedy the default.

C. Termination or expiration of this agreement shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of. Paragraphs 6 (Confidential Information), 7 (Protection of Personal Information), 88 (Intellectual Property Rights), 9 (Termination), 11 (Governing law) and 12 (Dispute resolution) of this agreement shall survive expiration or termination of it.

10. Force Majeure

A. Neither party shall be liable for any failure to perform as required by this agreement to the extent such failure to perform is due to circumstances reasonably beyond such party's control, including:

(i) labour disturbances, accident, failure to obtain any government approval required for full performance;

(ii) civil disorders or commotions, acts of aggression or terrorism, acts of God, energy or other conservation measures imposed by law or regulation, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrences.

11. Governing law

A. This agreement and all matters relating to or in connection with it (including any dispute) shall be governed by, and construed in accordance with, the laws of the state of Queensland, without regard to any conflicts of law principles.

12. Dispute resolution

A. In the event of a dispute arising out of or relating to this Agreement, including any question regarding its existence, validity or termination, the parties shall first seek settlement of that dispute by mediation in accordance with the LCIA Mediation Rules, which Rules are deemed to be incorporated by reference into this Paragraph.

B. If the dispute is not settled by mediation within 30 days of the commencement of the mediation, or such further period as the parties shall agree in writing, the dispute shall be referred to and finally resolved by arbitration under the LCIA Rules.

C. The number of arbitrators shall be one. The seat, or legal place, of arbitration shall be Brisbane Australia where CHQ is the defendant and London, England where GW is the defendant.

D. The language to be used in the arbitral proceedings shall be English. The governing law of this agreement to arbitrate shall be the substantive laws of the state of Queensland.

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SIGNATURE PAGE

THIS AGREEMENT has been entered into on the date stated at the beginning of it.

Signed for and on behalf of **GW RESEARCH LIMITED**

.....
Signature

Name (print)

HEAD OF LEGAL AFFAIRS
Title (print)

Signed for and on behalf of **CHILDREN'S HEALTH QUEENSLAND**

.....
Signature

Fiona Hogan
Name (print)

Health Service Chief Executive
Title (print)

APPENDIX A

CHQ Authorised Prescribers

Name of Authorised Prescriber	Anticipated no. of eligible patients authorised to receive treatment[1]
Geoff Wallace	<30

[1] The total number of patients on the CAS will not exceed 30 at any given time.

Appendix B

The following information (in addition to the AE information) will be reported to GW on a monthly basis (at the end of every month). The information given below may be provided in a spreadsheet format for ease of transfer. GW is happy to provide a template for this should CHQ require it. Recruitment of patients is likely to have occurred in a staggered manner, and therefore in some months there may be no change to the data in the spreadsheet – however, please still send all of the patient data in on a monthly basis to GW.

In the case of clinically significant (>3 x ULN) elevations of Liver Function Tests (LFTs) including transaminases in patients being treated with Epidiolex®, please ensure the following laboratory measures, at minimum, are obtained within 72 hours AST/ALT, GGT, Alk. Phos, Total Bilirubin and INR and followed until all abnormalities return to the baseline state as determined by the CHQ Authorised Prescribers with AST/ALT <3x ULN. These laboratory measures should be made available to the GW PV Department upon request as follow up to any adverse event of elevated LFTs reported to GW as an Adverse Event and recorded in the monthly treatment progress report.

Epidiolex® Monitoring (Baseline - 16 weeks)										
Subject # _____	**Baseline**		**4 weeks**		**8 weeks**		**12 weeks**		**16 weeks**	
Demographics										
Gender (M/F)										
Date of Birth (dd/mmm/yyyy)										
Diagnosis										
Etiology (underlying condition)										
Visit Information										
Visit Date (dd/mmm/yyyy)										
Body Weight (Kg)										
Epidiolex Dose (mg/kg/day)			_____ mg/kg/day _____ mg		_____ mg/kg/day _____ mg		_____ mg/kg/day _____ mg		_____ mg/kg/day _____ mg	
Did the patient report any Adverse Events at this Visit or have any Adverse Events previously reported been resolved? (Please circle - If "yes", please complete the AE Form provided below for each event)	YES	NO	YES	NO	YES	NO	YES	NO	YES	NO
Concomitant AED Medications (Please list each AED)	Total Daily Dose (add unit)	Plasma Level (add unit)	Total Daily Dose (add unit)	Plasma Level (add unit)	Total Daily Dose (add unit)	Plasma Level (add unit)	Total Daily Dose (add unit)	Plasma Level (add unit)	Total Daily Dose (add unit)	Plasma Level (add unit)

Epidiolex® Monitoring (Baseline - 16 weeks)					
Subject # ________	Baseline	4 weeks	8 weeks	12 weeks	16 weeks
Average # seizures per week (insert number into boxes in columns to the right)	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other
If "Other" please specify seizure type					

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Epidiolex® Monitoring (Baseline - 16 weeks)

Subject # ________	Baseline	4 weeks	8 weeks	12 weeks	16 weeks
Increased seizure intensity or duration in last month? (Add "Increased" (I) or "Decreased" (D) or No change (N) to the appropriate column from week 4 onwards)		☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other
No. of episodes of Status Epilepticus (SE) in last month (28 days)					
No. of uses of rescue medication in last month (28 days)					
No. of ER visits in the last month (28 days)					
No. of hospitalizations in the last month (28 days)					

Reason for Hospitalization 1 **Reason for Hospitalization 2** **Reason for Hospitalization 3** **Reason for Hospitalization 4** **Reason for Hospitalization 5**					

Epidiolex® Monitoring (Baseline - 16 weeks)					
Subject # _____	**Baseline**	**4 weeks**	**8 weeks**	**12 weeks**	**16 weeks**
Laboratory Parameters					
Visit /Sample Date (dd/mmm/yyyy)					
AST					
ALT					
BUN					
Creatinine					
Na^+					
K^+					
Cl^-					
HCO3					
RBC					
WBC					
HCT					
HGB					
MCV					
MHC					
MCHC					
Total bilirubin					
Gamma-glutamyl transferase (GGT)					
Alkaline phosphatase (AP)					
INR					

Epidiolex® Monitoring (Baseline - 16 weeks)					
Subject # ________	**Baseline**	**4 weeks**	**8 weeks**	**12 weeks**	**16 weeks**
Parent/Patient Global Impression of Change (Please check the relevant box)		☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done
Physician Global Impression of Change (Please check the relevant box)		☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done

Epidiolex® Monitoring (Weeks 28-52)						
Subject # _____	**28 weeks**		**40 weeks**		**52 weeks**	
Visit Date (dd/mmm/yyyy)						
Body Weight (Kg)						
Epidiolex Dose (mg/kg/day)	_____ mg/kg/day _____mg		_____ mg/kg/day _____mg		_____ mg/kg/day _____ mg	
Did the patient report any Adverse Events at this Visit or have any Adverse Events previously reported been resolved? (Please circle - If "yes", please complete the AE Form provided below for each event)	YES	NO	YES	NO	YES	NO
Concomitant AED Medications (Please list each AED)	Total Daily Dose (add unit)	Plasma Level (add unit)	Total Daily Dose (add unit)	Plasma Level (add unit)	Total Daily Dose (add unit)	Plasma Level (add unit)

Epidiolex® Monitoring (Weeks 28-52)			
Subject # _____	**28 weeks**	**40 weeks**	**52 weeks**
Visit / Sample Date (dd/mmm/yyyy)			
Laboratory Parameters			
AST			
ALT			
BUN			
Creatinine			
RBC			
WBC			
HCT			
HGB			
Na^+			
K^+			
Cl^-			
HCO3			
MCV			
MHC			
MCHC			
Total bilirubin			
Gamma-glutamyl transferase (GGT)			
Alkaline phosphatase (AP)			
INR			

Epidiolex® Monitoring (Weeks 28-52)			
Subject # ________	**28 weeks**	**40 weeks**	**52 weeks**
Average # seizures per week (insert number into boxes in columns to the right)	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other
If "Other" please specify seizure type			

Epidiolex® Monitoring (Weeks 28-52)			
Subject # ________	28 weeks	40 weeks	52 weeks
Increased seizure intensity or duration in last month? (Add "Increased" (I) or "Decreased" (D) or No change (N) to the appropriate column from week 4 onwards)	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other	☐ Clonic ☐ Tonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence ☐ Myoclonic-absence ☐ Focal seizures without impaired consciousness ☐ Focal seizures with impaired consciousness ☐ Focal seizures evolving to generalized tonic, clonic, or tonic-clonic components ☐ Other
No. of episodes of Status Epilepticus (SE) in last month (28 days)			
No. of uses of rescue medication in last month (28 days)			
No. of ER visits in the last month (28 days)			
No. of hospitalizations in the last month (28 days) Reason for Hospitalization 1 Reason for Hospitalization 2 Reason for Hospitalization 3 Reason for Hospitalization 4			

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Reason for Hospitalization 5			

Epidiolex® Monitoring (Weeks 28-52)			
Subject # _____	**28 weeks**	**40 weeks**	**52 weeks**
Parent/Patient Global Impression of Change (Please check the relevant box)	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done
Physician Global Impression of Change (Please check the relevant box)	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done	☐ Very much improved ☐ Much improved ☐ Slightly improved ☐ No change ☐ Slightly worse ☐ Much worse ☐ Very much worse ☐ Not done

Patient Withdrawal Form

Subject Number	
Date of Withdrawal (dd-mmm-yyyy)	
Epidiolex dose at time of decision to withdraw patient (mg/kg/day)	
Date of Last Dose (dd-mmm-yyyy)	
Reason for Withdrawal (verbatim)	
Primary Reason for Withdrawal (category)	1. Adverse Event 2. Sponsor discontinued study 3. Patient or caregiver withdrew consent to participate 4. Lost to follow-up 5. Patient met (protocol specified) withdrawal criteria 6. Patient was withdrawn from participation by the Investigator 7. Lack of Efficacy 8. Other (please specify)

NOTE – If the patient withdrawal is due to an adverse event please ensure the Adverse Event Form is filled out.

Adverse Event Form

Adverse Event (Diagnosis or Syndrome only (if known) or signs/ symptoms)	**Date Started**	**Date Stopped**	**Epidiolex Total Daily Dose at Time of Event** (mg/kg/day)	**Duration** (if <24 hours) (hh:mm)	**Outcome** 1=Recovered 2=Recovered with sequelae 3=Continuing 4=Subject died	**Severity** 1=Mild 2=Moderate 3=Severe	**Plausible Causal relationship to Study Medication** 1=Yes 2=No	**Action taken with Study Medication** 1=None 2=Dose reduced temporarily 3=Dose reduced 4=Study medication interrupted 5=Study medication stopped	**Serious Adverse Event** **0 = Non-serious** If yes, Reason for Seriousness 1. Results in death 2. Life-threatening 3. Hospitalisation or prolongation of existing hospitalisation 4. Persistent or significant disability 5. Congenital anomaly/birth defect 6. Important Medical Event