

(16/07/2021)

Revised 04/08/2021

Dear Professor Dominic Rowe,

Reference No: 520211007530144

Title: A Phase 3 Randomized, Placebo-Controlled Trial With a Longitudinal Natural History Run-In and Open-Label Extension to Evaluate BIIB067 Initiated in Clinically Presymptomatic Adults With a Confirmed Superoxide Dismutase 1 Mutation

Thank you for submitting the above application for ethical and scientific review. Macquarie University Human Research Ethics Committee HREC EXEC Medical Sciences Committee considered your application.

I am pleased to advise that ethical and scientific approval has been granted for this project to be conducted by Professor Dominic Rowe and other personnel: DR Balaji Kalband, Mr Richard Gan .

Approval Date: 15/07/2021

This research meets the requirements set out in the *National Statement on Ethical Conduct in Human Research* (2007, updated July 2018) (the *National Statement*).

Standard Conditions of Approval:

1. Continuing compliance with the requirements of the *National Statement*, which is available at the following website:
<http://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research>
2. This approval is valid for five (5) years, subject to the submission of annual reports. Please submit your reports on the anniversary of the approval for this protocol.
3. All significant safety issues, that adversely affect the safety of participants or materially impact on the continued ethical and scientific acceptability of the project, must be reported to the HREC within 72 hours.
4. Proposed changes to the protocol and associated documents must be submitted to the Committee for approval before implementation.

It is the responsibility of the Chief investigator to retain a copy of all documentation related to this project and to forward a copy of this approval letter to all personnel listed on the project.

Should you have any queries regarding your project, please contact the Ethics Secretariat on 9850 4194 or by email ethics.secretariat@mq.edu.au

The HREC EXEC Medical Sciences Committee Terms of Reference and Standard Operating Procedures are available from the Research Office website at: <https://www.mq.edu.au/research/ethics-integrity-and-policies/ethics/human-ethics>

The HREC EXEC Medical Sciences Committee wishes you every success in your research.

Yours sincerely,



Professor Anthony Eyers
Chair, HREC EXEC Medical Sciences Committee

This HREC is constituted and operates in accordance with the National Health and *Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007, updated July 2018)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*

The following documents have been reviewed and approved by MQ HREC (Medical Sciences):

- 233AS303_MQ HREC Initial Submission Cover Letter_14May2021, N/A, 14May2021
- List of RA's and Decisions_V2.0_10Mar2021, V2.0, 10Mar2021

- 233AS303 IDMC Charter V1.0_09Mar2021, V1.0, 09Mar2021
- Clinical Trial Protocol V2.0_16Dec2020, V2.0, 16Dec2020
- Placebo Justification_signed 04Jan2021, V1.0, 04Jan2021
- ATLAS_DesignSpecification_1.0.2_21Jan2021, 1.0.2, 21Jan2021
- ATLAS_ParticipantTrainingManual_1.0.1_20Jan2021, 1.0.1, 20Jan2021
- ATLAS_ScreenReport_1.0.0_22Jan2021, 1.0.0, 22Jan2021
- Greenphire ClinCard Cardholder FAQ - US (v6.0 Dec 2019), v6.0, Dec2019
- Greenphire Service Agreement Form_US_ClinCard__ConneX_Lyft_v10_01Apr2020, v10, 01Apr2020
- Greenphire_ClinCard_Cardholder_Rideshare_FAQ_v1.0_April_2019, v1.0, Apr2019
- Template - ConneX USA Travel Contact Card (v1.0 January 2019), v1.0, Jan2019
- Template - Greenphire ClinCard Msg Templates - US (v5.0 Feb 2018), v5.0, Feb2018
- Template - Greenphire ClinCard Travel Ref Guide for Subjects (v3.0 Oct 2016), v3.0, Oct2016
- Template - Greenphire Generic ClinCard (v3.0 June 2018), v3.0, Jun2018
- Template_-_Greenphire_ClinCard_Carrier_-_US_v4.0_Dec_2019, v4.0, Dec2019
- Template_-_Greenphire_Rideshare_Msg_Templates_-_US_v1.0_Apr_2019, v1.0, Apr2019
- Biogen 233AS303_ALSAQ-5_en_AU_v1.0_06 Apr 2021, v1.0, 06Apr2021
- Biogen 233AS303_ALSFRS-R_c_en_US_v1.1_06 Apr 2021, v1.1, 06Apr2021
- Biogen 233AS303_CGI-C (ALS)_en_US_v1.1_06 Apr 2021, v1.1, 06Apr2021
- Biogen 233AS303_CGI-S (ALS)_en_US_v1.1_06 Apr 2021, v1.1, 06Apr2021
- Biogen 233AS303_C-SSRS BS Life-6 Months-2 Years_en_AU_v1.0_06 Apr 2021, v1.0, 06Apr2021
- Biogen 233AS303_C-SSRS SLV_en_AU_v1.0_06 Apr 2021, v1.0, 06Apr2021
- Biogen 233AS303_EQ-5D-5L (PRO) Digital_en_AU_v1.0_06 Apr 2021, v1.0, 06Apr2021
- Biogen 233AS303_EQ-5D-5L (PRO)_en_AU_v1.0_06 Apr 2021, v1.0, 06Apr2021
- Biogen 233AS303_FSS_en_AU_v1.0_06 Apr 2021, v1.0, 06Apr2021
- Biogen 233AS303_PGI-C (ALS)_en_US_v1.1_06 Apr 2021, V1.1, 06Apr2021
- Biogen 233AS303_PGI-S (ALS)_en_US_v1.1_06 Apr 2021, v1.1, 06Apr2021
- Biogen 233AS303_ROADS_en_US_v1.0_06 Apr 2021, v1.0, 06Apr2021
- Biogen 233AS303_SF-36 General Health_en_AU_v1.0_06 Apr 2021, v1.0, 06Apr2021
- Biogen 233AS303_WPAI-GH_en_AU_v1.0_06 Apr 2021, v1.0, 06Apr2021
- 233AS303_Participant ID Card_AUS-Eng_V1.0_23Feb21, V1.0, 23Feb2021
- 233AS303 vent diary_version 2_19MAR2021, V2.0, 19Mar2021
- 233 IB V6_06Jan2021, V6, 06Jan2021
- Outline of Active Trials_30Sep2020, N/A, 30Sep2020
- 233AS303_Certificate of Insurance_Australia_12Nov2020, N/A, 12Nov2020
- Biogen_233AS303_MQ Main ICF_V1.0_12Apr2021, V1.0, 12Apr2021
- Biogen 233AS303 MQ PGx ICF_V1.0_12Apr2021, V1.0, 12Apr2021
- Biogen_233AS303 MQ FSR ICF_V1.0_12Apr2021, V1.0, 12Apr2021
- 233AS303 Participant Study Summary V1.0_29Apr2021, V1.0, 29 Apr 2021
- 233AS303_CT-2021-CTN-01808-1 v1_DRAFT_12May2021, v1_DRAFT, 12May2021
- Responses to HREC, 01Jul2021
- Biogen_ATLAS_Participant Engagement Brochure_US-ENG, V1.0, 16APR2021
- CRG endorsement_MQCRG2021038, 21Jun2021