

East Midlands - Leicester South Research Ethics Committee

Equinox House
City Link
Nottingham
NG2 4LA

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

24 January 2022

Dr. Vlada Injac
103 Haros str
Budapest
Hungary
1222

Dear Dr. Injac

Study title:	A Multicenter, 48-week Open-Label Safety Study of Adjunctive Troriluzole in Subjects with Obsessive Compulsive Disorder
REC reference:	21/EM/0167
Protocol number:	BHV4157-209
EudraCT number:	2020-004654-30
Amendment number:	Protocol Amendment version 2.1; IB version 7.0
Amendment date:	24 December 2021
IRAS project ID:	299151

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [BHV4157-209_UK_PA#2.1_IB v7.0_Amendment Tool_revised_29Dec2021]		29 December 2021
Cover Letter [BHV4157-209_UK_REC_PA#2.1_IBv.7_Cover letter]	NA	25 December 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [BHV4157-209_UK_MAC_Clinical Research Insurance Letter_17Jun2021]	NA	17 June 2021
GP/consultant information sheets or letters [BHV4157-209_UK_GP Letter_V2.0_07Dec2021_TC]	2.0	07 December 2021
GP/consultant information sheets or letters [BHV4157-209_UK_GP Letter_V2.0_07Dec2021]	2.0	07 December 2021
Investigator Brochure/SmPC [BHV4157-209_IB_v7.0_12Aug2021]	7.0	12 August 2021
Investigator Brochure/SmPC [BHV4157-209_IB_v.6.0 to v7.0_12Aug2021_TC]	7.0	12 August 2021
Letters of invitation to participant [GP Patient Invitation Letter_v1.0_07Dec2021_corr.pdf]	1	07 December 2021
Non-NHS/HSC Site Assessment Form [Site_Assessment_Form_Barnsley]	NA	04 January 2022
Non-NHS/HSC Site Assessment Form [Site_Assessment_Form_Teesside_04Jan2022.pdf]	NA	04 January 2022
Non-NHS/HSC Site Assessment Form [Site_Assessment_Form_West Yorkshire_04Jan2022.pdf]	NA	04 January 2022
Other [BHV4157-209_UK_PI Muthukrishnan_CV_22Sep2021]	NA	22 September 2021
Other [BHV4157-209_UK_PI Leving_CV_14Jun2021]	NA	14 June 2021
Other [BHV4157-209_UK_PI Connell_CV_08Apr2021]	NA	08 April 2021
Other [BHV4157-209_UK_PI Malik_CV_14Dec2021]	NA	14 December 2021
Participant information sheet (PIS) [BHV4157-209_UK SIS_v2.0_07Dec2021_TC]	2.0	07 December 2021
Participant information sheet (PIS) [BHV4157-209_UK SIS_v2.0_07Dec2021]	2.0	07 December 2021
Research protocol or project proposal [BHV4157-209_Protocol_V01.4 to V02.1_TC]	02.1	08 November 2021
Research protocol or project proposal [BHV4157-209_Protocol_V02.1_08Nov2021]	02.1	08 November 2021

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as

possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities— see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID - 299151:

Please quote this number on all correspondence

Yours sincerely



Mrs Jeanne-Anna Charly
Chair

E-mail: leicestersouth.rec@hra.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Damien Longson, Greater Manchester Mental Health NHS Foundation Trust

East Midlands - Leicester South Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 20 January 2022

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Jeanne-Anna Charly	Retired State Registered Nurse/Teacher	Yes	
Dr Brendan Lavery	Retired Head of Research Governance	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Helen Poole	Approvals Specialist