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**14-Jun-22**

**Professor Michael Millward**
**Linear Clinical Research**
**Ground Floor, B Block, QEII Medical Centre, Hospital Avenue**
**Nedlands WA 6009**

**Dear** Professor Millward,
**Re: Application No:** 2022-04-349
**Study Title:** AXA-042-FIH-01: A Phase 1a/1b, first-in-human, open-label, non-randomized, multicenter, dose-escalation and dose-expansion study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of AXA-042 as monotherapy and in combination with checkpoint inhibitors in subjects with advanced solid tumors.
**Application Type:** NEW
**Type of Review:** FULLBOARD

**Name of the Documents Submitted & Approved: Attachments**

AXA-042-FIH-01 Bellberry Master Optional Future Research PICF V1.0_23Mar2022
AXA-042-FIH-01 Bellberry Master Pregnancy Follow Up PICF V1.0_23Mar2022
AXA-042-FIH-01 Bellberry Master Main Dose Escalation PICF V1.0_28Apr2022
IB AXA-042 V1.0_04Mar2022
AXA-042-FIH-01 Protocol V1.0_23Mar2022
AXA-042-FIH-01 Participant Emergency Identification Card AUS V1.0_16Mar2022

Includes:
Caveat: Approval is grated for Part A only with approval for Part B subject to satisfactory submission and approval of justification of the dose for Part B. This should be submitted as an amendment along with any relevant updates to PICF and study documentation.

Receipt of the following document has been noted:
2022-04-349_Multicentre_(x2)_FullyExecuted_HRECIndemnity

Additional site covered by this approval:
2022-04-349-AA: Dr Charlotte Lemech, Scientia Clinical Research Ltd, New South Wales

The following documents are also approved/noted:
2022-04-349: AXA-042-FIH-01 Linear Site-Specific PICF Clauses V1.0_28Mar2022 <Approved>
2022-04-349: COVID-19 Testing For Participants on Treatment Studies PICF V1.0_28Jan2022 <Approved>
2022-04-349: Participant letter_Preparing for COVID-19 Community Cases_28Jan2022 <Approved>
2022-04-349: Sponsor Letter_ Active Community Cases in WA_24Jan2022 <Approved>
2022-04-349: Email template to participants on treatment studies for RAT self-testing_14Feb2022 <Approved>
2022-04-349: Sponsor Letter - Managing Participants and Projects during the COVID-19 Surge in WA_14Feb2022 <Approved>
2022-04-349: E-Questionniare - COVID-19 Symptom Questionnaire and Rapid Antigen Self-test Instructions V2_23Feb2022 <Approved>
2022-04-349: Linear Cancer Trials Participant Alert Card V2_Oct2019 <Approved>
2022-04-349-AA: SCR Corona Virus Response Plan Summary - External_Rev5.0_14Dec2021 <Approved>

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2022-04-349-AA: AXA-042-FIH-01_Site-specific-clauses-template_V1.0_30May2022 <Approved>

Please read the updated terms and conditions for new approvals, noting the change to progress report and extension requests.

**Date of Meeting:** 20-Apr-22
**Date of Approval:** 14-Jun-22
**Period of Approval:** 14-Jun-22 - 14-Jun-23

Thank you for submitting the above-mentioned application.

I wish to advise that the Bellberry Human Research Ethics Committee has approved this project and that the application meets the requirements of the National Statement subject to the conditions mentioned below. For clarity, the 'Date of Meeting' is a system-generated field. Please only take note of the 'Date of Approval' and 'Period of Approval' as relevant.

**CONDITIONS:-**

- **This letter constitutes ethical and scientific approval only. You must not commence the research project at any site until your Research Governance Office/ Institution/Organisational delegate has granted their approval. Sites are responsible for ensuring there are executed indemnities, contracts, and appropriate insurance in place before the commencement of the study at the site. Sites are also responsible for ensuring their site-specific documents are based on the current Master approved documentation**.
- All changes to the approved study documentation must be submitted to Bellberry via an Amendment Form for review and approval prior to implementation.
- Safety reporting and Serious Breaches should be reported to the Bellberry Human Research Ethics Committee as per the monitoring guidelines posted on the website www.bellberry.com.au
- A progress report must be completed annually for the duration of the trial. The due date for all additional sites will fall in line with the lead sites original approval date. Submission of the progress report is to be within 30 days before the due date. Requests for an annual extension will be granted upon successful completion and noting of a progress report.
- A final report is due on completion of all closeout activities (clinical trials) or final reconciliation of study activities (non-clinical trials)The site must also provide a copy of the Sponsor's final report where there are study outcomes that the HREC should be aware of such as issues related to participant safety
- The Principal Investigator must inform the HREC, by way of an amendment, of the outcomes of any audit by a regulator or organisation/body.
- The data collected for the purpose of this research project cannot be used for any other purpose without the approval of a Human Research Ethics Committee. Requests to use this data for other purposes must be made in the form of a formal research proposal
- All research data, including electronic data is to be stored by the Principal Investigator for 15 years after the research has been completed or after the last contact, whichever is the later. Data must be recorded in a durable and appropriately referenced form and comply with relevant privacy protocols.
- Copies of all Master/Site specific documentation and any other data used in this research may be inspected at any time by representatives of the Bellberry Human Research Ethics Committee. This may be in the form of a Bellberry site monitoring visit or requested electronically via a desktop audit.
- Bellberry Human Research Ethics Committee approval is conditional upon your meeting any statutory and licensing obligations; data custodian or other organisational authorisations that you may have with this project.

**Details of Ethics Committee:**

The Bellberry Human Research Ethics Committee (HREC) reviewed this study in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates) on the above meeting date. Bellberry Human Research Ethics Committees do not disclose personal details of its reviewing members. A member listing is

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available as an attachment in eProtocol. Please note that the Principal Investigator and Co-Investigators were not members of the Bellberry Human Research Ethics Committee that reviewed this study.

This study has been given the above reference number. Please remember to log on to eProtocol for all further correspondence with the Committee.

Please do not hesitate to contact me if further clarification is required.

Yours sincerely

**Brian Stoffell**

**Chair, Committee A**
**BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE**

Committee Name/NHMRC Codes: A/ EC00372; B/ EC00419; C/ EC00430; D/ EC00444;
E/ EC00450; F/ EC00455; G/ EC00458; H/ EC00459; I/ EC00468; J/ EC00469; K/ EC00470; L/ EC00471.

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