



A-STAR Study Co-ordinating Centre

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Tuesday 14th December 2021

Study Title: A-STAR: The UK-Irish Atopic eczema Systemic TherApy Register

REC Number: 18/WA/0200

IRAS Number: 237309

RE: Substantial Amendment 2

Dear Dr K J Craig,

We wish to submit Substantial Amendment 2 to the committee for review for the A-STAR study.

Here is a brief summary of the changes made to the study:

> Addition of nine new sites.

> Biorepository sub-study reimbursements: Participants of the biorepository sub-study will be offered a voucher to the value of £10 per visit to cover reasonable expenses during the course of the sub-study.

> Sample clarification: Clarification of samples collected during the study.

> Staff and site changes:

- Dublin and Dundee have been taken off the Biorepository section in the protocol as they will no longer be taking part in the biorepository part.
- Other staff changes made throughout protocol to reflect changes.

> Protocol Schedule of Events corrections:

- In the protocol, "Schedule of Events," there is no, "C," annotated assessment. Therefore other appendices have been rearranged to reflect this.
- For the Baseline 2 (3, 4 etc.) there is no need for the patient to re-sign a Consent Form so the, "X" has been removed from the Informed Consent row.
- Further clarification was entered if patients either switch therapy or re-start the same therapy after a break in treatment.

> Protocol procedural clarifications:

- In, "Section 7.2 - Baseline visit," for the, "e. physical examination," section, the Study Steering Committee decided that all adequately trained team members can conduct the skin assessments.
- In, "Section 12 - Data Capture and Data Management," in exceptional circumstances where a face-to-face visit cannot be arranged at site, data collection can be carried out over the phone, via video calls/virtual visits and also by mail/email.

> Typographical and grammatical corrections have been made throughout all the attached files to keep grammar and labelling consistent and correct across all the documents.

Please find the amended files associated with this amendment attached to this message.

File name	Version	Date
Cover Letter (Substantial Amendment 2)		14-DEC-2021
A-STAR Protocol V3.0 (09AUG2021) - Tracked	3.0	09-AUG-2021
A-STAR Adult Biorepository PIS-ICF - V3.0 (09AUG2021) - Tracked	3.0	09-AUG-2021
A-STAR Parents_Guardians Biorepository PIS-ICF - V3.0 (09AUG2021) - Tracked	3.0	09-AUG-2021
A-STAR Young Person & Biorepository PIS AF - V3.0 (09AUG2021) - Tracked	3.0	09-AUG-2021
A-STAR Protocol V3.0 (09AUG2021) - Clean	3.0	09-AUG-2021
A-STAR Adult Biorepository PIS-ICF - V3.0 (09AUG2021) - Clean	3.0	09-AUG-2021
A-STAR Parents_Guardians Biorepository PIS-ICF - V3.0 (09AUG2021) - Clean	3.0	09-AUG-2021
A-STAR Young Person & Biorepository PIS AF - V3.0 (09AUG2021) - Clean	3.0	09-AUG-2021
A-STAR OID (Non-Commercial) - Biorepository (V2.0 - 08JUL2021)	2.0	08-JUL-2021
237309 A-STAR - Substantial Amendment 2 (SA2) Tool		14-DEC-2021

Many thanks in advance for your consideration. We look forward to hearing from you soon and please let us know if there is a need for any further clarification or explanation.

Yours sincerely,



Professor Carsten Flohr

St John's Institute of Dermatology