A PROJECT OF THE BRITISH ASSOCIATION OF DERMATOLOGISTS

A-STAR

The UK-Irish **A**topic eczema **S**ystemic **T**her**A**py **R**egister

CASE REPORT FORM (CRF)

Research Centre Name: _____

Principal Investigator: _____

Research Site ID: |__|__|

Patient Study ID: |__|__|__|__|__|__|

Patient initials: |__|__|__|

INSTRUCTIONS FOR COMPLETING THE PAPER CRF

- This CRF consists of the following parts:

  1. Visit schedule
  2. Enrolment
  3. Baseline
  4. Follow up
  5. Concomitant medication
  6. Adverse Events
  7. End of Study

- The person completing the CRF must have signed a delegation log, and must sign/initial and date at the bottom of each page. Should different users complete different sections, they must sign/initial and date alongside the section they are completing.

- Answers must be clearly legible, preferable in capital letters, completed with a legible pen.

- All questions must be answered. A 'not applicable' (N/A) option is incorporated in some cases. In some instances, multiple answers may be given, and this will be explicitly stated.

- Please tick boxes in the following way: ☑ or ☒

- Abbreviations are not allowed.

- Display a date as follows: dd-mmm-yyyy, for example 23-JAN-2012. If a part of the date is missing, enter NA for the missing part. For example: day missing: NA/JAN/2012, day and month missing: NA/NA/2012, full date missing: NA/NA/NA.

- To correct an error cross through the answer with a single line, write the correct answer next to it, and initial and date in the following way*:* ~~ECZEMA~~ ECZEMA MR 31/Jan/2012. The original answer must remain legible, correction fluid must not be used.

- Data must be transcribed to the electronic CRF within 21 days of data collection.

- Print additional pages as required (e.g. concomitant medication)

Study visits and assessments	V1 Baseline (-28 days)	V1b Day 1[i]	V2 4 weeks (+/-2 wk)	V3 16 weeks (+/-4 wk)	V4 6 months (+/-4 wk)	V5 9 months (+/-4 wk)	V6 12 months ** and subseq. visits (+/-4 wk)	Baseline 2***
Informed consent	X							X
Inclusion/exclusion criteria	X							
Demographics	X							X
Personal/family history	X							
Atopic eczema and treatment history	X		X	X	X	X	X	X
Co-morbidities (including immediate and delayed allergies)	X		X	X	X	X	X	X
Concomitant medication	X		X	X	X	X	X	X
Physical examination [a]	X		X	X	X	X	X	X
Blood pressure (if applicable)	X		X	X	X	X	X	X
Treatment (prescribed)	X		X	X	X	X	X	X
Adverse events			X	X	X	X	X	X
Safety bloods [b]	X		X	X	X	X	X	X
EASI, EASI-50, EASI-75	X		X	X	X	X	X	X
IGA	X		X	X	X	X	X	X
POEM	X		X	X	X	X	X	X
Itch severity (numerical rating score)	X		X	X	X	X	X	X
CDLQI/DLQI/IDQOL[d]	X			X			X	X
EQ-5D-5L (adults) EQ-5D-Y (4-15 years old) [d]	X		X	X	X	X	X	X
ACT [d,e]	X			X			X	X
Collection of blood for FLG mutation and other genetic analysis (optional)[f]	X							
Collection and storage of blood samples for mechanistic studies, drug metabolite and trough level analyses (optional) [g]	X[h]		X	X			X	X
Skin biopsies (optional, ≥6 years) [g]	X[h]		X	X				
Skin microbiome samples (optional) [g]	X[h]		X	X				
Tape stripping (optional) [g]	X[h]		X	X				
Systemic immuno-modulatory therapy start		X[i]						

**Follow up will remain three-monthly while patients are on systemic therapy, but can reduce to six-monthly, once systemic treatment has been stopped.

***If patient switches main treatment, Baseline 2 assessments will be performed and then further visits will continue as per original schedule (D1, W4, W16, 6M, etc)

a - Includes height at baseline and weight at all time points. For minors, additionally height at all time points.

b - Full blood count, renal and liver function are recommended at all study visits. Other bloods to be done according to local practice (e.g. Hep B, Hep C and HIV). An additional blood sample at week 1 for patients in MTX may be collected according to local practice.

c - At the discretion of the local PI/medically qualified physician

d - After 12 months of participation, questionnaires to be done every 6 months regardless of treatment

e - For subjects with a diagnosis of asthma of ≥ 12 years old

f - Can be collected at any time during the study

g – Time points may be subject to change if decided by the Study Steering Committee

h - For patients participating in the bioresource, severity assessments (EASI, IGA, POEM and itch severity) need to be performed on the same day as the collection of biomaterial.

i - To be conducted as close to the baseline visit/assessments as possible, in particular for participants consenting to the collection of biomaterial for mechanistic studies. For patients only participating in the observational aspects of the study, therapy needs to start within a maximum of 28 days following the baseline assessment.

EASI - Eczema Area Severity Index	IDQOL/CDLQI/DLQI - (Infant's, Children's) Dermatology Life Quality Index
IGA - Investigator Global Assessment	EQ-5D - European Quality of Life measure score-5D
POEM - Patient Oriented Eczema Measure	ACT - Asthma Control Test

A-STAR: Enrolment

Patient Study ID: |___|___|___|___|___|___| **Initials:** |___|___|___|

Study enrolment	
Date patient signed informed consent	|__|__| |__|__|__| |__|__|__|__|(dd-mmm-yyyy)
Date patient enrolled (	|__|__| |__|__|__| |__|__|__|__|(dd-mmm-yyyy)
Date of baseline visit	|__|__| |__|__|__| |__|__|__|__|(dd-mmm-yyyy)
Is the patient part of an Early Access Medical Scheme (EAMS)?	O Yes O No

Informed consent	
Has the patient signed an Informed Consent/Assent Form?	O Yes O No
If the patient is a minor, have the parents/guardians signed an Informed Consent Form?	O Yes O No O N/A
Has the patient or parent/guardian agreed to provide samples for DNA analyses?	O Yes O No
Has the patient or parent/guardian signed the Informed Consent Form for the Optional Biorepository Sub-Study?	O Yes O No O N/A
Has the patient or parent/guardian agreed to be contacted in the future for further investigation and samples?	O Yes O No

Inclusion / exclusion criteria

	Inclusion criteria:	**YES**	**NO**
1	Paediatric and adult patients with atopic eczema who due to the severity of their disease and/or impact on quality of life are commencing on or switching to another systemic immuno-modulatory agent (e.g. CsA, AZA, MTX or biologic treatments).	O	O
2	Written informed consent for study participation obtained from the patient or parents / legal guardian, with assent as appropriate by the patient, depending on the level of understanding.	O	O
3	Participant's consent to participate in long-term follow up and access to all medical records, including hospital admission records	O	O

INITIALS / SIGNATURE:

DATE: ___/___/___

	and linkage to data held by NHS bodies or other national providers of healthcare data.		
4	Diagnosis of atopic eczema in keeping with the UK/Irish diagnostic criteria.	O	O
5	Willingness to comply with all study requirements.	O	O
6	Competent use of English language, according to patient's age (capable of understanding patient questionnaires).	O	O
Exclusion criteria:			
1	Insufficient understanding of the study by the patient and/or parent/guardian.	O	O
2	Patients who are currently participating in a randomised clinical trial.	O	O

UK diagnostic criteria

Patients must have:		**YES**	**NO**
1	An itchy skin condition in the last year	O	O
Plus three or more of the following:			
1	Visible flexural dermatitis	O	O
2	History of flexural involvement	O	O
3	History of generally dry skin	O	O
4	Personal history of atopic disease (children under 4 years: family history of atopic disease)	O	O
5	Onset before the age of 2 years (not used if child aged < 4 years)	O	O

A-STAR: Baseline

Patient Study ID: |___|___|___|___|___|___| **Initials:** |___|___|___|

Baseline date	
Visit date	|__|__| |__|__|__| |__|__|__|__|(dd-mmm-yyyy)
Age at this visit	|__|__|__|

Height and weight	
Height	|__|__|__| (cm)
Weight	|__|__|__|.|__| (kg)

Demographics	
Month and year of birth	|__|__|__| |__|__|__|__|(mmm-yyyy)
Sex at birth	O Female O Male O Undifferentiated O Unknown
Country of birth	Participant: _____ or □ Unknown
Ethnicity (multiple boxes can be ticked)	□ White (Europe, Russia, Middle East, North Africa, USA, Canada, Australia) □ Black African, Afro Caribbean □ African-American □ Asian-Chinese □ South Asian (India, Pakistan, Sri Lanka, Nepal, Bhutan, Bangladesh) □ Any other Asian background (Korea, China north of Huai-River) □ Japanese □ Hispanic or Latino □ Other; please specify: _____
Country of birth	Mother: _____ or □ Unknown Father: _____ or □ Unknown
Education status (ISCED 2011)	Use the highest education level of the patient, or the parents in case of a minor

INITIALS / SIGNATURE:

DATE: ___/___/___

	□ ISCED 0: Early childhood education ('less than primary' for educational attainment) □ ISCED 1: Primary education □ ISCED 2: Lower secondary education □ ISCED 3: Upper secondary education □ ISCED 4: Post-secondary non-tertiary education □ ISCED 5: Short-cycle tertiary education □ ISCED 6: Bachelor's or equivalent level □ ISCED 7: Master's or equivalent level □ ISCED 8: Doctoral or equivalent level
Occupation	□ Employed □ Self-employed □ Disability pension (unable to work) □ Retired □ Student or pupil □ Engaged on home duties □ Unemployed □ Other: _____

Eczema diagnosis	
Date of onset	|__|__| |__|__|__| |__|__|__|__| □ Unknown
How was the diagnosis of eczema established?	Clinically: O Yes O No Histopathology: O Yes O No

Past eczema treatments: Topical therapy (multiple can be selected)	
□ Corticosteroid	□ Crisaborole
□ Calcineurin inhibitors	□ Other
□ Tar ointments	

Past eczema treatments: phototherapy - Enter all treatment courses separately (for additional therapies print further CRF pages).

Type of therapy:

□ UVA

□ UVA-1

□ Narrowband-UVB

□ Broadband-UVB

□ UVB (unspecified)

□ UVAB

□ PUVA (oral or other)

□ Other:_____

Cumulative dose: |__|__|__| J/cm^2

Effect:

□ Excellent (Clearance)

□ Good

□ Moderate

□ Poor

□ Unknown

Reason for stopping:

□ Insufficient response

□ Relapse (after initial good response)

□ Side effect

□ Cumulative dose

□ Remission

□ Other (specify):

_____

Adverse effects: O Yes O No

Start date:

|__|__||__|__|__||__|__|__|__|

Course number: |__|__|__|

(To count as a separate course, one has to be off therapy for at least 3 months.)

Past eczema treatments: Systemic therapy - Enter all treatment courses separately (for additional therapies print further CRF pages).

Name of therapy:

□ oral Ciclosporin

□ oral Azathioprine

□ oral Methotrexate

□ oral Mycophenolate mofetil

□ subcutaneous Dupilumab

□ oral Prednisolone

□ subcutaneous Omalizumab

□ Other (specify below, including route of administration):

_____

□ Investigational medication (specify below & route of administration):

_____

Main treatment dose: |__|__|__| mg **Frequency:** □ daily □ weekly □ other

Start date: |__|__||__|__|__||__|__|__|__|

Duration (months): |__|__|__|

Effect:

□ Excellent (Clearance)

□ Good

□ Moderate

□ Poor

□ Unknown

Reason for stopping:

□ Insufficient response

□ Relapse (after initial good response)

□ Side effect

□ Cumulative dose

□ Remission

□ Other:_____

Course number: |__|__|__|

(To count as a separate course, one has to be off therapy for at least 3 months.)

A-STAR: Baseline

Patient Study ID: |__|__|__|__|__|__| **Initials:** |__|__|__|

Past eczema treatments: Hospitalisations

Hospitalization for eczema (inpatient) in the last 3 months	O Yes O No If yes, please report total number of days: |__|__|__|
Hospital day care appointments for eczema (outpatient) in the last 3 months	O Yes O No If yes, please report total number of visits: |__|__|__|

Current eczema treatment

Current topical therapy (for additional therapies print further CRF pages)

Name:_____

Classification:

□ Corticosteroid

O Mild O Moderate

O Potent O Ultra-potent

□ Calcineurin inhibitor

O Pimecrolimus 1%

O Tacrolimus 0.03%

O Tacrolimus 0.1%

□ Tar ointments

□ Crisaborole

□ Other; please specify: _____

Start date: |__|__||__|__|__||__|__|

Stop date: |__|__||__|__|__||__|__| □ **Ongoing**

Times a week: |__|__|__| *or* □ PRN

Name:_____

Classification:

INITIALS / SIGNATURE:

DATE: ___/___/___

□ Corticosteroid

O Mild O Moderate

O Potent O Ultra-potent

□ Calcineurin inhibitor

O Pimecrolimus 1%

O Tacrolimus 0.03%

O Tacrolimus 0.1%

□ Tar ointments

□ Crisaborole

□ Other; please specify: _____

Start date: |__|__||__|__|__||__|__|

Stop date: |__|__||__|__|__||__|__| □ **Ongoing**

Times a week: |__|__|__| *or* □ PRN

Name:_____

Classification:

□ Corticosteroid

O Mild O Moderate

O Potent O Ultra-potent

□ Calcineurin inhibitor

O Pimecrolimus 1%

O Tacrolimus 0.03%

O Tacrolimus 0.1%

□ Tar ointments

□ Crisaborole

□ Other; please specify: _____

Start date: |__|__||__|__|__||__|__|

Stop date: |__|__||__|__|__||__|__| □ **Ongoing**

Times a week: |__|__|__| *or* □ PRN

INITIALS / SIGNATURE:

DATE: ___/___/___

Current eczema treatment

Current phototherapy (for additional therapies print further CRF pages)

Type of therapy:

□ UVA
□ UVA-1
□ Narrowband-UVB
□ Broadband-UVB
□ UVB (unspecified)
□ UVAB
□ PUVA (oral or other)
□ Other: _____

Start date: |__|__||__|__|__||__|__|__|__|

Stop date: |__|__||__|__|__||__|__|__|__|

Ongoing □

Cumulative dose (at discontinuation):

|__|__|__| J/cm^2

Effect:

□ Excellent (Clearance)
□ Good
□ Moderate
□ Poor
□ Unknown

Reason for stopping:

□ Insufficient response
□ Relapse (after initial good response)
□ Side effect
□ Cumulative dose
□ Remission
□ Other:_____

Type of therapy:

□ UVA
□ UVA-1
□ Narrowband-UVB
□ Broadband-UVB
□ UVB (unspecified)
□ UVAB
□ PUVA (oral or other)
□ Other: _____

Start date: |__|__||__|__|__||__|__|__|__|

Stop date: |__|__||__|__|__||__|__|__|__|

Ongoing □

Cumulative dose (at discontinuation):

|__|__|__| J/cm^2

Effect:

□ Excellent (Clearance)
□ Good
□ Moderate
□ Poor
□ Unknown

Reason for stopping:

□ Insufficient response
□ Relapse (after initial good response)
□ Side effect
□ Cumulative dose
□ Remission
□ Other:_____

Current eczema treatment

Current systemic therapy (for additional therapies print further CRF pages)

Name of therapy:

□ oral Ciclosporin

□ oral Azathioprine

□ oral Methrotrexate

□ oral Mycophenolate mofetil

□ subcutaneous Dupilumab

□ oral Prednisolone

□ subcutaneous Omalizumab

□ Other (specify below, including route of administration):

_____

□ Investigational medication (specify below, including route of administration):

_____

Dose |___|___|___| mg □ Daily □ Weekly □ Other

Start date: |__|__||__|__|__||__|__|__|__|

Ongoing: O Yes O No

Stop date: |__|__||__|__|__||__|__|__|__|

Effect:

□ Excellent (Clearance)

□ Good

□ Moderate

□ Poor

□ Unknown

Reason for stopping:

□ Insufficient response

□ Relapse (after initial good response)

□ Side effect

□ Cumulative dose

□ Remission

□ Other:_____

Family history (Note: first degree relative refers to a parent, sibling or child)	
First degree relative with atopic eczema?	O Yes O No O Unknown
First degree relative with asthma?	O Yes O No O Unknown
First degree relative with allergic rhino-conjunctivitis?	O Yes O No O Unknown
First degree relative with eosinophilic oesophagitis?	O Yes O No O Unknown
First degree relative with atopic eye disease:	O Yes O No O Unknown
Other (please specify):_____	

Allergic comorbidities	
Asthma	(Physician diagnosed) O Yes O No O Unknown
Allergic rhinoconjunctivitis	(Physician diagnosed) O Yes O No O Unknown
Atopic eye disease	(Physician diagnosed) O Yes O No O Unknown
Eosinophilic oesophagitis	(Physician diagnosed) O Yes O No O Unknown
Food allergy	
Does the patient have any food allergies?	O Yes O No If yes, please specify the type of food: _____
If yes, was at least one diagnosed by a doctor?	O Yes O No
If yes, how was the diagnosis made?	□ Double-blind placebo-controlled oral food challenge □ Open food challenge □ Skin prick test □ Scratch test □ Specific IgE test □ Other (e.g. Atopy Patch Test) □ Unknown

Date of the test performed:	|__|__||__|__|__||__|__|__|__|
Contact allergies	
Has the patient ever been assessed for contact allergies with patch testing?	O Yes O No O Unknown
If yes, what was the outcome?	O Negative O Positive O Unknown If positive, what was the type of contact allergy? _____
Date of the test performed:	|__|__||__|__|__||__|__|__|__|
Aeroallergen sensitisation	
Is the patient significantly sensitised to at least one aeroallergen (i.e. skin prick test ≥3mm or specific IgE level >0.35IU/L)?	O Yes O No O Unknown
If yes, how was the diagnosis made?	O Skin prick test O Specific IgE test
Date of the test performed:	|__|__||__|__|__||__|__|__|__|

Other comorbidities

Malignancies (for additional history print further CRF pages)

Diagnosis:

_____

_____

Select classification:

Lymphoproliferative

□ Lymphoma,

□ Myeloma

□ Leukaemia

□ Other lymphoproliferative

Skin cancer

□ Non-melanoma skin cancer

□ Melanoma

□ Other skin cancer

Solid tumours

□ Brain neoplasms

□ Glioblastoma

□ Other

Year of diagnosis: |___|___|___|___|

Status: O Active O In remission O Relapsed

Further details:

_____

_____

Diagnosis:

_____

_____

Select classification:

Lymphoproliferative

□ Lymphoma,

□ Myeloma

□ Leukaemia

□ Other lymphoproliferative

Skin cancer

□ Non-melanoma skin cancer

□ Melanoma

□ Other skin cancer

Solid tumours

□ Brain neoplasms

□ Glioblastoma

□ Other

Year of diagnosis: |___|___|___|___|

Status: O Active O In remission O Relapsed

Further details:

_____

_____

Serious infections (pneumonia, septicaemia, bone/joint infection, opportunistic infection, soft tissue/skin infection and tuberculosis) (for additional history print further CRF pages)

Diagnosis: _____

Year of diagnosis: |___|___|___|___| **Status:** O Active O Latent O Resolved

Diagnosis: _____

Year of diagnosis: |___|___|___|___| **Status:** O Active O Latent O Resolved

Diagnosis: _____

Year of diagnosis: |___|___|___|___| **Status:** O Active O Latent O Resolved

Diagnosis: _____

Year of diagnosis: |___|___|___|___| **Status:** O Active O Latent O Resolved

Other comorbidities (for additional history print further CRF pages)

Diagnosis: _____

Year of diagnosis: |___|___|___|___| **Status:** O Ongoing O Resolved

Diagnosis: _____

Year of diagnosis: |___|___|___|___| **Status:** O Ongoing O Resolved

Diagnosis: _____

Year of diagnosis: |___|___|___|___| **Status:** O Ongoing O Resolved

Diagnosis: _____

Year of diagnosis: |___|___|___|___| **Status:** O Ongoing O Resolved

Concomitant medication

Is the patient taking any other concomitant medication? O Yes O No

If yes, record details in Section 5 (concomitant medication) of CRF.

General eczema questions

Exposures that trigger disease flares:	O Yes O No If yes, please select (multiple can be selected): □ Stress □ Infection □ Weather condition □ Sweating/exercise □ Exposure to aero-allergens □ Other : _____
Past episodes of skin infections?	O Yes O No If yes, please select: □ Viral skin infection (herpes simplex virus –HSV-, infection of AE, Mollusca contagiousa, etc) □ Bacterial skin infection (folliculitis, impertigo, etc)
Were any days lost from usual activities (e.g. work, study) due to eczema <u>in the last 3 months</u>?	O Yes O No If yes, how many days in total in the last 3 months: |___|___|

A-STAR: Baseline

Patient Study ID: |___|___|___|___|___|___| **Initials:** |___|___|___|

Baseline skin examination (with oversight by a dermatologist)	
Fitzpatrick Skin Type	□ Type I □ Type II □ Type III □ Type IV □ Type V □ Type VI
Clinical phenotype For guidance on the recognition of flexural and non-flexural eczema (dermatitis) see online training manual. Beware of black skin. Redness may be difficult to see and is not an essential criterion but there must be surface change, ie scaling, vesicles, oozing, crusting and/or lichenification.	- Flexural eczema O Yes O No If yes, which areas are involved (individual patches have to be ≥1cm) O Skin fold(s) around the eyes O Neck O Flexures of the arms (antecubital fossae) O Flexures of the legs (popliteal fossae) O Ankles - Non-flexural eczema O Yes O No If yes, which areas are involved? O Legs (at least one patch ≥2cm diameter BOTH sides) O Knees (patch ≥2cm diameter) O Hands (patch ≥2cm diameter BOTH sides) O Face (at least one non-flexural patch ≥2cm diameter) O Elbows (patch ≥2cm diameter) O Arms (at least one patch ≥2cm diameter BOTH sides) If yes, is there evidence of vesicles or a history of vesicular hand eczema? O Yes O No

INITIALS / SIGNATURE:

DATE: ___/___/___

	- Discoid eczema (at least 5 circular patches in total, each patch ≥2cm diameter) O Yes O No - Nodules (≥5 palpable nodules of the skin from long-term scratching (usually on the legs or arms), ≥1cm diameter each) O Yes O No - Follicular eczema (widespread eczematous hair follicle involvement, more commonly seen in darker skin types) O Yes O No
Widespread fine scale predominantly affecting the non-flexural areas of the limbs and body (ichthyosis)	O Yes O No
Keratosis pilaris (thickening around the base of hair follicles over upper arms, thighs or cheeks)	O Yes O No
Palmar hyperlinearity	O Yes O No
Erythroderma (≥90% BSA involvement)	O Yes O No

Skin infections	
Current skin infection	O Yes O No
Swab taken?	O Yes O No
Bacterial infections (1)	O Yes O No Organism: □ Methicillin Sensitive Staphylococcus Aureus (MSSA) □ Methicillin Resistant Staphylococcus Aureus (MRSA)

INITIALS / SIGNATURE:
DATE: ___/___/___

	□ Streptococcus □ Other organism: _____ Body site: _____
Bacterial infections (2)	Organism: □ Methicillin Sensitive Staphylococcus Aureus (MSSA) □ Methicillin Resistant Staphylococcus Aureus (MRSA) □ Streptococcus □ Other organism: _____ Body site:_____
Viral infections (1)	O Yes O No □ Herpes simplex □ Varicella zoster □ Other organism: _____ Body site: _____
Viral infections (2)	□ Herpes simplex □ Varicella zoster □ Other organism: _____ Body site:_____
Fungal scraping taken?	O Yes O No
Fungal infection (1)	O Yes O No Organism: _____ Body site: _____
Fungal infection (2)	Organism: _____ Body site: _____

A-STAR: Baseline

Patient Study ID: |___|___|___|___|___|___| **Initials:** |___|___|___|

Severity assessments (can be done by all trained staff)	
EASI (Score 0-72)	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__| Total score: |__|__|.|__|
vIGA-AD™ scale (5-point)	Test performed: O Yes O No □ 0 - Clear □ 1 – Minimal □ 2 – Mild □ 3 – Moderate □ 4 – Severe

Patient reported outcomes *(remember to enter answers from the questionnaire onto the eCRF using the questionnaires user guides).*	
POEM Please indicate who has completed the form: O Patient O Caregiver	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__|
Itch severity (NRS)	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__| Result: |__|__|
Please select: O **EQ5D-5L** (adults) O **EQ5D-Y** (4-16 years old)	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__|

INITIALS / SIGNATURE:
DATE: ___/___/___

A-STAR: Baseline

Patient Study ID: |___|___|___|___|___|___| **Initials:** |___|___|___|

Skin-specific quality of life score *Please select:* O **IDQOL** (<4 years) O **DLQI** (≥16 years) O **CDLQI** (4-15 years)	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__|
Asthma control test (≥ 12 years)	Test performed: O Yes O No O N/A Date: |__|__||__|__|__||__|__|__|__|

Details of physician completing/overseeing the skin examination	
Name & Initials:	
Signature:	
Date:	

Investigations performed: please enter the values directly in the eCRF	
Full blood count	Test undertaken? O Yes O No Date: |__|__||__|__|__||__|__|__|__|
Liver profile	Test undertaken? O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__|
Renal profile	Test undertaken? O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__|
TPMT level (for AZA patients)	Test undertaken? O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__|

INITIALS / SIGNATURE:

DATE: ___/___/___

Total IgE level	Test undertaken? O Yes O No Date as above □ *Or specify*: Date: |__|__|__|__|__|__|__|__|
Pregnancy test	Test undertaken? O Yes O No O N/A Date as above □ *Or specify*: Date: |__|__|__|__|__|__|__|__|
Virology	Test undertaken? O Yes O No Date as above □ *Or specify*: Date: |__|__|__|__|__|__|__|__| If yes, type of Virology test taken: VZV: O Yes O No Date as above □ *Or specify*: Date: |__|__|__|__|__|__|__|__| Hepatitis B serology: O Yes O No Date as above □ *Or specify*: Date: |__|__|__|__|__|__|__|__| Hepatitis C serology: O Yes O No Date as above □ *Or specify*: Date: |__|__|__|__|__|__|__|__| HIV serology: O Yes O No Date as above □ *Or specify*: Date: |__|__|__|__|__|__|__|__| Other virology test: O Yes (please specify):_____

	O No Date as above □ *Or specify*: Date: |__|__|__|__|__|__|__|__|__|__|

Imaging at baseline	
Have any of these scans been performed?	Chest X-ray O Yes O No Date: |__|__|__|__|__|__|__|__|__|__| CT scan O Yes O No Date: |__|__|__|__|__|__|__|__|__|__| MRI scan O Yes O No Date: |__|__|__|__|__|__|__|__|__|__|

A-STAR: Baseline

Patient Study ID: |___|___|___|___|___|___| **Initials:** |___|___|___|

Baseline management	
Main reason(s) for choosing specific treatment (systemic or phototherapy)	□ Comorbidities and/or results of baseline investigations □ Drug safety and side effect profile □ Anticipation of pregnancy and other family planning issues for both males and females □ Patient age □ History of prior systemic therapies (including response) □ Accessibility of treatment (including licensing) □ Patient preference □ Therapeutic profile *(select all that apply)* O Speed of onset O Magnitude of effect O Better long-term control after drug is stopped □ Other: _____
Relative contraindication(s) for selected treatment	O Yes O No

Bio-material donation	
Sample for DNA extraction	Has the sample been taken? O Yes O No Date of sample taken: |___|___||___|___|___||___|___|

For sites participating in the Bio-resource	
Research blood	Has the patient consented? O Yes O No Has the sample been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__|__|__|__|__|__|__|
Skin swabs for microbiome analyses	Has the patient consented? O Yes O No Have the samples been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__|__|__|__|__|__|__|
Tape stripping	Has the patient consented? O Yes O No O N/A Have the samples been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__|__|__|__|__|__|__|
Skin biopsy (>16 years)	Has the patient consented? O Yes O No O N/A Has the sample been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__|__|__|__|__|__|__|
Other: _____	Has the patient consented? O Yes O No Has the sample been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__|__|__|__|__|__|__|

A-STAR: Concomitant medication

Patient Study ID: |___|___|___|___|___|___| **Initials:** |___|___|___|

Current concomitant medication *(provide generic names)*	
|___|___|	Medication name: _____ Dose and unit: _____ Frequency: □ Once daily □ Weekly □ Unknown □ Twice daily □ Alternate days □ Every month □ Three times daily □ As needed □ Other □ Four times daily Reason: _____ Start date: |___|___||___|___|___||___|___|___|___| Stop date: |___|___||___|___|___||___|___|___|___| □ Ongoing
|___|___|	Medication name: _____ Dose and unit: _____ Frequency: □ Once daily □ Weekly □ As needed □ Twice daily □ Alternate days □ Unknown □ Three times daily □ Every month □ Other □ Four times daily Reason: _____ Start date: |___|___||___|___|___||___|___|___|___| Stop date: |___|___||___|___|___||___|___|___|___| □ Ongoing
|___|___|	Medication name: _____ Dose and unit: _____ Frequency: □ Once daily □ Weekly □ As needed □ Twice daily □ Alternate days □ Unknown □ Three times daily □ Every month □ Other □ Four times daily

INITIALS / SIGNATURE:

DATE: ___/___/___

	Reason: _____ Start date: |__|__||__|__|__||__|__|__|__| Stop date: |__|__||__|__|__||__|__|__|__| □ Ongoing
|__|__|	Medication name: _____ Dose and unit: _____ Frequency: □ Once daily □ Weekly □ As needed □ Twice daily □ Alternate days □ Unknown □ Three times daily □ Every month □ Other □ Four times daily Reason: _____ Start date: |__|__||__|__|__||__|__|__|__| Stop date: |__|__||__|__|__||__|__|__|__| □ Ongoing
|__|__|	Medication name: _____ Dose and unit: _____ Frequency: □ Once daily □ Weekly □ As needed □ Twice daily □ Alternate days □ Unknown □ Three times daily □ Every month □ Other □ Four times daily Reason: _____ Start date: |__|__||__|__|__||__|__|__|__| Stop date: |__|__||__|__|__||__|__|__|__| □ Ongoing

A-STAR: Adverse Events

Patient Study ID: |___|___|___|___|___|___| **Initials:** |___|___|___|

Adverse events |__|__|

Name of event: _____

Description of the event: _____

_____

Start date:
|__|__||__|__|__||__|__|__|__|

Severity:
O Severe O Moderate O Mild

Is it an SAE: O Yes O No Yes
If yes, select category:
□ Medically important event
□ Life threatening
□ Hospitalisation or prolongation
□ Persistent or significant disability
□ Death
□ Congenital anomaly

Outcome:
□ Unknown
□ Resolved with sequelae
□ Resolved
□ Not resolved
□ Death

If resolved, date of resolution:
|__|__||__|__|__||__|__|__|__|

Relationship to systemic immunomodulator:
□ Unlikely □ Likely □ Confirmed

Impact
□ Switch of therapy
□ Stop
□ None
□ Dose delay
□ Concomitant medication given
□ Change in dosage

Related to study specific procedure *(Study Co-ordinating Centre must be notified ASAP):*
□ Unlikely □ Likely □ Confirmed

Changes in severity of the same Adverse Event must be entered as a new event in eCRF

Start date *dd/mmm/yy*	Stop date *dd/mmm/yy*	Mild	Moderate	Severe
|__|__||__|__|__||__|__|__|	|__|__||__|__|__||__|__|__|	□	□	□
|__|__||__|__|__||__|__|__|	|__|__||__|__|__||__|__|__|	□	□	□
|__|__||__|__|__||__|__|__|	|__|__||__|__|__||__|__|__|	□	□	□
|__|__||__|__|__||__|__|__|	|__|__||__|__|__||__|__|__|	□	□	□
|__|__||__|__|__||__|__|__|	|__|__||__|__|__||__|__|__|	□	□	□

INITIALS / SIGNATURE:
DATE: ___/___/___

A-STAR: Adverse Events

Patient Study ID: |___|___|___|___|___|___| **Initials:** |___|___|___|

Adverse events |__|__|

Name of event: _____

Description of the event: _____

_____

Start date:
|__|__||__|__|__||__|__|__|__|

Severity:
O Severe O Moderate O Mild

Is it an SAE: O Yes O No Yes
If yes, select category:
□ Medically important event
□ Life threatening
□ Hospitalisation or prolongation
□ Persistent or significant disability
□ Death
□ Congenital anomaly

Outcome:
□ Unknown
□ Resolved with sequelae
□ Resolved
□ Not resolved
□ Death

If resolved, date of resolution:
|__|__||__|__|__||__|__|__|__|

Relationship to systemic immunomodulator:
□ Unlikely □ Likely □ Confirmed

Impact
□ Switch of therapy
□ Stop
□ None
□ Dose delay
□ Concomitant medication given
□ Change in dosage

Related to study specific procedure *(Study Co-ordinating Centre must be notified ASAP):*
□ Unlikely □ Likely □ Confirmed

Changes in severity of the same Adverse Event must be entered as a new event in eCRF

Start date *dd/mmm/yy*	Stop date *dd/mmm/yy*	Mild	Moderate	Severe
|__|__||__|__|__||__|__|__|	|__|__||__|__|__||__|__|__|	□	□	□
|__|__||__|__|__||__|__|__|	|__|__||__|__|__||__|__|__|	□	□	□
|__|__||__|__|__||__|__|__|	|__|__||__|__|__||__|__|__|	□	□	□
|__|__||__|__|__||__|__|__|	|__|__||__|__|__||__|__|__|	□	□	□
|__|__||__|__|__||__|__|__|	|__|__||__|__|__||__|__|__|	□	□	□

INITIALS / SIGNATURE:
DATE: ___/___/___

Encounter	
Visit date	|__|__| |__|__|__| |__|__|__|__|(dd-mmm-yyyy) Or *visit did not take place* □

Height and weight	
Height	|__|__|__| (cm) or □ N/A
Weight	|__|__|__|.|__| (kg)

Demographics	
Have there been any changes to the demographics since baseline? O Yes O No If yes, complete below:	
Education status (ISCED 2011)	Use the highest education level of the patient, or the parents in case of a minor □ ISCED 0: Early childhood education ('less than primary' for educational attainment) □ ISCED 1: Primary education □ ISCED 2: Lower secondary education □ ISCED 3: Upper secondary education □ ISCED 4: Post-secondary non-tertiary education □ ISCED 5: Short-cycle tertiary education □ ISCED 6: Bachelor's or equivalent level □ ISCED 7: Master's or equivalent level □ ISCED 8: Doctoral or equivalent level
Occupation	□ Employed □ Self-employed □ Disability pension (unable to work) □ Retired □ Student or pupil □ Engaged on home duties □ Unemployed □ Other: _____

Current eczema treatment

Have there been any changes to the topical therapy since last encounter:

O Yes O No

If yes, record in the relevant visit 'eczema treatment' and add new entry below (if applicable). If change was related to an Adverse Event, please also complete AE section.

Current topical therapy (for additional therapies print further CRF pages)

Name:_____

Classification:

□ Corticosteroid

O Mild O Moderate

O Potent O Ultra-potent

□ Calcineurin inhibitor

O Pimecrolimus 1%

O Tacrolimus 0.03%

O Tacrolimus 0.1%

□ Tar ointments

□ Crisaborole

□ Other; please specify: _____

Start date: |__|__||__|__|__||___|___|

Stop date: |__|__||__|__|__||___|___|

□ **Ongoing**

Times a week: |__|__|__| *or* □ PRN

Name:_____

Classification:

□ Corticosteroid

O Mild O Moderate

O Potent O Ultra-potent

□ Calcineurin inhibitor

O Pimecrolimus 1%

O Tacrolimus 0.03%

O Tacrolimus 0.1%

□ Tar ointments

□ Crisaborole

□ Other; please specify: _____

Start date: |__|__||__|__|__||__|__|

Stop date: |__|__||__|__|__||__|__|

□ **Ongoing**

Times a week: |___|___|___| *or* □ PRN

Name:_____

Classification:

□ Corticosteroid

O Mild O Moderate

O Potent O Ultra-potent

□ Calcineurin inhibitor

O Pimecrolimus 1%

O Tacrolimus 0.03%

O Tacrolimus 0.1%

□ Tar ointments

□ Crisaborole

□ Other; please specify: _____

Start date: |__|__||__|__|__||__|__|

Stop date: |__|__||__|__|__||__|__|

□ **Ongoing**

Times a week: |___|___|___| *or* □ PRN

Current eczema treatment

Current phototherapy (for additional therapies print further CRF pages)

Have there been any changes to the current phototherapy since last encounter:

O Yes O No

If yes, record in the relevant visit 'eczema treatment' and add new entry below (if applicable). If change was related to an Adverse Event, please complete AE section.

Type of therapy:

□ UVA
□ UVA-1
□ Narrowband-UVB
□ Broadband-UVB
□ UVB (unspecified)
□ UVAB
□ PUVA (oral or other)
□ Other: _____

Effect:

□ Excellent (Clearance)
□ Good
□ Moderate
□ Poor
□ Unknown

Start date: |__|__||__|__|__||__|__|__|__|

Stop date: |__|__||__|__|__||__|__|__|__|

Ongoing □

Cumulative dose (at discontinuation):

|__|__|__| J/cm^2

Type of therapy:

□ UVA
□ UVA-1
□ Narrowband-UVB
□ Broadband-UVB
□ UVB (unspecified)
□ UVAB
□ PUVA (oral or other)
□ Other: _____

Effect:

□ Excellent (Clearance)
□ Good
□ Moderate
□ Poor
□ Unknown

Start date: |__|__||__|__|__||__|__|__|__|

Stop date: |__|__||__|__|__||__|__|__|__|

Ongoing □

Cumulative dose (at discontinuation):

|__|__|__| J/cm^2

INITIALS / SIGNATURE:

DATE: ___/___/___

Current eczema treatment

Current systemic therapy (for additional therapies print further CRF pages)

Name of therapy:

□ oral Ciclosporin

□ oral Azathioprine

□ oral Methrotrexate

□ oral Mycophenolate mofetil

□ subcutaneous Dupilumab

□ oral Prednisolone

□ subcutaneous Omalizumab

□ Other (specify below, including route of administration):

_____

□ Investigational medication (specify below, including route of administration):

_____

Dose |___|___|___| mg □ Daily □ Weekly □ Other

Start date: |__|__||__|__|__||__|__|__|__|

Ongoing: O Yes O No

Stop date: |__|__||__|__|__||__|__|__|__|

Effect:

□ Excellent (Clearance)

□ Good

□ Moderate

□ Poor

□ Unknown

Reason for Stopping:

□ Insufficient response

□ Relapse (after initial good response)

□ Side effect

□ Cumulative dose

□ Remission

□ Other:_____

Concomitant medication

Is the patient taking any other concomitant medication? O Yes O No

If yes, record details in Section 5 (concomitant medication) of CRF.

Follow up general questions	
Were any days lost from usual activities (e.g. work) due to eczema since your last visit?	O N/A (not applicable at week 4 visit) O Yes O No If yes, how many days in total: |__|__|__|
Was there a change in diagnosis after enrolment?	O Yes O No If yes: □ CTCL □ Other: _____
Healthcare resource use	
Since your last visit, have you visited A&E?	O Yes O No If yes, was this related to your condition or to your condition medication? O Yes O No If yes, state how many times: |__|__|
Since your last visit, have you been admitted to hospital?	O Yes O No If yes, was this related to your condition or to your condition medication? O Yes O No If related, please list details: Date of admission: |__|__||__|__|__||__|__|__|__| Date of discharge: |__|__||__|__|__||__|__|__|__| Type of Ward: _____ Date of admission: |__|__||__|__|__||__|__|__|__| Date of discharge: |__|__||__|__|__||__|__|__|__| Type of Ward: _____

INITIALS / SIGNATURE:

DATE: ___/___/___

	Please consider completing the adverse event and/or concomitant medication log.
Since your last visit, have you seen a specialist at the hospital as an outpatient?	O Yes O No If yes, was this for reasons related to your condition or to your condition medication? O Yes O No How many visits? |__|__|__|
Since your last visit, have you seen a GP or a nurse?	O Yes O No If yes, was this for reasons related to your condition or to your condition medication? O Yes O No How many visits? |__|__|__|
Since your last visit, have you been taking any additional medication for your condition?	O Yes O No *If yes, please remember to update concomitant medication form.*

Skin examination (with oversight by a dermatologist)	
Clinical phenotype For guidance on the recognition of flexural and non-flexural eczema (dermatitis) see online training manual. Beware of black skin. Redness may be difficult to see and is not an essential criterion but there must be surface change, ie scaling, vesicles, oozing, crusting and/or lichenification.	- Flexural eczema O Yes O No If yes, which areas are involved (individual patches have to be ≥1cm) O Skin fold(s) around the eyes O Neck O Flexures of the arms (antecubital fossae) O Flexures of the legs (popliteal fossae) O Ankles - Non-flexural eczema O Yes O No

INITIALS / SIGNATURE:

	If yes, which areas are involved? O Legs (at least one patch ≥2cm diameter BOTH sides) O Knees (patch ≥2cm diameter) O Hands (patch ≥2cm diameter BOTH sides) O Face (at least one non-flexural patch ≥2cm diameter) O Elbows (patch ≥2cm diameter) O Arms (at least one patch ≥2cm diameter BOTH sides) If yes, is there evidence of vesicles or a history of vesicular hand eczema? O Yes O No - Discoid eczema (at least 5 circular patches in total, each patch ≥2cm diameter) O Yes O No - Nodules (≥5 palpable nodules of the skin from long-term scratching (usually on the legs or arms), ≥1cm diameter each) O Yes O No - Follicular eczema (widespread eczematous hair follicle involvement, more commonly seen in darker skin types) O Yes O No
Widespread fine scale predominantly affecting the non-flexural areas of the limbs and body (ichthyosis)	O Yes O No
Keratosis pilaris (thickening around the base of hair follicles over upper arms, thighs or cheeks)	O Yes O No
Palmar hyperlinearity	O Yes O No

INITIALS / SIGNATURE:

DATE: ___/___/___

Erythroderma (≥90% BSA involvement)	O Yes O No

Skin infections	
Current skin infection	O Yes O No
Swab taken?	O Yes O No
Bacterial infections (1)	O Yes O No Organism: □ Methicillin Sensitive Staphylococcus Aureus (MSSA) □ Methicillin Resistant Staphylococcus Aureus (MRSA) □ Streptococcus □ Other organism: _____ Body site: _____
Bacterial infections (2)	Organism: □ Methicillin Sensitive Staphylococcus Aureus (MSSA) □ Methicillin Resistant Staphylococcus Aureus (MRSA) □ Streptococcus □ Other organism: _____ Body site:_____
Viral infections (1)	O Yes O No □ Herpes simplex □ Varicella zoster □ Other organism: _____ Body site: _____
Viral infections (2)	□ Herpes simplex

	□ Varicella zoster □ Other organism: _____ Body site:_____
Fungal scraping taken?	O Yes O No
Fungal infection (1)	O Yes O No Organism: _____ Body site: _____
Fungal infection (2)	Organism: _____ Body site: _____

Severity assessments (can be done by all trained staff)	
EASI (Score 0-72)	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__| Total score: |__|__|.|__|
vIGA-AD™ scale (5-point)	Test performed: O Yes O No □ 0 - Clear □ 1 – Minimal □ 2 – Mild □ 3 – Moderate □ 4 – Severe

Patient reported outcomes *(remember to enter answers from the questionnaire onto the eCRF using the questionnaires user guides).*	
POEM Please indicate who has completed the form: O Patient O Caregiver	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__|

INITIALS / SIGNATURE:

DATE: ___/___/___

A-STAR: Follow up visit / Encounter	**Visit number** |___|___|
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

Itch severity (NRS)	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__| Result: |__|__|
Please select: O **EQ5D-5L** (adults) O **EQ5D-Y** (4-16 years old)	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__|
Skin specific quality of life score *Please select:* O **IDQOL** (<4 years) O **DLQI** (≥16 years) O **CDLQI** (4-15 years)	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__|
Asthma control test (≥ 12 years)	Test performed: O Yes O No O N/A Date: |__|__||__|__|__||__|__|__|__|

Reporting of disease control – (not applicable at Week 4)	
How many weeks was your atopic eczema well controlled <u>in the past 3 months</u>?	|__|__|
How many weeks was your atopic eczema completely controlled <u>in the past 3 months</u>?	|__|__|

Details of physician completing/overseeing the skin examination	
Name & Initials:	
Signature:	
Date:	

INITIALS / SIGNATURE:
DATE: ___/___/___

Investigations performed: please enter the values directly in the eCRF	
Full blood count	Test undertaken? O Yes O No Date: |__|__||__|__|__||__|__|__|__|
Liver profile	Test undertaken? O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__|
Renal profile	Test undertaken? O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__|
TPMT level (for AZA patients)	Test undertaken? O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__|
Total IgE level	Test undertaken? O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__|
Pregnancy test	Test undertaken? O Yes O No O N/A Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__|
Virology	Test undertaken? O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__| If yes, type of Virology test taken: VZV: O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__| Hepatitis B serology: O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__|

	Hepatitis C serology: O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__| HIV serology: O Yes O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__| Other virology test: O Yes (please specify):_____ O No Date as above □ *Or specify*: Date: |__|__||__|__|__||__|__|__|__|

Imaging follow up	
Have any of these scans been performed?	Chest X-ray O Yes O No Date: |__|__||__|__|__||__|__|__|__| CT scan O Yes O No Date: |__|__||__|__|__||__|__|__|__| MRI scan O Yes O No Date: |__|__||__|__|__||__|__|__|__|

A-STAR: Follow up visit / Encounter	**Visit number** |___|___|
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

Adverse Events
Has the patient experienced Adverse Events since the last visit?: O Yes O No If yes, record details in the Adverse Events section of CRF.

Bio-material donation	
Sample for DNA extraction	Has the sample been taken? O Yes O No Date of sample taken: |__|__||__|__|__||__|__|

For sites participating in the Bio-resource	
Research blood	Has the sample been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__||__|__|__||__|__|__|__|
Skin swab for microbiome analyses	Has the sample been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__||__|__|__||__|__|__|__|
Tape stripping	Has the sample been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__||__|__|__||__|__|__|__|

INITIALS / SIGNATURE:
DATE: ___/___/___

Skin biopsy (>16 years)	Has the sample been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__||__|__|__||__|__|__|__|
Other: _____	Has the sample been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__||__|__|__||__|__|__|__|

A-STAR: End of Study

Patient Study ID: |__|__|__|__|__|__| **Initials:** |__|__|__|

End of Study	
Date end of study was recorded (withdrawal from active participation AND linkage of data)	|__|__| |__|__|__| |__|__|__|__|

Withdrawn consent	
Has the patient / guardian withdrawn main study consent?	O Yes O No If yes, specify type: □ Withdrawal from patient questionnaires but continues in the study. Date of withdrawal 1: |__|__||__|__|__||__|__|__|__| □ Withdrawal from active participation but consented to review of medical records and data linkage. Date of withdrawal 2: |__|__||__|__|__||__|__|__|__| □ Withdrawal from active participation and data linkage. Date of withdrawal 3: |__|__||__|__|__||__|__|__|__| □ Withdrawal from active participation, data linkage and exclusion of data from analyses. Date of withdrawal 4: |__|__||__|__|__||__|__|__|__|

Death	
Is the patient dead?	O Yes O No *If yes, remember to complete SAE form):* Date of death: |__|__||__|__|__||__|__|__|__| Diagnosis in the death certificate: _____ _____

INITIALS / SIGNATURE:
DATE: ___/___/___

A-STAR: End of Study

Patient Study ID: |___|___|___|___|___|___| **Initials:** |___|___|___|

Loss to follow up	
Is the patient lost to follow up?	O Yes O No *If yes, date of last patient contact:* |__|__||__|__|__||__|__|__|__|

Data censored	
Has the data been censored	O Yes O No *If yes, what is the reason?* □ Patient participating in clinical trial □ Other: _____ Date when data censored: __|__||__|__|__||__|__|__|__|

INITIALS / SIGNATURE:

DATE: ___/___/___