Confidential

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

Patient study ID: |__|__|__|__|__|__|

Patient initials: |__|__|__|

Research Centre Name: _____

Research site ID: |__|__|

Chief Investigator: _____

INSTRUCTIONS FOR COMPLETING THE PAPER CRF

- This CRF consist 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.

VISIT SCHEDULE

Study visits and assessments	V_1 Baseline	V_2 4 weeks	V_3 12 weeks	V_4 6 months	V_5 9 months	V_6 12 months** and subsequent
Inclusion/exclusion criteria	X					
Informed consent	X					
Demographics	X					
Personal/family history	X					
Atopic Eczema and treatment history	X	X	X	X	X	X
Co-morbidities (including immediate and delayed allergies)	X	X	X	X	X	X
Concomitant medication	X	X	X	X	X	X
Physical examination	X	X	X	X	X	X
Blood pressure (if applicable)	X	X	X	X	X	X
Treatment (prescribed/ performed)	X	X	X	X	X	X
Adverse events		X	X	X	X	X
Safety bloods	X	X	X	X	X	X
EASI, EASI-50, EASI-75	X	X	X	X	X	X
IGA	X	X	X	X	X	X
POEM	X	X	X	X	X	X
CDLQI/DLQI/IDQOL	X		X			X
EQ-5D-5L (adults) / EQ-5D-Y (children)	X		X			X
ACQ [d,e]	X		X			X
Collection of blood for FLG mutation and other genetic analysis (optional)[f]	X					
Collection and storage of blood samples for future mechanistic studies, drug metabolite and trough level analyses (optional)	X	X	X			X
Skin biopsies (optional, >16 years)	X	X	X			
Skin microbiome samples (optional)	X	X	X			
Tape stripping (optional, ≤16 years)	X	X	X			
**Follow up will remain three-monthly while patients are on systemic therapy, but can reduce to six-monthly, once systemic treatment has been stopped.						
A - Includes height at baseline and weight at all timepoints						
B - To include full blood count, renal and liver function. 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						
F – Can be collected at any time during the study						
G – Timepoints are subject to change if decided by a study committee						
EASI - Eczema Area Severity Index						
IGA – Investigator Global Assessment						
POEM – Patient Oriented Eczema Measure						
IDQOL/CDLQI/DLQI – (Infant's, Children's) Dermatology Life Quality Index						
EQ-5D – European Quality of Life measure score-5D						
ACQ - Asthma Control Questionnaire						

A*STAR: Enrolment	**Site ID:** |___|___|
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

Study enrolment	
Date patient signed informed consent form	|___|___| |___|___|___| |___|___|___|___|(dd-mmm-yyyy)
Date patient enrolled (	|___|___| |___|___|___| |___|___|___|___|(dd-mmm-yyyy)
Date of baseline visit	|___|___| |___|___|___| |___|___|___|___|(dd-mmm-yyyy)

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?	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 agreed to be contacted in the future for further investigation and samples?	O Yes O No

UK Diagnostic Criteria			
Patient must have:		**YES**	**NO**
1.	An itchy skin condition in the last year	O	O
Plus <u>three or more</u> 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

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. CyA, 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.	Participants consent to participate in long-term follow up and access to all medical records, including hospital admission records and linkage to data held by NHS bodies or other national providers of healthcare data.	O	O
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

Baseline date	
Visit date	|__|__| |__|__|__|__| |__|__|__|__|(dd-mmm-yyyy)
Age at this visit	|__|__|__|
Height and weight	
Height	|__|__|__| (cm)
Weight	|__|__|__|.|__| (kg)
Body Mass Index (BMI)	|__|__|.|__|
Demographics	
Month and year of birth	|__|__|__||__|__|__|__| (mmm-yyyy)
Sex at birth	□ Male | □ Female | □ Undifferentiated | □ 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	Participant: _____ or □ Unknown 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 □ 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 treatment	
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: |__|__|__|

Past topical therapy (multiple can be selected)

□ Corticosteroid
□ Calcineurin inhibitors
□ Tar ointments
□ Crisaborole
□ Other

Past phototherapy - enter all treatment courses separately (for additional therapies print further CRF pages).

Type of therapy	Type of therapy
□ UVA	□ UVA
□ UVA-1	□ UVA-1
□ UVB (unspecified)	□ UVB (unspecified)
□ UVAB	□ UVAB
□ Narrowband-UVB	□ Narrowband-UVB
□ Broadband-UVB	□ Broadband-UVB
□ PUVA (oral or other)	□ PUVA (oral or other)
□ Other: _____	□ Other: _____
Start date	Start date
|__|__||__|__|__||__|__|__|__|	|__|__||__|__|__||__|__|__|__|
Course number: |__|__|__|	Course number: |__|__|__|
(To count as a separate course, one has to be off therapy for at least 3 months.)	*(To count as a separate course, one has to be off therapy for at least 3 months.)*
Cumulative dose: |__|__|__| J/cm^2	Cumulative dose: |__|__|__| J/cm^2
Effect:	Effect:
□ Excellent (Clearance)	□ Excellent (Clearance)
□ Good	□ Good
□ Moderate	□ Moderate
□ Poor	□ Poor
□ Unknown	□ Unknown

Reason for Stopping: □ Insufficient response □ Relapse (after initial good response) □ Side effect □ Cumulative dose □ Remission □ Other (specify): _____ Adverse effects: O Yes O No	Reason for Stopping: □ Insufficient response □ Relapse (after initial good response) □ Side effect □ Cumulative dose □ Remission □ Other (specify): _____ Adverse effects: O Yes O No
Past phototherapy - enter all treatment courses separately	
Type of therapy □ UVA □ UVA-1 □ UVB (unspecified) □ UVAB □ Narrowband-UVB □ Broadband-UVB □ PUVA (oral or other) □ Other: _____ Start date |__|__||__|__|__||__|__|__|__| Course number: |__|__|__| *(To count as a separate course, one has to be off therapy for at least 3 months.)* Cumulative dose: |__|__|__| J/cm^2 Effect: □ Excellent (Clearance) □ Good □ Moderate □ Poor □ Unknown	Type of therapy □ UVA □ UVA-1 □ UVB (unspecified) □ UVAB □ Narrowband-UVB □ Broadband-UVB □ PUVA (oral or other) □ Other: _____ Start date |__|__||__|__|__||__|__|__|__| Course number: |__|__|__| *(To count as a separate course, one has to be off therapy for at least 3 months.)* 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	Reason for Stopping: □ Insufficient response □ Relapse (after initial good response) □ Side effect □ Cumulative dose □ Remission □ Other (specify): _____ Adverse effects: O Yes O No
Past systemic therapy - enter all treatment courses separately (for additional therapies print further CRF pages)	
Name of therapy: □ oral Ciclosporin □ oral Azathioprine □ oral Methrotrexate □ oral Mycophenolate mofetil □ oral Prednisolone □ subcutaneous Dupilumab □ subcutaneous Omalizumab □ Other (specify below, including route of administration):_____ _____ □ Investigational medication (specify below & route of administration):_____ _____ Start date |__|__||__|__|__||__|__|__|__| Duration (months): |__|__|__| Course number: |__|__|__| *(To count as a separate course, one has to be off therapy for at least 3 months.)* Main treatment dose: |__|__|__| mg Frequency: □ daily □ weekly □ other	Name of therapy: □ oral Ciclosporin □ oral Azathioprine □ oral Methrotrexate □ oral Mycophenolate mofetil □ oral Prednisolone □ subcutaneous Dupilumab □ subcutaneous Omalizumab □ Other (specify below, including route of administration):_____ _____ □ Investigational medication (specify below & route of administration):_____ _____ Start date |__|__||__|__|__||__|__|__|__| Duration (months): |__|__|__| Course number: |__|__|__| *(To count as a separate course, one has to be off therapy for at least 3 months.)* Main treatment dose: |__|__|__| mg Frequency: □ daily □ weekly □ other

Effect: □ Excellent (Clearance) □ Good □ Moderate □ Poor □ Unknown Reason for Stopping: □ Insufficient response □ Relapse (after initial good response) □ Side effect □ Cumulative dose □ Remission □ Other: _____ _____ Adverse effects: O Yes O No	Effect: □ Excellent (Clearance) □ Good □ Moderate □ Poor □ Unknown Reason for Stopping: □ Insufficient response □ Relapse (after initial good response) □ Side effect □ Cumulative dose □ Remission □ Other: _____ _____ Adverse effects: O Yes O No
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Duration (months): |__|__|__| Course number: |__|__|__| *(To count as a separate course, one has to be off therapy for at least 3 months.)* Main treatment dose: |__|__|__| mg Frequency: □ Daily □ Weekly □ Other Effect: □ Excellent (Clearance) □ Good □ Moderate □ Poor □ Unknown Reason for Stopping: □ Insufficient response □ Relapse (after initial good response) □ Side effect □ Cumulative dose □ Remission □ Other: _____ _____ Adverse effects: O Yes O No	Duration (months): |__|__|__| Course number: |__|__|__| *(To count as a separate course, one has to be off therapy for at least 3 months.)* Main treatment dose: |__|__|__| mg Frequency : □ Daily □ Weekly □ Other Effect: □ Excellent (Clearance) □ Good □ Moderate □ Poor □ Unknown Reason for Stopping: □ Insufficient response □ Relapse (after initial good response) □ Side effect □ Cumulative dose □ Remission □ Other: _____ _____ Adverse effects: O Yes O No

Current eczema treatment

Current topical therapy

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

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	□ Crisaborole □ Other; please specify: _____ Start date: |__|__||__|__|__||__|__| Stop date |__|__||__|__|__||__|__| Ongoing □ Times a week: |__|__|__| *or* □ PRN
Current phototherapy	
Type of therapy □ UVA □ UVA-1 □ UVB (unspecified) □ UVAB □ Narrowband-UVB □ Broadband-UVB □ PUVA (oral or other) □ Other: _____ Start date: |__|__||__|__|__||__|__|__|__| Cumulative dose (at discontinuation): |__|__|__| J/cm^2 Stop date |__|__||__|__|__||__|__|__|__| Ongoing □ Effect: □ Excellent (Clearance) □ Good □ Moderate □ Poor □ Unknown	Type of therapy □ UVA □ UVA-1 □ UVB (unspecified) □ UVAB □ Narrowband-UVB □ Broadband-UVB □ PUVA (oral or other) □ Other: _____ Start date: |__|__||__|__|__||__|__|__|__| Cumulative dose (at discontinuation): |__|__|__| J/cm^2 Stop date |__|__||__|__|__||__|__|__|__| Ongoing □ Effect: □ Excellent (Clearance) □ Good □ Moderate □ Poor □ Unknown

Current systemic therapy	
Name of therapy: □ oral Ciclosporin □ oral Azathioprine □ oral Methrotrexate □ oral Mycophenolate mofetil □ oral Prednisolone □ subcutaneous Dupilumab □ subcutaneous Omalizumab □ Other (specify below, including route of administration):_____ □ Investigational medication (specify below, including route of administration):_____ _____ Start date |__|__|__|__|__|__|__|__|__|__| Dose |__|__|__| mg □ Daily □ Weekly □ Other Effect: □ Excellent (Clearance) □ Good □ Moderate □ Poor □ Unknown Ongoing: O Yes O No Stop date |__|__|__|__|__|__|__|__|__|__| Reason for Stopping: □ Insufficient response □ Relapse (after initial good response)	Name of therapy: □ oral Ciclosporin □ oral Azathioprine □ oral Methrotrexate □ oral Mycophenolate mofetil □ oral Prednisolone □ subcutaneous Dupilumab □ subcutaneous Omalizumab □ Other (specify below, including route of administration):_____ □ Investigational medication (specify, including route of administration): _____ _____ Start date |__|__|__|__|__|__|__|__|__|__| Dose |__|__|__| mg □ Daily □ Weekly □ Other Effect: □ Excellent (Clearance) □ Good □ Moderate □ Poor □ Unknown Ongoing: O Yes O No Stop date |__|__|__|__|__|__|__|__|__|__| Reason for Stopping: □ Insufficient response □ Relapse (after initial good response)

□ Side effect □ Cumulative dose □ Remission □ Other: Adverse effects: O Yes O No	□ Side effect □ Cumulative dose □ Remission □ Other: Adverse effects: O Yes O No

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's 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

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.

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
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? _____

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: _____ _____
Diagnosis: _____ _____ Select classification: **Lymphoproliferative** □ Lymphoma	Diagnosis: _____ _____ Select classification: **Lymphoproliferative** □ Lymphoma

□ Myeloma	□ Myeloma
□ Leukaemia	□ Leukaemia
□ Other lymphoproliferative	□ Other lymphoproliferative
Skin cancer	**Skin cancer**
□ Non-melanoma skin cancer	□ Non-melanoma skin cancer
□ Melanoma	□ Melanoma
□ Other skin cancer	□ Other skin cancer
Solid tumours	**Solid tumours**
□ Brain neoplasms	□ Brain neoplasms
□ Glioblastoma	□ Glioblastoma
□ Other	□ Other
Year of diagnosis: |__|__|__|__|	Year of diagnosis: |__|__|__|__|
Status:	Status:
O Active O In remission	O Active O In remission
O Relapsed	O Relapsed
Further details: _____	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: _____	Diagnosis: _____
_____	_____
Year of diagnosis: |__|__|__|__|	Year of diagnosis: |__|__|__|__|
Status:	Status:
O Active	O Active
O Latent	O Latent
O Resolved	O Resolved
Diagnosis: _____	Diagnosis: _____
_____	_____
Year of diagnosis: |__|__|__|__|	Year of diagnosis: |__|__|__|__|
Status:	Status:
O Active	O Active

O Latent O Resolved	O Latent O Resolved
Other comorbidities	
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
Diagnosis: _____ _____ Year of diagnosis: |__|__|__|__| Status: O Ongoing O Resolved	Diagnosis: _____ _____ Year of diagnosis: |__|__|__|__| Status: O Ongoing remission O Resolved

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):	

General eczema questions	
Exposures that trigger disease flares:	O Yes O No If yes, please select (multiple can be selected): □ Stress □ Infections □ Weather condition □ Sweating/exercise □ Exposure to aero-allergens □ Other : _____ _____
Past episodes of skin infections?	O Yes O No If yes, please select: □ Bacterial skin infection (folliculitis, impertigo, etc) □ Viral skin infection (herpes simplex virus –HSV-, infection of AE, Mollusca contagiousa, 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: |__|__|

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 Face (at least one non-flexural patch ≥2cm diameter) O Elbows (patch ≥2cm diameter) O Arms (at least one patch ≥2cm diameter BOTH sides) O Knees (patch ≥2cm diameter) O Legs (at least one patch ≥2cm diameter BOTH sides) O Hands (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
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 scrapping taken?	O Yes O No
Fungal infection (1)	O Yes O No Organism: _____ Body site: _____
Fungal infection (2)	Organism: _____ Body site: _____

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

A*STAR: Baseline	**Site ID:** |___|___|
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: |___|___||___|___|___||___|___|___|___|
Please select: O **EQ5D-5L** (adults) O **EQ5D-Y** (youth)	Test performed: O Yes O No Date: |___|___||___|___|___||___|___|___|___|
Skin specific quality of life score *Please select:* O **DLQI** (≥16 years) O **CDLQI** (4-15 years) O **IDQOL** (<4 years)	Test performed: O Yes O No Date: |___|___||___|___|___||___|___|___|___|
Asthma control test	Test performed: O Yes O No O N/A Date: |___|___||___|___|___||___|___|___|___|

Investigations performed	
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 O Not applicable 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 Not applicable 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: |__|__||__|__|__||__|__|__|__|

Bio-material donation	
Sample for DNA extraction	Has the patient consented? O Yes O No 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 swab for microbiome analyses	Has the patient consented? O Yes O No Has the sample been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__||__|__|__|__|__|__|__|
Tape stripping (≤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*: |__|__||__|__|__|__|__|__|__|
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: Follow up / Encounter

Site ID: |___|___|

Visit name: _____

Patient Study ID: |___|___|___|___|___|___|

Initials: |___|___|___|

Follow up visit details	
Visit date	|__|__| |__|__|__| |__|__|__|__|(dd-mmm-yyyy) Or *visit did not take place* □
Age at this visit:	|__|__|__|
Height and weight	
Height	|__|__|__| (cm) or □ N/A
Weight	|__|__|__|.|__| (kg)
Body Mass Index (BMI)	|__|__|.|__|

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

Topical therapy

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

O Yes O No O N/A

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.

Name:_____	Name:_____
Classification:	Classification:
□ Corticosteroid	□ Corticosteroid
O Mild O Moderate	O Mild O Moderate
O Potent O Ultra-potent	O Potent O Ultra-potent
□ Calcineurin inhibitor	□ Calcineurin inhibitor
O Pimecrolimus 1%	O Pimecrolimus 1%
O Tacrolimus 0.03%	O Tacrolimus 0.03%
O Tacrolimus 0.1%	O Tacrolimus 0.1%
□ Tar ointments	□ Tar ointments
□ Crisaborole	□ Crisaborole
□ Other; please specify:	□ Other; please specify:
_____	_____
Start date: |__|__||__|__|__||__|__|	Start date: |__|__||__|__|__||__|__|
Stop date |__|__||__|__|__||__|__|	Stop date |__|__||__|__|__||__|__|
Times a week: |__|__|__| *or* □ PRN	Times a week: |__|__|__| *or* □ PRN

Phototherapy

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

O Yes O No O N/A

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	Type of therapy
□ UVA	□ UVA
□ UVA-1	□ UVA-1

□ UVB (unspecified) □ UVAB □ Narrowband-UVB □ Broadband-UVB □ PUVA (oral or other) □ Other: _____ Start date: |__|__||__|__|__||__|__|__|__| Cumulative dose (at discontinuation): |__|__|__| J/cm^2 Stop date |__|__||__|__|__||__|__|__|__| Effect: □ Excellent (Clearance) □ Good □ Moderate □ Poor □ Unknown	□ UVB (unspecified) □ UVAB □ Narrowband-UVB □ Broadband-UVB □ PUVA (oral or other) □ Other: _____ Start date: |__|__||__|__|__||__|__|__|__| Cumulative dose (at discontinuation): |__|__|__| J/cm^2 Stop date |__|__||__|__|__||__|__|__|__| Effect: □ Excellent (Clearance) □ Good □ Moderate □ Poor □ Unknown

Systemic therapy (enter all courses separately)

Have there been any changes to the current systemic therapy since last encounter:
O Yes O No O N/A

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:

Name of therapy: □ oral Ciclosporin □ oral Azathioprine □ oral Methrotrexate □ oral Mycophenolate mofetil □ oral Prednisolone	Name of therapy: □ oral Ciclosporin □ oral Azathioprine □ oral Methrotrexate □ oral Mycophenolate mofetil □ oral Prednisolone

□ subcutaneous Dupilumab	□ subcutaneous Dupilumab
□ subcutaneous Omalizumab	□ subcutaneous Omalizumab
□ Other: _____	□ Other: _____
□ Investigational medication: _____	□ Investigational medication: _____
_____	_____
Start date	Start date
|__|__||__|__|__||__|__|__|__|	|__|__||__|__|__||__|__|__|__|
Dose |___|___|___| mg	Dose |___|___|___| mg
□ Daily □ Weekly □ Other	□ Daily □ Weekly □ Other
Effect:	Effect:
□ Excellent (Clearance)	□ Excellent (Clearance)
□ Good	□ Good
□ Moderate	□ Moderate
□ Poor	□ Poor
□ Unknown	□ Unknown
Ongoing: O Yes O No	Ongoing: O Yes O No
Stop date	Stop date
|__|__||__|__|__||__|__|__|__|	|__|__||__|__|__||__|__|__|__|
Reason for Stopping:	Reason for Stopping:
□ Insufficient response	□ Insufficient response
□ Relapse (after initial good response)	□ Relapse (after initial good response)
□ Side effect *(please record in AE section)*	□ Side effect *(please record in AE section)*
□ Cumulative dose	□ Cumulative dose
□ Remission	□ Remission
□ Other: _____	□ Other: _____

Concomitant medication
Have there been changes to the concomitant medication of the patient: O Yes O No If yes, record in Section 5 (concomitant medication) of CRF.

Follow up management (**If main eczema treatment has changed**)	
Main reasons for choosing specific treatment (systemic or phototherapy)	□ N/A □ Comorbidities □ Drug safety and side effect profile □ Anticipation of pregnancy and other family planning issues for both males and females □ Patient's age □ History of prior systemic therapies (including response) □ Accessibility of treatment (including licensing) □ Patient preference □ Therapeutic profile *(select which applies)* O Speed of onset: O Magnitude of effect O Better long term control after drug is stopped □ Other: _____
Reasons for change of therapy	□ N/A □ Lack of efficacy □ Adverse event *(complete Adverse Event CRF)* □ Interaction with other medication □ Child's wish □ Patient's request □ Other (Please specify): _____
Reasons for discontinuation of therapy	□ N/A □ Lack of efficacy □ Adverse event *(complete Adverse Event CRF)* □ Interaction with other medication □ Child's wish □ Patient's request □ Other (please specify): _____

Skin examination (with oversight by a dermatologist)	
Clinical phenotype For guidance on the recognition of flexural and non-flexural eczema 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 folds 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 Face (at least one non-flexural patch ≥2cm diameter) O Elbows (patch ≥2cm diameter) O Arms (at least one patch ≥2cm diameter BOTH sides) O Knees (patch ≥2cm diameter) O Legs (at least one patch ≥2cm diameter BOTH sides) O Hands (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	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) □ 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 scrapping taken?	O Yes O No
Fungal infection (1)	O Yes O No Organism: _____ Body site: _____
Fungal infection (2)	Organism: _____ Body site: _____

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

A*STAR: Follow up / Encounter

Site ID: |___|___|

Visit name: _____

Patient Study ID: |___|___|___|___|___|___|

Initials: |___|___|___|

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: _____ Date of admission: |__|__||__|__|__||__|__|__|__| Date of discharge: |__|__||__|__|__||__|__|__|__| Type of Ward: _____ Date of admission: |__|__||__|__|__||__|__|__|__|

	Date of discharge: |___|___||___|___|___||___|___|___|___| Type of Ward: _____ *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.*

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

A*STAR: Follow up / Encounter

Site ID: |___|___|

Visit name: _____

Patient Study ID: |___|___|___|___|___|___|

Initials: |___|___|___|

Severity assessment (can be done by all trained staff)	
EASI (Score 0-72)	Date: |__|__||__|__|__||__|__|__|__| Total score: |__|__|.|__|
vIGA-AD™ scale (5-point)	□ 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: |__|__||__|__|__||__|__|__|__|
Please select: O **EQ5D-5L** (adults) O **EQ5D-Y** (youth)	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__|
Skin specific quality of life score *Please select:* O **DLQI (**≥16 years) O **CDLQI** (4-15 years) O **IDQOL** (<4 years)	Test performed: O Yes O No Date: |__|__||__|__|__||__|__|__|__|
Asthma control test	Test performed: O Yes O No O N/A Date: |__|__||__|__|__||__|__|__|__|

Adverse events – add adverse events to Section 6 (Adverse Events) of CRF
Has the patient experienced Adverse Events since the last visit?: O Yes O No If yes, record details in Section 6 (Adverse Events) of CRF.

Investigations performed

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 O Not applicable 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 Not applicable 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 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 O Yes O No Date: |__|__||__|__|__||__|__|__|__|

Bio-material donation	
Sample for DNA extraction	Has the patient consented? O Yes O No 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 swab for microbiome analyses	Has the patient consented? O Yes O No Has the sample been taken: O Yes O No Date sample taken as above □ *Or specify*: |__|__||__|__|__||__|__|__|__|
Tape stripping (≤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*: |__|__||__|__|__||__|__|__|__|
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	**Site ID:** |___|___|
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

Current concomitant medication

Concomitant medication *(please provide **generic** names)*	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
Other concomitant medication *(please provide **generic** names)*	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
Other concomitant medication *(please provide **generic** names)*	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
Other concomitant medication *(please provide **generic** names)*	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
Other concomitant medication *(please provide **generic** names)*	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
Other concomitant medication *(please provide **generic** names)*	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
Other concomitant medication *(please provide **generic** names)*	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
Other concomitant medication *(please provide **generic** names)*	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	**Site ID:** |___|___|
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

Adverse Events

Name of event: ____

Description of the event: ____

____

Start date:

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

If resolved, date of resolution:

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

Severity:

O Mild O Moderate O Severe

Relationship to systemic immunomodulator:

☐ Confirmed ☐ Likely ☐ Unlikely

Is it an SAE: O No O Yes

If yes, select category:

☐ Hospitalisation or prolongation

☐ Congenital abnormality

☐ Persistent or significant disability

☐ Life threatening

☐ Death

☐ Medically important event

Impact

☐ Change in dosage

☐ Concomitant medication given

☐ Dose delay

☐ None severity assess

☐ Stop

☐ Switch of therapy

Outcome:

☐ Death

☐ Ongoing

☐ Resolved ☐ Resolved with sequelae

☐ Unkown

Related to study specific procedure (Study Co-ordinating Centre must be notified):

☐ Confirmed ☐ Likely ☐ Unlikely

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
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	☐	☐	☐
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	☐	☐	☐
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	☐	☐	☐
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	☐	☐	☐
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	☐	☐	☐

Adverse Events

Name of event: _____

Description of the event: _____

_____

Start date:

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

Severity:

O Mild O Moderate O Severe

Is it an SAE: O No O Yes

If yes, select category:

□ Hospitalisation or prolongation

□ Congenital abnormality

□ Persistent or significant disability

□ Life threatening

□ Death

□ Medically important event

Outcome:

□ Death

□ Not resolved

□ Resolved

□ Resolved with sequelae

□ Unkown

If resolved, date of resolution:

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

Relationship to systemic immunomodulator:

□ Confirmed □ Likely □ Unlikely

Impact

□ Change in dosage

□ Concomitant medication given

□ Dose delay

□ None

□ Stop

□ Switch of therapy

Related to study specific procedure (Study Co-ordinating Centre must be notified):

□ Confirmed □ Likely □ Unlikely

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
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	□	□	□
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	□	□	□
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	□	□	□
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	□	□	□
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	□	□	□

Adverse Events

Name of event: ____

Description of the event: ____

____

Start date:

|___|___||___|___|___||___|___|___|___|

If resolved, date of resolution:

|___|___||___|___|___||___|___|___|___|

Severity:

O Mild O Moderate O Severe

Relationship to systemic immunomodulator:

☐ Confirmed ☐ Likely ☐ Unlikely

Is it an SAE: O No O Yes

If yes, select category:

☐ Hospitalisation or prolongation
☐ Congenital abnormality
☐ Persistent or significant disability
☐ Life threatening
☐ Death
☐ Medically important event

Impact

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

Outcome:

☐ Death
☐ Not resolved
☐ Resolved
☐ Resolved with sequelae
☐ Unkown

Related to study specific procedure (Study Co-ordinating Centre must be notified):

☐ Confirmed ☐ Likely ☐ Unlikely

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
|___|___||___|___|___||___|___|___|	|___|___||___|___|___||___|___|___|	☐	☐	☐
|___|___||___|___|___||___|___|___|	|___|___||___|___|___||___|___|___|	☐	☐	☐
|___|___||___|___|___||___|___|___|	|___|___||___|___|___||___|___|___|	☐	☐	☐
|___|___||___|___|___||___|___|___|	|___|___||___|___|___||___|___|___|	☐	☐	☐
|___|___||___|___|___||___|___|___|	|___|___||___|___|___||___|___|___|	☐	☐	☐

Adverse Events

Name of event: _____

Description of the event: _____

_____

Start date:

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

Severity:

O Mild O Moderate O Severe

Is it an SAE: O No O Yes

If yes, select category:

□ Hospitalisation or prolongation

□ Congenital abnormality

□ Persistent or significant disability

□ Life threatening

□ Death

□ Medically important event

Outcome:

□ Death

□ Not resolved

□ Resolved

□ Resolved with sequelae

□ Unkown

If resolved, date of resolution:

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

Relationship to systemic immunomodulator:

□ Confirmed □ Likely □ Unlikely

Impact

□ Change in dosage

□ Concomitant medication given

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□ None

□ Stop

□ Switch of therapy

Related to study specific procedure (Study Co-ordinating Centre must be notified):

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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
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	□	□	□
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	□	□	□
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	□	□	□
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	□	□	□
|__|__||__|__|__||__|__|	|__|__||__|__|__||__|__|	□	□	□

A*STAR: End of Study	**Site ID:** |___|___|
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

End of study	
Date end of study was recorded (withdrawal from active participation and linkage of data)	Date: |___|___||___|___|___||___|___|___|___|
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: _____ _____
Lost 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: |__|__||__|__|__||__|__|__|__|