A-STAR: Enrolment & Baseline	
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)?	☐ Yes ☐ No

BEACON Study Co-enrolment	
Is the patient co-enrolled into the BEACON study?	☐ Yes ☐ No
If yes, what was the date of BEACON enrolment?	|__|__| |__|__|__| |___|___|___|___| (DD-MMM-YYYY)
If yes, what is participant's BEACON study ID?	_____

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

A-STAR: Enrolment & Baseline	
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

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).	☐	☐
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.	☐	☐
3	Participant's 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.	☐	☐
4	Diagnosis of atopic eczema in keeping with the UK/Irish diagnostic criteria.	☐	☐
5	Willingness to comply with all study requirements.	☐	☐
6	Competent use of English language, according to patient's age (capable of understanding patient questionnaires).	☐	☐

Inclusion / exclusion criteria			
Exclusion criteria:		**YES**	**NO**
1	Insufficient understanding of the study by the patient and/or parent/guardian.	☐	☐
2	Patients who are currently participating in a randomised clinical trial.	☐	☐

UK diagnostic criteria			
Patients must have:		**YES**	**NO**
1	An itchy skin condition in the last year	☐	☐
Plus three (or more) of the following:			
1	Visible flexural dermatitis	☐	☐

2	History of flexural involvement	☐	☐
3	History of generally dry skin	☐	☐
4	Personal history of atopic disease (children under 4 years: family history of atopic disease)	☐	☐
5	Onset before the age of 2 years (not used if child aged under 4 years)	☐	☐

Baseline date	
Visit date	|__|__| |__|__|__| |__|__|__|__| (DD-MMM-YYYY)

Height and weight	
Height (≤16 years of age)	|__|__|__| . |__| |__| (cm)
Weight	|__|__|__| . |__| (kg)

Demographics	
Date of birth	|__|__| |__|__|__| |__|__|__|__| (DD-MMM-YYYY)
Sex at birth	☐ Female ☐ Male ☐ Undifferentiated ☐ 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: _____
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 (early educational development) □ ISCED 0: Early childhood education (Pre-primary education) □ 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	|__|__|__| |__|__|__|__| (MMM-YYYY) □ Unknown
How was the diagnosis of eczema established?	Clinically: □ Yes □ No Histopathology: □ Yes □ No

A-STAR: Enrolment & Baseline	
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

Past eczema treatments: Topical therapy (multiple can be selected)

□ Corticosteroid

□ Calcineurin inhibitors

□ Tar ointments

□ Crisaborole

□ Other

Past eczema treatments: phototherapy

Enter all treatment courses separately (and for additional therapies print further CRF pages).

□ The patient has **never** received phototherapy before.

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):

_____

Start date: (MMM-YYYY)

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

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 (and for additional therapies print further CRF pages).

Name of therapy:

□ Oral Azathioprine

□ Oral Ciclosporin

□ Oral Methotrexate

□ Oral Mycophenolate mofetil

□ Oral Prednisolone

□ Subcutaneous Methotrexate

□ Subcutaneous Omalizumab

□ Abrocitinib

□ Baricitinib

□ Lebrikizumab

□ Nemolizumab

□ Rocatinlimab

□ Subcutaneous Dupilumab

□ Tralokinumab

□ Upadacitinib

□ 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: Enrolment & Baseline	
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

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

Current eczema treatment
Current topical therapy
Is the patient taking any topical therapy? □ Yes □ No If yes, record details in separate **Current Topical Therapy** paper CRF.
Current phototherapy
Is the patient taking any phototherapy? □ Yes □ No If yes, record details in separate **Current Phototherapy** paper CRF.
New systemic therapy
Please record details in separate **New Systemic Therapy** paper CRF.

Allergic comorbidities	
Asthma	(Physician diagnosed) □ Yes □ No □ Unknown
Allergic rhinoconjunctivitis	(Physician diagnosed) □ Yes □ No □ Unknown
Atopic eye disease	(Physician diagnosed) □ Yes □ No □ Unknown
Eosinophilic oesophagitis	(Physician diagnosed) □ Yes □ No □ Unknown
Food allergy	

Does the patient have any food allergies?	☐ Yes ☐ No If yes, please specify the type(s) of food: _____
If yes, was at least one diagnosed by a doctor?	☐ Yes ☐ No
If yes, how was the diagnosis made? Date of the test performed:	☐ 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?	☐ Yes ☐ No ☐ Unknown
If yes, what was the outcome?	☐ Negative ☐ Positive ☐ Unknown If positive, please specify the type(s) of food contact allergy? _____
Date of the test performed:	|___|___| |___|___|___| |___|___|___|___|
Aeroallergen sensitisation	
Is the patient significantly sensitised to at least one aeroallergen?	☐ Yes ☐ No ☐ Unknown If positive, please specify the type(s) of aeroallergen? _____
If yes, how was the diagnosis made?	☐ Skin prick test ☐ Specific IgE test

A-STAR: Enrolment & Baseline	
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

Date of the test performed:	|___|___| |___|___|___| |___|___|___|___|

Other comorbidities

Malignancies (for additional history print further CRF pages)

Diagnosis:

Lymphoproliferative

□ Lymphoma

□ Myeloma

□ Leukaemia

□ Other lymphoproliferative:

_____

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

Status: O Active O In remission O Relapsed

Skin cancer

□ Non-melanoma skin cancer

□ Melanoma

□ Other skin cancer:

_____

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

Status: O Active O In remission O Relapsed

Solid tumours

□ Brain neoplasms

□ Glioblastoma

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

Status: O Active O In remission O Relapsed

Diagnosis and 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:** ☐ Active ☐ Latent ☐ Resolved

Diagnosis: _____

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

Diagnosis: _____

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

Diagnosis: _____

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

Other comorbidities (for additional history print further CRF pages)

Diagnosis: _____

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

Diagnosis: _____

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

Diagnosis: _____

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

Diagnosis: _____

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

Smoking (not applicable below 16 years of age)

If the patient is below 16 years old, please tick here as N/A □

Has the patient ever smoked more than one cigarette a day?

□ Yes □ No (if no, please ignore the rest of the questions in this section)

If the patient ever smoked, what was the average number of cigarettes /day? _____

Age started smoking (years)

_____

Age stopped smoking (years)

_____

Does the patient currently smoke more than one cigarette a day?

□ Yes □ No

If yes, how many cigarettes does the patient smoke each day? _____

Alcohol consumption (not applicable below 16 years of age)

If the patient is below 16 years old, please tick here as N/A □

Does the patient drink alcohol?

□ Yes □ No (if no, please ignore the rest of the questions in this section)

If yes, how many alcohol units does a patient drink in an average week? N of units_____

Alcoholic Drink	Reference N of units	N of units for the patient
A pint of ordinary beer/lager (4%)	2.3	
A pint of strong lager	3	
A standard (175ml) glass of wine	2	
A large (250ml) glass of wine	3	
A small (25ml) glass of spirits	1	
A 275ml bottled alcopop	1.5	

A-STAR: Enrolment & Baseline	
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

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

Concomitant medication
Is the patient taking any other concomitant medication? ☐ Yes ☐ No If yes, record details in separate **Concomitant Medication** paper CRF.

General eczema questions	
Exposures that trigger disease flares:	☐ Yes ☐ 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?	□ Yes □ No If yes, please select: □ Bacterial skin infection (folliculitis, impertigo, etc) □ Viral skin infection (herpes simplex virus –HSV-, infection of AE, Molluscum contagiosum, etc)
Were any days lost from usual activities (e.g. work, study, holiday etc.) due to eczema <u>in the last 3 months</u>?	□ Yes □ 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.

Pay particular attention to black skin. Redness may be difficult to see and is not an essential criterion but there must be surface change (i.e. scaling, vesicles, oozing, crusting and/or lichenification).

Flexural eczema	□ Yes □ No If yes, which areas are involved (individual patches have to be ≥1cm)? O Ankles O Flexures of the arms (antecubital fossae) O Flexures of the legs (popliteal fossae) O Neck O Skin fold(s) around the eyes
Non-flexural eczema	□ Yes □ No If yes, which areas are involved? O Arms (at least one patch ≥2cm diameter BOTH sides) O Elbows (patch ≥2cm diameter) O Face (at least one non-flexural patch ≥2cm diameter) O Hands (patch ≥2cm diameter BOTH sides) O Knees (patch ≥2cm diameter) O Legs (at least one patch ≥2cm diameter BOTH sides)
Evidence of pompholyx (vesicular eczema) or a history of pompholyx	□ Yes □ No
Discoid eczema (at least 5 circular patches in total, each patch ≥2cm diameter)	□ Yes □ No
Nodular prurigo (≥5 palpable nodules of the skin from long-term scratching (usually on the legs or arms), ≥1cm diameter each)	□ Yes □ No

Follicular eczema (widespread eczematous hair follicle involvement, more commonly seen in darker skin types)	☐ Yes ☐ No
Widespread fine scale predominantly affecting the non-flexural areas of the limbs and body (ichthyosis)	☐ Yes ☐ No
Keratosis pilaris (thickening around the base of hair follicles over upper arms, thighs or cheeks)	☐ Yes ☐ No
Palmar hyperlinearity	☐ Yes ☐ No
Erythroderma (≥90% BSA involvement)	☐ Yes ☐ No

Skin infections	
Current skin infection	☐ Yes ☐ No
Swab taken?	☐ Yes ☐ No
Bacterial infections (1)	☐ Yes ☐ No If yes, organism: O Methicillin Sensitive Staphylococcus Aureus (MSSA) O Methicillin Resistant Staphylococcus Aureus (MRSA) O Streptococcus O Other organism: _____ Body site: _____

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

Fungal infection (2)	Fungal scraping taken: □ Yes □ No Organism: _____ Body site: _____

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

Patient reported outcomes (can use questionnaires user guides to enter answers from the questionnaires/paper CRF onto the eCRF)	
POEM Please indicate who has completed the form: □ Patient □ Caregiver	Test performed: □ Yes □ No Date: |___|___| |___|___|___| |___|___|___|___|
Itch severity (NRS)	Test performed: □ Yes □ No Date: |___|___| |___|___|___| |___|___|___|___|
Please select: □ **EQ5D-Y** (4-16 years old) □ **EQ5D-5L** (adults)	Test performed: □ Yes □ No Date: |___|___| |___|___|___| |___|___|___|___|

Please select: O **IDQOL** (<4 years) O **CDLQI** (4-15 years) O **DLQI** (≥16 years)	Test performed: □ Yes □ No Date: |__|__| |__|__|__| |__|__|__|__|
Asthma control test (≥ 12 years)	Test performed: □ Yes □ No Date: |__|__| |__|__|__| |__|__|__|__|
RECAP (eczema control questionnaire) Please indicate who has completed the form: □ Patient □ Caregiver	Test performed: □ Yes □ No Date: |__|__| |__|__|__| |__|__|__|__|

Safety investigations

Were any safety tests performed for this visit? □ Yes □ No

If yes, record details directly into eCRF, or, on separate **Safety Tests** paper CRF.

Imaging at baseline

Have any of these scans been performed?	**- Chest X-ray:** □ Yes □ No If yes, date: |__|__||__|__|__||__|__|__|__| **- CT scan:** □ Yes □ No If yes, date: |__|__||__|__|__||__|__|__|__| **- MRI scan:** □ Yes □ No If yes, date: |__|__||__|__|__||__|__|__|__| **- Fibroscan:** □ Yes □ No If yes, date: |__|__||__|__|__||__|__|__|__|

	If yes, please tick result: □ Cirrhosis □ Fatty Liver Disease □ Fibrosis □ Normal □ Not performed □ Not reported O Fibroscan Score : _____

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	□ Yes □ No If yes, please specify: _____

Research sample donation (ALL SITES)	
Sample for DNA extraction	Has the patient consented? ☐ Yes ☐ No Has the research sample been taken? ☐ Yes ☐ No If yes, date of research sample taken: |__|__||__|__|__||__|__|__|__|

Bioresource samples (BIORESOURCE SITES ONLY)
Were any Bioresource samples this visit? ☐ Yes ☐ No If yes, record details in separate **Bioresource Samples** paper CRF.

Details of team member completing/overseeing the skin examination	
Name:	
Details of team member completing this CRF	
Name:	
Signature:	
Date:	