

A-STAR: Follow-Up Visit	
Patient Study ID:	Initials:

Encounter	
Visit date	(DD-MMM-YYYY)
Visit Number	or Baseline

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

Demographics	
Have there been any changes to the demographics since baseline?	☐ Yes ☐ No If yes, please 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: _____

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Smoking (not applicable below 16 years of age)
If the patient is below 16 years old, please tick here as N/A ☐
Does the patient currently smoke more than one cigarette a day? ☐ Yes ☐ No (if no, please ignore the rest of the questions in this section)
If yes, how many cigarettes /day does the patient smoke? _____

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 _____																					
<table><tr><th>Alcoholic Drink</th><th>Reference N of units</th><th>N of units for the patient</th></tr><tr><td>A pint of ordinary beer/lager (4%)</td><td>2.3</td><td></td></tr><tr><td>A pint of strong lager</td><td>3</td><td></td></tr><tr><td>A standard (175ml) glass of wine</td><td>2</td><td></td></tr><tr><td>A large (250ml) glass of wine</td><td>3</td><td></td></tr><tr><td>A small (25ml) glass of spirits</td><td>1</td><td></td></tr><tr><td>A 275ml bottled alcopop</td><td>1.5</td><td></td></tr></table>	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	
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Has the patient ever felt that they should cut down on their drinking? ☐ Yes ☐ No Have people annoyed the patient by criticizing them drinking? ☐ Yes ☐ No Has the patient ever felt bad or guilty about their drinking? ☐ Yes ☐ No Has the patient ever had a drink first thing in the morning (as an “eye opener”) to steady your nerves or get rid of a hangover? ☐ Yes ☐ No																					

Current eczema treatment (topical therapy)	
Have there been any changes to the topical therapy since last encounter?	☐ Yes ☐ No If yes, please record and update details in separate Current Topical Therapy paper CRF.

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	If change was related to an Adverse Event, please complete information on Adverse Event CRF/eCRF.
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Current eczema treatment (phototherapy)	
Have there been any changes to the current phototherapy since last encounter since last encounter?	☐ Yes ☐ No If yes, please record and update details in separate <u>Current Phototherapy</u> paper CRF. If change was related to an Adverse Event, please complete information on Adverse Event CRF/eCRF.

Current eczema treatment (systemic therapy)	
Have there been any changes to the current systemic therapy since last encounter since last encounter?	☐ Yes ☐ No If yes, please record and update details in separate <u>Current Systemic Therapy</u> paper CRF. If change was related to an Adverse Event, please complete information on Adverse Event CRF/eCRF.

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Follow-up management (only complete if main eczema treatment has changed)	
Reason for choosing specific treatment (systemic or phototherapy):	☐ Accessibility of treatment (including licensing) ☐ Anticipation of pregnancy and other family planning issues for both males and females ☐ Comorbidities and/or results of baseline investigations ☐ Drug safety and side effect profile ☐ History of prior systemic therapies (including response) ☐ Patient age ☐ Patient preference ☐ Therapeutic profile (<i>select all that apply</i>) ☐ Speed of onset ☐ Magnitude of effect ☐ Better long-term control after drug is stopped ☐ Other: _____
Reason for change of therapy:	☐ Not applicable ☐ Lack of efficacy ☐ Adverse event (complete Adverse Event CRF) ☐ Interaction with other medication ☐ Child's wish ☐ Patient's request ☐ Other: _____
Reason for discontinuation of therapy:	☐ Not applicable ☐ Lack of efficacy ☐ Adverse event (complete Adverse Event paper CRF) ☐ Interaction with other medication ☐ Child's wish ☐ Patient's request ☐ Other: _____

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Concomitant medication
Have there been any changes in concomitant medications since the last visit? ☐ Yes ☐ No If yes, record details in separate Concomitant Medication paper CRF.

General eczema questions	
Were any days lost from usual activities (e.g. work, study, holiday etc.) due to eczema <u>in the last 3 months</u>?	☐ N/A (not applicable at Visit 2 (Week 4)) ☐ Yes ☐ No If yes, how many days in total:
Was there a change in diagnosis after enrolment?	☐ Yes ☐ No If yes, please select: ☐ CTCL ☐ Other: _____

Healthcare resource use	
<u>Since your last visit</u>, have you visited A&E?	☐ Yes ☐ No If yes, was this related to your eczema or to your eczema medication? ☐ Yes ☐ No If yes, state how many times:
<u>Since your last visit</u>, have you been admitted to hospital?	☐ Yes ☐ No If yes, was this related to your eczema or to your eczema medication? ☐ Yes ☐ No If related, please list details: Date of admission:

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	Date of discharge::
	Type of Ward:
	Date of admission:
	Date of discharge::
	Type of Ward:
<i>Please consider completing the <u>Adverse Event</u> and/or <u>Concomitant Medication</u> log.</i>	
<u>Since your last visit</u> , have you seen a specialist at the hospital as an outpatient?	☐ Yes ☐ No If yes, was this related to your eczema or to your eczema medication? ☐ Yes ☐ No If yes, state how many visits:
<u>Since your last visit</u> , have you seen a GP or a nurse?	☐ Yes ☐ No If yes, was this related to your eczema or to your eczema medication? ☐ Yes ☐ No If yes, state how many visits:
<u>Since your last visit</u> , have you been taking any additional medication for your condition?	☐ Yes ☐ No <i>If yes, please remember to update <u>Concomitant Medication</u> form.</i>

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Skin examination (performed on an annual basis with oversight by a dermatologist)	
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 $\geq 1\text{cm}$)? ☐ Ankles ☐ Flexures of the arms (antecubital fossae) ☐ Flexures of the legs (popliteal fossae) ☐ Neck ☐ Skin fold(s) around the eyes
Non-flexural eczema	☐ Yes ☐ No If yes, which areas are involved? ☐ Arms (at least one patch $\geq 2\text{cm}$ diameter BOTH sides) ☐ Elbows (patch $\geq 2\text{cm}$ diameter) ☐ Face (at least one non-flexural patch $\geq 2\text{cm}$ diameter) ☐ Hands (patch $\geq 2\text{cm}$ diameter BOTH sides) ☐ Knees (patch $\geq 2\text{cm}$ diameter) ☐ Legs (at least one patch $\geq 2\text{cm}$ diameter BOTH sides)
Evidence of pompholyx (vesicular eczema) or a history of pompholyx	☐ Yes ☐ No

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Discoid eczema (at least 5 circular patches in total, each patch ≥ 2 cm diameter)	☐ Yes ☐ No
Nodular prurigo (≥ 5 palpable nodules of the skin from long-term scratching (usually on the legs or arms), ≥ 1 cm 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 ($\geq 90\%$ BSA involvement)	☐ Yes ☐ No

Skin infections	
Current skin infection	☐ Yes ☐ No
Swab taken?	☐ Yes ☐ No
Bacterial infections (1)	☐ Yes ☐ No If yes, organism:

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	☐ Methicillin Sensitive Staphylococcus Aureus (MSSA) ☐ Methicillin Resistant Staphylococcus Aureus (MRSA) ☐ Streptococcus ☐ Other organism: _____ Body site: _____
Bacterial infections (2)	☐ Yes ☐ No If yes, organism: ☐ Methicillin Sensitive Staphylococcus Aureus (MSSA) ☐ Methicillin Resistant Staphylococcus Aureus (MRSA) ☐ Streptococcus ☐ Other organism: _____ Body site: _____
Viral infections (1)	☐ Yes ☐ No If yes, organism: ☐ Herpes simplex ☐ Varicella zoster ☐ Other organism: _____ Body site: _____
Viral infections (2)	☐ Yes ☐ No If yes, organism: ☐ Herpes simplex ☐ Varicella zoster

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	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:

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Itch severity (NRS)	Test performed: ☐ Yes ☐ No Date:
<i>Please select:</i> ☐ EQ5D-Y (4-16 years old) ☐ EQ5D-5L (adults)	Test performed: ☐ Yes ☐ No Date:
<i>Please select:</i> ☐ IDQOL (<4 years) ☐ CDLQI (4-15 years) ☐ 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.

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Imaging at follow-up

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 : _____

Adverse events

Did adverse events occur since the last visit? ☐ Yes ☐ No

If yes, record details in separate **Adverse Event** paper CRF.

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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 (if applicable)	
Name:	
Details of team member completing this CRF	
Name:	
Signature:	
Date:	