

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: _____

A-STAR: Follow-Up Visit

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

Initials: | | | |

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.

If change was related to an Adverse Event, please complete information on Adverse Event CRF/eCRF.

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 **Current Phototherapy** 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 **New Systemic Therapy** paper CRF.

If change was related to an Adverse Event, please complete information on Adverse Event CRF/eCRF.

A-STAR: Follow-Up Visit

Patient Study ID:

Initials:

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 (*select all that apply*)
 - 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: _____

A-STAR: Follow-Up Visit

Patient Study ID: |_|_|_|_|_|_|_|_|_|_|

Initials: |_|_|_|_|

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 in the last 3 months?

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

Since your last visit, 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: |_|_|_|

Since your last visit, 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:

|_|_|_|_|_|_|_|_|_|_|

A-STAR: Follow-Up Visit

Patient Study ID:

Initials:

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

A-STAR: Follow-Up Visit

Patient Study ID:

Initials:

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 ≥ 1 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 ≥ 2 cm diameter BOTH sides)
- Elbows (patch ≥ 2 cm diameter)
- Face (at least one non-flexural patch ≥ 2 cm diameter)
- Hands (patch ≥ 2 cm diameter BOTH sides)
- Knees (patch ≥ 2 cm diameter)
- Legs (at least one patch ≥ 2 cm diameter BOTH sides)

Evidence of pompholyx (vesicular eczema) or a history of pompholyx

Yes No

A-STAR: Follow-Up Visit

Patient Study ID:

Initials:

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

Skin infections

Current skin infection	<input type="checkbox"/> Yes <input type="checkbox"/> No
Swab taken?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Bacterial infections (1)	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, organism:

A-STAR: Follow-Up Visit

Patient Study ID:

Initials:

	<p><input type="radio"/> Methicillin Sensitive Staphylococcus Aureus (MSSA)</p> <p><input type="radio"/> Methicillin Resistant Staphylococcus Aureus (MRSA)</p> <p><input type="radio"/> Streptococcus</p> <p><input type="radio"/> Other organism: _____</p> <p>Body site: _____</p>
Bacterial infections (2)	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, organism:</p> <p><input type="radio"/> Methicillin Sensitive Staphylococcus Aureus (MSSA)</p> <p><input type="radio"/> Methicillin Resistant Staphylococcus Aureus (MRSA)</p> <p><input type="radio"/> Streptococcus</p> <p><input type="radio"/> Other organism: _____</p> <p>Body site: _____</p>
Viral infections (1)	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, organism:</p> <p><input type="radio"/> Herpes simplex</p> <p><input type="radio"/> Varicella zoster</p> <p><input type="radio"/> Other organism: _____</p> <p>Body site: _____</p>
Viral infections (2)	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, organism:</p> <p><input type="radio"/> Herpes simplex</p> <p><input type="radio"/> Varicella zoster</p>

A-STAR: Follow-Up Visit

Patient Study ID: |_|_|_|_|_|_|_|_|_|_|

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Itch severity (NRS)	Test performed: <input type="checkbox"/> Yes <input type="checkbox"/> No Date: _ _ _ _ _ _ _ _ _ _
<i>Please select:</i> <input type="checkbox"/> EQ5D-Y (4-16 years old) <input type="checkbox"/> EQ5D-5L (adults)	Test performed: <input type="checkbox"/> Yes <input type="checkbox"/> No Date: _ _ _ _ _ _ _ _ _ _
<i>Please select:</i> <input type="radio"/> IDQOL (<4 years) <input type="radio"/> CDLQI (4-15 years) <input type="radio"/> DLQI (≥16 years)	Test performed: <input type="checkbox"/> Yes <input type="checkbox"/> No Date: _ _ _ _ _ _ _ _ _ _
Asthma control test (≥ 12 years)	Test performed: <input type="checkbox"/> Yes <input type="checkbox"/> No Date: _ _ _ _ _ _ _ _ _ _

Disease control (not applicable at Visit 2 (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?	_ _ _ _

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.

A-STAR: Follow-Up Visit

Patient Study ID: |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

Initials: |_|_|_|_|_|_|

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.

A-STAR: Follow-Up Visit	
Patient Study ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Initials: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Research sample donation (ALL SITES)	
Sample for DNA extraction	Has the patient consented? <input type="checkbox"/> Yes <input type="checkbox"/> No Has the research sample been taken? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, date of research sample taken: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Bioresource samples (BIORESOURCE SITES ONLY)
Were any Bioresource samples this visit? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, record details in separate Bioresource Samples paper CRF.

Details of team member completing/overseeing the skin examination (if applicable)	
Name:	<input type="text"/>
Details of team member completing this CRF	
Name:	<input type="text"/>
Signature:	<input type="text"/>
Date:	<input type="text"/>