A-STAR: Adverse Events

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

Adverse events (for additional medications print further CRF pages) **AE #:** |___|___|

Name of event: ____

Description of the event: ____

____

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

Severity:
☐ Mild ☐ Moderate ☐ Severe

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

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

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

Relationship to systemic immunomodulator:
☐ Confirmed ☐ Likely ☐ Unlikely

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

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

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

Start date *(DD-MMM-YYYY)*		**Stop date** *(DD-MMM-YYYY)*	Mild	Moderate	Severe
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐

A-STAR: Adverse Events	
Patient Study ID: |___|___|___|___|___|___|	**Initials:** |___|___|___|

Adverse events (for additional medications print further CRF pages) — **AE #:** |___|___|

Name of event: ____

Description of the event: ____

____

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

Severity:
☐ Mild ☐ Moderate ☐ Severe

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

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

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

Relationship to systemic immunomodulator:
☐ Confirmed ☐ Likely ☐ Unlikely

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

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

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

Start date *(DD-MMM-YYYY)*		**Stop date** *(DD-MMM-YYYY)*	Mild	Moderate	Severe
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐