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
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐

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|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐
|___|___| |___|___|___| |___|___|___|___|	-	|___|___| |___|___|___| |___|___|___|___|	☐	☐	☐