

BCRD Study

‘Event of Special Interest’ (ESI)

Questionnaires

ESI Pack Version 3: 06/03/2025

These forms are sent to the site for completion when a participant experiences an adverse event that has been classed by the BCRD study team as being of special interest.

This list currently includes:

- Uveitis
- Pregnancy
- Macrophage Activation Syndrome

For all other serious adverse events that are reported (that are not included in the current list of ESIs), additional information will be requested via the database query system.



The University of Manchester



BCRD Event of Special Interest (ESI) report
Macrophage Activation Syndrome (MAS) PRIOR TO biologic therapy

BCRD ID:

HRN:

Please complete a separate form for each separate episode of MAS

Event Details (please annotate with any additional information including relevant clinical signs and symptoms)

Event date:

Diagnosis: Definite MAS ☐ Probable MAS ☐ Possible MAS ☐

List all treatment for systemic JIA at time of event:

List any prior treatment for systemic JIA:

List all treatment given for this episode of MAS:

Please provide values **at time of diagnosis**:

Peak temperature	_____ °C	Lactate dehydrogenase	_____ U/L
Ferritin	_____ ng/ml	Aspartate aminotransferase	_____ units/L
Platelets	_____ x 10 ⁹ /L	Fibrinogen	_____ mg/dL
		Triglycerides	_____ mg/dL

Any symptoms/problems associated with the following at any point during the episode of MAS?Skin rash Yes ☐ No ☐ Details: _____Cardiac Yes ☐ No ☐ Details: _____Respiratory Yes ☐ No ☐ Details: _____

If yes- was mechanical ventilation required?

Gastrointestinal Yes ☐ No ☐ Details: _____Renal Yes ☐ No ☐ Details: _____

If yes- was renal replacement therapy required?

Musculoskeletal Yes ☐ No ☐ Details: _____

If yes- was active arthritis confirmed?

Neurological/psychiatric (including lethargy, seizures, irritability, confusion, headache, mood changes, coma)

Yes ☐ No ☐ Details: _____

Haemorrhagic (including petechiae, ecchymoses, purpura, any bleeding, intravascular coagulation)

Yes ☐ No ☐ Details: _____**Was there an identifiable trigger?**Infection ☐ Disease flare ☐ Other ☐ Details: _____**What was the outcome?**Resolved ☐ Resolved with sequelae ☐ Not resolved ☐ Fatal ☐

If resolved, duration of episode _____ days

Was any new treatment commenced for sJIA? Yes ☐ No ☐ Details: _____

Form completed

By: _____

On: ____/____/____

Thank you for your help! Please return to: BCRD, Arthritis Research UK Epidemiology Unit,
 Unit 4 Rutherford House, 40 Pencroft Way, Manchester Science Park, M15 6SZ, or fax to
 0161 2751640



The University of Manchester



BCRD Event of Special Interest (ESI) report
Macrophage Activation Syndrome (MAS) AFTER COMMENCING biologic therapy

BCRD ID:

HRN:

Please complete a separate form for each separate episode of MAS

Event Details (please annotate with any additional information including relevant clinical signs and symptoms)

Biologic at time of event:

Date of event: ____/____/____

Any previous biologic:

 Diagnosis: Definite MAS ☐ Probable MAS ☐ Possible MAS ☐

List all treatment for systemic JIA at time of event:

List any prior treatment for systemic JIA:

List all treatment given for this episode of MAS:

Please provide values **at time of diagnosis**:

Peak temperature ____ °C

Ferritin ____ ng/ml

Platelets ____ x 10⁹ /L

Lactate dehydrogenase ____ U/L

Aspartate aminotransferase ____ units/L

Fibrinogen ____ mg/dL

Triglycerides ____ mg/dL

Any symptoms/problems associated with the following at any point during the episode of MAS?Skin rash Yes ☐ No ☐ Details: _____Cardiac Yes ☐ No ☐ Details: _____Respiratory Yes ☐ No ☐ Details: _____

If yes- was mechanical ventilation required?

Gastrointestinal Yes ☐ No ☐ Details: _____Renal Yes ☐ No ☐ Details: _____

If yes- was renal replacement therapy required?

Musculoskeletal Yes ☐ No ☐ Details: _____

If yes- was active arthritis confirmed?

Neurological/psychiatric (including lethargy, seizures, irritability, confusion, headache, mood changes, coma)

Yes ☐ No ☐ Details: _____

Haemorrhagic (including petechiae, ecchymoses, purpura, any bleeding, intravascular coagulation)

Yes ☐ No ☐ Details: _____**Was there an identifiable trigger?**Infection ☐ Disease flare ☐ Other ☐ Details: _____**What was the outcome?**Resolved ☐ Resolved with sequelae ☐ Not resolved ☐ Fatal ☐

If resolved, duration of episode ____ days

Was existing biologic stopped? Yes ☐ No ☐Was any new treatment commenced for sJIA? Yes ☐ No ☐ Details: _____

Form completed

By: _____

On: ____/____/____

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**BCRD Event of Special Interest
(ESI) Report PREGNANCY**

BCRD ID:

HRN:

Pregnancy Details:

Last biologic therapy recorded:

Expected date of delivery:

Please provide the following details regarding this event**CONCEPTION**

Was the patient on contraceptives?

☐

Yes

☐

No

Was the pregnancy planned?

☐

Yes

☐

No

Was patient receiving biologic therapy at the time of conception?

☐

Yes

☐

No

Did the patient opt for termination of pregnancy

☐

Yes

☐

No

→ If so, what was the gestation of the pregnancy at termination? _____ weeks

Please provide details of any previous pregnancies, including any complications, outcome and year?

GESTATION

Did the patient have any complications during pregnancy?

☐

Yes

☐

No

Details:

Date of event:

Was the patient hospitalised?

☐

Yes

☐

No

Did the patient experience any infections during pregnancy?

☐

Yes

☐

No

Details:

Date of event:

Was the patient hospitalised?

☐

Yes

☐

No

BCRD Event of Special Interest (ESI) Report PREGNANCY

• Did the patient remain on biologic therapy throughout the pregnancy?

☐

Yes

☐

No

→ If not, did they discontinue in the ☐ first ☐ second or ☐ third trimester?

• Did the patient remain on DMARD therapy throughout the pregnancy?

☐

Yes

☐

No

→ If not, did they discontinue in the ☐ first ☐ second or ☐ third trimester?

DELIVERY

What was the length of gestation?

Weeks

What was the date of delivery?

• Did the patient have any complications during labour and delivery?

☐

Yes

☐

No

If yes, please provide details:

• Did the baby have any congenital abnormalities?

☐

Yes

☐

No

If yes, please provide details:

POSTPARTUM

Did the patient develop any postpartum complications?

☐

Yes

☐

No

If yes, please provide details:

Specifically, did the patient develop any postpartum infections?

☐

Yes

☐

No

If yes, please provide details:

Is the patient breastfeeding?

☐

Yes

☐

No

Did the infant develop any neonatal complications?

☐

Yes

☐

No

If yes, please provide details:

Form completed

By: _____

On: ____/____/____

Thank you for your help!

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**BCRD Event of Special Interest (ESI) Report
UVEITIS**

BCRD ID:

HRN:

**Event Details** (please annotate with any additional information including **relevant clinical signs and symptoms**)

Biologic at time of event:

Date of Event:

Is this a new-onset uveitis? ☐ No ☐ Yes – please provide date of diagnosis: ____/____/____Or a relapse/worsening of uveitis? ☐ No ☐ Yes – please provide date of diagnosis: ____/____/____**Uveitis****localisation:**

- ☐ Right eye
- ☐ Left Eye
- ☐ Both sides

Uveitis type:

- ☐ anterior
- ☐ intermediate
- ☐ posterior
- ☐ panuveitis

Uveitis course

- ☐ Acute (episode characterised by sudden onset and limited duration)
- ☐ Recurrent (repeated episodes separated by periods of inactivity without treatment ≥ 3 months in duration)
- ☐ chronic (persistent uveitis with relapses in ≥ 3 months after discontinuing treatment)
- ☐ Not known

Is uveitis currently active? ☐ YES ☐ NO ☐ DON'T KNOW

• Has this patient had any Uveitis complications? (Please indicate below)?

Complication	No	Yes (please provide date)
Band keratopathy		
Cataract		
Synechiae		
Glaucoma or raised intraocular pressure		
Visual loss <0.4		
Visual loss <0.1		
Other (please specify)		

• Was additional medication necessary? No ☐ Yes ☐ details: _____• Was MTX or biologic medication stopped due to uveitis? No ☐ Yes ☐ details: _____
(please circle)

Form completed

By: _____

On: ____/____/____

Thank you for your help!

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