Pregnancy Reporting Form

Cover sheet for information only

This form is to be used to report details of any pregnancy from the time of informed consent by either a RITAZAREM trial participant or by the partner of a trial participant. Pages 1-3 should be submitted as part of the initial pregnancy notification, and then when the pregnancy outcome is known, page 3 should be completed, and the SAE section can be completed if necessary. Please note, **the mother must give her consent in order for the pregnancy to be followed up.** There is no specific consent form for this, but an email or letter from the PI is sufficient.

Initial Reporting: Please complete as fully as possible and send to the RITAZAREM Trial Coordinator in Cambridge, UK within **24 hours** of being notified.
Follow-up Information: Please complete a new Pregnancy Reporting form with just the study identifier details and all new or missing information only filled in. Please complete the SAE section of the form (page 4 onwards) if the outcome of the pregnancy classifies as an SAE. All SAEs must be followed up until resolution.

A Serious adverse event (SAE) is any untoward medical occurrence or effect that:

- Results in death
- Is life-threatening
- Requires hospitalization or prolongs an existing hospitalization
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly or birth defect
- Other important medical events that may not immediately life-threatening or result in death or hospitalisation, but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition above

Suspected Unexpected Severe Adverse Reaction (SUSAR), (an SAE attributable to rituximab, azathioprine, methotrexate or mycophenolate mofetil not listed in the reference safety information). Initial reports must be sent to the RITAZAREM trial co-ordinator within 24 hours of notification, and to the national competent authority, the Ethics Committee/Institutional Review Board by the lead site in each Member State within **7 days** of notification of the event. Follow-up information must be sent to the national competent authority, the Ethics Committee/Institutional Review Board and Sponsor within **8 days** of the initial report

FAX: + 44 (0) 1223 586767, or e-mail: ritazarem@medschl.cam.ac.uk

RITAZAREM Trial Coordination:

Chief Investigators: Dr David Jayne, Dr Peter Merkel
Trial Coordinators: Kim Mynard, Carol McAlear (USA and Canada)
Fax No: + 44 (0) 1223 586767
Tel No: + 44 (0) 1223 349350
Email: ritazarem@medschl.cam.ac.uk

Pregnancy Reporting Form

RITAZAREM

Please complete details of any pregnancy from the time of informed consent. For guidance on which events to report please refer to the study protocol.
Please fax or scan and email this form to ritazarem@medschl.cam.ac.uk within 24 hours of notification.

Trial details

Study Title: RITAZAREM

R&D No: A092559

EudraCT No: 2012-001102-14

Trial Subject details

Subject ID No:

Date of Birth: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Co-ordinating Site Pregnancy Ref. No:

Further Trial Subject details (Details of female partners of trial participants should be entered in Other Pregnancy Information section)

Gender: ☐ Male ☐ Female **Centre:** **Type of Report:** Initial Report ☐ Follow Up Report ☐

Treatment details (Investigational Medicinal Products for this trial are: Rituximab, Azathioprine, Methotrexate or Mycophenolate Mofetil)

IMP(s) patient was receiving at time of SAE (if applicable)	Dose	Units i.e.: mg	Freq. i.e.: O/D	Route of Admin. Use codes	Date of first dose	Action taken Use codes	End date (if applicable)	Name of Person making decision
					☐☐/☐☐☐/☐☐ (d d / m m m / y y)		☐☐/☐☐☐/☐☐ (d d / m m m / y y)	

Codes:

Route of Admin :		Action taken:	
1 = Oral	4 = Topical	1 = None	4 = Drug stopped permanently
2 = IV	5 = Suppository	2 = Dose Reduced	5 = Unknown
3 = Sub. Cut.	6 = Other	3 = Treatment Delayed	6 = N/A

Date of last treatment given prior to pregnancy: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Was treatment given at full dose prior to pregnancy? ☐ Yes ☐ No*

*Please specify:

Pregnancy Information:

Date of Last menses: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Date Pregnancy confirmed: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Anticipated Date of childbirth: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Mother has consented for Pregnancy monitoring: ☐ Yes ☐ No

History of Previous Pregnancies

Date of Delivery	Gestation (Weeks)	Mode of Delivery	Gender (M/F)	Weight (Kg)	Antenatal Problems	Post natal Problems
☐☐/☐☐☐/☐☐ (d d / m m m / y y)	☐☐					
☐☐/☐☐☐/☐☐ (d d / m m m / y y)	☐☐					
☐☐/☐☐☐/☐☐ (d d / m m m / y y)	☐☐					

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Subject ID No:

Date of Birth: d d / m m m / y y

Co-ordinating Site Pregnancy Ref. No:

Concomitant Treatment

IMP(s) patient was receiving at time of SAE (if applicable)	Dose	Units	Freq.	Route of Admin.	Date of first dose	Action taken	End date (if applicable)	Name of Person making decision
i.e.: Docetaxel		i.e.: mg	i.e.: O/D	Use codes	d d / m m m / y y	Use codes	d d / m m m / y y	
					d d / m m m / y y		d d / m m m / y y	
					d d / m m m / y y		d d / m m m / y y	
					d d / m m m / y y		d d / m m m / y y	

Codes:

Route of Admin :
1 = Oral
2 = IV
3 = Sub. Cut.
4 = Topical
5 = Suppository
6 = Other

Action taken:
1 = None
2 = Dose Reduced
3 = Treatment Delayed
4 = Drug stopped permanently
5 = Unknown
6 = N/A

Any relevant tests/ laboratory data?

Yes ☐ No ☐ (If yes, please specify below and continue on a separate sheet if necessary or attach **anonymised** print outs)

Date	Investigation	Result
d d / m m m / y y		
d d / m m m / y y		

Date	Investigation	Result
d d / m m m / y y		
d d / m m m / y y		

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R&D No: A092559

EudraCT No: 2012-001102-14

Trial Subject details

Subject ID No:

Date of Birth: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Co-ordinating Site Pregnancy Ref. No:

Pregnancy Outcome

Pregnancy Outcome:

- ☐ Not yet known
- ☐ Neonatal death
- ☐ Still birth
- ☐ Uneventful (Normal, healthy baby)
- ☐ Induced abortion
- ☐ Spontaneous abortion
- ☐ Birth defects (please specify in free text)
- ☐ Other (please specify in free text)

Date of delivery: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Gender: ☐ Male ☐ Female

Gestation (weeks): ☐☐

Delivery Method:

Antenatal Problems:

Postnatal Problems:

Other Pregnancy Information: (Give concurrent conditions, medical history, complications during pregnancy and/or birth, birth defects etc)

Birth Weight (KG):	**Baby's Length (CM):**

Cont. on separate sheet if necessary...

PI/CI:

PI/CI Signature:

PI/CI Name Printed:

Date: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Co-ordinating office use only:

Co-ordinator Signature:

Co-ordinator Name Printed:

Date: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Pregnancy SAE Reporting Form

RITAZAREM

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Trial details

Study Title: RITAZAREM

R&D No: A092559

EudraCT No: 2012-001102-14

Trial Subject details

Subject ID No:

Date of Birth: ☐☐/☐☐☐/☐☐ (d d m m m y y)

Co-ordinating Site Pregnancy Ref. No:

Specifics

Type of Report:
Initial Report ☐
Follow Up Report ☐

Centre No:

Has the Chief Investigator/ Principal Investigator been informed of this event prior to the completion of this form? ☐ Yes ☐ No

Gender:
Male ☐
Female ☐

Date Event reported: ☐☐/☐☐☐/☐☐ (d d m m m y y)

Serious Adverse Event

Serious Adverse Event Term:

Date of Onset: ☐☐/☐☐☐/☐☐ (d d m m m y y)

Outcome: ☐
1 = Recovered/ Resolved without Sequelae
2 = Ongoing
3 = Recovered/ Resolved with Sequelae
4 = Worsening
5 = Fatal
6 = Unknown

Date of Resolution: ☐☐/☐☐☐/☐☐ (d d m m m y y)

SAE Term Severity:

Why was the event serious?

- ☐ Resulted in death
- ☐ Life-threatening
- ☐ Required inpatient or prolonged existing hospitalisation
- ☐ Resulted in persistent or significant disability/incapacity
- ☐ Resulted in congenital anomaly/ birth defect
- ☐ Other Important Medical Event (Please specify)

Event Summary:

Severity Grades: - Mild - Moderate - Severe	**Signs and Symptoms:**	**Severity:**	**Signs and Symptoms:**	**Severity:**

(Give concise medical descriptions of the events including all relevant symptoms. **Please specify the severity or grade for all related symptoms**)

Please continue on another sheet if necessary...

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Trial Subject details

Subject ID No:

Date of Birth: ☐☐/☐☐☐/☐☐ (d d m m m y y)

Co-ordinating Site Pregnancy Ref. No:

Treatment details (Investigational Medicinal Products for this trial are: Rituximab, Azathioprine, Methotrexate or Mycophenolate Mofetil)

IMP(s) patient was receiving at time of SAE (if applicable)	Dose	Units *i.e.: mg*	Freq. *i.e.: O/D*	Route of Admin. *Use codes*	Date of first dose	Action taken *Use codes*	Date of last treatment given prior to SAE	Causality *Use codes*	Expected/ Unexpected *Use codes*	Name of Person making decision on causality & expectedness
					☐☐/☐☐☐/☐☐ (d d m m m y y)		☐☐/☐☐☐/☐☐ (d d m m m y y)			

Codes:

Route of Admin :		Action taken:		Causality:		Expectedness:
1 = Oral	4 = Topical	1 = None	4 = Dose reduced & Delayed	1 = Definitely	4 = Unlikely	1 = Expected
2 = IV	5 = Suppository	2 = Dose Reduced	5 = Drug stopped permanently	2 = Probably	5 = Not related	2 = Unexpected
3 = Sub. Cut.	6 = Other (please specify)	3 = Treatment Delayed	6 = Unknown	3 = Possibly	6 = Unknown/ Not assessable	

Was treatment given at full dose prior to event? Yes ☐ No* ☐

*Please specify:

Did reaction reappear after reintroduction of trial medication? Yes ☐ N/A ☐ No ☐

Did reaction abate after trial medication stopped? Yes ☐ N/A ☐ No ☐

Any relevant medical history/ concurrent conditions?

Yes ☐ No ☐ (If yes, please specify below and continue on a separate sheet if necessary)

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EudraCT No: 2012-001102-14

Trial Subject details

Subject ID No:

Date of Birth: d d / m m m / y y

Co-ordinating Site Pregnancy Ref. No:

Please continue on a separate sheet if necessary...

Concomitant medications	**Dose**	**Units** *i.e.: mg*	**Freq.** *i.e.: O/D*	**Route of Admin.** *Use codes*	**Date of first dose**	**Action taken** *Use codes*	**End date (if applicable)**	**Causality** *Use codes*	**Name of Person making decision on causality**
					d d / m m m / y y		d d / m m m / y y		
					d d / m m m / y y		d d / m m m / y y		
					d d / m m m / y y		d d / m m m / y y		
					d d / m m m / y y		d d / m m m / y y		
					d d / m m m / y y		d d / m m m / y y		
					d d / m m m / y y		d d / m m m / y y		

Treatment given to manage SAE	**Dose**	**Units** *i.e.: mg*	**Freq.** *i.e.: O/D*	**Route of Admin.** *Use codes*	**Date of first dose**	**End date (if applicable)**
					d d / m m m / y y	d d / m m m / y y
					d d / m m m / y y	d d / m m m / y y
					d d / m m m / y y	d d / m m m / y y

Codes:

Causality:
1 = Definitely
2 = Probably
3 = Possibly
4 = Unlikely
5 = Not related
6 = Unknown/ Not assessable

Action taken:
1 = None
2 = Dose Reduced
3 = Treatment Delayed
4 = Dose reduced & Delayed
5 = Drug stopped permanently
6 = Unknown

Route of Admin :
1 = Oral
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Co-ordinating Site Pregnancy Ref. No:

Any relevant tests/ laboratory data?

Yes ☐ No ☐ (If yes, please specify below and continue on a separate sheet if necessary or attach **anonymised** print outs)

Date	Investigation	Result
☐☐/☐☐☐/☐☐ (d d / m m m / y y)		
☐☐/☐☐☐/☐☐ (d d / m m m / y y)		

Date	Investigation	Result
☐☐/☐☐☐/☐☐ (d d / m m m / y y)		
☐☐/☐☐☐/☐☐ (d d / m m m / y y)		

No. of Additional pages attached to this form: ☐☐

Co-ordinating Site Trial SAE Ref. No:

Principal Investigator Sign Off:

Was the event considered to be a SUSAR? ☐ Yes ☐ No

PI Signature:

PI Name Printed:

Date: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Chief Investigator Sign Off:

Agree with Principal Investigator assessment of event? ☐ Yes ☐ No *If no, please attach discussion with site & send the outcome as a Follow Up form*

CI Signature:

CI Name Printed:

Date: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Co-ordinating office use only:

MedDRA Term:

Date event received in Co-ordinating office? ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Has the event been reported as a SUSAR by co-ordinating site? ☐ Yes ☐ No ☐ N/A

Date SUSAR reported to Main REC: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Date SUSAR reported to MHRA: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Reported to other PIs? ☐ Yes ☐ No

Co-ordinator Signature:

Co-ordinator Name Printed:

Date: ☐☐/☐☐☐/☐☐ (d d / m m m / y y)