CHECK LIST FORM-MONTH 12

(Please note Month 12 is from enrolment not randomisation)

RITAZAREM

Patient Details

Participant Initials: ☐☐☐

Date of Birth: ☐☐ / ☐☐☐ / ☐☐

Subject ID: ☐☐☐☐☐☐

Evaluation Date: ☐☐ / ☐☐☐ / ☐☐

Were the following forms completed for this visit?

Follow Up Form	☐ Done	☐ Not Done	**BVAS/WG**	☐ Done	☐ Not Done
Concomitant Meds	☐ Done	☐ Not Done	**CDA**	☐ Done	☐ Not Done
Treatment Form	☐ Done	☐ Not Done	**SF-36**	☐ Done	☐ Not Done
Clinical Labs	☐ Done	☐ Not Done	**EQ5D**	☐ Done	☐ Not Done
			PROMIS	☐ Done	☐ Not Done

Research Specimens

Were the following samples taken for this visit?

Serum	☐ Done	☐ Not Done	**Plasma**	☐ Done	☐ Not Done

If any of the forms or research specimens are not done, please explain why below.

Date: ☐☐ / ☐☐☐ / ☐☐ Signature:

Return forms to the RITAZAREM Data Manager by either email (**RITAZAREM@medschl.cam.ac.uk**) or fax (+44 1223 596471)

Cambridge Clinical Trials Unit, Cambridge University Hospitals NHS Foundation Trust, Addenbrookes Hospital, Clinical School Level 3 - Box 111, Hills Road Cambridge CB2 0QQ

FOLLOW UP FORM-MONTH 12

(Please note Month 12 is from enrolment not randomisation)

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

Weight: ☐☐☐.☐ kg **OR** ☐☐☐.☐ lb

1. Has the patient received any of the following treatments since the last evaluation? (check all that apply)

Note: Cumulative rituximab and intravenous methylpredniso(lo)ne doses will be recorded at 24 months

a. Predniso(lo)ne ☐ Yes ☐ No

→ If Yes, most recent dose ☐☐.☐ **mg/day**

Were there any significant deviations* from the glucocorticoid protocol since the last evaluation? ☐ Yes ☐ No

(*a significant deviation is defined as ±25% of the protocol specified dose, for a period greater than 2 weeks)

Please provide details of deviation

b. Rituximab ☐ Yes ☐ No

→ If Yes, ensure **Treatment form(s)** are completed

c. Azathioprine ☐ Yes ☐ No

→ If Yes, most recent dose ☐☐☐ **mg/day**

d. Methotrexate ☐ Yes ☐ No

→ If Yes, most recent dose ☐☐.☐ **mg/week**

e. Mycophenolate Mofetil ☐ Yes ☐ No

→ If Yes, most recent dose ☐☐.☐ **g/day**

f. Pneumocystis prophylaxis ☐ Yes ☐ No

→ If Yes, please specify **Co-trimoxazole** ☐

Dapsone ☐

Other ☐ **Name**

g. Aspirin ☐ Yes ☐ No

h. Warfarin ☐ Yes ☐ No

FOLLOW UP FORM-MONTH 12

(Please note Month 12 is from enrolment not randomisation)

RITAZAREM

Patient Details

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Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

2. Has any dose of Azathioprine, Methotrexate, or Mycophenolate Mofetil changed since the last evaluation? ☐ Yes ☐ No

If yes, date of dose change ☐☐/☐☐☐/☐☐

Please specify reason

Clinical side effect(s)/intolerance ☐ Yes ☐ No

If yes, please give details (eg. rash, nausea etc.)

Laboratory abnormality ☐ Yes ☐ No

If yes, please give details (eg. evidence of bone marrow suppression; renal or liver dysfunction etc.)

Other ☐ Yes ☐ No

If yes, please give details

3. Have any of the following clinical events occurred since the last evaluation?

a. Death ☐ Yes ☐ No If yes, Please complete **Death form**

b. Relapse of vasculitis ☐ Yes ☐ No If yes, Please complete **Relapse form**

c. Infection ☐ Yes ☐ No **If Yes, number of infections since the last visit:** ☐

If yes and non-SAE, Please ensure an **Infection form** is completed for **each infection**

d. SAEs ☐ Yes ☐ No If yes, Please ensure a **SAE form** is completed for **each SAE** and sent, and any additional follow up information supplied.

e. New Malignancy ☐ Yes ☐ No If yes, Please complete a **New Malignancy form**

Date: ☐☐/☐☐☐/☐☐ Signature: ☐

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TREATMENT FORM-RITUXIMAB

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐

Infusion Date: ☐☐/☐☐☐/☐☐

Rituximab ☐ **Induction Phase** ☐ **Maintenance Phase**

(Please circle) Week **1 2 3 4** Month **4 8 12 16 20**

Dose of Rituximab administered on this infusion date: ☐☐☐☐ mg

Was the rituximab infusion administered as per protocol? **YES** ☐ **NO** ☐

If no, please indicate:

☐ **Rituximab not administered as IgG <3g/L**

☐ **Incomplete, specify:**

☐ **Interrupted, specify:**

☐ **Other, specify:**

Was IV methylpredniso(lo)ne administered at this rituximab infusion? **YES** ☐ **NO** ☐

→ **If yes, what dose?** ☐☐☐☐ mg

Date: ☐☐/☐☐☐/☐☐ Signature

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BVAS/WG FORM-MONTH 12

(Birmingham Vasculitis Activity Score for Wegener's Granulomatosis)

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

Instruction

Tick ☐ or O only if abnormality is ascribable to the presence of active AAV: Wegener's Granulomatosis or Microscopic Polyangiitis.

☐ Tick box only if the abnormality is **persistent disease activity** since the last assessment and not worse within the **previous 28 days**

O Tick box only if the abnormality since the last assessment is **newly present or worse** within the **previous 28 days**.

☐ If no items are present in any section, tick "none".

Major items are in bold and marked with an *.

<u>All</u> AAV-related clinical features need to be documented on this form if they are related to active disease.

Use "OTHER" category as needed.

	Persistent	New/Worse	None
1. General			☐
a. Arthralgia/Arthritis	☐	O	
b. Fever (≥ 38 degrees ^{0}C)	☐	O	
2. CUTANEOUS			☐
a. Purpura	☐	O	
b. Skin Ulcer	☐	O	
c. ***Gangrene**	☐	O	
3. MUCOUS MEMBRANES/EYES			☐
a. Mouth ulcers	☐	O	
b. Conjunctivitis/Episcleritis	☐	O	
c. Retro-orbital mass/Proptosis	☐	O	
d. Uveitis	☐	O	
e. ***Scleritis**	☐	O	
f. ***Retinal exudates/Hemorrhage**	☐	O	
4. EAR, NOSE & THROAT			☐
a. Bloody nasal discharge/Nasal crusting/Ulcer	☐	O	
b. Sinus involvement	☐	O	
c. Swollen salivary gland	☐	O	
d. Subglottic inflammation	☐	O	
e. Conductive deafness	☐	O	
f. ***Sensorineural deafness**	☐	O	
5. CARDIOVASCULAR			☐
a. Pericarditis	☐	O	
6. GASTROINTESTINAL			☐
a. ***Mesenteric ischemia**	☐	O	
7. PULMONARY			☐
a. Pleurisy	☐	O	
b. Nodules or Cavities	☐	O	
c. Other infiltrate secondary to WG	☐	O	
d. Endobronchial involvement	☐	O	
e. ***Alveolar hemorrhage**	☐	O	
f. ***Respiratory failure**	☐	O	

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BVAS/WG FORM-MONTH 12

(Birmingham Vasculitis Activity Score for Wegener's Granulomatosis)

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

	Persistent	New/Worse	None
8. RENAL			☐
a. Hematuria (no RBC casts) (≥ 1 + or ≥ 10 RBC/hpf)	☐	O	
b. ***RBC casts and/or Glomerulonephritis on biopsy**	☐	O	
Note: If both hematuria and RBC casts are present, score only the RBC casts (the major item).			
c. ***Rise in Creatinine > 30% or fall in Creatinine clearance > 25%**	☐	O	
9. NERVOUS SYSTEM			☐
a. ***Meningitis**	☐	O	
b. ***Cord lesion**	☐	O	
c. ***Stroke**	☐	O	
d. ***Cranial nerve palsy**	☐	O	
e. ***Sensory peripheral neuropathy**	☐	O	
f. ***Motor mononeuritis multiplex**	☐	O	
10. OTHER (Describe all items and * items deemed major)			☐
a.	☐	O	
b.	☐	O	
c.	☐	O	
d.	☐	O	

11. TOTAL NUMBER OF ITEMS:

Major New/Worse	Minor New/Worse	Major Persistent	Minor Persistent

DETERMINING DISEASE STATUS	**12. CURRENT DISEASE STATUS** (check all that apply)	
Severe Flare: ≥ 1 new/worse Major item	**A. Severe flare/new disease**	☐
Limited Flare: ≥ 1 new/worse Minor item	**B. Limited flare/new disease**	☐
Persistent Disease: Continued (but not new/worse) activity	**C. Persistent disease**	☐
Remission: No active disease, including either new/worse or persistent items. **	**D. Remission**	☐

PHYSICIAN'S GLOBAL ASSESSMENT (PGA). Mark to indicate the amount of Vasculitis disease activity (not including longstanding damage) in the past 28 days.

Remission	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Maximum Activity**
	○	○	○	○	○	○	○	○	○	○	○	

***For the purpose of this trial, the definition of remission is BVAS/WG ≤ 1 (zero or one minor persistent BVAS/WG item)*

Date: ☐☐/☐☐☐/☐☐ Signature:

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CDA FORM-MONTH 12

(Combined Damage Assessment (CDA) Index)

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

Instruction:

This is for recording organ damage that has occurred in patients since the onset of vasculitis. Co-morbidity that exists before the onset of vasculitis must not be scored. A new patient should have a CDA of zero unless they have had vasculitis for at least 6 months, and the damage has developed or become worse since the onset of vasculitis. A finding must be present for 6 months to be scored. Damage is irreversible, and only rarely should a scored item not be carried forward. Where applicable, please include the primary data values, in addition to marking the relevant box.

Musculoskeletal		***None:*** ☐
	No	**Yes**
Osteoporosis/vertebral collapse	☐	☐
Bone fracture:	☐	☐
Due to renal dystrophy	☐	☐
Due to osteoporosis	☐	☐
Due to both	☐	☐
Muscle atrophy due to glucocorticoids:	☐	☐
Normal strength, atrophy on exam	☐	☐
Weak on examination, normal ADLs	☐	☐
Weak and has difficulty with ADLs	☐	☐
Avascular necrosis	☐	☐
Deforming/erosive arthritis	☐	☐
Osteomyelitis	☐	☐
Skin/Membranes		***None:*** ☐
	No	**Yes**
Alopecia	☐	☐
Mouth ulcers	☐	☐
Cutaneous scarring	☐	☐
Cutaneous ulcers	☐	☐
Striae	☐	☐
Gangrene with permanent tissue loss	☐	☐
Easy bruising	☐	☐

Ocular						***None:*** ☐
	No	**Yes**	**Please circle one**			
Proptosis	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Pseudotumor	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Scleral thinning	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Scleral perforation	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Optic nerve edema	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Optic nerve atrophy	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Retinal changes	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Retinal artery occlusion	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Retinal vein occlusion	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Low vision	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Diplopia	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Blindness	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Cataracts	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Glaucoma	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Orbital wall destruction	☐	☐	**If Yes,**	**Left**	**Right**	**Both**

CDA FORM-MONTH 12

(Combined Damage Assessment (CDA) Index)

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

Ear

None: ☐

	No	Yes	Please circle one			
Sensorineural hearing loss	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Conductive hearing loss	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Tympanic membrane perforation or scarring	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Tinnitus	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Eustachian tube dysfunction	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Auricular cartilage deformity	☐	☐	**If Yes,**	**Left**	**Right**	**Both**
Cholesteatoma	☐	☐	**If Yes,**	**Left**	**Right**	**Both**

Nose

None: ☐

	No	Yes
Chronic rhinitis/crusting	☐	☐
Nasolacrimal duct obstruction	☐	☐
Nasal bridge collapse/saddle nose	☐	☐
Nasal septal perforation	☐	☐
Anosmia	☐	☐
Ageusia	☐	☐

Sinuses

None: ☐

	No	Yes
Chronic sinusitis	☐	☐
Neo-ossification of sinuses	☐	☐

Subglottic stenosis

None: ☐

	No	Yes
No intervention required	☐	☐
Intervention required	☐	☐

Pulmonary

None: ☐

	No	Yes
Irreversible loss of lung function	☐	☐
Fixed large airway obstruction	☐	☐
Pulmonary hypertension	☐	☐
Pulmonary fibrosis	☐	☐
Pulmonary embolism	☐	☐
Pulmonary infarction	☐	☐
Vena caval filter	☐	☐
Continuous oxygen dependency	☐	☐
Chronic asthma	☐	☐
Pleural fibrosis	☐	☐
Chronic breathlessness	☐	☐
Forced Vital Capacity (FVC) (Liters)		
Forced Expiratory volume in 1 second(FEV1) (Liters)		
Right Ventricular Systolic Pressure (mm Hg)		

CDA FORM-MONTH 12

(Combined Damage Assessment (CDA) Index)

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Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

Cardiac

None: ☐

	No	Yes
Hypertension (defined as BP 142 / 90):	☐	☐
Pre-HTN: SBP 130-139 or DBP 80-89	☐	☐
Stage I: SBP 140-149 or DBP 90-99	☐	☐
Stage II: SBP >149 or DBP >99	☐	☐
Angina	☐	☐
Myocardial infarction	☐	☐
Percutaneous coronary intervention	☐	☐
Coronary artery bypass graft	☐	☐
LV dysfunction: EF: %	☐	☐
NYHA Class I/II	☐	☐
NYHA class III/IV	☐	☐
Third degree AV block	☐	☐
Valvular Disease:	☐	☐
Specify:		
Pericarditis or Pericardectomy	☐	☐

Vascular Disease

None: ☐

	No	Yes
Absent pulses in 1 limb	☐	☐
2nd episode of absent pulses in 1 limb	☐	☐
Major vessel stenosis	☐	☐
Claudication > 3 months	☐	☐
Minor tissue loss	☐	☐
Major tissue loss	☐	☐
Subsequent major tissue loss	☐	☐
Deep venous thrombosis	☐	☐
Complicated venous thrombosis	☐	☐
Cartoid artery disease	☐	☐
Renal artery stenosis	☐	☐
Arterial thrombosis/occlusion	☐	☐
Specify:		

Gastrointestinal

None: ☐

	No	Yes
Gut infarction/resection	☐	☐
Hepatic fibrosis	☐	☐
Mesenteric insufficiency/pancreatitis	☐	☐
Esophageal stricture/surgery	☐	☐
Chronic peritonitis	☐	☐

CDA FORM-MONTH 12

(Combined Damage Assessment (CDA) Index)

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Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

Renal

None: ☐

	No	Yes
Estimated/measured GFR<50%	☐	☐
Chronic kidney disease	☐	☐
End-stage renal disease	☐	☐
Dialysis	☐	☐
Renal transplant	☐	☐
Proteinuria:	☐	☐
<3g/24h	☐	☐
>3g/24h	☐	☐

Neurologic

None: ☐

	No	Yes
Seizures	☐	☐
Transverse myelitis	☐	☐
Sensory polyneuropathy	☐	☐
Mild	☐	☐
Moderate	☐	☐
Severe	☐	☐
Motor Neuropathy (mononeuritis)	☐	☐
Neuropathic pain	☐	☐
Cerebrovascular accident	☐	☐
2nd cerebrovascular accident	☐	☐
Cranial nerve lesion:	☐	☐
Specify:		

Psychiatric

None: ☐

	No	Yes
Cognitive impairment	☐	☐
Anxiety disorder due to vasculitis	☐	☐
Mood disorder due to vasculitis	☐	☐
Major pschosis	☐	☐

Endocrine

None: ☐

	No	Yes
Diabetes insipidus	☐	☐
Premature ovarian failure	☐	☐
Azoospermia	☐	☐
Impaired Fasting glucose	☐	☐
Diabetes mellitus	☐	☐

CDA FORM-MONTH 12

(Combined Damage Assessment (CDA) Index)

RITAZAREM

Patient Details

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Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

Hematology/Oncology

None: ☐

	No	Yes
Bladder cancer	☐	☐
Cervical cancer	☐	☐
Hemotopoetic malignancy	☐	☐
Solid tumor malignancy	☐	☐
Specify:		
Refractory cytopenia	☐	☐
Myelodysplastic syndrome	☐	☐

Other

None: ☐

	No	Yes
Weight gain > 10lbs/4.4Kg	☐	☐
Fibromyalgia	☐	☐
Drug induced cystitis:	☐	☐
With microscopic hematuria	☐	☐
With gross hematuria	☐	☐
Requiring transfusion	☐	☐
Requiring cystectomy	☐	☐
Damage requiring surgical intervention:	☐	☐
Specify:		
Medications to manage side effects of immunosuppressive agents	☐	☐
Specify:		
Hypogammaglobulinemia	☐	☐
Other	☐	☐
Specify:		

Thank you for completing the RITAZAREM CDA Form.

Date: ☐☐/☐☐☐/☐☐ Signature:

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CLINICAL LABORATORY TESTS FORM

RITAZAREM

Patient Details

Participant Initials: ☐☐☐

Date of Birth: ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐

Evaluation Date: ☐☐/☐☐☐/☐☐

Please select Assessment Point

☐ Screening ☐ Baseline (Month 0) ☐ Month 1.5 ☐ Month 3 ☐ Month 4 ☐ Month 8

☐ Month 12 ☐ Month 16 ☐ Month 20 ☐ Month 24 ☐ Month 27 ☐ Month 30

☐ Month 36 ☐ Month 42 ☐ Month 48

Laboratory Data

Clinical Labs

Haemoglobin

☐☐☐.☐ ☐g/dL ☐g/L ☐mmol/L

Date Test Done ☐☐/☐☐☐/☐☐ ☐Not measured

Platelets ☐☐☐ ☐x 10^9/L **Date Test Done** ☐☐/☐☐☐/☐☐ ☐Not measured

WBC ☐☐.☐ ☐x 10^3/mm^3 ☐x 10^9/L **Date Test Done** ☐☐/☐☐☐/☐☐ ☐Not measured

ESR ☐☐☐ ☐mm/h **Date Test Done** ☐☐/☐☐☐/☐☐ ☐Not measured

Creatinine

☐☐☐☐.☐ ☐µmol/L ☐g/dL ☐mg/dL

Date Test Done ☐☐/☐☐☐/☐☐ ☐Not measured

CRP ☐☐☐.☐ ☐mg/L ☐mg/dL

Date Test Done ☐☐/☐☐☐/☐☐ ☐Not measured

ALT ☐☐☐ ☐U/L

or

AST ☐☐☐ ☐U/L

Date Test Done ☐☐/☐☐☐/☐☐ ☐Not measured

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CLINICAL LABORATORY TESTS FORM

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐ **Assessment Point:** ☐

Laboratory Data

ANCA

Anti-PR3 ☐Positive ☐Negative **Date Test Done** ☐☐/☐☐☐/☐☐ ☐Not measured

Anti-MPO ☐Positive ☐Negative **Date Test Done** ☐☐/☐☐☐/☐☐ ☐Not measured

Lymphocyte markers

CD19

☐☐.☐☐☐☐ ☐x $10^3/mm^3$ ☐x $10^9/L$ ☐Cells/µL **Date Test Done** ☐☐/☐☐☐/☐☐ ☐Not measured

☐☐.☐ ☐%

Immunoglobulins

IgG ☐☐☐☐.☐ ☐g/L ☐mg/dL **Date Test Done** ☐☐/☐☐☐/☐☐ ☐Not measured

If IgG result is below 3g/L or 300mg/dL and patient is randomised to rituximab, please repeat IgG level in the month prior to the next scheduled rituximab dose. DO NOT administer further rituximab until IgG level has risen above 3g/L or 300mg/dL

IgM ☐☐☐☐.☐ ☐g/L ☐mg/dL ☐☐/☐☐☐/☐☐ ☐Not measured

IgA ☐☐☐☐.☐ ☐g/L ☐mg/dL ☐☐/☐☐☐/☐☐ ☐Not measured

Date: ☐☐/☐☐☐/☐☐ Signature: ☐

Return forms to the RITAZAREM Data Manager by either email (**RITAZAREM@medschl.cam.ac.uk**) or fax (+44 1223 596471)

Cambridge Clinical Trials Unit, Cambridge University Hospitals NHS Foundation Trust, Addenbrookes Hospital, Clinical School Level 3 - Box 111, Hills Road Cambridge CB2 0QQ

CONCOMITANT MEDICATIONS FORM

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐☐/☐☐

Please select Assessment Point

☐ Month 1.5 ☐ Month 3 ☐ Month 4 ☐ Month 8 ☐ Month 12 ☐ Month 16

☐ Month 20 ☐ Month 24 ☐ Month 27 ☐ Month 30 ☐ Month 36 ☐ Month 42

☐ Month 48

Concomitant medications (add more pages if applicable) Page ☐ of ☐

All drugs that are on previous Concomitant Medication Lists MUST be on this list if they are ongoing.

Please record ONLY PRESCRIBED MEDICATIONS. It is not necessary to list vitamins and other dietary supplements.

Please use key to complete the table

***Category** 1=Anticoagulant/Antiplatelet 2=IVIg 3=Antimicrobial (Antibiotic, Antiviral, Antifungal) 4=Other

****Frequency** 1=Once daily 2=Twice daily 3=Three times daily 4=Four times a day 5=Alternate days 6=Weekly 7=Other (Please specify) 0=As required

Medication Name Please use GENERIC NAMES ONLY	* Category	Dose	Units (eg mg)	**Frequency	New since last trial visit?	Comments
					Y/N	
					Y/N	
					Y/N	
					Y/N	
					Y/N	
					Y/N	
					Y/N	
					Y/N	
					Y/N	
					Y/N	

Date: ☐☐/☐☐☐☐/☐☐ Signature:

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EQ5D FORM-MONTH 12

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

Section to be completed by the RITAZAREM Participant

Instructions for the RITAZAREM participant:
By placing a tick in one box in each group below, please indicate which statement best describes your own health state today. Do not tick more than one box in each group.

Mobility

I have no problems walking about ☐
I have some problems in walking about ☐
I am confined to bed ☐

Self-care

I have no problems with self-care ☐
I have some problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

Usual activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

Pain/Discomfort

I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

Anxiety/Depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

Please turn over for the final question

EQ5D FORM-MONTH 12

RITAZAREM

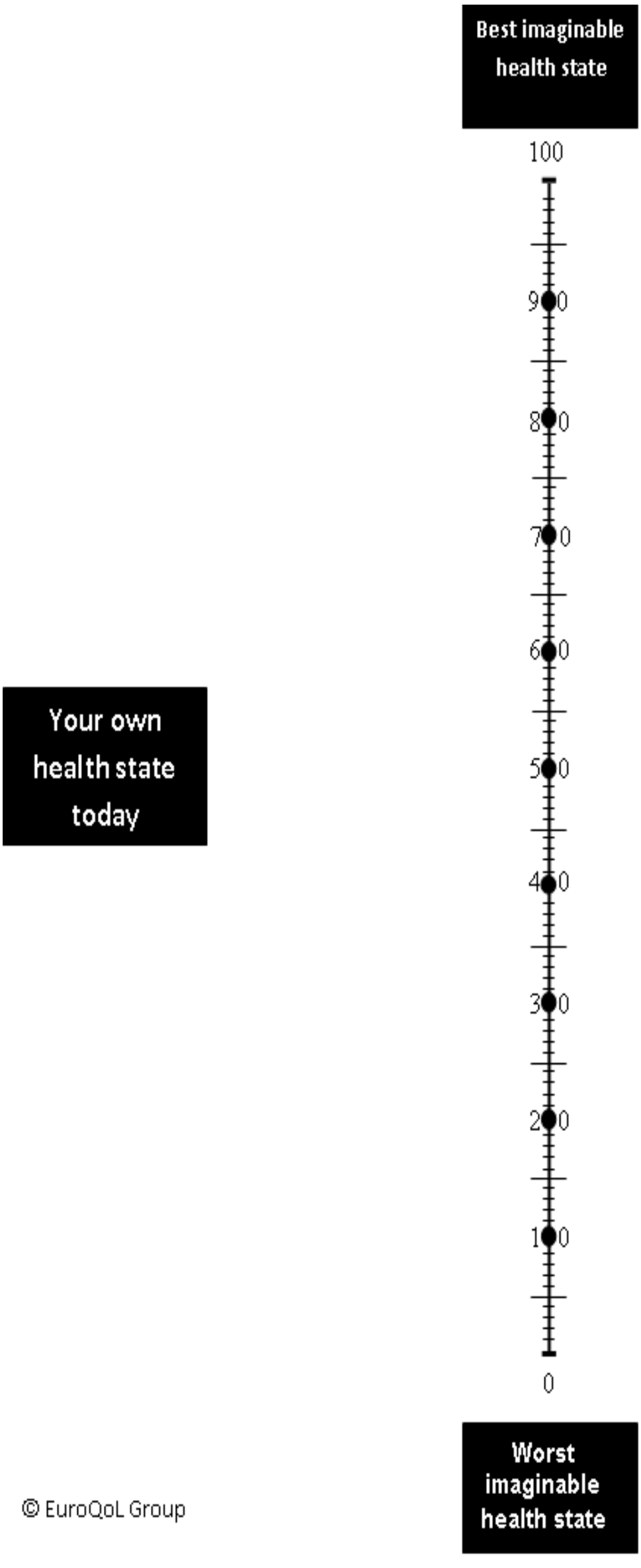
Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked by 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is.



PROMIS QUESTIONNAIRE MONTH 12

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Study ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

1. Fatigue

During the past 7 days	Not at all	A little bit	Somewhat	Quite a bit	Very much
I feel fatigued?	☐	☐	☐	☐	☐
I have trouble starting things because I am tired?	☐	☐	☐	☐	☐
How run-down did you feel on average?	☐	☐	☐	☐	☐
How fatigued were you on average?	☐	☐	☐	☐	☐

2. Pain

During the past 7 days	Not at all	A little bit	Somewhat	Quite a bit	Very much
How much did pain interfere with your day to day activities?	☐	☐	☐	☐	☐
How much did pain interfere with work around the home?	☐	☐	☐	☐	☐
How much did pain interfere with your ability to participate in social activities?	☐	☐	☐	☐	☐
How much did pain interfere with household chores?	☐	☐	☐	☐	☐

3. Physical Ability

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do it
Are you able to do chores such as vacuuming or yard work?	☐	☐	☐	☐	☐
Are you able to go up and down stairs at a normal pace?	☐	☐	☐	☐	☐
Are you able to go for a walk of at least 15 minutes?	☐	☐	☐	☐	☐
Are you able to run errands and shop?	☐	☐	☐	☐	☐

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PROMIS QUESTIONNAIRE MONTH 12

RITAZAREM

Patient Details

Participant Initials: ☐☐☐

Date of Birth: ☐☐ / ☐☐☐ / ☐☐

Study ID: ☐☐☐☐☐☐

4. PATIENT'S GLOBAL ASSESSMENT. Please mark the circle below that best indicates how active you believe your vasculitis has been in the past 28 days. Consider how much your vasculitis (the disease <u>itself</u>) is causing you problems. <u>Do not</u> count the effects of other medical problems or side effects of medications.

Remission	0	1	2	3	4	5	6	7	8	9	10	Maximum Activity
	○	○	○	○	○	○	○	○	○	○	○	

Instructions to RITAZAREM Participant

Please check that you have answered each question on every page

Please return this form to your RITAZAREM Clinician, Research Nurse or Coordinator

Thank you for taking the time to complete the RITAZAREM PROMIS Questionnaire.

SF-36 (V1) FORM-MONTH 12

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐ **Evaluation Date:** ☐☐/☐☐☐/☐☐

Section to be completed by the RITAZAREM Participant

Instructions for the RITAZAREM participant:

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing the survey!

Your Health and Well Being

1. <u>In general</u>, Would you say your health is:

*(Please tick **one** box)*

Excellent ☐

Very Good ☐

Good ☐

Fair ☐

Poor ☐

2. Compared to one year ago, how would you rate your health in general now?

*(Please tick **one** box)*

Much better now than one year ago ☐

Somewhat better now than one year ago ☐

About the same as one year ago ☐

Somewhat worse now than one year ago ☐

Much worse now than one year ago ☐

SF-36 (V1) FORM-MONTH 12

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐

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3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

*(Please tick **one** box on each line)*

		Yes, Limited a lot	Yes, Limited a little	No, Not Limited at all
A.	**<u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports**	☐	☐	☐
B.	**<u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling or playing golf**	☐	☐	☐
C.	**Lifting or carrying groceries**	☐	☐	☐
D.	**Climbing <u>several</u> flights of stairs**	☐	☐	☐
E.	**Climbing <u>one</u> flight of stairs**	☐	☐	☐
F.	**Bending, kneeling or stooping**	☐	☐	☐
G.	**Walking <u>more than a mile</u>**	☐	☐	☐
H.	**Walking <u>several hundred yards</u>**	☐	☐	☐
I.	**Walking <u>one hundred yards</u>**	☐	☐	☐
J.	**Bathing and dressing yourself**	☐	☐	☐

4. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

*(Please tick **one** box on each line)*

		Yes	No
A.	**Cut down on the amount of time you spent on work or other activities**	☐	☐
B.	**Accomplished less than you would like**	☐	☐
C	**Were limited in the kind of work or other activities**	☐	☐
D.	**Had difficulty performing the work or other activities (i.e. it took more effort)**	☐	☐

SF-36 (V1) FORM-MONTH 12

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐

5. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

*(Please tick **one** box on each line)*

		Yes	No
A.	**Cut down on the <u>amount of time</u> you spent on work or other activities**	☐	☐
B.	**Accomplished less than you would like**	☐	☐
C.	**Did work or other activities less carefully than usual**	☐	☐

6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

*(Please tick **one** box)*

Not at all ☐

Slightly ☐

Moderately ☐

Quite a bit ☐

Extremely ☐

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

*(Please tick **one** box)*

None ☐

Very Mild ☐

Mild ☐

Moderate ☐

Severe ☐

Very Severe ☐

SF-36 (V1) FORM-MONTH 12

RITAZAREM

Patient Details

Participant Initials: ☐☐☐

Date of Birth: ☐☐ / ☐☐☐ / ☐☐

Subject ID: ☐☐☐☐☐☐

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8. During the <u>past 4 weeks</u> how much did <u>pain</u> interfere with your normal work (including work both outside the home and housework)?

*(Please tick **one** box)*

Not at all ☐

Slightly ☐

Moderately ☐

Quite a bit ☐

Extremely ☐

---

9. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question please give the one answer that comes closest to the way you have been feeling

*(Please tick **one** box on each line)*

How much time during <u>the past 2 weeks</u>:

		All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
A.	**Did you feel full of life?**	☐	☐	☐	☐	☐	☐
B.	**Have you been very nervous?**	☐	☐	☐	☐	☐	☐
C.	**Have you felt so down in the dumps that nothing could cheer you up?**	☐	☐	☐	☐	☐	☐
D.	**Have you felt calm and peaceful?**	☐	☐	☐	☐	☐	☐
E.	**Did you have a lot of energy?**	☐	☐	☐	☐	☐	☐
F.	**Have you felt downhearted and depressed?**	☐	☐	☐	☐	☐	☐
G.	**Did you feel worn out?**	☐	☐	☐	☐	☐	☐
H.	**Have you been happy?**	☐	☐	☐	☐	☐	☐
I.	**Did you feel tired?**	☐	☐	☐	☐	☐	☐

SF-36 (V1) FORM-MONTH 12

RITAZAREM

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** ☐☐/☐☐☐/☐☐

Subject ID: ☐☐☐☐☐☐

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc.)?

*(Please tick **one** box)*

All of the time ☐

Most of the time ☐

Some of the time ☐

A little of the time ☐

None of the time ☐

11. How TRUE or FALSE is each of the following statements for you?

*(Please tick **one** box on each line)*

		Definitely true	Mostly true	Don't know	Mostly false	Definitely false
A.	**I seem to get sick a little easier than other people**	☐	☐	☐	☐	☐
B.	**I am healthy as anybody I know**	☐	☐	☐	☐	☐
C.	**I expect my health to get worse**	☐	☐	☐	☐	☐
D.	**My health is excellent**	☐	☐	☐	☐	☐

Instructions to RITAZAREM Participant

Please check that you have answered each question on every page

Please return this form to your RITAZAREM Clinician, Research Nurse or Coordinator

Thank you for taking the time to complete the RITAZAREM SF-36 form