

Participant ID:

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Participant initials:

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WEEK 6 CRF



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Date of visit	D	D	M	M	M	Y	Y	Y	Y
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SECTION 1 – PHYSICAL EXAMINATION

Measurement of target lesion	Max longitudinal length (mm)								
	Max perpendicular width (mm)								
PG status	Target lesion healed – no longer using dressings	<input type="checkbox"/> (1)							
	Target lesion still requiring treatment	<input type="checkbox"/> (2)							
	Target lesion healed but ongoing treatment for other lesions	<input type="checkbox"/> (3)							
If applicable, the date that the target lesion stopped requiring dressings	D	D	M	M	M	Y	Y	Y	Y

SECTION 2 – MEDICATION

		Yes	No
Is the patient currently taking any of the following drugs?	Methotrexate	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
	Azathioprine	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
	Leflunomide	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
	Anti-TNF	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
	Mercaptopurine (6-MP, Puri-Nethol®)	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
	Tetracyclines	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
	Mycophenolate	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
Has the patient taken any other treatment that could influence pyoderma gangrenosum? Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (2)	If yes, please give details of drug name(s) (dose not required):		

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SECTION 3 – INVESTIGATOR GLOBAL ASSESSMENT OF EFFICACY

Since the **BASELINE** visit, has the **target lesion** improved?

Grade		Tick below
0	Completely clear: except for possible residual hyperpigmentation	<input type="checkbox"/> (0)
1	Almost clear: very significant clearance (about 90%); however, patchy remnants of dusky erythema and/or very small ulceration	<input type="checkbox"/> (1)
2	Marked improvement: significant improvement (about 75%); however, a small amount of disease remaining (i.e remaining ulcers, although have decreased in size, minimal erythema and/or barely perceptible border elevation)	<input type="checkbox"/> (2)
3	Moderate improvement: intermediate between slight and marked; representing about 50% improvement	<input type="checkbox"/> (3)
4	Slight improvement: some improvement (about 25%); however, significant disease remaining (i.e remaining ulcers with only minor decrease in size, erythema or border elevation)	<input type="checkbox"/> (4)
5	No change from baseline	<input type="checkbox"/> (5)
6	Worse	<input type="checkbox"/> (6)



SECTION 4 – INFLAMMATION ASSESSMENT OF THE TARGET LESION

Please tick one box only for each section

Erythema		
None	<i>No erythema</i>	<input type="checkbox"/> (0)
Slight	<i>Mild pink colour</i>	<input type="checkbox"/> (1)
Moderate	<i>Moderate pink colour</i>	<input type="checkbox"/> (2)
Severe	<i>Reddish colour</i>	<input type="checkbox"/> (3)
Very severe	<i>Dark red or violaceous</i>	<input type="checkbox"/> (4)
Border elevation		
None	<i>Border is flat with ulcer and surrounding skin, no elevation</i>	<input type="checkbox"/> (0)
Slight	<i>Slight elevation of border above ulceration and surrounding skin</i>	<input type="checkbox"/> (1)
Moderate	<i>Noticeable elevation of border above ulceration and surrounding skin</i>	<input type="checkbox"/> (2)
Severe	<i>Significant elevation of border above ulceration and surrounding skin</i>	<input type="checkbox"/> (3)
Very severe	<i>Border rolled high above ulceration and surrounding skin</i>	<input type="checkbox"/> (4)
Exudate		
None	<i>Wound is dry</i>	<input type="checkbox"/> (0)
Slight	<i>Spotting of clear fluid</i>	<input type="checkbox"/> (1)
Moderate	<i>Moderate amount of discharge, partially discoloured</i>	<input type="checkbox"/> (2)
Severe	<i>Heavy, discoloured discharge</i>	<input type="checkbox"/> (3)
Very severe	<i>Copious, offensive or blood stained discharge</i>	<input type="checkbox"/> (4)

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SECTION 5 – TRIAL CHECKLIST			
For patients in either the RCT or observational study, have the following been done?	Yes	No	NA
Completed the <i>Trial Medication change log</i> if applicable	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (8)
Recorded this visit in the hospital notes	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
For patients in the RCT only, have the following been done?			
<i>Routine samples</i> as you would in normal care? <i>Recommended samples are: full blood count, urea & electrolytes, CRP, rheumatoid factor, auto-antibodies, ANCA, serum immunoglobulins, ulcer swab for bacteriology</i>	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
<i>Urine pregnancy test</i> (women of child-bearing potential only) and pregnancy advice	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (8)
Digital images of the target lesion <i>Please refer to the digital image guidance in Section 5 of this patient file and complete the digital image log</i> <i>Remember to take the image of the same lesion you took an image of at the baseline appointment</i>	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
Completed the <i>Adverse Event log</i> if applicable	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (8)

SECTION 6 – CRF SIGN-OFF	
I confirm that the information contained in this CRF is accurate to the best of my knowledge:	
_____	_____
Signed	Date

- Please send the TOP copy of all sheets in this CRF to the co-ordinating centre in the envelope provided in the patient file.
- BOTTOM copies should be filed in the patient file
- Please consider this patient for systemic therapy if the disease is not controlled on topical therapy