

Participant ID:
Participant initials:

BASELINE CRF

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Date of visit	D	D	M	M	M	Y	Y	Y	Y
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SECTION 1 – DEMOGRAPHICS & DIAGNOSIS OF PG

Date of birth	D	D	M	M	M	Y	Y	Y	Y	
Gender	Male		<input type="checkbox"/> (1)							
	Female		<input type="checkbox"/> (2)							
Presentation of PG	Classical PG		<input type="checkbox"/> (1)							
	Cribriform		<input type="checkbox"/> (2)							
	Peristomal		<input type="checkbox"/> (3)							
	Bullous		<input type="checkbox"/> (4)							
	Unsure		<input type="checkbox"/> (5)							
Has the patient had a previous episode of PG?	Yes <input type="checkbox"/> (1)		No <input type="checkbox"/> (0)				Unknown <input type="checkbox"/> (8)			
Date of onset (approx) for this episode	D	D	M	M	M	Y	Y	Y	Y	Tick if unknown <input type="checkbox"/> (8)
Specialty referred from	Dermatology		<input type="checkbox"/> (1)							
	Rheumatology		<input type="checkbox"/> (2)							
	Gastroenterology		<input type="checkbox"/> (3)							
	General Medicine		<input type="checkbox"/> (4)							
	Other (please specify)		<input type="checkbox"/> (5)							
Are you seeing this patient as an out-patient or an in-patient ?	Out-patient <input type="checkbox"/> (1)				In-patient <input type="checkbox"/> (2)					
Why did you choose to treat the patient with topical or systemic therapy? <i>Free text</i>	<i>e.g topical therapy not working, mild disease, patient choice</i>									

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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):		

SECTION 3 – UNDERLYING DISEASE <small>that may pre-dispose to PG</small>			
Has the patient EVER been diagnosed with any of the following?			
Diagnosis	Yes	No	If the box is unshaded, please provide further details
Crohn's disease	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
Ulcerative colitis	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
Myeloma	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
Haematological malignancy - <i>please specify type</i>	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
Other malignancy - <i>please specify type</i>	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
Rheumatoid arthritis	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
Other inflammatory arthritis - <i>please specify type</i>	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
Monoclonal gammopathy	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	

SECTION 4 – OTHER RELEVANT CONDITIONS <small>that may involve monitoring of treatment</small>			
Does the patient have a CURRENT diagnosis of any of the following?			
Diagnosis	Yes	No	Provide further details if relevant
Diabetes	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
Mild renal impairment - <i>anything clinically significant should be excluded</i>	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	
Epilepsy	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	

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**SECTION 5 – PHYSICAL EXAMINATION**

Blood pressure (systolic / diastolic)				/			
Weight (kg)							
Number of ulcers on entire body							
Location of target lesion <i>If multiple lesions are present, the target lesion should be the lesion that is most able to be photographed on a single plane (i.e. not around the curvature of a limb). If there is only 1 lesion, don't exclude because you are not able to take an image – in this case physical measurements can be used.</i>	Write in free text (e.g. abdomen, shoulder)			Right	Left	N/A	
				<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	
Measurement of target lesion	Max longitudinal length (mm)						
	Max perpendicular width (mm)						

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SECTION 6 – 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 7 – TRIAL CHECKLIST		
For patients in either the RCT or observational study, have the following been done?	Yes	No
Asked the patient to complete the ' <i>baseline patient questionnaire</i> ' located in this patient's file	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
Biopsy of the lesion <i>This is not a requirement, but we are interested whether one has been requested</i>	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
Arranged follow-up appointment for 2 weeks' time	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
For patients in the RCT only, have the following been done?		
Routine samples 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)
Bloods taken for creatinine & glucose Creatinine result: ____ µmol/L Glucose result: ____ mmol/l <i>Please record these results if known at baseline. If unknown please record on the week 2 CRF.</i>	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
Urine pregnancy test (women of child-bearing potential only) and pregnancy advice	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)
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>	<input type="checkbox"/> (1)	<input type="checkbox"/> (0)

Please now follow the 'What to do next' sheet located behind this CRF

SECTION 8 – CRF SIGN-OFF	
I confirm that the information contained in this CRF is accurate to the best of my knowledge:	
Signed _____	Date _____