Participant ID:
Participant initials:
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SCREEN

SCREENING CRF

Date of screening	D	D	M	M	M	Y	Y	Y	Y

vdat

Is the patient / has the patient got:		Yes	No
Able to give informed consent	infcon_n	☐(1)	☐(0)
At least 18 years old	al18_n	☐(1)	☐(0)
A diagnosis of pyoderma gangrenosum made by the recruiting dermatologist (note: if the patient is taking nicorandil or hydr (hydroxycarbamide) consider whether this is a drug-induced ulce	pgdia_n	☐(1)	☐(0)
Measurable ulceration (e.g not pustular pyoderma g	mesulc_n	☐(1)	☐(0)

If you have ticked any grey boxes, the patient is NOT eligible for the study – please ensure you now complete the screening log

Has the patient / is the patient:		Yes	No
A diagnosis of granulomatous pyoderma gangrenos	gpgdia_n	☐(1)	☐(0)
Received either of the study medications or IVIG the month	recmed_n	☐(1)	☐(0)
Participating in another clinical trial (intervention)	interv_n	☐(1)	☐(0)

If you have ticked any grey boxes, the patient is NOT eligible for the study – please ensure you now complete the screening log

Has the patient / is the patient:		Yes	No
Pregnant, lactating or at risk of pregnancy	preg_n	☐(1)	☐(0)
Known hypersensitivity to either prednisolone or cic	hypers_n	☐(1)	☐(0)
Clinically significant renal impairment, such that you treat the patient with either prednisolone or ciclosp	renimp_n	☐(1)	☐(0)
Any pre-treatment investigations, the results of whi not to use prednisolone or ciclosporin	ptinv_n	☐(1)	☐(0)
A diagnosis of malignancy or pre-malignant disease where prednisolone or ciclosporin might interfere with ongoing therapy, (e.g see section 10.3.2 of protocol)	malig_n	☐(1)	☐(0)
The patient has a concurrent medical condition that means that you would not normally treat the patient with **either** prednisolone or ciclosporin, (e.g. a degree of hypertension that wou either of the study drugs, advanced heart failure, poorly controlled diabetes, history of peptic ulcer, malignancy in previous years)	conmed_n	☐(1)	☐(0)
Currently taking any contra-indicated medications [a live vaccine in the last 2 weeks, Rosuvastatin (CRE	contra_n	☐(1)	☐(0)

If you ticked any grey boxes, the patient is eligible for the observational study only

If all white boxes are ticked, the patient is eligible for the RCT or observational study depending on your treatment choice

Which study have you entered the patient into (please tick **one** option only)?

RCT ☐(1) Observational study (2) ☐ study_n

Note – all fields ending '_n' contain the numeric value and have an equivalent field ending '_d' containing the descriptive text

What next

- Complete the **baseline CRF** – behind this sheet in the patient file
- Complete the **Screening log** in the site file

CRF SIGN-OFF

PLEASE NOTE THIS IS A SOURCE DOCUMENT **Data entered:** ☐

I confirm that the information contained in this CRF is accurate to the best of my knowledge:

_____ _____

Signed Date

VISITS

Date of visit	D	D	M	M	M	Y	Y	Y	Y

visdat

SECTION 1 – DEMOGRAPHICS & DIAGNOSIS OF PG

DEMOG

Date of birth *dobdat*	D D M M M Y Y Y Y		
Gender *gender_nt*	Male		☐(1)
	Female		☐(2)
Presentation of PG *pgpres_n*	Classical PG		☐(1)
	Cribriform		☐(2)
	Peristomal		☐(3)
	Bullous		☐(4)
	Unsure		☐(5)
Has the patient had a **previous** episode of PG? *prevpg_n*	Yes ☐(1)	No ☐(0)	Unknown ☐(8)
Date of onset (approx) for **this episod** *odatest (onset date estimated)*	D D M M M Y Y Y Y *odat*		Tick if unkno *odatunk*
Specialty referred from *refspec_n*	Dermatology		☐(1)
	Rheumatology		☐(2)
	Gastroenterology		☐(3)
	General Medicine		☐(4)
	Other (please specify) *rsodet*		☐(5)
Are you seeing this patient as an **out-patient** or an **in-patient?** *inout_n*	Out-patient ☐(1)	In-patient ☐(2)	
Why did you choose to treat the patient with topical or systemic therapy? *Free text*	*e.g topical therapy not working, mild disease, patient choice* *tdet1* *tdet2* *tdet3*		

Note – all fields ending '_n' contain the numeric value and have an equivalent field ending '_d' containing the descriptive text

CDRUG

pending

CTION 2 – MEDICATION			Yes	No
Is the patient **currently** taking any of the following drugs?	Methotrexate	*meth_n*	☐(1)	☐(0)
	Azathioprine	*azat_n*	☐(1)	☐(0)
	Leflunomide	*lefl_n*	☐(1)	☐(0)
	Anti-TNF	*atnf_n*	☐(1)	☐(0)
	Mercaptopurine (6-MP, Puri-Nethol®)	*pure_n*	☐(1)	☐(0)
	Tetracyclines	*tetr_n*	☐(1)	☐(0)
	Mycophenolate	*myco_n*	☐(1)	☐(0)
Has the patient taken any other treatment that could **influence** pyoderma gangrenosum? Yes☐(1) No☐(2) *other_n*	If yes, please give details of drug name(s) (dose not required): *othdet1* *othdet2*			

Note – all fields ending '_n' contain the numeric value and have an equivalent field ending '_d' containing the descriptive text

MEDHIST

TION 3 – UNDERLYING DISEASE that may pre-dispose to PG

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 *crohn_n*	☐(1)	☐(0)	
Ulcerative colitis *ucol_n*	☐(1)	☐(0)	
Myeloma *myel_n*	☐(1)	☐(0)	
Haematological malig *hmalig_n* *please specify type*	☐(1)	☐(0)	*hmtype*
Other malignancy – p *omalig_n* *type*	☐(1)	☐(0)	*omtype*
Rheumatoid arthritis *rarth_n*	☐(1)	☐(0)	

Other inflammatory *please specify type*	oarth_n	☐(1)	☐(0)	oatype
Monoclonal gamm	mongam_n	☐(1)	☐(0)	

Note – all fields ending '_n' contain the numeric value and have an equivalent field ending '_d' containing the descriptive text

SECTION 4– OTHER RELEVANT CONDITIONS that may involve monitoring of treatment

Does the patient have a *CURRENT* diagnosis of any of the following?

Diagnosis	Yes	No	Provide further details if relevant
Diabetes diab_n	☐(1)	☐(0)	diadet
Mild renal impairment – *anything clinically significant s* mri_n *excluded*	☐(1)	☐(0)	mridet
Epilepsy epil_n	☐(1)	☐(0)	epildet

PHYEXAM

SECTION 5 – PHYSICAL EXAMINATION

bp_nd

Blood pressure (systolic / diastolic)	bpsys_t	/	bpdia_t	
Weight (kg)	wtkg_t	pending		
Number of ulcers on entire body	ulc_t			

Location of target lesion	*Write in free text (e.g abdomen, shoulder)*	Right	Left	N/A
	lesloc	☐(1)	☐(2)	☐(8)
		leslrn_n		
	Max longitudinal length (mm)	leslon_t		
	Max perpendicular width (mm)	lesper_t		

Note – all fields ending '_n' contain the numeric value and have an equivalent field ending '_d' containing the descriptive text.

Also, all fields ending '_t' contain the full text entry, and have a corresponding field ending 'n' containing the numeric equivalent value.

nodress stoma

TLESION

TION 6 – INFLAMMATION ASSESSMENT OF THE TARGET LESION

e tick one box only for each section

Erythema		
None	*No erythema*	☐(0)
Slight	*Mild pink colour*	☐(1)

eryth_n

Moderate	*Moderate pink colour*	☐(2)
Severe	*Reddish colour*	☐(3)
Very severe	*Dark red or violaceous*	☐(4)
Border elevation		
None	*Border is flat with ulcer and surrounding skin, no elevation*	☐(0)
Slight	*Slight elevation of border above ulceration and surrounding skin*	☐(1)
Moderate	*Noticeable elevation of border above ulceratio surrounding skin* belev_n	☐(2)
Severe	*Significant elevation of border above ulceration and surrounding skin*	☐(3)
Very severe	*Border rolled high above ulceration and surrounding skin*	☐(4)
Exudate		
None	*Wound is dry*	☐(0)
Slight	*Spotting of clear fluid*	☐(1)
Moderate	*Moderate amount of discharge, partially disco* exud_n	☐(2)
Severe	*Heavy, discoloured discharge*	☐(3)
Very severe	*Copious, offensive or blood stained discharge*	☐

Note – all fields ending '_n' contain the numeric value and have an equivalent field ending '_d' containing the descriptive text

SECTION 7 – TRIAL CHECKLIST

For patients in either the RCT or observational study, have the following been done?	Yes	No
HAsked the patient to complete the ***'baseline patient questionn*** tie not entered	☐(1)	☐(0)
Biopsy of the lesion *This is not a requirement, but we are interested whether one has requested* not entered	☐(1)	☐(0)
H Arranged ***follow-up appo*** im not entered	☐(1)	☐(0)
ients in the RCT only, have the following been done?		
Routine samples as you would in normal care? *Recommended samples are: full blood count, urea & electrolytes, CRP, r auto-antibodies, ANCA, serum immunoglobu bacterio* not entered	☐(1)	☐(0)
Bloods taken for ***creatinine & glucose*** pending ***Creatinine result:*** _____ µmol/L ***Glucose result:*** ____ mmol/l *Please record these re* creat_t *seline. If unknown please* gluc_t *2 CRF.*	☐(1) bloods_n	☐(0)

Urine pregnancy test (women of child-bearing potential only) and pregnancy advice	☐(1)	☐(0)
Digital images of the target lesion **not entered** *Please refer to the **digital image guidance** in Section 5 of this patient file and complete the **Digital image log***	☐(1)	☐(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

PQ

Date of completion	D	D	M	M	M	Y	Y	Y	Y
			compdat						

estdat

ABOUT YOUR ULCER

1) We are interested in your thoughts about the **ulcer your doctor is assessing**. Please complete the table below. Feel free to ask your doctor if you do not understand how to answer these questions.

Note – fields ending '_n' contain the numeric value, while corresponding fields ending '_d' contain the descriptive text

Colour (please tick ***one*** option in this section)		
None	*No redness*	☐ (0)
Slight	*Mild pink colour*	☐ (1)
Moderate ucol_n	*Moderate pink colour*	☐ (2)
Severe	*Reddish colour*	☐ (3)
Very severe	*Dark red or purple colour*	☐ (4)
Thickness of the edge of the ulcer (please tick ***one*** option in this section)		
None	*Border is flat with ulcer and surrounding skin, no thickening*	☐ (0)
Slight	*Slight thickening of border above ulceration and surrounding skin*	☐ (1)
Moderate uthick_n	*Noticeable thickening of border above ulceration and surrounding skin*	☐ (2)
Severe	*Significant thickening of border above ulceration and surrounding skin*	☐ (3)
Very severe	*Border rolled high above ulceration and surrounding skin*	☐ (4)

Pus or discharge (please tick ***one*** option in this section)		
None	*Wound is dry*	☐(0)
Slight	*Spotting of clear fluid*	☐(1)
Moderate upus_n	*Moderate amount of discharge, partially discoloured*	☐(2)
Severe	*Heavy, discoloured discharge*	☐(3)
Very severe (4)	*Copious, offensive or blood stained discharge*	☐(4)

Data Entry:

ABOUT PAIN

How much pain has your pyoderma gangrenosum given you today?

pains_n

☐(0) None
☐(1) Mild
☐(2) Moderate
☐(3) Severe
☐(4) Extreme

Have you taken any painkillers today?

paink_n

☐(1) Yes

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☐(0) No

ABOUT YOU

What is your ethnic origin? Please tick the appropriate box below.

ethnic_n

White	☐(1)
Black - Caribbean	☐(2)
Black - African	☐(3)
Black – Other	☐(4)
Asian – Indian	☐(5)
Asian – Pakistani	☐(6)
Asian – Bangladeshi	☐(7)
Asian – Chinese	☐(8)
Asian – Other	☐(9)

Mixed	☐ (10)
Other	☐ (11)
Unknown / not given	☐ (12)

EQ5D

QUALITY OF LIFE – EQ-5D

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Note – fields ending '_n' contain the numeric value, while corresponding fields ending '_d' contain the descriptive text.

Also, fields ending '_t' contain the entered text,

Mobility

I have no problems in walking about ❑ (0)

qmob_n

I have some problems in walking about ❑ (1)

I am confined to bed ❑ (2)

Self-Care

I have no problems with self-care ☐(0)

I have some problems washing or dressing myself ☐(1)

I am unable to wash or dress myself ☐(2)

qcare_n

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

I have no problems with performing my usual activities ☐(0)

I have some problems with performing my usual activities ☐(1)

I am unable to perform my usual activities ☐(2)

qact_n

Pain/Discomfort

I have no pain or discomfort ☐(0)

I have moderate pain or discomfort ☐(1)

I have extreme pain or discomfort ☐(2)

qpain_n

Anxiety/Depression

I am not anxious or depressed ☐(0)

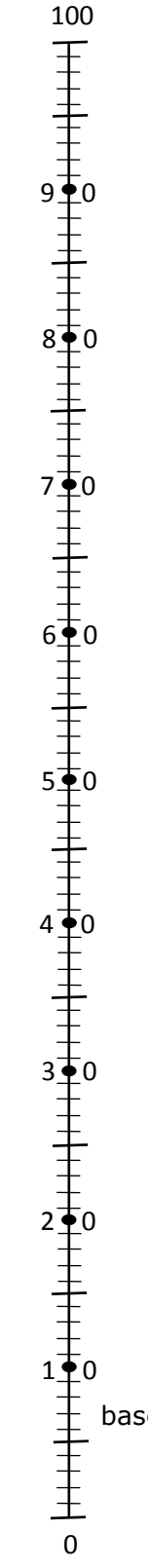
I am moderately anxious or depressed ☐(1)

qanx_n

I am extremely anxious or depressed ❑(2)

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 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do



PLEASE NOTE THIS IS A SOURCE DOCUMENT

hstate_t

Your own health state

PLEASE NOTE THIS IS A SOURCE DOCUMENT

DLQI

ermatology Life Quality Index

Score dscore

The aim of this questionnaire is to measure how much your skin problem has affected your life **over the last week**. Please tick one box for each question.

	Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been? ditch_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	
	Over the last week, how **embarrassed** or **self conscious** have you been because of your skin? demb_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	
	Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden?** dshop_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin influenced the **clothes** you wear? dclothes_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin affected any **social** or **leisure** activities? dsocial_n	Very much A lot	☐(3) ☐(2)	

		A little Not at all	☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin made it difficult for you to do any **sport**? dsport_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, has your skin prevented yo **working** or **studying**? dwork_n	yes no	☐(1) ☐(0)	Not relevant ☐(8)
	If "No", over the last week how much has your skin been a problem at **work** or **studying**? dwmuch_n	A lot A little Not at all	☐(2) ☐(1) ☐(0)	
	Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**? dpart_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin caused any **sexual difficulties**? dsex_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time? dtreat_n	Very much A lot A little	☐(3) ☐(2) ☐(1) ☐(0)	

		Not at all		Not relevant ☐(8)

Note – fields ending '_n' contain the numeric value, while corresponding fields ending '_d' contain the descriptive text

NOT ENTERED

YOUR CONTACT DETAILS

Please complete your contact details below.

We would like these details so that members of the ***research team at the co-ordinating centre*** can get in touch with you during the period of the research. We will not pass these details on to anyone other than members of the study team without your permission, and will hold this information on a password protected database.

Title (Please circle as appropriate)	Mr	Mrs	Miss	Ms	Dr	Other
Forename						
Surname						

PLEASE NOTE THIS IS A SOURCE DOCUMENT

Address	
Postcode	
Telephone number (home)	
Telephone number (mobile)	
Email address (if available)	
What is the best time to contact you?	

GP CONTACT DETAILS (if known)

We will contact your GP and let him/her know that you are taking part in this study.

Name of GP	
Address	
Postcode	
Telephone number	

Thank you for completing these questions.

Please return these forms to your doctor (or if you have been sent them by post, please return them to the research team in the reply paid envelope provided).

STOP GAP Trial Manager
Nottingham Clinical Trials Unit
Office B39, Medical School
Queen's Medical Centre
Derby Road
Nottingham
NG7 2UH

STOP GAP RESEARCH STUDY

PATIENT DIARY 1 (0-6 WEEKS)

Observational Study patients

ID number	
Initials	

Thank you for taking part in this medical research study which is looking at the best way to treat pyoderma gangrenosum.

This booklet is for you to keep and record the following:

- How much pain your ulcer has caused you
- Whether you are still using dressings for your ulcer

This diary should be completed **every day** for 6 weeks.

Once you have completed the diary, please take it to the hospital when you see the doctor who is treating your pyoderma gangrenosum.

From time to time, we may call you to find out how you are getting on. Please have this diary to hand during these telephone calls.

If you have any queries about completing this diary, please do not hesitate to contact the study team: **0115 8230489 or 0115 8230486**

Your local STOP GAP study doctor is: THIS PAGE IS NOT ENTERED

Name	
Hospital name	
Telephone number	

The co-ordinating centre is:

Trial Manager	Eleanor Mitchell
Trial Administrator	Julie Barnes
Address	Nottingham Clinical Trials Unit B39, Medical School Queen's Medical Centre Nottingham NG7 2UH
Telephone number	0115 8230489 / 0115 8230486
Email address	stopgap@nottingham.ac.uk

If you decide at any time that you would like to withdraw from this research study, you are free to do so, without having to give a reason.

Please telephone either your study doctor or trial manager (details above) to let us know.

It is important that you tell us as soon as you stop using your dressings. Please remember to contact us when you stop using dressings for your ulcer.

The ulcer being studied is:

_____

Participant ID: | | | | | | |

Participant initials: | | | |

BASELINE PATIENT QUESTIONNAIRE

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PDIARY

notdone

Week number is denoted by field 'recno'

1: week commencing date: _____ commdat

The **date** I started using cream/ointment was: _____ tabdat

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild pg_mon ☐ Severe ☐ Extreme	☐ None ☐ Mild pg_tues ☐ Severe ☐ Extreme	☐ None ☐ Mild pg_wed ☐ Severe ☐ Extreme	☐ None ☐ Mild pg_thur ☐ Severe ☐ Extreme	☐ None ☐ Mild pg_fri ☐ Severe ☐ Extreme	☐ None ☐ Mild pg_sat ☐ Severe ☐ Extreme	☐ None ☐ Mild pg_sun ☐ Severe ☐ Extreme
Have you taken any painkillers for your PG?	☐ pn_mon ☐ No	☐ pn_tues ☐ No	☐ pn_wed ☐ No	☐ pn_thur ☐ No	☐ pn_fri ☐ No	☐ pn_sat ☐ No	☐ pn_sun ☐ No
Have you been using dressings?	☐ drs_mon ☐ No	☐ drs_tues ☐ No	☐ drs_wed ☐ No	☐ drs_thur ☐ No	☐ drs_fri ☐ No	☐ drs_sat ☐ No	☐ drs_sun ☐ No

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

WEEK 2: week commencing date: ________________________

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers for your PG?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

WEEK 3: week commencing date: ___________________________

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers for your PG?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

WEEK 4: week commencing date: ______________________

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any	☐ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes

painkillers for your PG?	☐ No	☐ No	☐ No	☐ No	☐ No	☐ No	☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!							

WEEK 5: week commencing date: _____

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild	☐ None ☐ Mild	☐ None ☐ Mild	☐ None ☐ Mild	☐ None ☐ Mild	☐ None ☐ Mild	☐ None ☐ Mild

	☐ Moderate ☐ Severe ☐ Extreme	☐ Moderate ☐ Severe ☐ Extreme	☐ Moderate ☐ Severe ☐ Extreme	☐ Moderate ☐ Severe ☐ Extreme	☐ Moderate ☐ Severe ☐ Extreme	☐ Moderate ☐ Severe ☐ Extreme	☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers for your PG?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!							

WEEK 6: week commencing date: _____

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**

How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers for your PG?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

WEEK 7: week commencing date: ___________________________

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers for your PG?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

WEEK 8: week commencing date: ________________________

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers for your PG?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

PDIARYEND

Since you started your _____ have you taken your tablets:

notdone

☐ Every day

☐ Most days

tabtake

☐ Some days

☐ Never

If you would like to add any comments, please do so here:

comm1 comm2 comm3

STOP GAP RESEARCH STUDY

PATIENT DIARY 1 (0-6 WEEKS)

RCT patients

ID number	
Initials	

Thank you for taking part in this medical research study which is looking at the best way to treat pyoderma gangrenosum.

This booklet is for you to keep and record the following:

- How much pain your ulcer has caused you
- Whether your pyoderma gangrenosum has affected your daily activities
- Whether you are still using dressings for your ulcer
- Any illnesses you have experienced
- Any visits you have made to your GP or hospital

This diary should be completed **every day** for 6 weeks.

Once you have completed the diary, please take it to the hospital when you see the doctor who is treating your pyoderma gangrenosum.

From time to time, we may call you to find out how you are getting on. Please have this diary to hand during these telephone calls.

If you have any queries about completing this diary, please do not hesitate to contact the study team: **0115 8230489 or 0115 8230486**

NOT ENTERED

Your local STOP GAP study doctor is:

Name	
Hospital name	
Telephone number	

The co-ordinating centre is:

Trial Manager	Eleanor Mitchell
Trial Administrator	Julie Barnes
Address	Nottingham Clinical Trials Unit Office B39, Medical School Queen's Medical Centre Nottingham NG7 2UH
Telephone number	0115 8230489 / 0115 8230486
Email address	stopgap@nottingham.ac.uk

If you decide at any time that you would like to withdraw from this research study, you are free to do so, without having to give a reason.

Please telephone either your study doctor or trial manager (details above) to let us know.

It is important, however, that you **do not** stop taking the tablets suddenly as this can be very dangerous. Please talk to your doctor first who will be able to advise you what to do.

It is also important that you tell us as soon as you stop using your dressings. Please remember to contact us when you stop using dressings for your ulcer.

NOT ENTERED

The ulcer being studied is:

_____

Participant ID:

Participant initials:

BASELINE PATIENT QUESTIONNAIRE

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PDIARY

notdone

Wvee[illegible]ncing date: _____ commdat _____

Note: Week number is denoted by the value in the field 'recno'

The **date** I started taking tablets on: _____ tabdat _____

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild pg_mon ☐ Extreme	☐ None ☐ Mild pg_tues ☐ Extreme	☐ None ☐ Mild pg_wed ☐ Extreme	☐ None ☐ Mild pg_thur ☐ Extreme	☐ None ☐ Mild pg_fri ☐ Extreme	☐ None ☐ Mild pg_sat ☐ Extreme	☐ None ☐ Mild pg_sun ☐ Extreme
Have you taken any painkillers?	pn_mon	pn_tues	pn_wed	pn_thur	pn_fri	pn_sat	pn_sun
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Ye ☐ No	sumwk_t – total of all 'yes' answers for week			Yes No	☐ Yes ☐ No
Have you been using dressings?	drs_mon	drs_tues	drs_wed	drs_thur	drs_fri	drs_sat	drs_sun

Participant ID:

Participant initials:

BASELINE PATIENT QUESTIONNAIRE

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Have you had any health problems? *Please specify*	Not entered						

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication

gps_t – total of all ticked answers for week

GP Surgery	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐

gph_t – total of all ticked answers for week

pn_t – total of all ticked answers for week

dn_t – total of all ticked answers for week

opa_t – total of all ticked answers for week

ip_t – total of all ticked answers for week

oth_t – total of all ticked answers for week

othdet1 | othdet2 | othdet3

Note: All fields that end with '_t' contain the actual text input. They all have a corresponding field ending '_n' which contain the numeric value if appropriate.

WEEK 2: week comn

EudraCT No 2008-008

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems?							

Please specify							
!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!							
Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

WEEK 3: week commencing date: ___________________________

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health							

problems? *Please specify*							

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication

GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

WEEK 4: week commencing date: _____

Participant ID: | | | | | | |

Participant initials: | | | |

BASELINE PATIENT QUESTIONNAIRE

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	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems?							

Please specify							
!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!							
Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

WEEK 5: week commencing date: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems?							

Please specify							
!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!							
Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

WEEK 6: week commencing date: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems?							

Please specify							
!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!							
Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

WEEK 7: week commencing date: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems?							

Please specify							
!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!							
Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

WEEK 8: week commencing date: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your **pyoderma gangrenosum (PG)** given you **today**?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Extreme
Have you taken any painkillers?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems?							

Please specify							
!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!							
Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

PDIARYEND

notdone

Not entered

Since you started your _____ _____ have you taken your tablets:

☐ Every day

☐ Most days

tabtake

☐ Some days

☐ Never

If you would like to add any comments, please do so here:

comm1

comm2

comm3

Please now record any prescriptions you have been given for your pyoderma gangrenosum (e.g tablets, creams, dressings, bandages etc).

Prescription type / name of medicine	Dose / number of items (if applicable)
pres1	pres1dos
pres2	pres2dos
pres3	pres3dos
pres4	pres4dos
pres5	pres5dos
pres6	pres6dos

VISITS

Date of visit	D	D	M	M	M	Y	Y	Y	Y
					visdat				

PHYEXAM

Note: All fields ending '_t' contain the actual text input; they all have corresponding fields ending '_n' which contain the corresponding numeric value if appropriate

SECTION 1 – PHYSICAL EXAMINATION

Measurement of target lesion	Max longitudinal length (mm)	leslon_t
	Max perpendicular width (mm)	lesper_t

CDRUG

pending

SECTION 2 – MEDICATION		Yes	No
Is Is the patient **currently** taking any of the following drugs?	Methotrexate meth_n	☐(1)	☐(0)
	Azathioprine azat_n	☐(1)	☐(0)
	Leflunomide lefl_n	☐(1)	☐(0)
	Anti-TNF atnf_n	☐(1)	☐(0)
	Mercaptopurine (6-MP, Puri-Nethol®) pure_n	☐(1)	☐(0)
	Tetracyclines tetr_n	☐(1)	☐(0)
	Mycophenolate myco_n	☐(1)	☐(0)
Has the patient taken any other treatment that could **influence** pyoderma gangrenosum? Yes☐(1) No☐(2) other_n	If yes, please give details of drug name(s) (dose not required): othdet1 othdet2		

RESULTS

pending confirm

SECTION 3 – RESULTS

Was a biopsy of the target lesion taken?	Yes ☐(1)	No ☐(0) *go to Section 4*
If yes, does the biopsy suggest the lesion is **NOT** PG?	Yes ☐(1) Please **exclude** this participant **immediately** and complete a change of status CRF located in section 8 of the patient file	No ☐(0)
If you did not previously record the creatinine & glucose result in the baseline CRF, please do so here	Creatinine (µmol/L)	creat_t
	Glucose (mmol/l)	gluc_t

IGAEFF

pending

Note: All fields ending '_t' contain the actual text input; they all have corresponding fields ending '_n' which contain the corresponding numeric value if appropriate

SECTION 4 – INVESTIGATOR GLOBAL ASSESSME

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

lesimp_n

Grade		Tick below
0	Completely clear: except for possible residual hyperpigmentation	☐(0)
1	Almost clear: very significant clearance (about 90%); however, patchy remnants of dusky erythema and/or very small ulceration	☐(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)	☐(2)
3	Moderate improvement: intermediate between slight and marked; representing about 50% improvement	☐(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)	☐(4)
5	No change from b	☐(5)
6	Worse	☐(6)

Note: Fields ending with '_n' contain the numeric entry; they have a corresponding field ending '_d' which contain the corresponding text description

TLESION

pending

SECTION 5 – INFLAMMATION ASSESSMENT OF THE TARGET LESION

Please tick one box only for each section

Erythema

eryth_n

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

not entered

SECTION 6 – TRIAL CHECKLIST			
For patients in either the RCT or observational study, have the following been done?	Yes	No	NA
H Arranged ***follow-up appointn***	☐(1)	☐(0)	☐(8)
Completed the ***Trial Medication change log*** if applicable	☐(1)	☐(0)	☐(8)
Recorded this visit in the hospital notes	☐(1)	☐(0)	
ients in the RCT only, have the following been done?			

Routine samples as you would in normal care? *Recommended samples are: full blood count, urea & electrolytes, CRP, rheumatoid factor, auto-antibodies, ANCA, serum immunoglobulins, ulcer swab for bacteriology*	☐(1)	☐(0)	
Urine pregnancy test (women of child-bearing potential only) and pregnancy advice	☐(1)	☐(0)	☐(8)
Completed the ***Adverse Event log*** if applicable	☐(1)	☐(0)	☐(8)

SECTION 7 – 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**

Participant ID:
Participant initials:

PATIENT QUESTIONNAIRE WEEK 2

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PQ

Date of completion	D	D	M	M	M	Y	Y	Y	Y

compdat

We are interested in your thoughts about the **ulcer your doctor is assessing**

1. Overall since your **first** appointment, how much has your ulcer improved?

uimp_n

0	Completely clear (skin colour may have changed)	☐(0)
1	Almost clear (about 90% improvement)	☐(1)
2	Marked improvement (about 75% improvement)	☐(2)
3	Moderate improvement (about 50% improvement)	☐(3)
4	Slight improvement (about 25% improvement)	☐(4)
5	No change	☐(5)
6	Worse	☐(6)

2. Please assess your ulcer by completing the table below:

Colour (please tick ***one*** option in this section)		
None	*No redness*	☐(0)
Slight	*Mild pink colour*	☐(1)

PLEASE NOTE THIS IS A SOURCE DOCUMENT

ucol_n	Moderate	*Moderate pink colour*	☐(2)
	Severe	*Reddish colour*	☐(3)
	Very severe	*Dark red or purple colour*	☐(4)
	Thickness of the edge of the ulcer (please tick ***one*** option in this section)		
	None	*Border is flat with ulcer and surrounding skin, no thickening*	☐(0)
	Slight	*Slight thickening of border above ulceration and surrounding skin*	☐(1)
uthick_n	Moderate	*Noticeable thickening of border above ulceration and surrounding skin*	☐(2)
	Severe	*Significant thickening of border above ulceration and surrounding skin*	☐(3)
	Very severe	*Border rolled high above ulceration and surrounding skin*	☐(4)
	Pus or discharge (please tick ***one*** option in this section)		
	None	*Wound is dry*	☐(0)
	Slight	*Spotting of clear fluid*	☐(1)
upus_n	Moderate	*Moderate amount of discharge, partially discoloured*	☐(2)
	Severe	*Heavy, discoloured discharge*	☐(3)
	Very severe	*Copious, offensive or blood stained discharge*	☐(4)

Note: Fields ending 'n' contain the numeric entry; they have a corresponding field ending '_d' with the short text description

PLEASE NOTE THIS IS A SOURCE DOCUMENT

Thank you for taking the time to fill in this questionnaire. Once completed, please return it in the stamped addressed envelope provided to:

STOP GAP Trial Manager
Nottingham Clinical Trials Unit
Office B39, Medical School
Queen's Medical Centre
Derby Road
Nottingham
NG7 2UH

PLEASE NOTE THIS IS A SOURCE DOCUMENT

VISITS

Date of visit	D	D	M	M	M	Y	Y	Y	Y
				visdat					

PHYEXAM

pending

SECTION 1 – PHYSICAL EXAMINATION									
Measurement of target lesion	Max longitudinal length (mm)	leslon_t							
	Max perpendicular width (mm)	lesper_t							
PG status pgstat_n	Target lesion healed – no longer using dressings	☐(1)							
	Target lesion still requiring treatment	☐(2)							
	Target lesion healed but ongoing treatment for other lesions	☐(3)							
If applicable, the date that the target lesion stopped requiring dressings	D	D	M	M	M	Y	Y	Y	Y
				pgstop					

CDRUG

pending

SECTION 2 – MEDICATION			Yes	No
Is Is the patient **currently** taking any of the following drugs?	Methotrexate	meth_n	☐(1)	☐(0)
	Azathioprine	azat_n	☐(1)	☐(0)
	Leflunomide	lefl_n	☐(1)	☐(0)
	Anti-TNF	atnf_n	☐(1)	☐(0)
	Mercaptopurine (6-MP, Puri-Nethol®)	pure_n	☐(1)	☐(0)
	Tetracyclines	tetr_n	☐(1)	☐(0)
	Mycophenolate	myco_n	☐(1)	☐(0)
Has the patient taken any other treatment that could **influence** pyoderma gangrenosum? Yes☐(1) No☐(2) other_n	If yes, please give details of drug name(s) (dose not required): othdet1 othdet2			

IGAEFF

pending

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	☐(0)
1	Almost clear: very significant clearance (about 90%); however, patchy remnants of dusky erythema and/or very small ulceration	☐(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	☐(2)
3	Moderate improvement: intermediate between slight and marked; representing about 50% improvement	☐(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)	☐(4)
5	No change from baseline	☐(5)
6	Worse	☐(6)

lesimp_n – contains numeric value; also field with '_d' ending containing text description

TLESION

pending

SECTION 4 – INFLAMMATION ASSESSMENT OF THE TARGET LESION

Please tick one box only for each section

Erythema		
None	*No erythema*	☐(0)
Slight	*Mild pink colour*	☐(1)
Moderate	*Moderate pink colour*	☐(2)
Severe	*Reddish colour*	☐(3)
Very severe	*Dark red or violaceous*	☐(4)
Border elevation		
None	*Border is flat with ulcer and surrounding skin, no elevation*	☐(0)
Slight	*Slight elevation of border above ulceration and surrounding skin*	☐(1)
Moderate	*Noticeable elevation of border a urrounding skin*	☐(2)

eryth_n

belev_n

Severe	*Significant elevation of border above ulceration and surrounding skin*	☐(3)
Very severe	*Border rolled high above ulceration and surrounding skin*	☐(4)
Exudate		
None	*Wound is dry*	☐(0)
Slight	*Spotting of clear fluid*	☐(1)
Moderate	*Moderate amount of discharg* exud_n	☐(2)
Severe	*Heavy, discoloured discharge*	☐(3)
Very severe	*Copious, offensive or blood stained discharge*	☐(4)

Note: fields ending '_n' contain the numeric value; they have a corresponding field ending '_d' containing the short text description

not entered

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

Participant ID:
Participant initials:

PATIENT QUESTIONNAIRE WEEK 6

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VISITS

Date of completion	D	D	M	M	M	Y	Y	Y	Y

visdat

We are interested in your thoughts about the **ulcer your doctor is assessing**

PQ

1. Overall since your **first** appointment, how much has your ulcer improved?

uimp_n

0	Completely clear (skin colour may have changed)	☐(0)
1	Almost clear (about 90% improvement)	☐(1)
2	Marked improvement (about 75% improvement)	☐(2)
3	Moderate improvement (about 50% improvement)	☐(3)
4	Slight improvement (about 25% improvement)	☐(4)
5	No change	☐(5)
6	Worse	☐(6)

2. Please assess your ulcer by completing the table below:

Colour (please tick ***one*** option in this section)		
None	*No redness*	☐(0)
Slight	*Mild pink colour*	☐(1)

PLEASE NOTE THIS IS A SOURCE DOCUMENT

ucol_n

Moderate	*Moderate pink colour*	☐(2)
Severe	*Reddish colour*	☐(3)
Very severe	*Dark red or purple colour*	☐(4)
Thickness of the edge of the ulcer (please tick ***one*** option in this section)		
None	*Border is flat with ulcer and surrounding skin, no thickening*	☐(0)
Slight	*Slight thickening of border above ulceration and surrounding skin*	☐(1)
Moderate	*Noticeable thickening of border above ulceration and surrounding skin*	☐(2)
Severe	*Significant thickening of border above ulceration and surrounding skin*	☐(3)
Very severe	*Border rolled high above ulceration and surrounding skin*	☐(4)
Pus or discharge (please tick ***one*** option in this section)		
None	*Wound is dry*	☐(0)
Slight	*Spotting of clear fluid*	☐(1)
Moderate	*Moderate amount of discharge, partially discoloured*	☐(2)
Severe	*Heavy, discoloured discharge*	☐(3)
Very severe	*Copious, offensive or blood stained discharge*	☐(4)

uthick_n

upus_n

EQ5D

Note: fields ending '_n' contain the numeric value; they have a corresponding field ending '_d' containing the short text description

PLEASE NOTE THIS IS A SOURCE DOCUMENT

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ☐(0)

I have some problems in walking about ☐(1)

I am confined to bed ☐(2)

qmob_n

Self-Care

I have no problems with self-care ☐(0)

I have some problems washing or dressing myself ☐(1)

I am unable to wash or dress myself ☐(2)

qcare_n

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

I have no problems with performing my usual activities ☐(0)

I have some problems with performing my usual activities ☐(1)

I am unable to perform my usual activities ☐(2)

qact_n

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Participant ID:
Participant initials:

PATIENT QUESTIONNAIRE WEEK 6

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Pain/Discomfort

I have no pain or discomfort ☐(0)

I have moderate pain or discomfort ☐(1)

I have extreme pain or discomfort ☐(2)

qpain_n

Anxiety/Depression

I am not anxious or depressed ☐(0)

I am moderately anxious or depressed ☐(1)

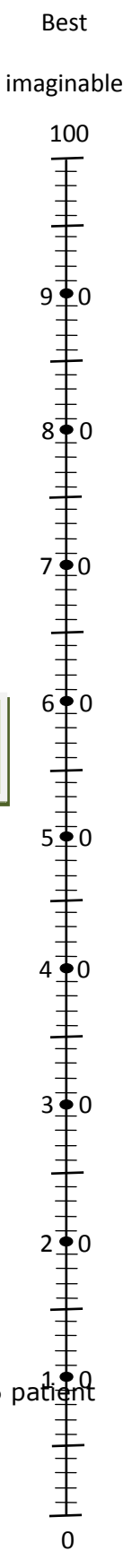
I am extremely anxious or depressed ☐(2)

qanx_n

Note: fields ending '_n' contain the numeric value; they have a corresponding field ending '_d' containing the short text description

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 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do



week 6 patient

RCE DOCUMENT

Your own

health state

hstate_t

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Note: fields ending '_t' contain the actual text entry; they have a corresponding field ending '_n' containing the numeric equivalent if appropriate

PLEASE NOTE THIS IS A SOURCE DOCUMENT

EQ-5D™ is a trade mark of the EuroQol Group

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Participant ID:
Participant initials:

PATIENT QUESTIONNAIRE WEEK 6

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DLQI

matology Life Quality Index

Score

dscore

The aim of this questionnaire is to measure how much your skin problem has affected your life **over the last week**. Please tick one box for each question.

	Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been? ditch_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	
	Over the last week, how **embarrassed** or **self conscious** have you been because of your skin? demb_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	
	Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden?** dshop_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin influenced the **clothes** you wear? dclothes_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin affected any **social** or **leisure** activities? dsocial_n	Very much	☐(3)	

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		A lot A little Not at all	☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin made it difficult for you to do any **sport**? dsport_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, has your skin prevented you from **working** or **studying**? dwork_n	yes no	☐(1) ☐(0)	Not relevant ☐(8)
	If "No", over the last week how much has your skin been a problem at **work** or **studying**? dwmuch_n	A lot A little Not at all	☐(2) ☐(1) ☐(0)	
	Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**? dpart_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin caused any **sexual difficulties**? dsex_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time? dtreat_n	Very much A lot	☐(3) ☐(2)	

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		A little Not at all	☐(1) ☐(0)	Not relevant ☐(8)

Note: fields ending '_n' contain the numeric value; they have a corresponding field ending '_d' containing the short text description

Thank you for taking the time to fill in this questionnaire. Once completed, please return it in the stamped addressed envelope provided to:

STOP GAP Trial Manager
Nottingham Clinical Trials Unit
Office B39, Medical School
Queen's Medical Centre
Derby Road
Nottingham
NG7 2UH

PLEASE NOTE THIS IS A SOURCE DOCUMENT

STOP GAP RESEARCH STUDY

PATIENT DIARY 2 (+6 WEEKS)

RCT patients

ID number	
Initials	

Thank you for taking part in this medical research study which is looking at the best way to treat pyoderma gangrenosum.

This booklet is for you to keep and record the following:

- Whether your pyoderma gangrenosum has affected your daily activities
- Whether you are still using dressings for your ulcer
- Any illnesses you have experienced
- Any visits you have made to your GP or hospital

This diary should be completed **every day** until your ulcer has healed or after 6 months since you started your tablets (whichever comes first).

Once you have completed the diary, please take it to the hospital when you see the doctor who is treating your pyoderma gangrenosum.

From time to time, we may call you to find out how you are getting on. Please have this diary to hand during these telephone calls.

If you have any queries about completing this diary, please do not hesitate to contact the study team: **0115 8230489 or 0115 8230486**

not entered

Your local STOP GAP study doctor is:

Name	
Hospital name	
Telephone number	

The co-ordinating centre is:

Trial Manager	Eleanor Mitchell
Trial Administrator	Julie Barnes
Address	Nottingham Clinical Trials Unit Office B39, Medical School Queen's Medical Centre Nottingham NG7 2UH
Telephone number	0115 8230489 / 0115 8230486
Email address	stopgap@nottingham.ac.uk

If you decide at any time that you would like to withdraw from this research study, you are free to do so, without having to give a reason.

Please telephone either your study doctor or trial manager (details above) to let us know.

It is important, however, that you **do not** stop taking the tablets suddenly as this can be very dangerous. Please talk to your doctor first who will be able to advise you what to do.

It is also important that you tell us as soon as you stop using your dressings. Please remember to contact us when you stop using dressings for your ulcer.

not entered

The ulcer being studied is:

_____

Participant ID:

Participant initials:

PATIENT QUESTIONNAIRE WEEK 6

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PDIARY

Week number is given by value of field 'recno'

notdone

commdat

tabdat

The **date** I started taking tablets on: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Have you been able to work/do usual activities?	☐ Yes ☐ No	sumwk_t – total of 'yes' answers for week					Yes No
Have you been using dressings?	drs_mon	drs_tues	drs_wed	drs_thur	drs_fri	drs_sat	drs_sun
Have you had any health problems? *Please specify*	not entered						

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication		
GP Surgery	gps_t – total of ticked answers for week	☐
GP Home	gph_t – total of ticked answers for week	☐
Practice Nurse	pn_t – total of ticked answers for week	☐
District Nurse	dn_t – total of ticked answers for week	☐
Out Patient Appointment	opa_t – total of ticked answers for week	☐
In Patient	ip_t – total of ticked answers for week	☐
Other, please specify:	oth_t – total of ticked answers for week othdet1 othdet2 othdet3	☐

Participant ID: | | | | | | |

Participant initials: | | | |

PATIENT QUESTIONNAIRE WEEK 6

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WEEK 2: week commencing date: _____

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems? *Please specify*							

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of

the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

Participant ID: | | | | | | |

Participant initials: | | | |

PATIENT QUESTIONNAIRE WEEK 6

www.stopgaptrial.co.uk

WEEK 3: week commencing date: _____

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems? *Please specify*							

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of

the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

WEEK 4: week commencing date: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems? *Please specify*							

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of

the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

Participant ID: | | | | | | |

Participant initials: | | | |

PATIENT QUESTIONNAIRE WEEK 6

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WEEK 5: week commencing date: _____

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems? *Please specify*							

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of

the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

Participant ID: | | | | | | |

Participant initials: | | | |

PATIENT QUESTIONNAIRE WEEK 6

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WEEK 6: week commencing date: _____

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems? *Please specify*							

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of

the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

Participant ID: | | | | | | |

Participant initials: | | | |

PATIENT QUESTIONNAIRE WEEK 6

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WEEK 7: week commencing date: _____

	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems? *Please specify*							

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of

the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

WEEK 8: week commencing date: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Have you been able to work/do usual activities?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you been using dressings?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Have you had any health problems? *Please specify*							

!!! IMPORTANT……PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of

the medication							
GP Surgery	☐	☐	☐	☐	☐	☐	☐
GP Home	☐	☐	☐	☐	☐	☐	☐
Practice Nurse	☐	☐	☐	☐	☐	☐	☐
District Nurse	☐	☐	☐	☐	☐	☐	☐
Out Patient Appointment	☐	☐	☐	☐	☐	☐	☐
In Patient	☐	☐	☐	☐	☐	☐	☐
Other, please specify:	☐	☐	☐	☐	☐	☐	☐

PDIARYEND

Since you started your _____ not entered _____ have you taken your tablets:

☐ Every day

☐ Most days

☐ Some days

☐ Never

tabtake

If you would like to add any comments, please do so here:

comm1 comm2 comm3

Please now record any prescriptions you have been given for your pyoderma gangrenosum (e.g tablets, creams, dressings, bandages etc).

Prescription type / name of medicine	Dose / number of items (if applicable)
pres1	pres1dos
pres2	pres2dos
pres3	pres3dos
pres4	pres4dos
pres5	pres5dos
pres6	pres6dos

This form should be completed when the participant ends their involvement in the trial

VISITS

of visit	D	D	M	visdat	Y	Y	Y	Y

PHYEXAM

pending

SECTION 1 – PHYSICAL EXAMINATION

Measurement of target lesion	Max longitudinal length (mm)	leslon_t
	Max perpendicular width (mm)	lesper_t
Number of ulcers on entire body		ulc_t
PG status pgstat_n	Target lesion healed – no longer using dressings	☐(1)
	Target lesion still requiring treatment	☐(2)
	Target lesion healed but ongoing treatment for other lesions	☐(3)

If applicable, the date that the target lesion stopped requiring dressings	D	D	M	M	M	Y	Y	Y	Y
				pgstop					

CDRUG

pending

SECTION 2 – MEDICATION		Yes	No
Is Is the patient **currently** taking any of the following drugs?	Methotrexate meth_n	☐(1)	☐(0)
	Azathioprine azat_n	☐(1)	☐(0)
	Leflunomide lefl_n	☐(1)	☐(0)
	Anti-TNF atnf_n	☐(1)	☐(0)
	Mercaptopurine (6-MP, Puri-Nethol®) pure_n	☐(1)	☐(0)
	Tetracyclines tetr_n	☐(1)	☐(0)
	Mycophenolate myco_n	☐(1)	☐(0)

Has the patient taken any other treatment that could **influence** pyoderma gangrenosum? Yes☐(1) No☐(2) other_n	If yes, please give details of drug name(s) (dose not required): othdet1 othdet2

Note: fields ending '_n' contain the numeric value, and have corresponding fields ending '_d' containing the short text description

IGAEFF

pending

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	☐(0)
1	Almost clear: very significant clearance (about 90%); however, patchy remnants of dusky erythema and/or very small ulceration	☐(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)	☐(2)
3	Moderate improvement: intermediate between slight and marked; representing about 50% improvement	☐(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)	☐(4)
5	No change from baseline	☐(5)
6	Worse	☐(6)

lesimp_n

TLESION

pending

SECTION 4 – INFLAMMATION ASSESSMENT OF THE TARGET LESION

Please tick one box only for each section

Erythema		
None	*No erythema*	☐(0)
Slight	*Mild pink colour*	☐(1)
Moderate	*Moderate pink colour*	☐(2)
Severe	*Reddish colour*	☐(3)
Very severe	*Dark red or violaceous*	☐(4)
Border elevation		
None	*Border is flat with ulcer and surrounding skin, no elevation*	☐(0)
Slight	*Slight elevation of border above ulceration and surrounding skin*	☐(1)
Moderate	*Noticeable elevation of border above ulc ding skin*	☐(2)
Severe	*Significant elevation of border above ulceration and surrounding*	☐(3)

eryth_n

belev_n

	skin	
Very severe	*Border rolled high above ulceration and surrounding skin*	☐(4)
Exudate		
None	*Wound is dry*	☐(0)
Slight	*Spotting of clear fluid*	☐(1)
Moderate	*Moderate amount of discharge, partiall* exudh_n	☐(2)
Severe	*Heavy, discoloured discharge*	☐(3)
Very severe	*Copious, offensive or blood stained discharge*	☐(4)

Note: fields ending '_n' contain the numeric value, and have corresponding fields ending '_d' containing the short text description

Not entered

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

PQ

estdat

Date of completion	D	D	M	M	Y	Y	Y	Y

compdat

We are interested in your thoughts about the **ulcer your doctor is assessing**

1. Overall since your **first** appointment, how much has your ulcer improved?

uimp_n

0	Completely clear (skin colour may have changed)	☐(0)
1	Almost clear (about 90% improvement)	☐(1)
2	Marked improvement (about 75% improvement)	☐(2)
3	Moderate improvement (about 50% improvement)	☐(3)
4	Slight improvement (about 25% improvement)	☐(4)
5	No change	☐(5)
6	Worse	☐(6)

2. Please assess your ulcer by completing the table below:

ucol_n

Colour (please tick ***one*** option in this section)		
None	*No redness*	☐(0)
Slight	*Mild pink colour*	☐(1)

PLEASE NOTE THIS IS A SOURCE DOCUMENT

Moderate	*Moderate pink colour*	☐(2)
Severe	*Reddish colour*	☐(3)
Very severe	*Dark red or purple colour*	☐(4)
Thickness of the edge of the ulcer (please tick ***one*** option in this section)		
None	*Border is flat with ulcer and surrounding skin, no thickening*	☐(0)
Slight	*Slight thickening of border above ulceration and surrounding skin*	☐(1)
Moderate	*Noticeable thickening of border above ulceration and surrounding skin*	☐(2)
Severe	*Significant thickening of border above ulceration and surrounding skin*	☐(3)
Very severe	*Border rolled high above ulceration and surrounding skin*	☐(4)
Pus or discharge (please tick ***one*** option in this section)		
None	*Wound is dry*	☐(0)
Slight	*Spotting of clear fluid*	☐(1)
Moderate	*Moderate amount of discharge, partially discoloured*	☐(2)
Severe	*Heavy, discoloured discharge*	☐(3)
Very severe	*Copious, offensive or blood stained discharge*	☐(4)

uthick_n

upus_n

EQ5D

nding with '_n' contain the numeric value; they have corresponding fields ending '_d' which
hort text description

PLEASE NOTE THIS IS A SOURCE DOCUMENT

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❑(0)

I have some problems in walking about ❑(1)

I am confined to bed ❑(2)

qmob_n

Self-Care

I have no problems with self-care ❑(0)

I have some problems washing or dressing myself ❑(1)

I am unable to wash or dress myself ❑(2)

qcare_n

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

I have no problems with performing my usual activities ❑(0)

I have some problems with performing my usual activities ❑(1)

I am unable to perform my usual activities ❑(2)

qact_n

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Participant ID:
Participant initials:

PATIENT QUESTIONNAIRE FINAL

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Pain/Discomfort

I have no pain or discomfort ❑(0)

I have moderate pain or discomfort ❑(1)

I have extreme pain or discomfort ❑(2)

qpain_n

Anxiety/Depression

I am not anxious or depressed ❑(0)

I am moderately anxious or depressed ❑(1)

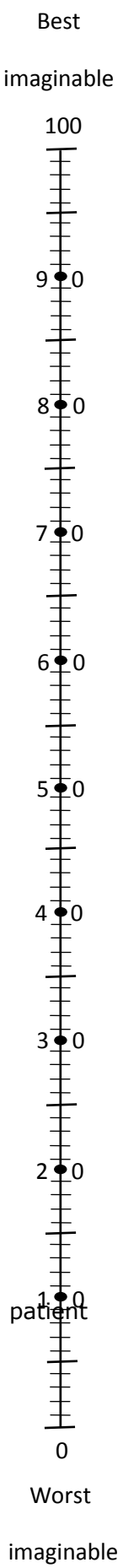
I am extremely anxious or depressed ❑(2)

qanx_n

Note: fields ending with '_n' contain the numeric value; they have corresponding fields ending '_d' which contain the short text description

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 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do



RCE DOCUMENT

Your own

health state

hstate_t

PLEASE NOTE THIS IS A SOURCE DOCUMENT

Note: fields ending with '_t' contain the actual text input; they have corresponding fields ending '_n' which contain the numeric value if appropriate

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PLEASE NOTE THIS IS A SOURCE DOCUMENT

Participant ID:
Participant initials:

PATIENT QUESTIONNAIRE FINAL

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DLQI

natology Life Quality Index

Score

dscore

The aim of this questionnaire is to measure how much your skin problem has affected your life **over the last week**. Please tick one box for each question.

	Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been? ditch_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	
	Over the last week, how **embarrassed** or **self conscious** have you been because of your skin? demb_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	
	Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden?** dshop_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin influenced the **clothes** you wear? dclothes_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin affected any **social** or **leisure** activities? dsocial_n	Very much	☐(3)	

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		A lot A little Not at all	☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin made it difficult for you to do any **sport**? dsocial_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, has your skin prevented you from **working** or **studying**? dwork_n	yes no	☐(1) ☐(0)	Not relevant ☐(8)
	If "No", over the last week how much has your skin been a problem at **work** or **studying**? dwmuch_n	A lot A little Not at all	☐(2) ☐(1) ☐(0)	
	Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**? dpart_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much has your skin caused any **sexual difficulties**? dsex_n	Very much A lot A little Not at all	☐(3) ☐(2) ☐(1) ☐(0)	Not relevant ☐(8)
	Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time? dtreat_n	Very much A lot	☐(3) ☐(2)	

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		A little Not at all	☐(1) ☐(0)	Not relevant ☐(8)

Note: fields ending with '_n' contain the numeric value; they have corresponding fields ending '_d' which contain the short text description

Thank you for taking the time to fill in this questionnaire. Once completed, please return it in the stamped addressed envelope provided to:

STOP GAP Trial Manager
Nottingham Clinical Trials Unit
Office B39, Medical School
Queen's Medical Centre
Derby Road
Nottingham
NG7 2UH

PLEASE NOTE THIS IS A SOURCE DOCUMENT

We are interested to know whether the patient has had a recurrence of their pyoderma gangrenosum since they completed the trial.

Please use the hospital notes to complete this form. We would like to know of any recurrences since <insert date of final visit>.

EOTCRF

Question number		
1	Since the date given above, has the patient had a further episode of PG? furpg	☐ Yes, go to Q2 ☐ No, go to Q3
2	If yes, what was the date of the **first** recurrence? frecdat	D D M M M Y Y Y Y
3 4	Following the patient's final study visit, ~~how did you~~ treat them? treat	The trial drug was tapered ☐
		Maintenance dose given ☐
		Other (please specify) ☐ _____ trtoth _____
4	Any further comments	comm1 comm2 comm3

CRF SIGN-OFF

I confirm that the information contained in this CRF is accurate to the best of my knowledge:

_____ _____

Signed Date