Biomarkers and Stratification To Optimise outcomes in Psoriasis

BASELINE CRF

BSTOP ID: ☐☐ **B S T** ☐☐☐☐

Non BADBIR cohort

For protocol version 8 and consent version 7

Initials: ☐☐☐ **DOB:** d d m m y y **Sex at birth: Male** ☐ **Female** ☐

ETHNICITY (Please circle): White / Black or Black British / Asian or Asian British / Chinese, Japanese, Korean or Indochinese / Mixed background / Other

If **Other** or **Mixed background**, please specify: ____________________

PATIENT CONSENT

- > **Is the patient due to enrol onto BADBIR or already on BADBIR?** **YES** ☐ **NO** ☐ NO is required for this CRF
- > **Has the patient given written Informed Consent for BSTOP? i.e., has the patient initialled all mandatory items 1-10 on the consent form?** **YES** ☐ **NO** ☐ Not eligible for recruitment if NO
- > **Date of Consent to B-STOP:** d d m m y y

OPTIONAL PATIENT CONSENT ANSWERS

- > **Does the patient consent to NHS data linkage?** (Question 11) **YES** ☐ **NO** ☐

The patient NHS number and Post Code should be added directly onto CAPTURE. Only provide this information on the CRF if you are sending it to the central study team and only via secure means (e.g. an nhs.net email).

NHS No ____________________ **Post Code** __________

- > **Does the patient consent to being recalled?** (Question 12) **YES** ☐ **NO** ☐

Patient contact information should be added directly onto CAPTURE. Only provide this information on the CRF if you are sending it to the central study team and only via secure means (e.g. an nhs.net email). Minimum of 1 field required.

Patient contact email address (preferred) ____________________

Patient contact phone number ____________________

Patient address including postcode ____________________

DIAGNOSIS - PSORIASIS

Year of Diagnosis y y y y **Year first seen by a dermatologist** y y y y

Year of Onset y y y y

Does the patient have a diagnosis of Psoriatic Arthritis by a Rheumatologist?

YES ☐ **NO** ☐ **Year of Rheumatologist diagnosis** y y y y

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MEDICAL HISTORY - GENERAL MEDICAL HISTORY

Has the patient ever been diagnosed with (required treatment for) any of the following illnesses? (tick all that apply) **No history** ☐

Hypertension	**Yes**	**Year of Onset**
Hypertension	☐	y y y y
Cardiovascular Disease	**Yes**	**Year of Onset**
Angina	☐	y y y y
Dyslipidaemia	☐	y y y y
Myocardial Infarction	☐	y y y y
Stroke/Cerebrovascular Disease	☐	y y y y
Peripheral Vascular Disease	☐	y y y y
Autoimmune Disorders	**Yes**	**Year of Onset**
Thyroid Disease	☐	y y y y
Alopecia Areata	☐	y y y y
Vitiligo	☐	y y y y
Psoriatic arthritis	☐	y y y y
Thrombosis	**Yes**	**Year of Onset**
Deep Vein Thrombosis	☐	y y y y
Pulmonary embolism	☐	y y y y
Liver Disease	**Yes**	**Year of Onset**
NAFLD (Including fatty liver and NASH)	☐	y y y y
Inherited Liver Disease (inc haemochromatosis)	☐	y y y y
Auto Immune Hepatitis	☐	y y y y
Drug Induced Hepatitis	☐	y y y y
Viral Hepatitis	☐	y y y y
Hepatitis A	☐	y y y y
Hepatitis B	☐	y y y y
Hepatitis C	☐	y y y y
Alcoholic Liver Disease	☐	y y y y
Fibrosis	☐	y y y y
Cirrhosis	☐	y y y y
Cholestatic Liver (Primary Biliary Cirrhosis)	☐	y y y y
Cholestatic Liver (Primary Sclerosing Cholangitis)	☐	y y y y
Cholestatic Liver (Other/Unspecified)	☐	y y y y
Asthma	**Yes**	**Year of Onset**
Asthma	☐	y y y y
COPD	**Yes**	**Year of Onset**
COPD (inc. chronic bronchitis, emphysema)	☐	y y y y

Kidney Disease	**Yes**	**Year of Onset**
Chronic Kidney Disease	☐	y y y y
Glomerular Disease	☐	y y y y
Renovascular Kidney Disease	☐	y y y y
Inherited Renal Disease (polycystic kidney disease)	☐	y y y y
Demyelination	**Yes**	**Year of Onset**
Optic Neuritis	☐	y y y y
Multiple Sclerosis	☐	y y y y
Transverse Myelitis	☐	y y y y
Chronic inflammatory demyelinating polyneuropathy	☐	y y y y
Guillain-Barre Syndrome	☐	y y y y
Wilson's Disease	☐	y y y y
Peptic Ulcer	**Yes**	**Year of Onset**
Peptic Ulcer	☐	y y y y
Epilepsy	**Yes**	**Year of Onset**
Epilepsy	☐	y y y y
Non-skin Cancer (please specify type and site)		**Year of Onset**
		y y y y
		y y y y
		y y y y
Psychiatric	**Yes**	**Year of Onset**
Depression	☐	y y y y
Anxiety	☐	y y y y
Inflammatory Bowel Disease	**Yes**	**Year of Onset**
Crohn's Disease	☐	y y y y
Ulcerative colitis	☐	y y y y
Irritable Bowel Syndrome	☐	y y y y
Diabetes	**Yes**	**Year of Onset**
Type I	☐	y y y y
Type 2	☐	y y y y
Type Unspecified	☐	y y y y
Impaired Glucose Tolerance	☐	y y y y
Polycystic Ovary Syndrome (PCOS)	**Yes**	**Year of Onset**
Polycystic Ovary Syndrome (PCOS)	☐	y y y y

OTHER (e.g. major operations)

______________________ ______________________

______________________ ______________________

FAMILY HISTORY OF PSORIASIS

Does the patient have any family history of Psoriasis? **YES** ☐ **NO** ☐

Family Member **Relationship and Paternal/Maternal side if relevant**	**Type of Psoriasis** **Plaque/Inverse/Guttate/Pustular/Erythrodermic/Unknown**

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SKIN CANCER RISK FACTORS

Please indicate the patient's Fitzpatrick skin type

Description	Type	Yes
Burns easily, never tans	1	
Burns easily, tans minimally	2	
Burns moderately, tans gradually	3	
Burns minimally, tans well	4	
Rarely burns, tans profusely	5	
Never burns, deeply pigmented	6	

History of prior neoplastic or pre-cancerous lesions? **YES** ☐ **NO** ☐

Type	Site	Number
SCC		
BCC		
Melanoma		
Melanoma in situ		
Actinic keratosis		
Bowen's disease		
Keratoacanthoma		

SMOKING AND ALCOHOL HISTORY

SMOKING

Has the patient ever smoked more than one cigarette? **YES** ☐ **NO** ☐

If Yes, what was the average number of cigarettes per day? ☐

Age started smoking ☐

Age stopped smoking ☐

Does the patient currently smoke more than one cigarette per day? **YES** ☐ **NO** ☐

If Yes, how many cigarettes does the patient smoke each day? ☐

ALCOHOL

Does the patient drink alcohol? **YES** ☐ **NO** ☐

If yes, how many units in an average week? ☐

Alcoholic Drink	No. of Units
A pint of ordinary beer/lager (4%)	2.3
A pint of strong lager	3
A standard (175ml) glass of wine	2
A large (250ml) glass of wine	3
A small (25ml) glass of spirits	1
A 275ml bottled alcopop	1.5

BSTOP ID: | | | B | S | T | | | | |

INITIALS | | | |

BIOLOGIC DRUG THERAPY

Please complete details for the patient's current or expected biologic psoriasis treatment as well as any previous biologic treatments:

Has the patient ever been exposed to biologics treatment? **Yes** ☐ **No** ☐

Is this the patient's first exposure to biologics? **Yes** ☐ **No** ☐

Current Biologic Drug

Drug name	Trade Name	Maintenance Dose (mg)	Frequency	Date of treatment initiation	Batch Number	Is the start date estimated?
				d d m m y y		Yes ☐ No ☐

Previous Biologic Drugs

Drug name	Trade Name	Maintenance Dose (mg)	Frequency	Date of treatment	Date of final dose	* Reason for	Is the final dose
				d d m m y y	d d m m y y		Yes ☐ No ☐
				d d m m y y	d d m m y y		Yes ☐ No ☐
				d d m m y y	d d m m y y		Yes ☐ No ☐
				d d m m y y	d d m m y y		Yes ☐ No ☐
				d d m m y y	d d m m y y		Yes ☐ No ☐
				d d m m y y	d d m m y y		Yes ☐ No ☐

*** Reasons for stopping**

1 - Inefficacy, 2 - Remission, 3 - Adverse Events, 4 - Other, 5 - Not Known

BSTOP ID: | | | B | S | T | | | | | INITIALS | | | |

CONVENTIONAL AND SMALL MOLECULE THERAPY

Please complete details for the patient's current or expected conventional/small molecule psoriasis treatments, as well as any previous conventional treatments:

Has the patient ever been exposed to conventional/small molecule therapy? **Yes** ☐ **No** ☐

Current Conventional and/or small molecule Drugs

Drug name	Drug Route (If Methotrexate)	Maintenance Dose (mg)	Frequency	Date of treatment initiation	Is the start date estimated?
	Oral ☐ SC ☐			d d m m y y	Yes ☐ No ☐
	Oral ☐ SC ☐			d d m m y y	Yes ☐ No ☐

Previous Conventional and small molecule Drugs

Drug name	Drug Route (If Methotrexate)	Maintenance Dose (mg)	Frequency	Date of treatment initiation	Date of final dose	* Reason for stopping	Is the final dose date estimated?
	Oral ☐ SC ☐			d d m m y y	d d m m y y		Yes ☐ No ☐
	Oral ☐ SC ☐			d d m m y y	d d m m y y		Yes ☐ No ☐
	Oral ☐ SC ☐			d d m m y y	d d m m y y		Yes ☐ No ☐
	Oral ☐ SC ☐			d d m m y y	d d m m y y		Yes ☐ No ☐
	Oral ☐ SC ☐			d d m m y y	d d m m y y		Yes ☐ No ☐
	Oral ☐ SC ☐			d d m m y y	d d m m y y		Yes ☐ No ☐

*** Reasons for stopping**

1 - Inefficacy, 2 - Remission, 3 - Adverse Events, 4 - Other, 5 - Not Known

OTHER DRUG THERAPY

Is the patient currently using either of the following topical treatments?

Topical Pimecrolimus	Yes		No	
Topical Tacrolimus	Yes		No	

Please list all the patient's concomitant therapies (current and past) for any indication. PLEASE NOTE over the counter and self-medication is <u>not required</u>.

Please note we do not need details of topical therapy for psoriasis but for the two mentioned above

Drug name	Date Started	Start date estimated?	Date Stopped	Stop date estimated?
	d d m m y y	Yes ☐ No ☐	d d m m y y	Yes ☐ No ☐
	d d m m y y	Yes ☐ No ☐	d d m m Y Y	Yes ☐ No ☐
	d d m m y y	Yes ☐ No ☐	d d m m Y Y	Yes ☐ No ☐
	d d m m y y	Yes ☐ No ☐	d d m m Y Y	Yes ☐ No ☐
	d d m m y y	Yes ☐ No ☐	d d m m Y Y	Yes ☐ No ☐
	d d m m y y	Yes ☐ No ☐	d d m m Y Y	Yes ☐ No ☐
	d d m m y y	Yes ☐ No ☐	d d m m Y Y	Yes ☐ No ☐
	d d m m y y	Yes ☐ No ☐	d d m m Y Y	Yes ☐ No ☐
	d d m m y y	Yes ☐ No ☐	d d m m Y Y	Yes ☐ No ☐
	d d m m y y	Yes ☐ No ☐	d d m m Y y	Yes ☐ No ☐

UV THERAPY

Has the patient every received UV therapy? **YES** ☐ **NO** ☐

If yes, please complete the following details

UV Therapy	Yes	No. of courses	No. of treatments	Cumulative dose (J/cm^2)
Broadband UVB				
Narrowband UVB				
Total body PUVA				
Oral PUVA				
Topical PUVA				
Hand and foot PUVA				
Oral PUVA				
Topical PUVA				

PSORIASIS ASSESSMENT

What type of psoriasis does the patient currently have? Please also record any past history of psoriasis types:

If unsure, tick unknown. If no, leave unticked.

Type	CURRENT	PAST HISTORY	UNKNOWN
Chronic Plaque Psoriasis (CPP)			
└→ Small (≤ 3cm diam)			
└→ Large (> 3cm diam)			
Flexural/intertriginous			
Seborrheic psoriasis			
Scalp			
Palms/soles (non-pustular)			
Nails			
└→ If yes, indicate number of nails affected			
Guttate psoriasis			
Unstable psoriasis			
Erythrodermic			
Generalised pustular psoriasis (GPP)			
Localised pustular psoriasis (LPP)			
└→ Acrodermatitis Hallopeau			
└→ Palmoplantular pustulosis			
Psoriatic Arthritis			
└→ Axial arthritis			
└→ Peripheral arthritis			
Other (please specify)			

Has the patient ever been hospitalised for psoriasis? YES ☐ NO ☐

DISEASE SEVERITY - Please indicate the current disease severity *ideally from sample collection date, but within past 6 months is ok

PASI ☐☐.☐ **DLQI** ☐☐ **Date of disease severity assessment:** d d m m y y

Physician Global Assessment (PGA)

Severe ☐ Moderate to Severe ☐ Moderate ☐ Mild ☐ Almost Clear ☐ Clear ☐

Patient Global Assessment (PtGA)

Severe ☐ Moderate to Severe ☐ Moderate ☐ Mild ☐ Almost Clear ☐ Clear ☐

BSA - For patients with Pustular Psoriasis only

BSA ☐ **Date of BSA assessment:** d d m m y y

DISEASE SEVERITY - Continued

Most severe recorded PASI __ __ . __ **Date of disease severity assessment:** d d m m y y

CLINICAL MEASUREMENTS

Systolic ______ *mmHg* **Diastolic** ______ *mmHg*

Height ______ *cm* **Weight** ______ *kg* **Waist** ______ *cm*

LABORATORY VALUES

Include those collected before baseline, but recent results (i.e. within the last 4 weeks)

Laboratory value	Result	Date	
Haemoglobin count (g/dL)		d d m m y y	
White blood count (x10^9/L)		d d m m y y	
Platelet count (x10^9/L)		d d m m y y	
Creatinine (µmol/L)		d d m m y y	
Transaminase ALT (IU/L)		d d m m y y	
Cholesterol total (mmol/L)		d d m m y y	
Triglycerides (mmol/L)		d d m m y y	
HDL (mmol/L)		d d m m y y	

SAMPLE COLLECTION

Please tick boxes to confirm collection

> **FOR ALL PATIENTS - DNA SAMPLE** 2 x 6ml PINK TOP EDTA tube 1 2

- *Post on collection day using postal kits and Tracked Returns labels provided. Refer to the* ***SOP for BSTOP Partner Sites*** *document for guidance*

Please confirm the date the samples were taken d d m m y y

Clinician's Name ______________________

Clinician's Signature ______________________ Date: d d m m y y