Please complete or attach patient

Follow-up Number ☐

BIR Biologic Interventions Register

BADBIR ID: ☐☐☐☐☐☐☐☐☐

BAD Biologic Interventions Register Clinical Follow-Up Questionnaire

BIOLOGIC / IMMUNOMODULATOR COHORT ONLY:

Biologic Therapy

Since the patient's last follow up have their been any changes to their biologic / immunomodulatory therapy? Yes ☐ No ☐

If yes, **please record all changes for biologic**

Drug	Batch Number	Dose / unit	Frequency	Date started *ddmmyy*	Date of final dose *ddmmyy*	*Stop reason

***Stop reasons:** (1) Inefficacy (2) Remission (3) Adverse Events (4) Inefficacy and Adverse Events (5) Patient Non-Compliance (6) Titration (7) Financial Consideration (8) Patient Choice (9) Other (please provide detail)*

If **infliximab or Stelara** please provide the administration dates

	d d m m y y	mg/kg

HUMIRA ONLY: Did the patient receive the 80mg loading dose? **Yes** ☐ **No** ☐

TALTZ ONLY: Was the recommended opening schedule followed? (i.e. 160mg at week 0, 80mg at weeks 2, 4, 6, 8, 10, and 12) **Yes** ☐ **No** ☐ **Currently Unknown** (will advise at next follow-up) ☐

COSENTYX ONLY: Was the recommended opening schedule followed? (i.e. 300mg at weeks 0, 1, 2, 3 & 4) **Yes** ☐ **No** ☐ **Currently Unknown** (will advise at next follow-up) ☐

Were any scheduled doses missed? For Taltz/Cosentyx was there any deviation from the opening schedule? If yes please record details:

please record an adverse event if appropriate

CONVENTIONAL COHORT ONLY:

Conventional Therapy

Since the patient's last follow up have there been any changes to their systemic therapy? Yes ☐ No ☐

If yes, **please record all changes for systemic agents:**

Drug	Dose / unit	Frequency	Date started *ddmmyy*	Date of final dose *ddmmyy*	*Stop reason

***Stop reasons:** (1) Inefficacy (2) Remission (3) Adverse Events (4) Inefficacy and Adverse Events (5) Patient Non-Compliance (6) Titration (7) Financial Consideration (8) Patient Choice (9) Other (please provide detail)*

Since the patient's last follow up have they started biologic therapy? Yes ☐ No ☐

If yes please enter details of their biologic therapy in the Biologics Only box at the top of this page.

UV Therapy

Since the patients last follow-up have they had any UV therapy? Yes ☐
If yes please complete the following: No ☐

UV Therapy Details	Yes	No. of Courses	No. of Treatments	Cumulative Dose (J/cm^2)	Data Known to be Accurate?
Broadband UVB					
Narrowband UVB					
TOTAL BODY PUVA					
Oral PUVA					
Topical PUVA					
HAND AND FOOT PUVA					
Oral PUVA					
Topical PUVA					
UVA 1					

Concomitant Therapy

Since the patient's last follow up have they had any changes to their concomitant therapy?
Please list all changes below: *(please note we do not need details of topical therapy for psoriasis except for tacrolimus and pimecrolimus)*

Drug	Start date	Stop date	Are these dates estimated?

Lab Values

Please complete the following laboratory values (recent i.e. within last 6 months):

LABORATORY VALUES	Result	Date
Haemoglobin count (g/dL)		
White cell count (x10^9/L)		
Platelet count (x10^9/L)		
Creatinine (µmol/L)		
Transaminase ALT (U/L)		
Cholesterol (mmol/L)		
Triglyceride (mmol/L)		
HDL (mmol/L)		

FUP7 + : Lab Values not required

Since date of last data entry has your patient experienced any adverse events)?

Yes ☐

No ☐

An adverse event (AE) is defined as any medically untoward event occurring in a patient whether or not related to any treatment or medication

A serious adverse event (SAE) is defined by the classifications in the box below

Please enter details of ALL adverse events (both serious and non-serious) from this follow-up period

Event No.	Short description of event (please record diagnosis if available)	**Description of event**	**Start date**	Start Date Estimated?	Stop date	Stop Date Estimated?	Is the event ongoing?	Is the event related to biologic therapy? *Yes, No or Possibly* *Not required for conventional cohort patients*	Yellow Card Sent?	Is the event a SAE ? If yes please select code (see below)	Is the event an ESI? If yes please select from list (see below)	Outcome of the event?
								If 'Yes' Name of Biologic:________		If 'Hospitalisation' Admission Date:________ Discharge Date:________		Resolved ☐ Resolved w/ Sequelae ☐ Not Resolved ☐ Unknown ☐ Death ☐
								If 'Yes' Name of Biologic:________		If 'Hospitalisation' Admission Date:________ Discharge Date:________		Resolved ☐ Resolved w/ Sequelae ☐ Not Resolved ☐ Unknown ☐ Death ☐
								If 'Yes' Name of Biologic:________		If 'Hospitalisation' Admission Date:________ Discharge Date:________		Resolved ☐ Resolved w/ Sequelae ☐ Not Resolved ☐ Unknown ☐ Death ☐
								If 'Yes' Name of Biologic:________		If 'Hospitalisation' Admission Date:________ Discharge Date:________		Resolved ☐ Resolved w/ Sequelae ☐ Not Resolved ☐ Unknown ☐ Death ☐
								If 'Yes' Name of Biologic:________		If 'Hospitalisation' Admission Date:________ Discharge Date:________		Resolved ☐ Resolved w/ Sequelae ☐ Not Resolved ☐ Unknown ☐ Death ☐

Code	SAE Classification
1	Death
2	Hospitalisation
3	IV Anti-biotics/virals/fungals
4	Significant loss of function or disability
5	Congenital malformation
6	Was in any way life threatening
7	Medically Important Event

If any of the events you have listed include any of the following, an Event of Special Interest (ESI) form needs to be completed:

- *Aplastic anaemia, pancytopaenia or serious neutropenia*
- *Cerebrovascular Accident (CVA)*
- *Hepatitis B Reactivation*
- *Lymphoproliferative Disease*
- *Malignancy (not inc. skin)*
- *Melanoma / Skin Cancer (inc. Bowens Disease)*
- *Drug misuse, abuse, overdose and medication*
- *Myocardial Infarction/Acute Coronary Disease*
- *Pregnancy*
- *Progressive Multifocal Leukoencephalopathy*
- *Pulmonary Embolism*
- *Serious Congestive Heart Failure*
- *Serious Hepatic Dysfunction/Failure*
- Serious Hypersensitivity Reaction
- Serious Infection (excl. TB)
- Serious Lupus/Lupus like illness
- Serious Psoriasis Flare *(Overnight Hospitalisation Only)*
- Serious Skin Reaction
- Surgery *(Overnight Hospitalisation Only)*
- Tuberculosis (Not Latent)

Current Disease Severity

Please indicate the current disease severity (i.e. at the time the patient started the new drug)

BSA ☐☐ ***Only if the patient has pustular psoriasis,***

Date of BSA …../……/……

Please details of all PASI's that have been completed since the patients last follow-up.

PASI	Date of PASI	Psoriasis Global Assessment

Psoriasis Global Assessment score:

- Severe
- Moderate to severe
- Moderate
- Mild
- Almost clear
- Clear

Has the patient been diagnosed with psoriatic arthritis by a rheumatologist? **Yes** ☐ **No** ☐

if this is a new diagnosis please remember to add this as an adverse event

Additional Information

What is the patient's current weight and waist circumference?

Weight ☐☐☐ kg

Waist circumference ☐☐☐ cm

FUP9 + :
Weight / Waist not required

If the patient is under 16 year of age on the date of this follow-up, please provide a height measurement: ☐☐☐ cm

Patient Follow-up Questionnaire

The patient questionnaire should also be completed containing:

Occupation Qus ☐
DLQI ☐
EuroQol ☐

Lifestyle Qus ☐
CAGE ☐
***HAQ** ☐

If paediatric patient:

cDLQ ☐
EQ-5D-y ☐
***cHAQ** ☐

FUP 7+ :
Patient Questionnaire is not required

(*Only if patient has a rheumatologist's diagnosis of inflammatory arthritis)

Signature

Please sign and date below:

Clinician's signature:_____ **Date:** _____