British Society for Rheumatology

Rheumatoid Arthritis Register

Switching a cohort

Version 2 - 02/10/2023

Before requesting a cohort switch please check the following:

- Patient has a diagnosis of Rheumatoid Arthritis
- Started an eligible drug within the last 24 months (Drug eligibility can be checked on our website)
- Drug start date is known
- DAS28 or Low Disease Activity (switch from originator to a biosimilar) is available
- A new current version Consent Form is completed (including patient initials and signature)

→ If all of the above are available please continue with the registration.

Go to the patient summary page for the patient you want to re-register. On the menu on the left hand side, click 'Switch Cohort'

Patient Status: Trainin	ng - Current	[Click here	to reveal Pat	ient Identifiable	Data]			
Menu	Study ID:	Co	hort: Anti-TN	F	Created by P	CDDD DA on 00 (00 /20	10	
View All Patients Add a New Patient	Consent Da	Follow up	Due date	Follow up status	Date entered	Date last updated	Editable?	Quick Actions
View Records in Edit Window	Select	Baseline [†]	04/08/2019	Queried	06/08/2019	06/08/2019	Edit window not open	
Currently Due Follow-Ups	Select	1 +	01/12/2019	Completed	10/01/2020	10/01/2020	Edit window not open	
Follow-Ups Due Next Month	Select	2 *	04/05/2020	Completed	07/05/2020	13/05/2020	Edit window not open	
Follow-Ups Due Next 3 Months	Select	3 +	04/02/2021	Completed	16/08/2021	16/08/2021	Edit window not open	
This Patient	Select Edit	4 +	04/08/2021			06/08/2019	Can be opened	
RA Details	Select Edit	5 +	04/02/2022			06/08/2019	Can be opened	
Switch Cohort		6 +	04/08/2022			06/08/2019	Edit window not open	
	Unsolved	Queries rega	arding this col	aort				

Choose the appropriate drug from the dropdown list and complete the start date, dose and unit and frequency. Please provide a DAS28 score (or disease indication) at the time of switch in the 'Any other information' box.

Patient Status: Training - Current [Click here to reveal Patient Identifiable Data]

Switch Cohort from Anti-TNF

If the patient has commenced a new therapy, they might need to be switched into a new cohort. Please refer to the criteria for registration as a cohort switch Here For the new cohort, a new baseline will be created and the follow-ups will reset as a new registration. The current cohort record will be cut-off at the date of exposure to the new drug; any existing data after the cut-off date will be moved to the new cohort record for this patient. Please ensure that the existing follow ups are fully complete to the best of your knowledge before requesting a cohort switch.

New drug: < Please Choose>
Commenced date: dd/mm/yyyyy
Dose & unit: < Please Choose> +
Frequency: < Please Choose>
Subsequent infusions & batch:
Any other information:
Request Cohort Switch Cancel

Once you complete the form, a feedback note with the details will appear under the 'Unsolved Queries regarding this cohort' section on the patient summary. The admin team will check the details and raise any necessary queries before switching the cohort and generating the new patient ID.

Patient Status: Training	g - Current	[Click here	to reveal Pat	ient Identifiable	Data]			
	Study ID:		hort: Anti, TN	5				
Menu	Consent Da	te: 04/08/2019	Consented B	r iy:	Created by B	SRBR RA on 06/08/20)19	
View All Patients		Follow	Due date	Follow up	Date	Date last	Editable?	Quick
Add a New Patient		up	Duc date	status	entered	updated	Europer	Actions
View Records in Edit Window	Select	Baseline ⁺	04/08/2019	Queried	06/08/2019	06/08/2019	Edit window not open	
Currently Due Follow-Ups	Select	1 +	01/12/2019	Completed	10/01/2020	10/01/2020	Edit window not open	
Follow-Ups Due Next Month	Select	2 *	04/05/2020	Completed	07/05/2020	13/05/2020	Edit window not open	
Follow-Ups Due Next 3 Months	Select	3 †	04/02/2021	Completed	16/08/2021	16/08/2021	Edit window not open	
This Patient	Select Edit	4 +	04/08/2021			06/08/2019	Can be opened	
RA Details	Select Edit	5 +	04/02/2022			06/08/2019	Can be opened	
Switch Cohort		6 †	04/08/2022			06/08/2019	Edit window not open	
Send Feedback	Unsolved C	Jueries regard	ding this cohor	t		Description		

Cohort

Switch

Open

Cohort switch request has been raised for this patient. Current Cohort:Inflectra New Drug: Rixathon (rituximab biosimilar) Start Date: 14/09/2023 Dose: 1000

mg - Fortnightly Batch and Dosage details: Other Information: DAS 4.2 on 10/09/2023 New consent form available

The new ID will appear at the top of the patient summary. The patient status will be set to 'Awaiting approval' until the registration is complete and has been checked. The admin team will also leave a feedback note on the cohort switch request letting you know what information we need.

Patient Status: Awaiti	ng Approval	[Click here t	to reveal P	atient Identifiable	Data]				1			
	Study ID	Colo	auto Davran	-11								
Menu	Consent Date	Not Entered	Consenter	ed By: Not Entered	Created by .	on 21/01/2	2022					
View All Patients	Fol	low up D	ue date	Follow up status	Date entered	Date last updated	Editable?	Quick Actions				
Add a New Patient	Select Bas	eline ⁺ 13,	/01/2022	In Edit Window	21/01/2022	21/01/2022	Days left to edit: 14 🕜	Verified Queried Missed Raise Queries				
View Records in Edit Window	Edit 1 ⁺	13,	/07/2022			21/01/2022	Cannot yet be opened	Verified Queried Missed Raise Queries				
Currently Due Follow-Ups	Unsolved Q	ueries regar	rding this o	cohort								
Follow-Ups Due Next Month	No unsolved	d queries										
Follow-Ups Due Next 3 Months	Feedback re	garding thi	s patient									
This Patient	No Feedbac	k Unsol	ved Queri	es regarding this	cohort							
Demographics							Description			FUP	Status	Ту
RA Details Switch Cohort	Solved Que	ries n	Cohort mg - O 1 Reply	switch request has b nce a week Batch an v received	een raised for this d Dosage details: (patient. Current Coho Other Information: DA	rt:Anti-TNF New Drug: Bene S = 3.44 on 13/01/2022	pali (etanercept biosimilar) Start Date: 13/01/2022	Dose: 50		0.000	Coho
	No Solved C	Querie	21 Jan uploac	2022 11:29AM BSRE a new consent form	BR RA: The new stu n and add the HAC	idy ID for this patient is Q/EQ5D. Please also an	s Please complete the swer the TB/Herpes Zoster c	current therapy and co-morbidities sections of the uestions on the Additional Information page	e baseline,		Open	Switc
+ New Query												
	Previous C	ohort										
	Study ID:	Coh	ort: Anti-T	INF								
	Consent Date	04/08/2019	Consented	d By:	Created by B	SRBR RA on 06/08/2019	9					
		Follow up	Due da	te Follow up st	atus Date ente	red Date last upda	ated Editable?	Quick Actions				
	Select	Baseline ⁺	04/08/20	019 Queried	06/08/201	9 06/08/2019	Edit window not o	ben Verified Queried Missed Raise Queries				
	Select	1 +	01/12/20	019 Completed	10/01/202	10/01/2020	Edit window not o	ben Verified Queried Missed Raise Queries				

Click **Select** to enter into the baseline form, you have 14 days to enter data before the edit window is closed.

	Study ID:	Cohort: Bene	pali				
Menu	Consent Date: Not En	tered Consen	• ted By: Not Entered	Created by	on 21/01/2	022	
View All Patients	Follow up	Due date	Follow up status	Date entered	Date last updated	Editable?	Quick Actions
Add a New Patient	Select Baseline +	Click	Select ,	21/01/2022	21/01/2022	Days left to edit: 14 😯	
/iew Records in Edit Window	Edit 1 ⁺	13/07/2022			21/01/2022	Cannot yet be opened	
Currently Due follow-Ups	Unsolved Queries r	egarding this	cohort				
ollow-Ups Due Iext Month	No unsolved queries						
ollow-Ups Due lext 3 Months	Feedback regarding	g this patient					
his Patient	No Feedback						
emographics							
A Details							
witch Cohort	Solved Queries reg	arding this co	hort				
	No Solved Queries						
Send Feedback							

You will be asked to add the Consent Form details and to upload a new Consent Form. Enter the date that the <u>PATIENT</u> signed the consent form. Click on **Confirm consent date.**

Study ID:	Cohort: Benepali Baseline FUP Status: In Edit Window Due Date: 13/01/2022
Datient	Concent Form
Patient summary	Consent Potnik
CBQ	Consent Details
Consent	Date the patient signed consent form:
Disease Activity	
Biologic Targeted Therapy	Consent obtained by:
Other Current Therapy	Consent Form Version: 1
Previous Biologics DMARDs / Steroids	Upload Consent Form (Up to 2MB) Choose file No file chosen
Comorbidity	Save Tutorial
Additional Info	
COVID-19 Vaccine	

Select the appropriate person from the list of approved team members from the drop list.

Please leave a feedback note if that team member is not included on the list.

Add the Consent Form Version number* from consent and select **Choose file.** *please use the current version of the consent form, available on our website <u>here</u>.

Study ID:	Cohort: Benepali Baseline FUP Status: In Edit Window Due Date: 13/01/2022
Patient	Consent Form
Patient summary	Consent Details
CBQ	
Consent	Date the patient signed consent form: 01/01/2022
Disease Activity	
Biologic Targeted Therapy	Consent obtained by:
Other Current Therapy	Consent Form Version: 9
Previous Biologics DMARDs / Steroids	Upload Consent Form (Up to 2MB)
Comorbidity	Save Tutorial
Additional Info	
COVID-19 Vaccine	
HROoL	
Once you	have uploaded the consent form, click on 'Other Current Therapy' on the menu to continue.

If the patient is not currently receiving any other therapies, select **No** and then click **Update**.



If the patient is currently receiving any other therapies, select **Yes** and click **Update.**

Patient Status: Aw	aiting Approval [Click here to reveal Patient Identifiable Data]
Study ID:	Cohort: Erelzi Baseline FUP Status: In Edit Window Due Date: 01/11/2021
Patient	Other Current Therapy
Patient summary	Is the patient currently receiving any other therapies?
CBQ	• Yes
Consent	1 Select Yes
Disease Activity	○ No
Biologic Targeted Therapy	O - not set -
Other Current Therapy	Update 2 Click Update
Previous Biologics DMARDs / Steroid	7 Tutorial Advance to Next Section
Comorbidity	
Additional Info	Suggestion
COVID-19 Vaccine	Please ensure all current drugs are listed. All comorbidities should also be listed in the Comorbidity page.
HRQoL	

Selecting update will give the option to add record of drugs. Click **Add New** to begin to add drugs.

Patient Status: Awaitir	ng Approval [Click here to reveal Patient Identifiable Data]
Study ID: Co	hort: Erelzi Baseline FUP Status: In Edit Window Due Date: 01/11/2021
Patient	Other Current Therapy
Patient summary	Is the patient surrently receiving any other therapies?
CBQ	Yes
Consent	
Disease Activity	O No
Biologic Targeted Therapy	O - not set -
Other Current Therapy	Update
Previous Biologics / DMARDs / Steroids	
Comorbidity	No current therapy entered yet. Click "Add New" to enter details or use the boxout above to indicate there is no past/current therapy.
Additional Info	
COVID-19 Vaccine	Add New Click Add New
HRQoL	Tutorial Advance to Neut Section
HAQ	Advance to Next Section
EuroQOL	Suggestion
Other	Please ensure all current drugs are listed. All comorbidities should also be listed in the Comorbidity page.
Preview Queries	у така така така така така така така так

Select the drug type from the drop down list. Indicate if the date is estimated and click **Save Page.** We only ask for start dates for **DMARDs ONLY.** Other therapy can be entered without a start date.

If the drug is not list please leave details in Feedback/Comments.

Patient Status: Awa	iting Approval [Click her	e to reveal Patient Identifiable Da	ta]	
Study ID:	Cohort: Erelzi Baseline	FUP Status: In Edit Window	Due Date: 01/11/20	
Patient	Current Therap	у		NB The criteria for entering part missing dates is as follows:
Patient summary	Drug			 Enter (15' for a missing day
CBQ				
Consent	Primary drug type:	Methotrexate	\$	• Enter '06' for a missing month
Disease Activity	Commenced date (dd/mm/yyyy format, optional):	15/06/2019	Please indicate the date is
Biologic Targeted				estimated
Other Current	Dates estimated:		S	
Therapy	○ - not set -			
Previous Biologics / DMARDs / Steroids	• Yes Ir	ndicate if estimat	ed date	
Comorbidity	O No			
Additional Info				
COVID-19 Vaccine	Route: - not se	t - 🗢		
HRQoL		Click Save		
HAQ	Ca			
EuroQOL	If the drug you wa	nt to enter is not available in the	drop down on this page	please provide the details in Feedback/Comments section
Other			and pug	

Continue the same process until all the patient's Other Current Therapy has been added.



Click on 'Comorbidity' from the menu to continue.

If the patient has no comorbidities please select **No comorbidities** and **Update**.



Click on 'Advance to Next Section' to continue to the Additional Info page.

If the patient has comorbidities please select **Comorbidities** and **Update**. Click **Add New** to enter details.



Select comorbidity from drop down list. Enter Year of onset and indicate if date was estimated. For **Other comorbidities** not listed please enter details in Comorbidity detail.

Patient Patient summary	Comorbidity
CBQ	Comorbidity
Consent	Comorbidity: < Please Choose> Select comorbidity from dropdown
Disease Activity	
Biologic Targeted	Year of onset:
Therapy	Date estimated:
Other Current	
Therapy	• - not set -
Previous Biologics / DMARDs / Steroids	Yes
Comorbidity	No
Additional Info	
COVID-19 Vaccine	Comorbidity detail:
HRQoL	
HAQ	
EuroQOL	

Scroll down to the bottom of the page and click **Save Page** to save record.



When providing Cancer as a co-morbidity please list each cancer separately, providing details of cancer, specifying diagnosis and site(s)

Study ID: Co	hort: Inflectra Baseline FUP Status: Due Date: 15/10/2019
Patient	Comorbidity
Patient summary	Comorbidity
CBQ	Comorbidity:
Consent	Control Statistic Choose
Disease Activity	Year of onset:
Biologic Targeted	
Therapy	Date estimated:
Other Current	• not set -
Therapy	
Previous Biologics /	Yes
DMARDs / Steroids	No
Comorbidity	
Additional Info	Comorbidity detail:
COVID-19 Vaccine	
HRQoL	
HAQ	
EuroQOL	If the patient has (or has ever had) cancer, please specify date of diagnosis and site(s):
Other	
Preview Queries	
Close Edit Window	

If a patient is diabetic please indicate how the patient's diabetes is controlled:

IT the patient is diabetic, now is the disease controlled:
insum dependent.
o - not set -
◎ Yes
No
Tablet controlled:
ont set -
Yes
No
Diet controlled:
o - not set -
Yes
No
Save page Cancel

Continue the same process until all the patient's comorbidity records have been added.

Patient Status: Awa	iting Approval [Click here to reveal Patient Identifiable Data]
Study ID:	Cohort: Erelzi Baseline FUP Status: In Edit Window Due Date: 01/11/2021
Patient	Comorbidity
Patient summary	Comorbidities
CBQ	Please confirm whether the patient has reported comorbidities:
Consent	riedse commit whether the patient has reported comorbialities.
Disease Activity	O No comorbidities
Biologic Targeted	Comorbidities (use 'Add New' to enter details after clicking 'Update')
Therapy	O - not set -
Other Current	
Therapy	Update
DMARDs / Steroids	
Comorbidity	Comorbidity type Onset Year Detail
Additional Info	Select High blood pressure 1990 Delete
	Add New Tutorial Advance to Next Section CIICK to MOVE ONLO the Next Section
TAQ	Suggestion
EuroQUL	Please ensure all comorbidities are listed. All current drugs should also be listed in the Current Drug Therapy page.
Other	
Preview Queries	

On the additional info page, scroll down and complete the TB test and Herpes Zoster question.

Study ID Co	ohort: Benepali Baseline FU	JP Status: In Edit Window Due Date: 13/01/2022
Patient	Additional Info	
Patient summary	Smoking Status	Has the patient had a QuantiEFRON_ELISPOT (or other Gamma interferon based assays for TB) test?
CBQ	Does the patient currently s	
Consent	not set -	In the set -
Disease Activity	• not set -	O Ves
Biologic Targeted	 Current Smoker 	
Therapy	O Ev Smakar	O No
Other Current	O Ex-Sinoker	
Inerapy	 Never smoked 	details:
Previous Biologics / DMARDs / Steroids	 Not Available 	
Comorbidity		
Additional Info	Blood Pressure	
COVID-19 Vaccine	Systolic (mm):	Test Date:
HRQoL	Diastolic (mm):	
HAQ		Has the patient recieved the Herpes zoster vaccine
EuroQOL	Height (cm):	• not set -
		O Yes
Continue	to the HAO	O No
and EQ-	5D section	O Don't know
		Vaccination date:

Continue to add patient completed **HAQ and EuroQOL** via the side menu bar.

Patient Status: Aw	aiting Approval [Click here to reveal Patient Identifiable Data]	
Study ID:	Cohort: Erelzi Baseline FUP Status: In Edit Window Due Date: 01/11/2021	
Patient	Physical Ability (HAQ)	
Patient summary	1 Dressing and Conserving	
CBQ	1. Dressing and Grooming	
Consent	a. Dress yourself, including tying shoelaces and doing buttons:	< Please Choose > 🔶
Disease Activity	b. Shampoo your hair:	< Please Choose >
Therapy	2. Rising	
Other Current Therapy	a. Stand up from an armless straight chair:	< Please Choose > 🗘
Previous Biologics DMARDs / Steroid	b. Get in and out of bed:	< Please Choose > 🗘
Comorbidity	3. Eating	
Additional Info	a. Cut vour meat:	< Plassa Chaosa >
COVID-19 Vaccine		
HRQoL	b. Lift a full cup or glass to your mouth:	< Please Choose > 🗢
HAQ	c. Open a new carton of milk (or soap powder):	< Please Choose >
EuroQOL		
Other	4. Walking	
Preview Queries	a. Walk outdoors on flat ground:	< Please Choose >
Close Edit Windov		

Complete all questions for all of the HAQ with answers from the drop down menu

Patient	Physical Ability (HAQ)
Patient summary	
CBQ	1. Dressing and Grooming
Consent	a. Dress yourself, including tying shoelaces and doing buttons: Without any difficulty \$
Disease Activity	b. Shampoo your hair:
Biologic Targeted Therapy	2 Pieire < Please Choose >
Other Current	2. Rising Without any difficulty
Therapy	a. Stand up from an armless straight chair:
Previous Biologics / DMARDs / Steroids	b. Get in and out of bed: With much difficulty
Comorbidity	3. Fating
Additional Info	Missing
COVID-19 Vaccine	a. Cut your meat: < Please Choose > <

Enter the date completed and click **Save page and advance** at the bottom of the page to move on to the EuroQOL form.

Date completed:		
Save page and advance	Tutorial	

Complete all sections of the EuroQOL, enter the date completed and **Save page** and advance to move on to the Preview Queries section.

Studie ID. C.	hant Fuelai Baaalina FUE Statur la Fait Mindau Due Data 01/11/2021	
study ID: Co	onort: Ereizi Baseline FOP Status: in Edit Window Due Date: 01/11/2021	
Patient	EuroQOL	
Patient summary	EO-5D	
CBQ	1. Mobility:	<please choose=""> 🗢</please>
Disease Activity	2. Self Care:	<please choose=""> 🔶</please>
iologic Targeted herapy	3. Usual Activities:	<please choose=""> 🗢</please>
Other Current herapy	4. Pain/Discomfort:	<please choose=""> 🗘</please>
revious Biologics / MARDs / Steroids	5. Anxiety/Depression:	<please choose=""> \$</please>
omorbidity	Compared with my general level of health over the past 12 months, my health state today is:	<please choose=""> 🗢</please>
dditional Info OVID-19 Vaccine	How do you feel today [0 - 100]:	
IRQoL	Date completed:	
EuroQOL	Save page and advance Click to move onto the next section	

→ Continue to Close Edit Window

If you are happy to complete the record you can select **Close Edit Window** within the FUP record. **NB** Once you have done this you will not be able to make any further amend to the baseline record.

Patient	Close Edit Window
Patient summary	If you have finished entering all baseline or follow-up information for the current patient, you may manually close the edit window. This will return control of the record to the study
CBQ	administration team and allow them to report on the data.
Consent	You will retain "read only" access to all the data you entered, but will no longer be able to make changes. If you require to make changes, please provide details in feedback section
Disease Activity	
Biologic Targeted Therapy	Close Edit Window
Other Current Therapy	
Previous Biologics / DMARDs / Steroids	
Comorbidity	
Additional Info	
COVID-19 Vaccine	
HRQoL	
HAQ	
EuroQOL	
Other	
Preview Queries	
Close Edit Window	
Feedback / Comments	

Once we have all the necessary information, the patient status will be changed back to 'Current'.

Menu	Study I Consent	D: Date: 19/01/2	Cohort: Bene	pali ed Bv: Not Entered	Created by	on 21/01/20	22	
View All Patients		Follow up	Due date	Follow up status	Date entered	Date last updated	Editable?	Quick Actions
Add a New Patient	Select	Baseline ⁺	13/01/2022	Completed	21/01/2022	21/01/2022	Edit window not open	
View Records in Edit Window	Edit	1 *	13/07/2022			21/01/2022	Cannot yet be opened	
Currently Due Follow-Ups	Unsolved Queries regarding this cohort							
Follow-Ups Due Next Month	No unsolved queries							
Follow-Ups Due Next 3 Months	Feedba	ck regarding) this patient					
This Patient	No Fee	edback						
Demographics		abden						
RA Details								
Switch Cohort	Solved	Queries rega	arding this co	hort				
	No Sol	lved Queries						
Send Feedback								