

IBD Registry PMS

Guide for entering essential data for
2016 / 2017 Biologics
Key Performance Indicators (KPIs)

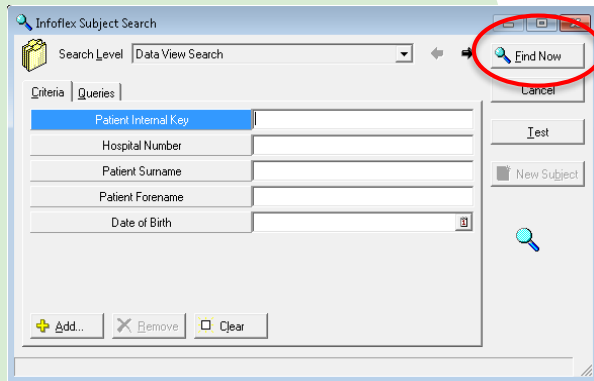
*If the patient's details have already been entered
on the PMS jump to slide 3*

Presentation title: Registering a new patient

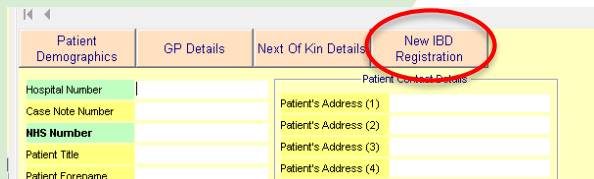
Click the *Binoculars* button.



Enter hospital number, then click *Find Now*.

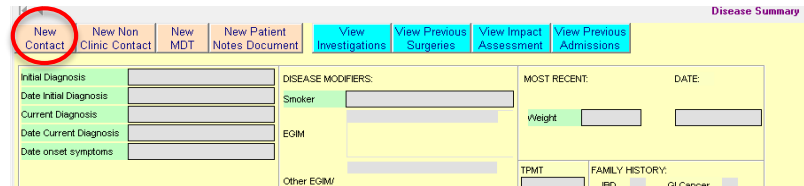


Click *OK* when asked to search PAS.
Select patient. Confirm by clicking *OK*

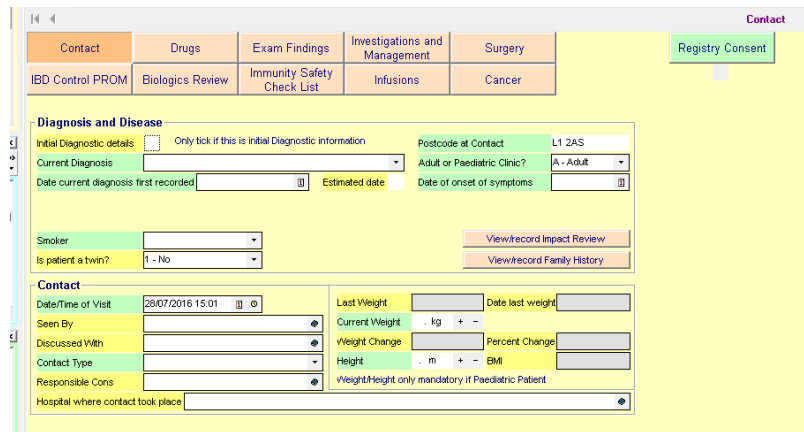


The demographics details appear.
Click *New IBD Registration*.

Disease Summary page opens.



Click *New Contact* to add data on the contact event details.



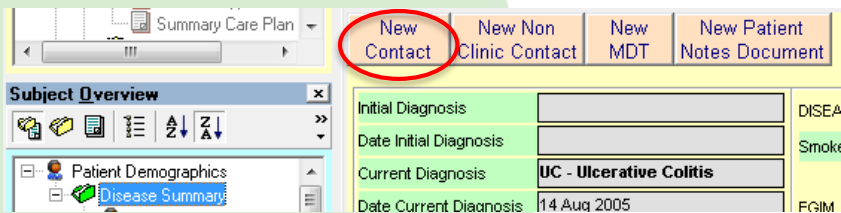
Complete *Diagnosis and Disease* and *Contact* fields. Enter additional details in fields on this page, as much or as little as required. Click *Save*.

Presentation title: Pre-treatment checks

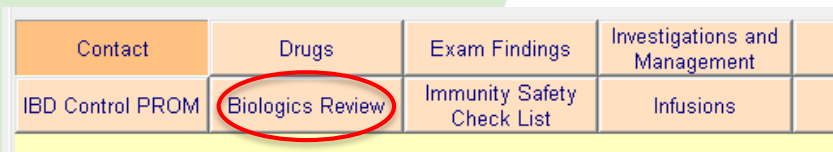
KPI: Was the patient screened before starting on a biological therapy?

Search for patient record using binoculars button 

Once patient record has been located, click on *Disease Summary* in Subject Overview pane.

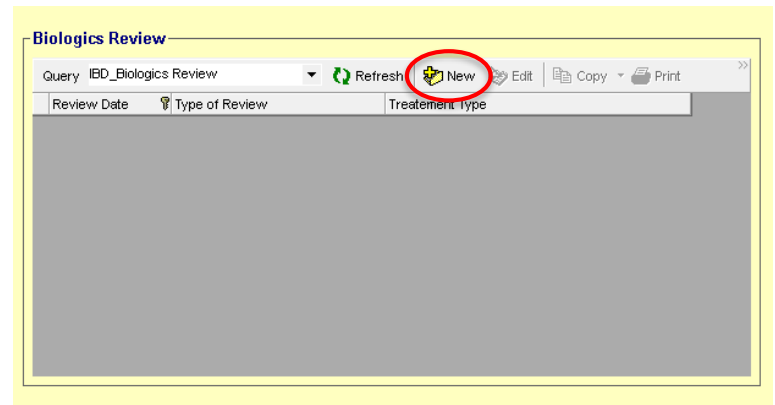


Click *New Contact* button.
Contact screen opens:



Click *Biologics Review* button.

Biologics Review panel opens. Click *New*



See next slide for details.

Tip: to speed up entering data, use the tab key to navigate to a field; use the cursor arrows to choose an answer from a drop down menu.

Presentation title: Pre-treatment checks

KPI: Was the patient screened before starting on a biological therapy?

On Biologics screen complete the fields marked by red arrows:

Biologics

Review Date: 23/07/2018 **Complete this page at each review**

Biologics Drug Review

Type of review: [dropdown]
Age Category at Review: A - Adult
Treatment type: [dropdown]
Patient receiving concomitant immunosuppression: [checkbox]
Concomitant therapies: [text field]
Other Concomitant Therapy: [dropdown]
Physicians Global Assessment: [dropdown]

Scoring

HBI Total Score: [input] **Please only enter one relevant score**
Modified UCDAI: [input]
Weighted PCDAI: [input]
FUCAI: [input]
SCCAI: [input]

Biologic Medication

Drug	Dose	Units	Freq	Route	Date Started	Review Date
------	------	-------	------	-------	--------------	-------------

Go to Initiation or Review Page **Initiation** Review



Click *Initiation* to add the relevant initiation data:

Initiation

Date initial treatment given: [input] Has the patient previously failed to respond or is intolerant to IMM drugs/steroids?: [checkbox]
Specify drugs not tolerated/reacted to: [text field] Any acute reaction recorded?: [checkbox]

UC

Clinical indication (UC): [dropdown]
Extent of UC Adult: [dropdown]

Crohn's

Clinical indication (CD): [dropdown] If Crohn's perianal involvement: [dropdown]
Location Crohn's Adult: [dropdown]
Disease Proximal to terminal ileum (Montreal L4): [dropdown]

Other

Clinical indication (IBOU): [dropdown]
Clinical indication Other: [dropdown]
Other Clinical Indication: [text field]

Is the patient biologics naive?: [checkbox]
Reason for stopping previous biologic treatment: [dropdown]
Other reason for stopping biologic: [text field]

CXR: [dropdown] HIV Serology: [dropdown]
CdIrf Test: [dropdown] TB Test: [dropdown]
HCV Serology: [dropdown] Stool culture test: [dropdown]
HBV Serology: [dropdown] VZV serology: [dropdown]

Back

Make sure to click **Save New Entry (F5)**. **Save New Entry (F5)** Cancel

entering (see red arrows above):

- Review Date
- Treatment type
- Type of review (Initiation)
- Concomitant medications
- Physician's Global assessment and Disease Score

A response needs to be entered into all fields in the table to confirm pre-treatment screening has been completed (blue arrows):

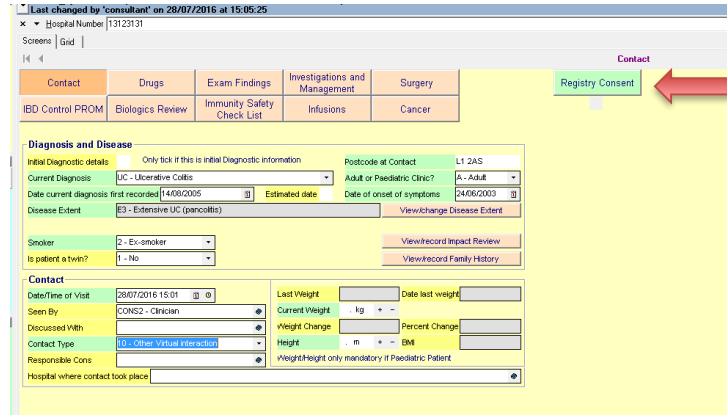
- CXR
- HCV Serology
- HBV Serology
- HIV Serology (Adults only)
- TB Test

Presentation title: Recording patient consent

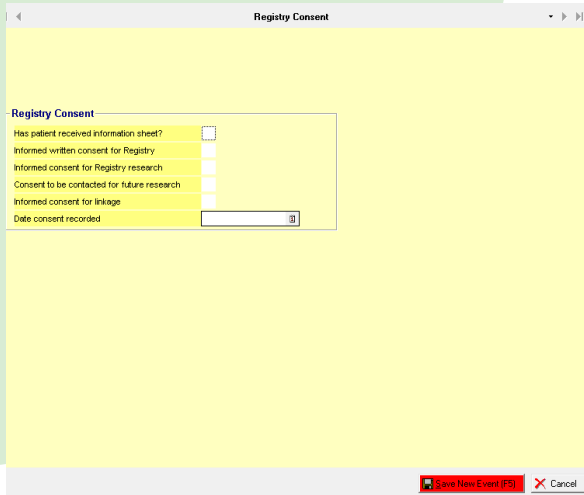
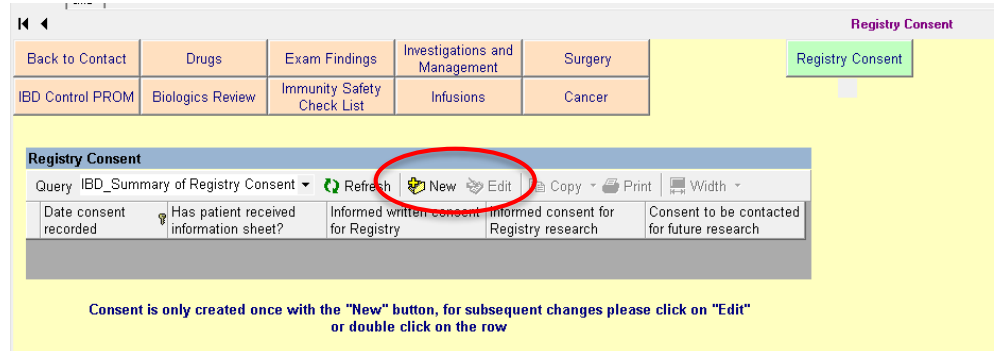
KPI: Is there a record of consent having been discussed with each patient?

Patients on biologics should be approached regarding Registry consent, so as well as the data items regarding each Biologics review please complete the following:

- Has patient received information sheet?
- Informed written consent for Registry
- Consent for Registry research
- Consent to be contacted for future research
- Consent for data linkage
- Date consent recorded/changed



From a New Contact screen, click *Registry Consent*:

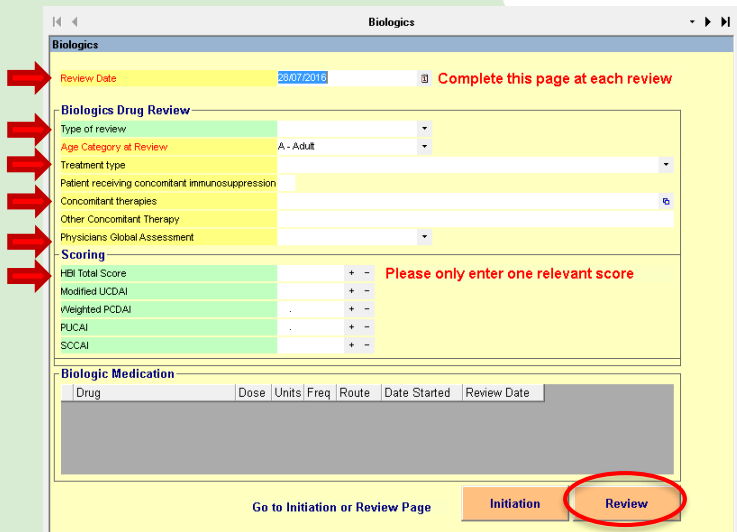
Click *New* or *Edit* buttons to generate or amend consent record.

Presentation title: Data required for follow-up reviews

KPI: Did a post-induction review or a 12-month review take place?

KPI: Was there a formal assessment of disease activity recorded at that time?

Select patient. Create a *New Contact*. Via *Biologics Review* tab *Add* a new event. Complete the fields marked by red arrows:



Review Date: 23/07/2016 Complete this page at each review

Biologics Drug Review

Type of review: [dropdown]

Age Category at Review: A - Adult

Treatment type: [dropdown]

Patient receiving concomitant immunosuppression: [checkbox]

Concomitant therapies: [text]

Other Concomitant Therapy: [text]

Physicians Global Assessment: [dropdown]

Scoring

HBI Total Score: [input] Please only enter one relevant score

Modified UCDAI: [input]

Weighted PCDAI: [input]

FUCAI: [input]

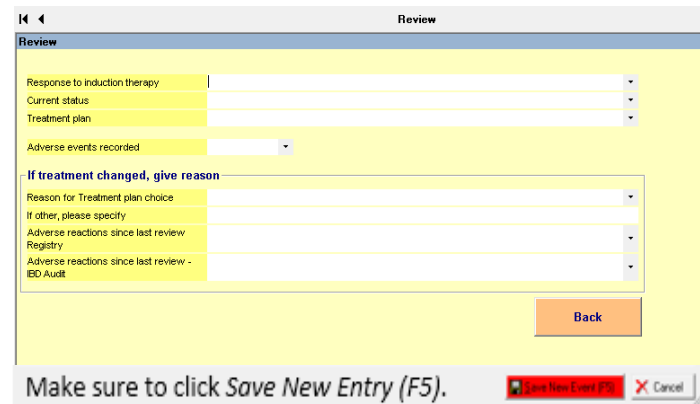
SOCAI: [input]

Biologic Medication

Drug	Dose	Units	Freq	Route	Date Started	Review Date

Go to Initiation or Review Page Initiation Review

Click *Review* and add further details, as needed:



Review

Response to induction therapy: [dropdown]

Current status: [dropdown]

Treatment plan: [dropdown]

Adverse events recorded: [dropdown]

If treatment changed, give reason

Reason for Treatment plan choice: [dropdown]

If other, please specify: [text]

Adverse reactions since last review - Registry: [dropdown]

Adverse reactions since last review - IBD Audit: [dropdown]

Back

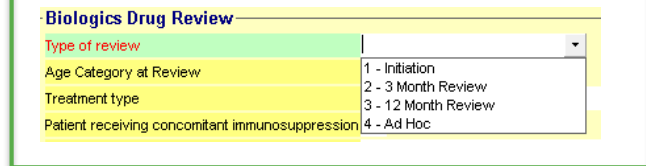
Make sure to click *Save New Entry (F5)*. Save New Entry (F5) Cancel



entering (see red arrows above):

- Review Date
- Treatment type
- Type of review (3 or 12 mnth)
- Concomitant medications
- Physician's Global assessment
- Disease Score (one of)

Follow the same steps for a review at 12 months. Select the appropriate *Type of review*:



Biologics Drug Review

Type of review: [dropdown menu open]

Age Category at Review: [dropdown]

Treatment type: [dropdown]

Patient receiving concomitant immunosuppression: [checkbox]