This form gathers core data on IBD patients. Please complete all * marked questions. Shaded areas must be completed by clinicians and patient demographics can be completed by a non-clinical staff. A summary report will be available to download to save time in future consultations.

NIHR | BioResource

*Attach barcode here*

IBD

# IBD Clinical Data sheet *(v.5 22/01/19)*

| Patient Name:<br>Hospital No: | Designation of person(s) extracting data: ☐ Doctor ☐ IBD Nurse ☐ Research Nurse ☐ Other (*please state*) _____ |
|---|---|

## Clinical Details:

*Is the patient NEWLY diagnosed with IBD (*within the last 6 months):* ☐ Yes ☐ No ☐ N/K

→ *Is the patient willing to join the more detailed INCEPTION cohort for newly diagnosed patients?*

*Current IBD Diagnosis: ☐ Crohn's ☐ UC ☐IBD – unspecified (IBDU)
_____

*Date /year of first IBD diagnosis:
*(can add just year, if exact date not known)* _____

Level of certainty regarding diagnosis of **IBD** ☐ 1 ☐ 2 ☐ 3
*(1 = not certain; 3 = very certain)*

Certainty of diagnosis **CD vs UC vs IBDU** ☐ 1 ☐ 2 ☐ 3
*(1 = not certain; 3 = very certain)*

Has IBD diagnosis been confirmed by a hospital specialist?
☐ Yes ☐ No ☐ N/K

↓

Diagnostic methods *(indicate all relevant at the time of diagnosis or used subsequently):*

☐ Endoscopy ☐ Radiology ☐ Histology ☐ Surgery
☐ Other_____ ☐ N/K

Physician's global assessment of current IBD ***inflammatory*** activity *(i.e. on the day of BioResource blood sampling)*:

☐ Normal ☐ Mild ☐ Moderate ☐ Severe ☐ Unknown

Has the patient ever been admitted to hospital for an IBD flare?

☐ Yes ☐ No ☐ N/K

Have there been any changes in IBD diagnosis *(e.g. UC to CD)*?

☐ Yes ☐ No

Year of change in IBD diagnosis _____

Enter change in IBD diagnosis:

☐ UC to CD ☐ IBDU – type unspecified to CD

☐ CD to UC ☐ IBDU – type unspecified to UC

☐ Other

## CROHN's

*Macroscopic extent (Select all that apply):
***NB** - a frequent mistake is to assume that a patient who has had a right hemicolectomy has had colonic involvement when in fact they just had ileal disease: please be sure about this!*

**NB** *a bit of 'spill-over' inflammation in the caecum does not make it colonic.*

☐ Oesophago-gastric ☐ Duodenal ☐ Jejunal ☐ Ileal ☐ Colonic ☐ Rectal

*Ever had perianal involvement?:
*(Often not easy to find in medical notes - you may find it easier to ask the patient!)*

☐ Yes ☐ No ☐ N/K

What type of perianal lesion has the patient had? *(Select all that apply):*

☐Tags / fissures / ulcers

☐Perianal abscess

☐Simple fistula (single fistula, little clinical problem)

☐Complex fistula (more than one or branching or recto-vaginal or major problem)

☐Other _____

*Behaviour: ☐B1 (inflammatory) ☐B2 (stenosing) ☐B3 (*internal* penetrating*)

**If the only fistulae have been perianal this does not make it B3*

*If B3, Please specify the nature of the internal perforating / penetrating disease (*Select all that apply*):

☐Internal abscess (mesenteric, intra-abdominal, paracolic, pelvic etc)

☐Entero-enteric or entero-colic fistula

☐Entero- vesical or colo-vesical fistula

☐Entero- cutaneous or colo-cutaneous fistula

☐Other _____

*Has the patient had surgery for Crohn's? ☐ Yes ☐ No ☐ N/K

| | Year | What op? (*Enter number(s) from list below*) | Which hospital? |
|---|---|---|---|
| *Op1 | …… | …… | …… |
| *Op2 | …… | …… | …… |
| *Others | …… | …… | …… |

1. Colectomy and ileostomy
2. Colectomy and ileo-anal pouch
3. Defunctioning ileostomy / Colostomy
4. Drainage of intra-abdominal abscess
5. Ileal / jejunal resection
6. Ileal / jejunal stricturoplasty
7. Ileo-caecal resection (Right hemicolectomy)
8. Partial colectomy
9. Proctectomy
10. Strictureplasty
11. Insertion of seton suture
12. Drainage of perianal abscess
13. Perianal fistula repair
14. Closure of Stoma
15. Other_____

*Does the patient currently have a stoma? ☐ Yes ☐ No ☐ N/K

## ULCERATIVE COLITIS OR IBD-UNCLASSIFIED (INDETERMINATE COLITIS)

*Maximum macroscopic extent **ever**:

☐ Rectum ☐ Recto-sigmoid ☐ < Splenic ☐ <Hepatic ☐ Total ☐ Unknown

Maximum macroscopic extent at **last assessment**:

☐ Rectum ☐ Recto-sigmoid ☐ < Splenic ☐ <Hepatic ☐ Total ☐ Quiescent/normal throughout ☐ Unknown

*Has the patient undergone surgical colectomy?

☐ Yes ☐ No ☐ N/K

* Date _____

* Indication for colectomy:

☐ Acute severe UC ☐ Chronic continuous UC ☐ Dysplasia ☐ Colorectal Cancer ☐ N/K

* Does the patient still have a rectal stump in situ?

☐ Yes ☐ No ☐ N/K

Has the patient undergone reconstructive surgery with an ileo-anal pouch?

☐ Yes ☐ No ☐ N/K

Is the pouch still in place?

☐ Yes ☐ No ☐ N/K

## Extra intestinal manifestations and co-morbidities

For EACH please tick YES (Y) or No (N) – **Do tick 'no' if patient has not been diagnosed with and has no symptoms of the listed conditions! If equivocal, please tick 'not known'**

****If No for all please tick here**: ☐ No for all**

**Primary Sclerosing Cholangitis (*incl PSC / AIH overlap, small duct PSC*):**

☐ Y ☐ N ☐ N/K

**Enteropathic arthritis :**

☐ Y ☐ N ☐ N/K

**Erythema Nodosum**:

☐ Y ☐ N ☐ N/K

**Iritis / uveitis (confirmed by Ophthalmology):**

☐ Y ☐ N ☐ N/K

**Orofacial Granulomatosis (oral Crohn's):**

☐ Y ☐ N ☐ N/K

**Psoriasis:**

☐ Y ☐ N ☐ N/K

**Ankylosing Spondylitis:**

☐ Y ☐ N ☐ N/K

**Multiple Sclerosis:**

☐ Y ☐ N ☐ N/K

**Lymphoma:**

☐ Y ☐ N ☐ N/K

Date of diagnosis: _____

**Other malignancy:**

☐ Y ☐ N ☐ N/K

Type of malignancy: _____
Date of diagnosis: _____

**Serious infections:**

☐ Y ☐ N ☐ N/K

Infection type: (*specify e.g. TB, pneumonia*) _____
Date of diagnosis: _____

**Other** (extra-intestinal manifestations of IBD or other inflammatory/auto-immune diseases (separate with a comma):

_____

## Treatment history – Please indicate which of these drugs the patient has taken

*(Complete all that apply)*

Please use the chart on the next page to select an adverse event number

| Treatment for IBD | Year of starting | Currently on it? Y / N / NK | Year of stopping | Was the treatment effective?<br>1. Yes<br>2. Unable to assess (unable to tolerate)<br>3. Unable to assess (on therapeutic dose < 4 months)<br>4. No (on therapeutic dose >4 months - did not work)<br>5. Worked for <12 months then lost response<br>6. Worked for >12 months then lost response<br>7. Not known (e.g. started anti-TNF at same time, partial response only) | Significant adverse events requiring Rx cessation or dose reduction?<br>Y / N / NK<br>specify number(s) from chart below |
|---|---|---|---|---|---|
| *(example)* | *2011* | *N* | *2011* | *2* | *Y – 13 (ALT=450), 16* |
| Azathioprine | | | | | |
| Mercaptopurine | | | | | |
| Methotrexate | | | | | |

Has the patient ever been tried on low dose thiopurine and allopurinol ☐Yes ☐No ☐N/K
*(for example if developed side effects)*

| | Year of starting | Currently on it? | Year of stopping | Was the treatment effective?<br>1. Yes<br>2. No<br>3. Unable to assess (e.g. had to stop due to side effects)<br>4. Not known | Significant adverse events?<br>Y / N / NK<br>specify number(s) from chart below |
|---|---|---|---|---|---|
| Ciclosporin | | | | | |

| | Year of starting | Currently on it? | Year of stopping | Was the treatment effective?<br>1. Yes<br>2. No<br>3. Partial (response but not remission)<br>4. Unable to assess (e.g. unable to tolerate)<br>5. Worked for < 12 months then lost response<br>6. Worked for > 12 months then lost response<br>7. Only at high dose / increased frequency<br>8. Not known | Significant adverse events?<br>Y / N / NK<br>specify number(s) from list below |
|---|---|---|---|---|---|
| Infliximab | | | | | |
| Adalimumab | | | | | |
| Golimumab | | | | | |
| Vedolizumab | | | | | |
| Ustekinumab | | | | | |

| | Year of starting | Currently on it? | Year of stopping | Was the treatment effective?<br>1. Yes - (remission with no other drug used)<br>2. Partial (response but not remission)<br>3. No (did not respond despite an adequate trial of therapy)<br>4. Unsure (e.g. not on it for long enough, started more than one drug at same time)<br>5. Worked for < 12 months then lost response<br>6. Worked for > 12 months then lost response<br>7. Not known | Significant adverse events?<br>Y / N / NK<br>specify number(s) from list below |
|---|---|---|---|---|---|
| Mesalazine (5 ASA) | | | | | |

| | Year of starting | Currently on it? | Year of stopping | Was the treatment effective?<br>1. Yes<br>2. No<br>3. Initially responded then lost response<br>4. Unable to assess (e.g. unable to tolerate)<br>5. Not known | Significant adverse events?<br>Y / N / NK<br>↓<br>specify number(s) from list below |
|---|---|---|---|---|---|
| Oral steroids (prednisolone or budesonide) | | | | | |

| | Year of starting | Currently on it? | Year of stopping | Was the treatment effective?<br>1. Yes (no 'rescue' therapy needed)<br>2. No (required additional rescue therapy)<br>3. Unable to assess (e.g. unable to tolerate)<br>4. Not known | Significant adverse events?<br>Y / N / NK<br>↓<br>specify number(s) from list below |
|---|---|---|---|---|---|
| IV steroids | | | | | |

| | Year of starting | Currently on it? | Year of stopping | Was the treatment effective?<br>1, Yes<br>2, No<br>3, Partial (response but not remission)<br>5, Not known | Significant adverse events?<br>Y / N / NK<br>↓<br>specify number(s) from list below |
|---|---|---|---|---|---|
| Tofacitinib | | | | | |
| Any other drug? (what) | | | | | |
| | | | | | |

**Please use the numbers in this table to complete the significant adverse events column in the treatment history tables above**

| Adverse Event | Adverse Event | Adverse Event |
|---|---|---|
| 1. Abdominal pain | 14. Injection site reaction | 27. Psychosis |
| 2. Anaemia | 15. Interstitial nephritis | 28. Rash |
| 3. Anaphylaxis or anaphylactoid reaction | 16. Joint pain | 29. Raised lipids |
| 4. Could not tolerate | 17. Leucopaenia<br>a) Minimum white cell count<br>b) Minimum neutrophil count | 30. Renal Impairment |
| 5 Demyelination or other neurological symptoms | 18. Malaise | 31. Sepsis |
| 6. Diarrhoea | 19. Nasopharyngitis | 32. Thrombocytopenia |
| 7. Deranged LFTs<br>a) Maximum ALT<br>b) Maximum ALP<br>c) Maximum bilirubin | 20. Nausea / vomiting | 34. Other |
| 8. Exacerbation of IBD symptoms | 21. Neutropaenia<br>a) Minimum white cell count<br>b) Minimum neutrophil count | 34. Not known |
| 9 Fever | 22. None | |
| 10. Flu-like symptoms | 23. Osteopenia | |
| 11. Hypertension | 24. Pancreatitis<br>a) maximum amylase<br>b) maximum lipase | |
| 12. Hypotension | 25.Pancytopaenia | |
| 13. Infection<br>a) bacterial<br>b) viral<br>c) TB / Tuberculosis<br>d) Other / not known | 26.Psoriasis | |

## Demographics (*Section to be completed by research staff)*

*Smoking status at ***DIAGNOSIS*** *(please tick one option):*

☐ Never smoked

☐ Not known

☐ Smoking at diagnosis:

*Roughly how many cigarettes was the patient smoking at the time of diagnosis?

☐ Less than 5 ☐ 5+ ☐ Pipe only ☐ N/K

* ☐ Had quit before diagnosis:

Roughly how long before diagnosis did patient quit smoking?

☐ Less than 1 month ☐ 1-6 months ☐ More than 6 months ☐ N/K

***CURRENT*** smoking status:

☐Not smoking ☐Smoking ☐Other ☐Not known

Family history of IBD?

☐ Yes ☐ No ☐ N/K

| Which relative? | Which type of IBD? | Relative name *(if participant willing to share)?* |
|---|---|---|
| …… | …… | …… |
| …… | …… | …… |
| …… | …… | …… |

Alongside IBD BioResource there are two parallel projects with overlapping objectives – please identify which of these parallel projects the patient has signed consent for:

☐ PrediCCt ☐ IBD Registry

Has the IBD BioResource consent been signed?

***This section is a vital field for NIHR accrual data*** :

☐ Y ☐ N

Date of consent: _____

Which version of consent form has been used?:

☐ 1 ☐ 2 ☐ 2.1 ☐ 3 ☐ 4 ☐ 5

Date of most recent clinic review (i.e. when were data re clinical features last updated?): _____

Please enter the patient's UK IBD Genetics Consortium identifier number (if known):
*If entering multiple numbers, please separate with a comma in REDCap*

_____

Has the patient withdrawn from the IBD BioResource study?

☐ Y ☐ N ☐ N/K

Withdrawal status?

☐ Withdrawn with no participation

☐ Withdrawn with no participation and data removed

☐ Deceased

☐ Other

Date withdrawal requested: _____

Date of actual withdrawal: _____

Withdrawal form ID number: _____

Withdrawn by: _____

Other studies notified (IBD Registry, PrediCCt):

☐ Y ☐ N ☐ N/K