ICHOM

International Consortium for Health Outcomes Measurement

INFLAMMATORY BOWEL DISEASE DATA COLLECTION REFERENCE GUIDE

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INFLAMMATORY BOWEL DISEASE

We are thrilled that you are interested in measuring outcomes for your patients with inflammatory bowel disease. It is our hope that this Reference Guide will facilitate the process of implementing this Set of Patient-Centered Outcome Measures and ensure the collection of comparable data for global benchmarking and learning.

Introducing ICHOM and the Reference Guide

ICHOM brings together patient representatives, clinician leaders, and registry leaders from all over the world to develop Sets of Patient-Centered Outcome Measures, which are comprehensive yet parsimonious Sets of outcomes and case-mix variables we recommend all providers to track.

Each Set focuses on patient-centered results, and provides an internationally-agreed upon method for measuring each of these outcomes. We do this because we believe that standardized outcomes measurement will open up new possibilities to compare performance globally, allow clinicians to learn from each other, and rapidly improve the care we provide our patients.

Our Sets include initial conditions and risk factors to enable meaningful case-mix adjustment globally, ensuring that comparisons of outcomes will take into account the differences in patient populations across not just providers, but also countries and regions. A comprehensive data dictionary, as well as scoring guides for patient-reported outcomes, is included in the appendix.

Our aim is to make these Sets freely accessible to healthcare institutions worldwide to begin measuring, and ultimately benchmark the outcomes they achieve. In order to have a guide from which we can benchmark outcomes, we require feedback from initial implementation efforts. As such, this Reference Guide may undergo revisions on a regular basis. If you have any suggestions or would like to provide feedback, please contact info@ichom.org

Working Group Members for Inflammatory Bowel Disease

The following individuals dedicated both time and expertise to develop the ICHOM Set for Inflammatory Bowel Disease in partnership with ICHOM, under the leadership of Professor Simon Travis, Professor of Clinical Gastroenterology at the University of Oxford.

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Supporting Organizations

The Inflammatory Bowel Disease Set is made possible only through the support of the following sponsor*:

Thank you.

Oxford Academic Health Science Network

Treatment Approaches Covered for Inflammatory Bowel Disease

For Inflammatory Bowel Disease, the following treatment approaches (or interventions) are covered by our Set:

Treatment Approaches	Medical | Surgical | Supportive
Conditions Covered	An adult (>16) with a diagnosis of Inflammatory Bowel Disease (IBD) including Crohn's disease, ulcerative colitis and indeterminate colitis (or IBD unclassified)

ICHOM Set of Patient-Centered Outcome Measures for Inflammatory Bowel Disease

Case-Mix Variables

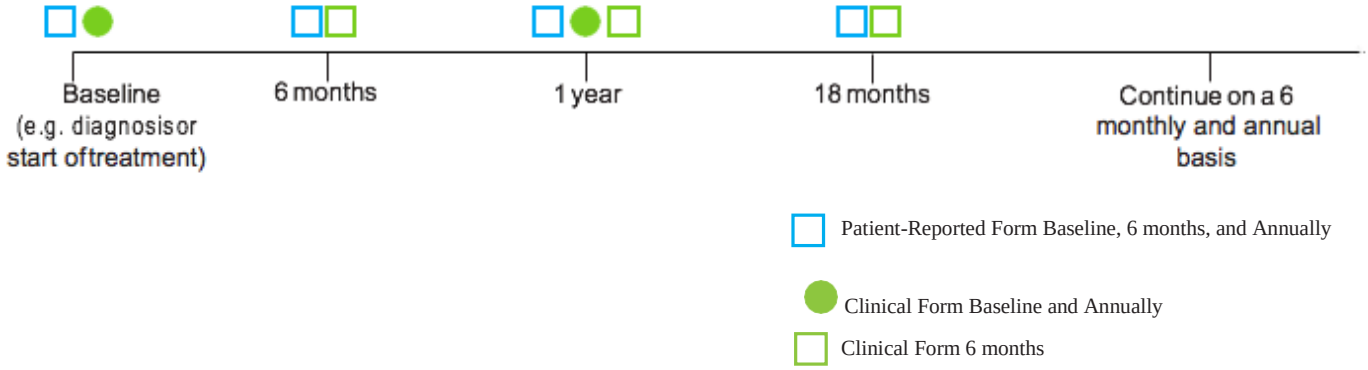
Patient Population	Measure	Timing	Data Source
Demographic Factors			
All patients	Year of birth	Baseline	Clinical
	Sex		
	Education level		Patient-reported
	Smoking status	Baseline and annually	
	Body height	Baseline	Clinical
	Body weight		
Baseline clinical factors			
All patients	Comorbidities including autoimmune conditions	Baseline	Patient-reported
	Previous infection	Baseline and annually	Clinical
Baseline condition factors			
All patients	Diagnosis	Baseline	Clinical
	Date of diagnosis		
	Disease phenotype		
	Presence of extra-intestinal manifestations	Baseline and annually	
Treatment Factors			
Surgical patients	Type of IBD-related surgery	Baseline and annual follow-up	Clinical
Medical patients	Current medication		
Patients diagnosed with colorectal cancer	Participation in a colorectal cancer surveillance programme		

Outcomes

Patient Population	Measure	Timing	Data Source
Symptoms, function and quality of life			
All patients	Change in bowel symptoms	Baseline and 6 monthly	Patient-reported
	Missing planned activities		
	Night symptoms		
	Pain or discomfort		
	Energy and fatigue		
	Anxiety or depressed		
	Overall control over IBD		
	Weight		
All patients with Crohn's Disease	Fistulae symptoms		
Disutility of care			
All patients	Steroid use	Baseline and follow-up	Clinical
	Occurrence and impact of complication from an IBD intervention		
Healthcare utilization			
All patients	Time spent in hospital	Baseline and follow-up	Clinical
Survival and disease control			
All patients	Presence of anaemia	Baseline and follow-up	Clinical
	Disease activity and remission		Patient-reported and Clinical
	Colorectal cancer		Clinical
	Overall survival	Ongoing	
	Cause of death		

Measurement Timeline

The following timeline illustrates when the Set variables should be collected from patients, clinicians, and administrative sources. Links to the sample questionnaires may be found in the legend below.



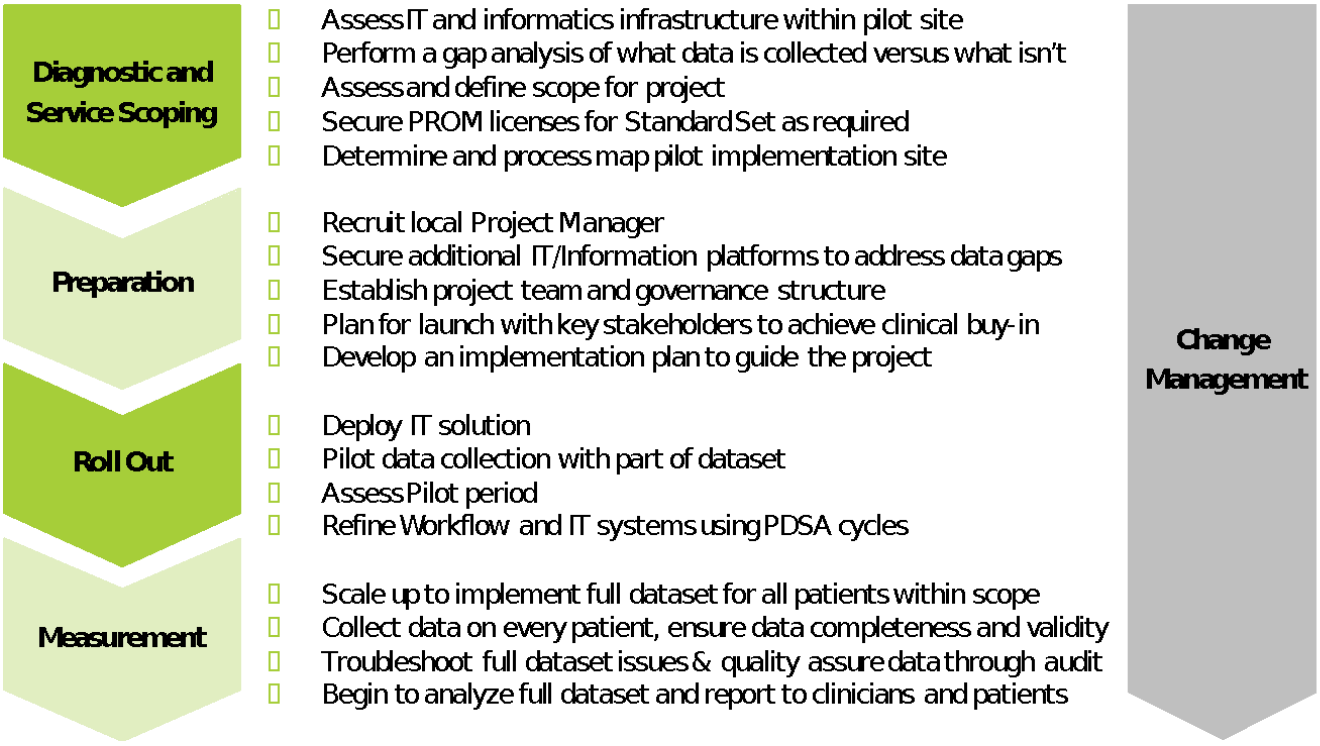
Collecting Patient-Reported Outcome Measures

Survey used	Licensing Information	Scoring Information
Self-Administered Comorbidity Questionnaire (SCQ)	The SCQ is not copyrighted and a license is not needed. It may be found at: Sangha et al (2003) The self-administered comorbidity questionnaire: A new method to assess comorbidity for clinical and health services research. Arthritis Care & Research 49(2): 156-163 https://onlinelibrary.wiley.com/doi/full/10.1002/art.10993	Sangha et al (2003) The self-administered comorbidity questionnaire: A new method to assess comorbidity for clinical and health services research. Arthritis Care & Research 49(2): 156-163
IBD-Control PROM	Licensing information to be determined. Please contact the corresponding author at: kbodger@liverpool.ac.uk It may be found at: Bodger et al. Development and validation of a rapid, generic measure of disease control from the patient's perspective: the IBD-Control questionnaire. Gut 2014;63(7):1092-102.	Bodger et al. Development and validation of a rapid, generic measure of disease control from the patient's perspective: the IBD-Control questionnaire. Gut 2014;63(7):1092-102. (Please note, only some questions of the IBD-Control questionnaire are asked, therefore a total score is not applicable or requested within this guide)

The Growing ICHOM Community

There is a growing community of healthcare providers implementing the Set. To support your organization in implementing the set and the measurement of outcomes data, we have outlined a framework to guide the implementation and reporting of patient-centered outcomes. All materials can be downloaded for free from ICHOM Connect, for further information or to enquire about implementation support offered by ICHOM Partners, please contact us: info@ichom.org.

Implementation framework:
The framework below, outlines the structured process to guide the implementation of an ICHOM Set at your organization. Typically, an implementation project takes 9 months to complete.



Implementation Study:
We are keen to find out if you have implemented or are implementing our Sets. Please fill in this survey: bit.ly/InitialImp or contact info@ichom.org for more information.

Translating the Set Tools:

PROMs within the ICHOM Sets are available in a number of languages. To check the availability of translations, we advise contacting the Tool authors directly to obtain and translate the PROM surveys into your desired language. To independently translate PROM surveys, if permitted by its license, we recommend following the 10 steps outlined below:*[1]

Step 1	Preparation	Initial work carried out before the translation work begins
Step 2	Forward Translation	Translation of the original language, also called source, version of the instrument into another language, often called the target language
Step 3	Reconciliation	Comparing and merging more than one forward translation into a single forward translation
Step 4	Back Translation	Translation of the new language version back into the original language
Step 5	Back Translation Review	Comparison of the back-translated versions of the instrument with the original to highlight and investigate discrepancies between the original and the reconciled translation, which is then revised in the process of resolving the issues
Step 6	Harmonization	Comparison of back translations of multiple language versions with each other and the original instrument to highlight discrepancies between the original and its derivative translations, as well as to achieve a consistent approach to translation problems
Step 7	Cognitive Debriefing	Testing the instrument on a small group of relevant patients or lay people in order to test alternative wording and to check understandability, interpretation, and cultural relevance of the translation
Step 8	Review of Cognitive Debriefing Results and Finalization	Comparison of the patients' or lay persons' interpretation of the translation with the original version to highlight and amend discrepancies
Step 9	Proofreading	Final review of the translation to highlight and correct any typographic, grammatical or other errors
Step 10	Final Report	Report written at the end of the process documenting the development of each translation

*These ten steps follow the ISPOR Principles of Good Practice: The Cross-Cultural Adaptation Process for Patient-Reported Outcome Measures [1] Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A., et al. (2005). Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: Report of the ISPOR task force for translation and cultural adaptation. Value in Health, 8(2), 94–104. doi:10.1111/j.1524-4733.2005.04054.x.

Appendix

Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM Inflammatory Bowel Disease Set as consistently as possible to the Working group recommendation. ICHOM is actively preparing for benchmarking efforts based on this data, and all data submitted for comparisons will need to be transformed into the following data structure if not already structured as such. **For technical use an Excel version of this data dictionary is also available for download on ICHOM Connect. Excel data dictionary is the most up-to-date version and it is the recommended document to plan data collection.**

Please timestamp all variables. Some Set variables are collected at multiple timepoints, and we will ask you to submit these variables in a concatenated VARIABLEID_TIMESTAMP form for future analyses. For example, VARIABLEID_BASE (baseline); VARIABLEID_6MO (6 month follow-up); VARIABLEID_1YR (1 year follow-up), etc.

Case-Mix Variables

Variable ID:	N/A
Variable:	Patient ID
Definition:	Indicate the patient's medical record number
Supporting Definition:	This number will not be shared with ICHOM. In the case patient-level data is submitted to ICHOM for benchmarking or research purposes, a separate ICHOM Patient Identifier will be created and cross-linking between the ICHOM Patient Identifier and the medical record number will only be known at the treating institution
Displayed Value:	N/A
Inclusion Criteria:	All patients
Timing:	On all forms
Data Source:	Administrative or clinical
Type:	Numerical
Value Domain:	N/A
Response Options:	According to institution

Demographic Factors

Variable ID:	YearOfBirth
Variable:	Year of Birth
Definition:	Year of birth
Supporting Definition:	None
Displayed Value:	In what year were you born?
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Date by YYYY
Value Domain:	Date
Response Options:	YYYY
Variable ID:	Sex
Variable:	Sex
Definition:	The patient's sex at birth

Supporting Definition:	For statistical purposes, the following category codes, labels and definitions are preferred: CODE 1 Male: Persons who have male or predominantly masculine biological characteristics, or male sex assigned at birth. CODE 2 Female: Persons who have female or predominantly feminine biological characteristics, or female sex assigned at birth. CODE 3 Other: Persons who have mixed or non-binary biological characteristics (if known), or a non-binary sex assigned at birth The value meaning of 'Other' has been assigned to Code 3 for this value domain, which replaces 'Intersex or indeterminate' for the superseded value domain Sex code N. Terms such as 'indeterminate,' 'intersex', 'non-binary', and 'unspecified' are variously used to describe the 'Other' category of sex. The label 'Other' is used because a more descriptive term has not been widely agreed within the general community. Sex refers to the chromosomal, gonadal and anatomical characteristics associated with biological sex. Where there is an inconsistency between anatomical and chromosomal characteristics, sex is based on anatomical characteristics.
Displayed Value:	Please indicate your sex at birth
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	1= Male 2= Female 3= Other 999= Undisclosed
Variable ID:	EducationLevel
Variable:	Level of Education
Definition:	Highest level of education completed based on local standard definitions of education levels
Supporting Definition:	This measure may vary based on local standards for education levels so please consult the International Standard Classification to select what level most closely relates to your education experience. Please follow this link here: http://uis.unesco.org/sites/default/files/documents/international-standard-classification-of-education-isced-2011-en.pdf
Displayed Value:	Please indicate your highest level of schooling.
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= None 1= Primary 2= Secondary 3= Tertiary
Variable ID:	SmokingStatus
Variable:	Smoking status
Definition:	A person's current and past smoking behavior

Supporting Definition:	Daily smoker: A person who smokes daily Weekly smoker: A person who smokes at least weekly but not daily Former smoker: A person who does not smoke at all now, but has smoked at least 100 cigarettes or a similar amount of other tobacco products in his/her lifetime Never-smoker: A person who does not smoke now and has smoked fewer than 100 cigarettes or similar amount of other tobacco products in his/her lifetime
Displayed Value:	Please indicate your smoking behavior. More detailed definitions are as follows: Daily smoker: A person who smokes daily Weekly smoker: A person who smokes at least weekly but not daily Former smoker: A person who does not smoke at all now, but has smoked at least 100 cigarettes or a similar amount of other tobacco products in his/her lifetime Never-smoker: A person who does not smoke now and has smoked fewer than 100 cigarettes or similar amount of other tobacco products in his/her lifetime
Inclusion Criteria:	All patients
Timing:	Baseline Annually
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0 = Current every day smoker 1 = Current weekly smoker 2 = Former smoker 3 = Never smoker 4 = Others 999 = Unknown if ever smoked

Baseline clinical factors

Variable ID:	HeightValue
Variable:	Body height
Definition:	The height of a person, measured in the indicated units
Supporting Definition:	The measurement protocol described below are those recommended by the International Society for the Advancement of Kinanthropometry as described by Norton et al. (1996), and the World Health Organization (WHO Expert Committee 1995), which was adapted from Lohman et al. (1988). Measurement protocol: Height measurements can be based on recumbent length or standing height. In general, length measurements are recommended for children under 2 years of age and height measurements for others. The measurement of height requires a vertical metric rule, a horizontal headboard, and a non-compressible flat even surface on which the subject stands. The equipment may be fixed or portable, and should be described and reported. The graduations on the metric rule should be at 0.1 cm intervals, and the metric rule should have the capacity to measure up to at least 210 cm. Measurement intervals and labels should be clearly readable under all conditions of use of the instrument. Apparatus that allows height to be measured while the subject stands on a platform scale is not recommended. Adults and children who can stand: The subject should be measured without shoes (i.e. is barefoot or wears thin socks) and wears little clothing so that the positioning of the body can be seen. Anything that may affect or interfere with the measurement should be noted on the data collection form (e.g. hairstyles and accessories, or physical problems). The subject

stands with weight distributed evenly on both feet, heels together, and the head positioned so that the line of vision is at right angles to the body. The correct position for the head is in the Frankfort horizontal plan (Norton et al. 1996). The arms hang freely by the sides. The head, back, buttocks and heels are positioned vertically so that the buttocks and the heels are in contact with the vertical board.
To obtain a consistent measure, the subject is asked to inhale deeply and stretch to their fullest height. The measurer applies gentle upward pressure through the mastoid processes to maintain a fully erect position when the measurement is taken. Ensure that the head remains positioned so that the line of vision is at right angles to the body, and the heels remain in contact with the base board.
The movable headboard is brought onto the top of the head with sufficient pressure to compress the hair.
The measurement is recorded to the nearest 0.1 cm. Take a repeat measurement. If the two measurements disagree by more than 0.5 cm, then take a third measurement. All raw measurements should be recorded on the data collection form. If practical, it is preferable to enter the raw data into the database as this enables intra-observer and, where relevant, inter-observer errors to be assessed.
The subject's measured height is subsequently calculated as the mean of the two observations, or the mean of the two closest measurements if a third is taken, and recorded on the form. If only a mean value is entered into the database then the data collection forms should be retained.
It may be necessary to round the mean value to the nearest 0.1 cm. If so, rounding should be to the nearest even digit to reduce systematic over reporting (Armitage & Berry 1994). For example, a mean value of 172.25 cm would be rounded to 172.2 cm, while a mean value of 172.35 cm would be rounded to 172.4 cm.
Infants:
For the measurement of supine length of children up to and including 2 years of age, two observers are required. One observer positions the head correctly while the other ensures the remaining position is correct and brings the measuring board in contact with the feet. The subject lies in a supine position on a recumbent length table or measuring board. The crown of the head must touch the stationary, vertical headboard. The subject's head is held with the line of vision aligned perpendicular to the plane of the measuring surface. The shoulders and buttocks must be flat against the table top, with the shoulders and hips aligned at right angles to the long axis of the body. The legs must be extended at the hips and knees and lie flat against the table top and the arms rest against the sides of the trunk. The measurer must ensure that the legs remain flat on the table and must shift the movable board against the heels. In infants care has to be taken to extend the legs gently. In some older children two observers may also be required.
In general, length or height is measured and reported to the nearest 0.1 cm. For any child, the length measurement is approximately 0.5–1.5 cm greater than the height measurement. It is therefore recommended that when a length measurement is applied to a height-based reference for children over 24 months of age (or over 85 cm if age is not known), 1.0 cm be subtracted before the length measurement is compared with the reference. It is also recommended that as a matter of procedure and data recording accuracy, the date be recorded when the change is made from supine to standing height measure.
Validation and quality control measures:
All equipment, whether fixed or portable should be checked prior to each measurement session to ensure that both the headboard and floor (or footboard) are at 90 degrees to the vertical rule. With some types of portable anthropometer it is necessary to check the correct alignment of the headboard, during each measurement, by means of a spirit level. Within- and, if relevant, between-

	observer variability should be reported. They can be assessed by the same (within-) or different (between-) observers repeating the measurement of height, on the same subjects, under standard conditions after a short time interval. The standard deviation of replicate measurements (technical error of measurement (Pederson & Gore 1996)) between observers should not exceed 5 mm and be less than 5 mm within observers. Extreme values at the lower and upper end of the distribution of measured height should be checked both during data collection and after data entry. Individuals should not be excluded on the basis of true biological difference. Last digit preference, and preference or avoidance of certain values, should be analysed in the total sample and (if relevant) by observer, survey site and over time if the survey period is long.
Displayed Value:	Please indicate your body height.
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Numerical
Value Domain:	Quantity
Response Options:	Numerical value of height
Variable ID:	HeightUnit
Variable:	Body height units
Definition:	Units of body height
Supporting Definition:	None
Displayed Value:	Please indicate what units of measurement (centimeters or inches) that you recorded your height in.
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	1 = centimeters 2 = inches
Variable ID:	WeightValue
Variable:	Body weight
Definition:	The body weight of a person, measured in the indicated units
Supporting Definition:	The collection of anthropometric measurements, particularly in those who are overweight or obese or who are concerned about their weight, should be performed with great sensitivity and without drawing attention to an individual's weight.
Displayed Value:	Please indicate your body weight.
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Numerical
Value Domain:	Quantity
Response Options:	Numerical value of weight
Variable ID:	WeightUnit
Variable:	Body weight units
Definition:	Units of body weight
Supporting Definition:	None
Displayed Value:	Please indicate what units of measurement (kilograms or pounds) that you recorded your weight in.

Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	1 = kilograms 2 = lbs
Variable ID:	BMIValue
Variable:	Body mass index
Definition:	Body mass index
Supporting Definition:	Height and weight are used to calculate BMI. BMI calculated as kg/m2.
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Single answer
Value Domain:	Quantity
Response Options:	None
Variable ID:	COMORB_IBD
Variable:	Comorbidities
Definition:	Have you been told by your doctor or care provider that you have any of the following? Tick all that apply.
Supporting Definition:	None
Displayed Value:	Have you ever been told by a doctor that you have any of the following? (select all that apply)
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Patient-reported
Type:	Multiple answer Separate multiple entries with ";"
Value Domain:	Code
Response Options:	0=The patient has no other diseases 1=High cholesterol (sometimes referred to as hyperlipidemia) 2=Problems caused by stroke 3=Ankylosing spondylitis 4=Primary sclerosing cholangitis 999 = unknown
Variable ID:	ComorbiditiesSACQ
Variable:	SACQ Comorbidities
Definition:	Indicate whether the patient has a documented history of any of the following comorbidities
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Have you been told by a doctor that you have any of the following?
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Patient-reported
Type:	Multiple answer Separate multiple entries with ";"
Value Domain:	Code
Response Options:	0 = I have no other diseases 1 = Heart disease (For example, angina, heart attack, or heart failure) 2 = High blood pressure

	3 =Lung disease (For example, asthma, chronic bronchitis, or emphysema) 4 = Diabetes 5 = Ulcer or stomach disease 6 = Kidney disease 7 = Liver disease 8 = Anemia or other blood disease 9 = Cancer/Other cancer (within the last 5 years) 10 = Depression 11 = Osteoarthritis, degenerative arthritis 12 = Back pain 13= Rheumatoid arthritis 14= Other medical problems
Variable ID:	ComorbiditiesSACQ_HeartDiseaseFU1
Variable:	SACQ comorbidities: Heart Disease: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for Heart disease (For example, angina, heart attack, or heart failure)
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for heart disease (For example, angina, heart failure, or heart attack)?
Inclusion Criteria:	If answered 1= Heart disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_HeartDiseaseFU2
Variable:	SACQ comorbidities: Heart Disease: Follow-Up Question 2
Definition:	Please indicate if the patient's heart disease limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your heart disease limit your activities?
Inclusion Criteria:	If answered 1= Heart disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_HighBloodPressureFU1
Variable:	SACQ comorbidities: High Blood Pressure: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for high blood pressure
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for high blood pressure?
Inclusion Criteria:	If answered 2= High blood pressure to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported

Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_HighBloodPressureFU2
Variable:	SACQ comorbidities: High Blood Pressure: Follow-Up Question 2
Definition:	Please indicate if the patient's high blood pressure limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your high blood pressure limit your activities?
Inclusion Criteria:	If answered 2= High blood pressure to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_LungDiseaseFU1
Variable:	SACQ comorbidities: Lung Disease: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for lung disease
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for lung disease?
Inclusion Criteria:	If answered 3= Lung disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_LungDiseaseFU2
Variable:	SACQ comorbidities: Lung Disease: Follow-Up Question 2
Definition:	Please indicate if the patient's lung disease limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your lung disease limit your activities?
Inclusion Criteria:	If answered 3= Lung disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_DiabetesFU1
Variable:	SACQ comorbidities: Diabetes: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for diabetes
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.

Displayed Value:	Do you receive treatment for diabetes?
Inclusion Criteria:	If answered 4= Diabetes to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_DiabetesFU2
Variable:	SACQ comorbidities: Diabetes: Follow-Up Question 2
Definition:	Please indicate if the patient's diabetes limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your diabetes limit your activities?
Inclusion Criteria:	If answered 4= Diabetes to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_StomachDiseaseFU1
Variable:	SACQ comorbidities: Stomach Disease: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for an ulcer or stomach disease
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for an ulcer or stomach disease?
Inclusion Criteria:	If answered 5= Ulcer or stomach disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_StomachDiseaseFU2
Variable:	SACQ comorbidities: Stomach Disease: Follow-Up Question 2
Definition:	Please indicate if the patient's ulcer or stomach disease limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your ulcer or stomach disease limit your activities?
Inclusion Criteria:	If answered 5= Ulcer or stomach disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_KidneyDiseaseFU1
Variable:	SACQ comorbidities: Kidney Disease: Follow-Up Question 1

Definition:	Please indicate if the patient receives treatment for kidney disease
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for kidney disease?
Inclusion Criteria:	If answered 6= Kidney disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_KidneyDiseaseFU2
Variable:	SACQ comorbidities: Kidney Disease: Follow-Up Question 2
Definition:	Please indicate if the patient's kidney disease limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your kidney disease limit your activities?
Inclusion Criteria:	If answered 6= Kidney disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_LiverDiseaseFU1
Variable:	SACQ comorbidities: Liver Disease: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for liver disease
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for liver disease?
Inclusion Criteria:	If answered 7= Liver disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_LiverDiseaseFU2
Variable:	SACQ comorbidities: Liver Disease: Follow-Up Question 2
Definition:	Please indicate if the patient's liver disease limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your liver disease limit your activities?
Inclusion Criteria:	If answered 7= Liver disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code

Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_BloodDiseaseFU1
Variable:	SACQ comorbidities: Blood Disease: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for anemia or other blood disease
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for anemia or other blood disease?
Inclusion Criteria:	If answered 8= Anemia or other blood disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_BloodDiseaseFU2
Variable:	SACQ comorbidities: Blood Disease: Follow-Up Question 2
Definition:	Please indicate if the patient's anemia or other blood disease limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your anemia or other blood disease limit your activities?
Inclusion Criteria:	If answered 8= Anemia or other blood disease to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_CancerFU1
Variable:	SACQ comorbidities: Cancer: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for cancer/another cancer
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for cancer/another cancer?
Inclusion Criteria:	If answered 9= Cancer/Other cancer to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_CancerFU2
Variable:	SACQ comorbidities: Cancer: Follow-Up Question 2
Definition:	Please indicate if the patient's cancer/other cancer limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your cancer/other cancer limit your activities?
Inclusion Criteria:	If answered 9= Cancer/Other cancer to ComorbiditiesSACQ

Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_DepressionFU1
Variable:	SACQ comorbidities: Depression: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for depression
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for depression?
Inclusion Criteria:	If answered 10= Depression to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_DepressionFU2
Variable:	SACQ comorbidities: Depression: Follow-Up Question 2
Definition:	Please indicate if the patient's depression limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your depression limit your activities?
Inclusion Criteria:	If answered 10= Depression to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_OsteoarthritisFU1
Variable:	SACQ comorbidities: Osteoarthritis: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for osteoarthritis/degenerative arthritis
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for osteoarthritis/degenerative arthritis?
Inclusion Criteria:	If answered 11= Osteoarthritis, degenerative arthritis to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_OsteoarthritisFU2
Variable:	SACQ comorbidities: Osteoarthritis: Follow-Up Question 2

Definition:	Please indicate if the patient's osteoarthritis/degenerative arthritis limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your osteoarthritis/degenerative arthritis limit your activities?
Inclusion Criteria:	If answered 11= Osteoarthritis, degenerative arthritis to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_BackPainFU1
Variable:	SACQ comorbidities: Back Pain: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for back pain
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for back pain?
Inclusion Criteria:	If answered 12= Back pain to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_BackPainFU2
Variable:	SACQ comorbidities: Back Pain: Follow-Up Question 2
Definition:	Please indicate if the patient's back pain limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your back pain limit your activities?
Inclusion Criteria:	If answered 12= Back pain to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_RheumatoidArthritisFU1
Variable:	SACQ comorbidities: Rheumatoid Arthritis: Follow-Up Question 1
Definition:	Please indicate if the patient receives treatment for rheumatoid arthritis
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Do you receive treatment for rheumatoid arthritis?
Inclusion Criteria:	If answered 13= Rheumatoid arthritis to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer

Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_RheumatoidArthritisFU2
Variable:	SACQ comorbidities: Rheumatoid Arthritis: Follow-Up Question 2
Definition:	Please indicate if the patient's rheumatoid arthritis limits their function
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	Does your rheumatoid arthritis limit your activities?
Inclusion Criteria:	If answered 13= Rheumatoid arthritis to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0= No 1= Yes
Variable ID:	ComorbiditiesSACQ_Other
Variable:	SACQ comorbidities: Other Medical Problems
Definition:	Please indicate what other medical problems the patient is experiencing
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.
Displayed Value:	What other medical problems are you experiencing?
Inclusion Criteria:	If answered 14= Other medical problems to ComorbiditiesSACQ
Timing:	Baseline
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	String
Response Options:	None
Variable ID:	ComorbiditiesSACQ_Score
Variable:	Score of the SACQ comorbidities questionnaire
Definition:	Please indicate the summed score for all of the patient's comorbidities
Supporting Definition:	An individual can receive a max of 3 points for each medical condition: 1 point for the presence of the problem, another point if he/she receives treatment for it, and an additional point if the problem causes a limitation in function. The Max score a patient can receive is 45 points
Displayed Value:	What is the total summed score of the patient's SACQ responses?
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Numerical value
Value Domain:	Quantity
Response Options:	Total summed score
Variable ID:	INFECTHBV
Variable:	HBV infection
Definition:	Have you been previously diagnosed with or treated for Hepatitis B virus?
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Clinical

Type:	Single answer
Value Domain:	Code
Response Options:	0 = No 1 = Yes
Variable ID:	INFECTHIV
Variable:	HIV infection
Definition:	Have you previously been diagnosed with or treated for human immunodeficiency virus (HIV)?
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0 = No 1 = Yes
Variable ID:	PREVINFECTTB
Variable:	Previous TB infection
Definition:	Have you previously been diagnosed with or treated for tuberculosis (TB)?
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0 = No 1 = Yes

Baseline condition factors

Variable ID:	DIAG
Variable:	Diagnosis
Definition:	Indicate the diagnosis
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0= Crohn's disease 1= Ulcerative colitis 2= Indeterminate IBD or colitis unclassified
Variable ID:	DATEOFDIAG
Variable:	Date of diagnosis
Definition:	Indicate the date of diagnosis
Supporting Definition:	MM/YYYY
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical

Type:	Date by MM/YYYY
Value Domain:	Date
Response Options:	MM/YYYY
Variable ID:	DISAGEONSET
Variable:	Age of onset
Definition:	Tracked via Montreal Classification
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=A1 -- Age of onset 16 yr or younger 1=A2 -- Age of onset 17--40 yr 2=A3 -- Age of onset over 40
Variable ID:	DISLOCALBEHAV
Variable:	Disease location and behavior
Definition:	Tracked via Montreal Classification
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	CD only
Timing:	Baseline and annually
Data Source:	Clinical
Type:	Multiple answers
Value Domain:	Code
Response Options:	0=L1 CD Localisation -- terminal ileum 1=L2 CD Localisation -- Colon 3=L3 CD Localisation -- Ileocolon 4=L4 CD Localisation -- Upper gastrointestinal 14=P -- perianal disease 5=B1 Behaviour -- Nonstricturing, nonpenetrating 6=B2 Behaviour -- Stricturing 7=B3 Behaviour -- Penetrating
Variable ID:	DISEXT
Variable:	Disease extent
Definition:	Tracked via Montreal Classification
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	UC + IBDU
Timing:	Baseline and annually
Data Source:	Clinical
Type:	Multiple answers
Value Domain:	Code
Response Options:	0=S0 Disease Severity -- Remission, no symptoms 1=S1 Disease Severity -- Mild UC, passage of four or fewer stools/day (with or without blood), absence of any systemic illness, and normal inflammatory markers (ESR) 2=S2 Disease Severity -- Moderate UC, passage of more than four stools per day but with minimal signs of systemic toxicity 3=S3 Disease Severity -- Severe UC, passage of at least six bloody stools daily, pulse rate of at least 90 beats per minute, temperature of at least 37.5°C, haemoglobin or less than 10.5g/100mL, and ESR of at least 30 mm/h

	4=UC extent -- E1 Ulcerative proctitis, Involvement limited to the rectum (that is, proximal extent of inflammation is distal to the rectosigmoid junction) 5=UC extent -- E2 Left--sided UC (distal UC), Involvement limited to a proportion of the colorectal distal to the splenic flexure 6 = UC extent -- E3 Extensive UC (pancolitis), Involvement extends proximal to the splenic flexure
Variable ID:	DISSEV
Variable:	Disease severity
Definition:	Tracked via Montreal Classification
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	UC + IBDU
Timing:	Baseline and annually
Data Source:	Clinical
Type:	Multiple answers
Value Domain:	Code
Response Options:	0=S0 -- Assymptomatic 1=S1 -- Mild UC, passage of four or fewer stools/day (with or without blood), absence of any systemic illness, and normal inflammatory markers (ESR) 2=S2 -- Moderate UC, passage of more than four stools per day but with minimal signs of systemic toxicity 3=S3 -- Severe UC, passage of at least six bloody stools daily, pulse rate of at least 90 beats per minute, temperature of at least 37.5°C, haemoglobin or less than 10.5g/100mL, and ESR of at least 30 mm/h
Variable ID:	PRESEIM
Variable:	Presence of extra-intestinal manifestations
Definition:	Eye, skin, joint, hepatobiliary or other
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Data Source:	Clinical
Type:	Multiple answers
Value Domain:	Code
Response Options:	0 = None 1 = Skin 2 = Joint 3 = Hepatobiliary 4 = Eye 5 = Other 999 = Unknown

Treatment factors

Variable ID:	IBDSURG
Variable:	IBD-related surgeries
Definition:	Indicate all IBD-related surgeries (operations) the patient has been subject to at any time
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and annually

Data Source:	Clinical
Type:	Multiple answers
Value Domain:	Code
Response Options:	0= No IBD related surgery 1= Small bowel resection 2= Ileocecal resection 3= Strictureplasty 4= Segmental colectomy (with or without stoma) 5= Total colectomy and ileostomy 6= Pouch surgery 7= Creation of ileorectal anastomosis 8= Proctectomy 9= Perianal disease surgery 888= other
Variable ID:	SURGMETH
Variable:	Method of IBD-related surgery
Definition:	If the patient has received IBD-related surgery indicate the method of surgical procedure
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=single-port laparoscopic surgery 1= multiport laparoscopic surgery 2=conventional open surgery
Variable ID:	SURGDATE
Variable:	Date of IBD-related surgery
Definition:	Please indicate the date of surgery
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Value Domain:	Date
Response Options:	DD/MM/YYYY
Variable ID:	COLECT
Variable:	Colectomy
Definition:	Indicate whether the patient has undergone a colectomy
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients who have had colectomy surgery
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0 = Patient has not undergone colectomy 1= Patient has undergone colectomy 999 = Unknown

Variable ID:	DX
Variable:	Current medication for IBD
Definition:	What type of medication for IBD does the patient currently take (regardless of when started)?
Supporting Definition:	Other medications include but are not limited to probiotics, cellular therapy, nutritional, symptom control
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Multiple answers
Value Domain:	Code
Response Options:	0= No IBD medication currently taken 1= mesalamine (or mesalazine) 2= Steroids 3= Immunomodulators: thiopurines (e.g. azathioprine, 6-mercaptopurine), methotrexate or other immunomodulators (e.g. mycophenylate, cyclosporine, tacrolimus) 4= Biologics - Anti-TNF agents (e.g. adalimumab, Certolizumab pegol, Golimumab, Infliximab) 5= Biologics - Integrin receptor antagonists (e.g. natalizumab, vedolizumab) 6= Biologics - Interleukin-antagonists (e.g. ustekinumab) 7= JAK-inhibitors 8= Nutritional therapy 888= Others
Variable ID:	COLOPROG
Variable:	Colorectal cancer surveillance programme
Definition:	Was the patient in a colorectal cancer surveillance programme prior to their diagnosis of colorectal cancer?
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients who have been diagnosed with colorectal cancer
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=Yes 1=No (programme is available) 2=No (no surveillance programme available) 999=Unknown

Outcomes

Symptoms, function and quality of life

Variable ID:	**IBDCON1**
Variable:	**Question 1a of the IBD-Control**
Definition:	Do you believe your IBD has been well controlled in the past two weeks?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly

Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0=Yes 1=No 999=Not sure
Variable ID:	IBDCON2
Variable:	Question 1b of the IBD-Control
Definition:	Do you believe your current treatment is useful in controlling your IBD?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0=Yes 1=No 999=Not sure 3=Please tick if not currently taking any treatment
Variable ID:	IBDCON3
Variable:	Question 2 of the IBD-Control
Definition:	Over the past 2 weeks, have your bowel symptoms been getting worse, getting better or not changed?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0=Better 1=No change 2=Worse
Variable ID:	IBDCON4
Variable:	Question 3a of the IBD-Control
Definition:	In the past 2 weeks, did you miss any planned activities because of IBD? (e.g. attending school/college, going to work or a social event)
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0=Yes 1=No 999=Not sure
Variable ID:	IBDCON5

Variable:	Question 3b of the IBD-Control
Definition:	In the past 2 weeks, did you wake up at night because of symptoms of IBD?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and 6 monthly
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0=Yes 1=No 999=Not sure
Variable ID:	IBDCON6
Variable:	Question 3c of the IBD-Control
Definition:	In the past 2 weeks, did you suffer from significant pain or discomfort?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0=Yes 1=No 999=Not sure
Variable ID:	IBDCON7
Variable:	Question 3d of the IBD-Control
Definition:	In the past 2 weeks, did you often feel lacking in energy (or fatigued) (by 'often' we mean more than half of the time)
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0=Yes 1=No 999=Not sure
Variable ID:	IBDCON8
Variable:	Question 3e of the IBD-Control
Definition:	In the past 2 weeks, did you feel anxious or depressed because of your IBD?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Data Source:	Patient-reported
Type:	Single answer

Value Domain:	Code
Response Options:	0=Yes 1=No 999=Not sure
Variable ID:	IBDCON9
Variable:	Question 3f of the IBD-Control
Definition:	In the past 2 weeks, did you think you needed a change to your treatment?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0=Yes 1=No 999=Not sure
Variable ID:	FISTSYMPT
Variable:	Fistula
Definition:	Do you experience symptoms from any of the following fistula?
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Data Source:	Patient-reported
Type:	Multiple answers
Value Domain:	Code
Response Options:	1=No fistula 2=Perianal fistula 3=Rectovaginal fistula 4=Enterocutaneous fistula 5=Other fistula
Variable ID:	WeightValue
Variable:	Body weight
Definition:	The body weight of a person, measured in the indicated units
Supporting Definition:	The collection of anthropometric measurements, particularly in those who are overweight or obese or who are concerned about their weight, should be performed with great sensitivity and without drawing attention to an individual's weight.
Displayed Value:	Please indicate your body weight.
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Numerical value
Value Domain:	Quantity
Response Options:	Numerical value of weight
Variable ID:	WeightUnit
Variable:	Body weight units
Definition:	Units of body weight
Supporting Definition:	None

Displayed Value:	Please indicate what units of measurement (kilograms or pounds) that you recorded your weight in.
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	1 = kilograms 2 = lbs
Variable ID:	WEIGHTINTE
Variable:	Intentional weight loss
Definition:	If any weight loss has occurred, was this intentional? (i.e. were you trying to lose weight?)
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=No 1=Yes

Disutility of care

Variable ID:	STERUSE
Variable:	Steroid use
Definition:	Please indicate whether prednisolone has been used in the last 12 months
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=No use of prednisolone in the last 12 months 1=Use of prednisolone in the last 12 months of less than 3 months total duration 2=Use of prednisolone in the last 12 months for more than 3 months total duration
Variable ID:	COMPOCCUR
Variable:	Occurrence of a complication
Definition:	Indicate whether the patient experienced a (unexpected or expected) complication whist during IBD intervention (this can be any type of intervention) or 3 months following intervention
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=No complication occurred 1= Yes, complication occurred
Variable ID:	COMPOUT

Variable:	Outcome of the complication
Definition:	Indicate whether the patient experienced a (unexpected or expected) complication whist during IBD intervention (this can be any type of intervention) or 3 months following intervention
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	If answered "1= Yes, complication occurred" to COMPOCCUR
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=No further intervention required 1=Surgical intervention required 2=Radiological intervention required 3=Endoscopic intervention required 4=Medical intervention required

Variable ID:	COMPHOSP
Variable:	Outcome of the complication – hospitalization
Definition:	Did the complication leading to prolonged hospitalization
Supporting Definition:	(i.e. longer than reasonably expected)
Displayed Value:	None
Inclusion Criteria:	If answered "1= Yes, complication occurred" to COMPOCCUR
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=No 1=Yes 999=Unknown

Variable ID:	COMPHOSPDAY
Variable:	Outcome of the complication – hospitalization
Definition:	If the complication lead to prolonged hospitalization, indicate the total number of days the patient was hospitalized for
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	If answered "1= Yes" to COMPHOSP
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Numerical
Value Domain:	Quantity
Response Options:	None

Variable ID:	COMPADM
Variable:	Outcome of the complication - unplanned admission
Definition:	Did the complication lead to an unplanned admission
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	If answered "1= Yes, complication occurred" to COMPOCCUR
Timing:	Baseline and follow-up
Data Source:	Clinical

Type:	Single answer
Value Domain:	Code
Response Options:	0=No 1=Yes 999=Unknown
Variable ID:	COMPADMDAY
Variable:	Outcome of the complication - unplanned admission
Definition:	If the complication lead to an unplanned admission, indicate the total length of stay for all unplanned admissions due to complication within 1 year
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	If answered "1= Yes" to COMPADM
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Numerical
Value Domain:	Quantity
Response Options:	None

Healthcare utilization

Variable ID:	HOSPADM_IBD
Variable:	All IBD-related admission to hospitals
Definition:	How many times has the patient been admitted (requiring at least an overnight stay) to a hospital/acute care facility in the last 12 months (IBD-related)?
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Numerical
Value Domain:	Quantity
Response Options:	None
Variable ID:	HOSPADMPLA
Variable:	All IBD-related planned admissions to hospitals
Definition:	How many times has the patient been admitted (requiring at least an overnight stay) to a hospital/acute care facility in the last 12 months (IBD-related) for a planned admission?
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Numerical
Value Domain:	Quantity
Response Options:	None
Variable ID:	HOSPADMUNP
Variable:	All IBD-related unplanned admissions to hospitals
Definition:	How many times has the patient been admitted (requiring at least an overnight stay) to a hospital/acute care facility in the last 12 months (IBD-related) for a unplanned admission?
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients

Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Numerical
Value Domain:	Quantity
Response Options:	None
Variable ID:	TOTLENST
Variable:	Total length of all admissions and readmissions
Definition:	Total length of all, (all-cause) admissions and readmissions within 1 year
Supporting Definition:	In days
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Numerical
Value Domain:	Quantity
Response Options:	None
Variable ID:	TOTEDVIS
Variable:	Total number of emergency room visits
Definition:	Total number of emergency room or emergency department visits within 1 year
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Numerical
Value Domain:	Quantity
Response Options:	None

Survival and Disease Control

Variable ID:	ANAEMIA
Variable:	Presence of anaemia
Definition:	Indicate if there is evidence of anaemia?
Supporting Definition:	Anaemia is defined by the WHO as a haemoglobin (at sea level) of <12.0 g/dl in non-pregnant women, <11.0g/dl in pregnant women and <13.5 g/dl in men
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=No 1=Yes 999=Unknown
Variable ID:	DISACTCR1
Variable:	Disease activity - clinical remission
Definition:	Is the patient clinically in remission?
Supporting Definition:	This could be determined using any recognised assessment or questionnaire.
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Single answer

Value Domain:	Code
Response Options:	0=No 1=Yes 999=Unknown
Variable ID:	DISACTCR2
Variable:	Disease activity - biological remission
Definition:	Is the patient in biological remission?
Supporting Definition:	This could be determined using any approach, e.g. endoscopically, radiological, histologically
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=No 1=Yes 999=Unknown
Variable ID:	DISACTCR3
Variable:	Disease activity - method of determining biological remission
Definition:	If the patient is in biological remission, how was this determined?
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Multiple answers
Value Domain:	Code
Response Options:	0= Endoscopically (e.g. endoscopy, colonoscopy) 1= Radiologically (e.g. fluoroscopy, CT, MRI) 2= Biochemistry (e.g. CRP, faecal calprotectin) 3=Histologically (tissue analysis)
Variable ID:	DISACTPR
Variable:	Disease activity
Definition:	In the last 6 months, my disease has been
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Patient-reported
Type:	Single answer
Value Domain:	Code
Response Options:	0=Constantly active giving me symptoms every day 1=Often active, giving me symptoms most days 2=Sometimes active, giving me symptoms on some days (for instance 1–2 days/week) 3=Occasionally active, giving me symptoms 1–2 days/month; 4=Rarely active, giving me symptoms on a few days in the past 6 months 5=I was well in the past 6 months, what I consider a remission or absence of symptoms
Variable ID:	COLOCA
Variable:	Colorectal cancer

Definition:	Has colorectal cancer been diagnosed?
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=No 1=Yes 999=Unknown
Variable ID:	COLODYS
Variable:	Colorectal dysplasia
Definition:	If colorectal cancer has been diagnosed, had colorectal dysplasia previously been diagnosed?
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Baseline and follow-uo
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0=No 1=Yes 999=Unknown
Variable ID:	VitalStatus
Variable:	Vital status
Definition:	Indicate if the person has deceased, regardless of cause
Supporting Definition:	None
Displayed Value:	None
Inclusion Criteria:	All patients
Timing:	Ongoing
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0 = No 1 = Yes 999 = Unknown
Variable ID:	DeceasedDate
Variable:	Date of death
Definition:	The date of death of the person
Supporting Definition:	It is recommended that in cases where all components of the date of death are not known or where an estimate is arrived at from age, a valid date be used together with a flag to indicate that it is an estimate. For record identification and/or the derivation of other metadata items that require accurate date of death information, estimated dates of death should be identified by a date accuracy indicator to prevent inappropriate use of date of death data. The linking of client records from diverse sources, the sharing of patient data, and data analysis for research and planning all rely heavily on the accuracy and integrity of the collected data. In order to maintain data integrity and the greatest possible accuracy an indication of the accuracy of the date collected is critical. The

	collection of Date accuracy indicator may be essential in confirming or refuting the positive identification of a person. For this reason it is strongly recommended that the data element Date accuracy indicator also be recorded at the time of record creation to flag the accuracy of the data.
Displayed Value:	None
Inclusion Criteria:	If answered "1= Yes" to VitalStatus
Timing:	Baseline and follow-up
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Value Domain:	Date
Response Options:	DD/MM/YYYY
Variable ID:	CauseOfDeathIBD
Variable:	Cause of death is inflammatory bowel disease
Definition:	Death attributable to inflammatory bowel disease
Supporting Definition:	Indicate if death is noted to be directly attributable to inflammatory bowel disease
Displayed Value:	None
Inclusion Criteria:	If answered "1= Yes" to VitalStatus
Timing:	Ongoing
Data Source:	Clinical
Type:	Single answer
Value Domain:	Code
Response Options:	0 = No 1 = Yes 999 = Unknown

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Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change
1.01	Contact Information	Removed inactive email address: ichomteam@ichom.org
4.0.0	Data Dictionary, Appendix	Harmonisation updates
4.0.0	Whole Document	Wording change. Replacing 'Standard Sets' to 'Sets of Patient-Centered Outcome Measures'

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