

REGISTRATION FORM

Registration

Date of Registration [e_assessdt]

Demographics

Birth Date (mm/yyyy) [birthdt]

Date of Diagnosis:

Day [diagday]

Month [diagmon]

Year [diagyear]

Unknown [diagdtunk]

Date of diagnosis not available but: [diagdtmonths]

Less than 4 months: [1]

More than 4 months: [2]

Patient's Diagnosis [e_diagnosis]

Crohn's Disease [1]

Ulcerative Colitis [2]

Indeterminate Colitis [3]

Gender [e_gender]

Male [1]

Female [2]

Ethnicity [ethnicity]

Hispanic [1]

Non-Hispanic [3]

Not Assessed/Collected [98]

Race (Check all that apply)

American Indian or Alaska Native [raceAIAN]

Asian [raceASIAN]

Black or African American [raceBKAA]

Native Hawaiian or other Pacific Islander [raceNKOP]

White [raceWH]

Other (specify) [raceOTH]

Not Assessed/Collected [raceNAC]

Other Race [e_racespec]

Parents Education

Mother [mother_edu]

Did not graduate high school [1]

Graduated high school/GED [2]

Some College [3]

Graduated College [4]

Attended Graduate School [5]

Unknown [99]

Father [father_edu]

Did not graduate high school [1]

Graduated high school/GED [2]

Some College [3]

Graduated College [4]

Attended Graduate School [5]

Unknown [99]

Patient Info

Health Insurance

Health Insurance Health Insurance [phi]

Medicaid [1]

Commercial [2]

Both Medicaid and Commercial [3]

No Insurance [4]

Don't Know [99]

Height/Weight

Recent Past Height from at least 6 months prior to this visit (to the nearest tenth): Unit: [e_prevht] cm

Unknown [e_prevhtna]

Date the height was measured: Day [htday] Month [htmon] Jan Year [htyear]

Recent Past Weight from at least 4 months prior to this visit (to the nearest tenth): Unit: [e_prevwt] kg

Unknown [e_prevwtna]

Date the weight was measured: Day [wtday] Month [wtmon] Jan Year [wtyear]

Extent of Disease

Extent of Disease: Crohn's Disease/Indeterminate colitis subjects only (select one for each category):

Macroscopic Lower GI Disease [e_exchrn]

None [0]

Ileal only [1]

Colonic only [2]

Ileocolonic [3]

Not Assessed [8]

Don't Know [9]

Macroscopic Upper GI Disease proximal to the ligament of Treitz [e_exchrn_upper_prox]

Yes [1]

No [0]

Not Assessed [2]

Don't Know [99]

Macroscopic Upper GI Disease distal to the ligament of Treitz [e_exchrn_upper_dist]

Yes [1]
No [0]
Not Assessed [2]
Don't Know [99]

What is the Crohn's Disease Phenotype? (Select one) [e_crphen]

Inflammatory, non-penetrating, non-stricturing [1]
Stricturing only [2]
Penetrating only [3]
Both stricturing and penetrating [5]
Don't Know [4]

Perianal Phenotype [e_perianaldis]

Yes [1]
No [0]
Don't Know [2]

Extent of Disease: Ulcerative Colitis subjects only

Extent of disease [e_disuculcproc]

Ulcerative Proctitis (rectum only) [1]
Left sided Ulcerative Colitis (distal to the splenic flexure only) [2]
Extensive Ulcerative Colitis (extends proximal to the splenic flexure) [3]
Pancolitis (the entire colon) [4]
Not Assessed completely (colonoscopy incomplete) [6]
Don't Know [7]

Ulcerative Colitis Behavior: Has the patient ever had severe disease (defined as PUCAI \geq 65 or severe disease determined by PGA) as an inpatient or outpatient? [uc_behav]

Yes [1]
No [0]
Don't Know [2]

VISIT DATA FORM

Assessment

Date of assessment: [s_assessdt]

Since the last visit documented in the database were there any visits that were not captured? (select one) [s_visnotdoc]

Yes [1]
No [0]
Don't Know [2]

Number of visits not captured [s_visnotdocy]
Current visit data entered by [s_entry]
Primary Attending Gastroenterologist [s_primprov]
Secondary provider [s_secprov]

Colectomy/Ostomy

Has the patient had a colectomy? (If Yes, and the patient's diagnosis is UC, the patient should be inactivated) (select one) [s_colectomy]

Yes [1]

No [0]

Don't Know [2]

Date of colectomy [s_colectomydt]

Does the Patient currently have an ileostomy or colostomy? (select one) [s_ileocolo]

Yes [1]

No [0]

Don't Know [2]

What is the patient's current diagnosis? (select one) [s_currdx]

Crohn's Disease [1]

Ulcerative Colitis [2]

Indeterminate Colitis [3]

Symptoms

In the following set of questions, describe the symptoms on the worst day in the last 7 days

General well-being related to IBD (select one) [s_wellbeing]

Well/Normal [7]

Fair [8]

Poor [3]

Don't Know/Not Assessed [6]

Limitations in daily activities related to IBD (select one) [s_limitdact]

None [1]

Occasional [2]

Frequent [3]

Don't Know/Not Assessed [4]

Abdominal pain due to IBD (select one) [s_abdpain]

None [1]

Mild [2]

Moderate to Severe [6]

Don't Know/Not Assessed [5]

Stools

In the following set of questions, describe the patient's stools on the worst day in the last 7 days

Total number of stools per day (enter 0 if none) [s_totstool]

Not Assessed [totstlna]

Most stools were (select one) [s_moststool]

Formed [1]

Partially Formed [2]

Liquid [3]

Don't Know/Not Assessed [4]

Number of liquid/watery stools per day (enter 0 if none) [s_liquidstool]

Not Assessed: liqstlna

Did the patient report bloody stools? (select one) [s_bloodystool]

Yes [1]

No [0]

Don't Know/Not Assessed [2]

If blood was present, the typical amount was (select one) [bloodamt]

Small amount in less than 50% of stools [5]

Small amount in greater than 50% of stools [6]

Large amount [2]

Not available/assessed [4]

Nocturnal diarrhea (select one) [s_nocdia]

Yes [1]

No [0]

Not available/assessed [2]

Extraintestinal Manifestations

Fever 38.5 degrees C (101.3 degrees F) for 3 of last 7 days? (select one) [s_fever]

Yes [1]

No [0]

Not available/assessed [2]

Definite arthritis? (select one) [s_arth]

Yes [1]

No [0]

Not available/assessed [2]

Uveitis? (select one) [s_uveitis]

Yes [1]

No [0]

Not available/assessed [2]

Erythema nodosum? (select one) [s_eryth]

Yes [1]

No [0]

Not available/assessed [2]

Pyoderma gangrenosum? (select one) [s_pyoderm]

Yes [1]

No [0]

Not available/assessed [2]

Exam

Abdominal exam (select one) [s_abdexam]

No tenderness, no mass [1]

Mild tenderness or questionable mass without tenderness [2]

Moderate to severe tenderness, involuntary guarding, definite mass [3]

Don't Know [4]

Not Assessed [5]

Perirectal disease at current exam (select one) [s_peridis]

Normal or asymptomatic tag, non-draining fistula without tenderness, no deep fissuring or abscess [1]
Mildly inflamed skin tag(s), 1 to 2 indolent fistulas with scant drainage (NO tenderness, deep fissures or abscess) [2]
Severely inflamed tag(s), active fistula with drainage, tenderness, abscess, or deep fissure [3]
Don't Know [4]
Not Assessed [5]

Current Height (default unit in cm) [s_ht]

Unit: cm

Not Assessed: [htna]

Current Weight (default unit in kg) [s_wt]

Unit: kg

Not Assessed: [wtna]

Current BMI [s_bmi]

For patients less than 18 years old, has height, weight and BMI been plotted on a growth chart? (select one) [s_plotvitals]

Yes [1]

No [0]

Don't Know [2]

Disease Assessment

Physicians Global Assessment of current disease status (select one) [s_pga]

Quiescent [1]

Mild [2]

Moderate [3]

Severe [4]

Don't Know/Not Assessed [5]

Extent of Disease: Crohn's Disease/Indeterminate Colitis patients only (select one for each category)

Macroscopic Lower GI Disease? [s_exchrn_lower]

None [0]

Ileal only [1]

Colonic only [2]

Ileocolonic [3]

Not Assessed [8]

Don't Know [9]

Macroscopic Upper GI Disease proximal to the ligament of Treitz? [s_exchrn_upper_prox]

Yes [1]

No [2]

Not Assessed [8]

Don't Know [99]

Macroscopic Upper GI Disease distal to the ligament of Treitz? [s_exchrn_upper_dist]

Yes [1]

No [2]

Not Assessed [8]

Don't Know [99]

For CD/IC patients only: Current Crohn's Disease Phenotype (select one) [s_cdpheno]

Inflammatory, non-penetrating, non-stricturing [1]

Strictureing [2]
Penetrating [3]
Both Strictureing and Penetrating [5]
Don't Know [4]

For CD/IC patients only: Perianal Phenotype? (select one) [s_peipheno]

Yes [1]
No [0]
Don't Know [2]

Extent of Disease: Ulcerative Colitis subjects only

Extent of Disease: Ulcerative Colitis subjects only (select one) [s_extdisuc]

Ulcerative Proctitis (rectum only) [1]
Left sided Ulcerative Colitis [2]
Extensive Ulcerative Colitis [3]
Pancolitis (the entire colon) [4]
Not assessed completely [5]
Don't Know [6]

For UC patients only: Ulcerative Colitis Behavior: Has the patient ever had severe disease? [s_ucbehavior]

Yes [1]
No [0]
Don't know [2]

Nutritional and Growth Status

Nutritional Status (select one) [s_nutrstatus]

Satisfactory [1]
At Risk [2]
In failure [3]
Not Assessed [5]

For patients less than 18 years old: Growth Status (select one) [s_growthstatus]

Satisfactory [1]
At Risk [2]
In failure [3]
Not Assessed [5]

Since the last visit, has the patient been in continuous remission? (select one) [remission]

Yes [1]
No [0]
Don't Know [2]

Since the last visit, has the patient had a serious infection? (Note: A serious infection is one that requires hospitalization or IV therapy) (select one) [s_infec]

Yes [1]
No [0]
Don't Know [2]

If yes, indicate infection [s_infecy]

Are there psychosocial risk factors that are felt to significantly impact the patient's medical care? (select one)

[s_adherence]

Yes [1]

No [0]

Don't Know [2]

Laboratory Analysis

Was a blood sample drawn for laboratory analysis? (select one) [bldsample]

Yes [1]

No [0]

Don't Know [2]

Date of lab sample [s_lbdtd]

C-Reactive Protein [crp]

Not Done [0]

Done on same date as above [1]

Done on different date than above [2]

Date of sample [s_crpdtd]

Result [s_crp]

Outside quantifiable range [s_crpunkn]

If result is outside the quantifiable range, select one: [crprange]

Below level of quantification [1]

Above level of quantification [2]

Lab? (select one) [s_crplab]

LabCorp [1]

Quest [2]

In-house [3]

Other [4]

Hematocrit [hem]

Not Done [0]

Done on same date as above [1]

Done on different date than above [2]

Hematocrit Date of sample [s_hemdt]

Result [s_hem]

Erythrocyte Sedimentation Rate (ESR) [esr]

Not Done [0]

Done on same date as above [1]

Done on different date than above [2]

Date of sample [s_esrdtd]

Result [s_esr]

Outside quantifiable range [s_esrunkn]

If result is outside the quantifiable range, select one: [esrrange]

Below level of quantification [1]

Above level of quantification [2]

Albumin [alb]

Not Done [0]

Done on same date as above [1]

Done on different date than above [2]

Date of sample [s_albdt]

Result [s_alb]

Medications

Is the patient currently taking any non-biologic prescription medications for IBD? (select one) [ibdmed]

Yes [1]

No [0]

Don't Know [2]

Aminosalicylates

Is the patient taking any oral aminosalicylates? [aminotaking]

Yes [1]

No [0]

Sulfasalazine [sulfataking]

Dose (mg/day) [s_azuldose]

Pentasa [penttaking]

Dose (mg/day) [s_pentdose]

Asacol [asataking]

Dose (mg/day) [s_asadose]

Apriso [aprtaking]

Dose (mg/day) [s_aprisodose]

Lialda [liataking]

Dose (mg/day) [s_lialdadose]

Colazal [colataking]

Dose (mg/day) [s_coladose]

Delzicol [delztaking]

Dose (mg/day) [s_delzdose]

Salofalk [salofalktaking]

Dose (mg/day) [s_salofalkdose]

Rectal Therapy

Is the patient taking any rectal therapy? [rectaking]

Yes [1]

No [0]

Rowasa [rwstaking]

Dose (mg/day) [s_rowasadose]

Canasa [cantaking]

Dose (mg/day) [s_canasadose]

Hydrocortisone enema/suppository [hdrtaking]

Dose (mg/day) [s_hydrocortdose]

Mesalazine [mesalazinetaking]

Dose mg/day [s_mesalazinedose]

Corticosteroids

Is the patient taking any corticosteroids? [cortaking]

Yes [1]

No [0]

Prednisone [pdstaking]

Dose (mg/day) [s_preddose]

Budesonide [bdstaking]

Dose (mg/day) [s_budedose]

Methylprednisolone [mpredtaking]

Dose (mg/day) [s_mpreddose]

Immunomodulators

Is the patient taking any immunomodulators? [imodtaking]

Yes [1]

No [0]

6MP [_mptaking]

Dose (mg/day) [s_6mpdose]

Azathioprine [azataking]

Dose (mg/day) [s_azadose]

Allopurinol [alptaking]

Dose (mg/day) [s_allopdose]

Methotrexate [mthtaking]
Dose (mg/wk) [s_methdose]

Methotrexate Route: [s_methroute]

Folic Acid [folictaking]
Dose (mg/day) [s_folicdose]

Other Immune Suppressants

Is the patient taking cyclosporine, tacrolimus or sirolimus? [suprntaking]

Yes [1]

No [0]

Cyclosporine [cyclotaking]
Dose (mg/day) [s_cyclodose]

Tacrolimus [tacrotaking]
Dose (mg/day) [s_tacrodose]

Sirolimus [sirotaking]
Dose (mg/day) [s_sirodose]

Antibiotics for IBD

Is the patient taking any antibiotic for IBD? [antbiotaking]

Yes [1]

No [0]

Cipro [ciprotaking]
Dose (mg/day) [s_ciprodose]

Flagyl [flagltaking]
Dose (mg/day) [s_flagldose]

Rifaximin [rifaxtaking]
Dose (mg/day) [s_rifaxdose]

Biologics Information

Medication	Dose	Treatment Period	Dosing Interval (for maintenance medications only)
Remicade [infmabtaking]	mg [s_inflixcurrdose]	Maintenance [1] Induction [2] [infmabtrt]	Weeks [s_inflixcurrinterval]
Cimzia [cimztaking]	mg [s_cimziacurrdose]	Maintenance [1] Induction [2] [cimztrt]	Weeks [s_cimziacurrinterval]

Humira [humratakng]	mg [s_humiracurrdose]	Maintenance [1] Induction [2] [humratrt]	Weeks [s_humiracurrinterval]
Tysabri [tysabrtaking]	mg [s_tysabricurrdose]	Maintenance [1] Induction [2] [tysabrtrt]	Weeks [s_tysabricurrinterval]
Simponi [simptaking]	mg [s_simpdose]	Maintenance [1] Induction [2] [simptrt]	Weeks [s_simpdi]
Stelara [steltaking]	mg [s_steldose]	Maintenance [1] Induction [2] [steltrt]	Weeks [s_steldi]
Entyvio [entyvtaking]	mg [s_entyvdose]	Maintenance [1] Induction [2] [entyvtrt]	Weeks [s_entyvdi]
Inflectra [inflectratakng]	mg [s_inflectradose]	Maintenance [1] Induction [2] [inflectratrt]	Weeks [s_inflectradi]
Remsima [remsimatakng]	mg [s_remsimadose]	Maintenance [1] Induction [2] [remsimatrt]	Weeks [s_remsimadi]

Other prescription medications for IBD (per site discretion)

Medication	Dose	New Medication today?	If No, started:
[othmedtaking]	mg [othmeddose]	Yes [1] No [0] Don't Know [2] [othmednew]	Less than 1 month ago [1] More than 1 month ago [0] Don't Know [2] [othmedstart]
	mg	Yes [1] No [0] Don't Know [2]	Less than 1 month ago [1] More than 1 month ago [0] Don't Know [2]

Is the patient currently taking the following?

An enteral caloric intake supplement? (select one) [s_entsupr]

Yes [1]

No [0]

Don't Know [2]

Enteral nutrition as primary therapy? (select one) [s_enthupr]

Yes [1]

No [0]

Don't Know [2]

TPMT

Has the TPMT been measured? (select one) [s_tpmtmeasured]

Yes [1]

No [0]

TPMT Genotype (select one) [s_tpmtgeno]

Normal [1]

Heterozygous [2]

Homozygous recessive [3]

Not Done [4]

TPMT Genotype date [s_tpmtgenodt]

TPMT Phenotype (select one) [s_tpmtpheno]

Normal/High [5]

Intermediate [1]

Low [3]

Not Done [4]

TPMT Phenotype date [s_tpmtphenodt]

6MP/AZA

Has the patient had 6MP metabolites measured more recently than the test indicated above? (select one) [s_thiometab]

Yes [1]

No [0]

Don't Know [2]

If Yes, most recent measurement date [s_thiometabdt]

Most recent 6-TGN level [s_6tgn]

Outside quantifiable range [_tgunkn]

If result is outside the quantifiable range, select one: [_tgnrange]

Below level of quantification [1]

Above level of quantification [2]

Most recent 6-MMPN [_mpunkn]

Outside quantifiable range [_mpunkn]

If result is outside the quantifiable range, select one: [_mmpnrange]

Below level of quantification [1]

Above level of quantification [2]

Remicade Patients

Has the patient had Remicade trough level measured more recently than the test above? (select one)

[s_inflixtroughmeas]

Yes [1]

No [0]

Don't know [2]

Remicade trough level [s_inflixtrough]

If result is outside the quantifiable range, select one: [inflixtroughqnt]

Below level of quantification [0]

Above level of quantification [1]

Date of Remicade trough level measurement [s_inflixtroughdt]

Remicade Trough Lab? (select one) [s_inflixtroughlab]

LabCorp (Esoterix) [1]

Prometheus [2]

MAYO [3]

ARUP [4]

Has the patient had Remicade antibody levels measured more recently than the test above? (select one) [s_inflixantibodymeas]

Yes [1]

No [0]

Don't Know [2]

Remicade antibody level [s_inflixantibody]

If result is outside the quantifiable range, select one: [inftrrange]

Below level of quantification [0]

Above level of quantification [1]

Date of Remicade antibody level measurement [s_inflixantibodydt]

Humira Patients

Has the patient had Humira trough level measured more recently than the test above? (select one)

[humira_trough_msr]

Yes [1]

No [0]

Don't know [2]

Humira trough level [humira_trough_lv]

If result is outside the quantifiable range, select one: [humira_trough_qnt]

Below level of quantification [0]

Above level of quantification [1]

Date of Humira trough level measurement [humira_trough_dt]

Humira Trough Lab? (select one) [humira_trough_lab]

LabCorp (Esoterix) [1]

Prometheus [2]

MAYO [3]

ARUP [4]

Has the patient had Humira antibody levels measured more recently than the test above? (select one)

[humira_antibody_msr]

Yes [1]

No [0]

Don't know [2]

Humira antibody level [humira_antibody_lv]

If result is outside the quantifiable range, select one: [humira_antibody_qnt]

Below level of quantification [0]

Above level of quantification [1]

Date of Humira antibody level measurement [humira_antibody_dt]

ACTIVATION STATUS FORM

Status [actvtn]

Activated [1]

Deactivated [2]

Removed [3]

Date of status change: [actvtndt] dd/mm/yyyy

Reason for deactivation of this subject: [inactrs]

Transferred to an adult gastroenterologist [1]

Transferred to another pediatric gastroenterology practice [2]

Transferred to another physician who is not a gastroenterologist [3]

Colectomy for ulcerative colitis [4]

Moved to another city [5]

Lost to follow-up [6]

Death [8]

Other [9]

Other specify [inactrssp]

HOSPITALIZATION FORM

Complete only for patients that have been admitted

Date of admission: mm/dd/yyyy [hspadmt]

Discharge Date: mm/dd/yyyy [hspdscdt]

Is hospitalization IBD related? [hspibdrel]

Yes [1]

No [2]

Not Sure [3]

Was an intra-abdominal GI surgery performed during the admission? [hpsurg]

Yes [1]

No [2]

Not Sure [3]

Comments [hspcomm]