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):

Macrosopic Lower GI Disease [e_exchn]
None [0]
Ileal only [1]
Colonic only [2]
Ileocolonic [3]
Not Assessed [8]
Don’t Know [9]

Macrosopic Upper GI Disease proximal to the ligament of Treitz [e_exchn_upper_prox]
Yes [1]
No [0]
Not Assessed [2]
Don’t Know [99]

Macrosopic Upper GI Disease distal to the ligament of Treitz [e_exchn_upper_dist]
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_disuculproc]
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 ≥ 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]
Stricturing [2]
Penetrating [3]
Both Stricturing 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)

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

**Laboratory Analysis**

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

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

**Date of lab sample** [s_lbdt]

**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_crpdt]

**Result** [s_crp]
- Outside quantifiable range [s_crpunkn]

If result is outside the quantifiable range, select one:

- 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_esrdt]

**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_mesarazinedose]

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

Biologics Information

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>Treatment Period</th>
<th>Dosing Interval (for maintenance medications only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remicade</td>
<td>mg</td>
<td>Maintenance [1]</td>
<td>Weeks</td>
</tr>
<tr>
<td>[infmabtaking]</td>
<td>[s_inflixcurrdose]</td>
<td>Induction [2]</td>
<td>[s_inflixcurrinterval]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[infmabtrt]</td>
<td></td>
</tr>
<tr>
<td>Cimzia</td>
<td>mg</td>
<td>Maintenance [1]</td>
<td>Weeks</td>
</tr>
<tr>
<td>[cimztaking]</td>
<td>[s_cimziacurrdose]</td>
<td>Induction [2]</td>
<td>[s_cimziacurrinterval]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[cimztrt]</td>
<td></td>
</tr>
</tbody>
</table>
### Other prescription medications for IBD (per site discretion)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>New Medication today?</th>
<th>If No, started:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Don’t Know [2]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>[othmeddose]</td>
<td>[othmednew]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Don’t Know [2]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>[othmeddose]</td>
<td>[othmednew]</td>
<td></td>
</tr>
<tr>
<td>Humira [humrataking]</td>
<td>[s_humiracurrdose]</td>
<td>Maintenance [1] Induction [2] [humratt]</td>
<td>[s_humiracurrinterval]</td>
</tr>
<tr>
<td>Tysabri [tysabrtaking]</td>
<td>[s_tysabricurrdose]</td>
<td>Maintenance [1] Induction [2] [tysabrtt]</td>
<td>[s_tysabricurrinterval]</td>
</tr>
<tr>
<td>Simponi [simptaking]</td>
<td>[s_simpdose]</td>
<td>Maintenance [1] Induction [2] [simptrt]</td>
<td>[s_simpdi]</td>
</tr>
<tr>
<td>Stelara [steltaking]</td>
<td>[s_steldose]</td>
<td>Maintenance [1] Induction [2] [stelt]</td>
<td>[s_steldi]</td>
</tr>
<tr>
<td>Entyvio [entyvtaking]</td>
<td>[s_entyvdose]</td>
<td>Maintenance [1] Induction [2] [entyvt]</td>
<td>[s_entyvdi]</td>
</tr>
<tr>
<td>Inflectra [inflectrataking]</td>
<td>[s_inflectradose]</td>
<td>Maintenance [1] Induction [2] [inflectr]</td>
<td>[s_inflectradi]</td>
</tr>
<tr>
<td>Remsima [remsimataking]</td>
<td>[s_remsimadose]</td>
<td>Maintenance [1] Induction [2] [remsim]</td>
<td>[s_remsimadi]</td>
</tr>
</tbody>
</table>

### 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: [tgndn]
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: [inflxtroughqnt]
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_lvl]

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_lvl]

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]
HOSPITALIZATION FORM
Complete only for patients that have been admitted

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

Discharge Date: mm/dd/yyyy [hspscdt]

Is hospitalization IBD related? [hspibdrel]
Yes [1]
No [2]
Not Sure [3]

Was an intra-abdominal GI surgery performed during the admission? [hspsurg]
Yes [1]
No [2]
Not Sure [3]

Comments [hspcomm]