## Patient Information-Section 1 (Page 1 of 10)

[enroll01]

Site ID [SiteIdentifier]				
Subject ID [SubjectIdentifier]				
1. Date of assessment [e_assessdt]				
(mm/dd/yyyy)				
2. Patient birthdate: [birthdt]				
(mm/dd/yyyy)				
3. Gender (select one) [e_gender]				
C Male [1]				
C Female [2]				
4. Racial category (select one) [e_race]				
C American Indian / Alaska Native [1]				
C Asian [2]				
C Native Hawaiian or other Pacific Islander [3]				
C Black or African American [4]				
C White [5] C More than one race [6]				
C Other [7]				
C Don't know [8]				
If Other, specify: [e racespec]				
5. Ethnic category (select one) [e_ethnicity]				
C Hispanic or Latino [1] C Jewish [2]				
C None of the above [3] C Don't know [4]				

Email: <a href="mailto:support@clinipace.com">support@clinipace.com</a>
Voice: (919) 306-3008

CLINPACE

Today: 2007-02-26 19:16 User: View Forms

### Patient Information-Section 2 (Page 2 of 10)

[enroll02]

```
Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
6. Patient's health insurance [e insurance]

← Medicaid only [1]

                                              C Commercial only [2]

    Medicaid plus commercial [3]

                                              r None [4]
C Don't know [5]
7a. Month of diagnosis (please enter the 2-digit month) [e diagnnth]
7b. Year of diagnosis (please enter the 4-digit year) [e diagyear]
8. Patient's Diagnosis [e diagnosis]

← Crohn's disease [1]

C UC [2]

← Indeterminate Colitis [3]

9. Extent of disease (check all that apply)
Mouth [e dismouth]
   Esophagus [e_disesoph]
T Stomach [e disstom]
   Duodenum [e disduodenum]
  Jejunum [e disjejunum]
  Heum [e disileum]
   Right colon [e_disrtcoln]
  Transverse colon [e distranscol]
   Left colon [e disltcoln]
   Rectum [e disrectum]
   Perianal [e_disperianal]
   Extra-intestinal (e.g. pancreas, liver) [e_disexintest]
```

Email: support@clinipace.com

Voice: (919) 306-3008



Today: 2007-02-26 19:19 User: View Forms

### Tests (Page 3 of 10)

[enroll03]

```
Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
10. Tests performed (check all that apply)
Complete Blood Count (CBC) [e_tstbldcount]
☐ Erythrocyte Sedimentation Rate (ESR) [e tstesr]
C-Reactive Protein (CRP) [e_tstcrp]
Liver function tests [e tstliver]
  Stool tests for pathogens [e tststool]
  Upper GI small bowel series X-ray [e_tstgi]
CT scan of abdomen with oral contrast [e_tstctscan]
  MRI small bowel series [e tstmri]
  Capsule videoendoscopy of small bowel [e tstcapsule]
  EGD with biopsy [e tstegdbiop]
  EGD without biopsy [e tstegdnobiop]
  Colonoscopy with biopsy [e_tstcolonbiop]
  Colonoscopy without biopsy [e tstcolonnobiop]
  IBD Serology [e tstibdser]
  TPMT [e_tsttpmt]
  Ophthalmological exam [e_tstophthal]
  DEXA bonescan for mineralization [e_tstdexa]
  Skin test for Tuberculosis [e_tsttuber]
  Chest X-ray [e tstchest]
  None of the above [e_tstnone]
11. Patient has been treated for IBD with: [e ibdtreated]
C Surgery [1]
  Tube feedings
               [2]
  Neither [3]
```

Email: support@clinipace.com

Voice: (919) 306-3008



Today: 2007-02-26 19:19 User: View Forms

### Patient History (Page 4 of 10)

[enrol104]

```
Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
12. General well-being (select one) [e wellbeing]
C Very Well [1]

    Slightly below par

c Poor [3]
                                              C Very Poor [4]
C Terrible [5]
                                              C Don't Know [6]
13. Abdominal pain (select one) [e abdpain]
C None [1]
                                              C Mild [2]

← Moderate [3]

                                              C Severe [4]
C Don't know [5]
Stools
14. Total (average number per day) [e_totstoo1]
15. Most stools are: [e moststool]
← Formed [1]
C Partially formed [2]
C Liquid [3]
16. Liquid (average number per day) [e_liquidstool]
                 (enter 0 if none)
17. Bloody (average number per day) [e bloodstool]
                 (enter 0 if none)
18. If blood is present, the typical amount is: [e bldpres]
C Small [1]
C Large [2]
19. Nocturnal diarrhea (select one) [e_nocdia]
C Yes [1]
C No [0]
C Don't know [2]
```

Email: support@clinipace.com

Voice: (919) 306-3008

CLIMPACE

Today: 2007-02-26 19:19 User: View Forms

### Physical Exam (Page 5 of 10)

[enroll05]

```
Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
20. Patient Global Assessment [e_glob]
                 (1-10)
21. Is the patient's activity limited? [e actlim]
C No [1]
C Occasional [2]
C Severe [3]
22. Weight (select one) [e_weight]
C Normal [1]
                                            Mild subpar [2]
Greater than 10% loss [3]
                                            C Don't know [4]
23. Abdomen (select one) [e_abdomen]
C Mass [1]
                                             C Tender [2]
C Both [3]

← Neither [4]

C Don't know [5]
24. Abdominal mass (select one) [e_abdmass]
r None [1]
                                             C Dubious [2]
C Definite [3]
                                             C Definite and tender [4]
C Don't know [5]
25. Perirectal disease (check all that apply)
None or asymptomatic tags [e_perinone]
T Anal fissure [e_perianal]
Indolent fistula [e_periindo]
Active fistula [e_periactive]
  Don't know [e_peridk]
26. Other (check all that apply)
  Fever 38.5 C for 3 of last 7 days [e_othfever]
Oral aphthae [e_othoral]
☐ Arthralgia or arthritis [e_otharth]
Uveitis [e_othuveitis]
  Abscess (at any site) [e_othabscess]
Frythema nodosum [e_otheryth]
Pyoderma gangrenosum [e_othpyo]
  Stricture [e_othstrict]
  None of the above [e_othnone]
  Another chronic illness or condition [e_othchron]
If another chronic illness or condition, specify: [e_othspec]
```

Email: <a href="mailto:support@clinipace.com">support@clinipace.com</a>
Voice: (919) 306-3008

PACE

Today: 2007-02-26 19:20 User: View Forms

### **Current Medications (Page 6 of 10)**

[enroll06]

```
Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
For 27-36, check all current medications:

    □ 27. Azulfidine (sulfasalazine) [e azul]

Dose [e_azuldose]
                 mg/day
(to the nearest tenth)
28. Pentasa (mesalamine) [e_pent]
Dose [e_pentdose]
                 mg/day
(to the nearest tenth)
C 29. Asacol (mesalamine) [e asacol]
Dose [e asadose]
                 mg/day
(to the nearest tenth)
7 30. Colazal (balsalazide) [e_cola]
Dose [e_coladose]
(to the nearest tenth)
T 31. Prednisone [e_pred]
Dose [e_preddose]
                 ma
(to the nearest tenth)
Frequency [e predfreq]
C QD, total daily dose [1]
C QOD [2]
If Other Frequency, please specify: [e predfreqothsp]
T 32. Budesonide [e_bude]
Dose [e_budedose]
                 mg/day
(to the nearest tenth)
33. Infliximab [e_inflix]
Dose [e_inflixdose]
```

```
(to the nearest tenth)
  34. Methotrexate [e meth]
Dose [e_methdose]
                 mg/day
(to the nearest tenth)
Route (select one) [e_methroute]
C Subcutaneous [1]
C PO
       [2]
35. 6MP or AZA (select one) [e 6mpaza]

← 6-mercaptopurine (6MP)

C Azathioprine (AZA) [2]
Dose [e_6mpazadose]
                 mg/day
(to the nearest tenth)
36. Other Medications (check all that apply)
Acid suppression medication [e medacid]
   Calcium supplement [e medcalc]
  Ciprofloxacin or other antibiotic except Flagyl [e medcipro]
  Cyclosporine or tacrolimus [e_medcyclo]
Flagyl (metronidazole) [e_medflag]
  Formula supplement (elemental or polymeric) [e_medsupp]
  Hydrocortisone per rectum [e medhydro]
   Iron supplement [e mediron]
  Multiple mineral supplement [e_medmineral]
  Multiple vitamin supplement [e medvit]
  Rowasa or Canasa (mesalamine) per rectum [e_medrowa]
  Tube feeding [e medtube]
  Vitamin D supplement [e medvitd]
Zinc supplement [e_medzinc]
   Probiotic [e_medpro]
  Other IBD medications [e_medoth]
If other IBD medications, specify: [e medothsp]
```

Voice: (919) 306-3008



Today: 2007-02-26 19:20 User: View Forms

### Measurements-Section 1 (Page 7 of 10)

[enrol107]

```
Site ID
        [SiteIdentifier]
Subject ID [SubjectIdentifier]
37. Weight
            [e wt]
(to the nearest tenth)
Units
       [e wtunit]
r kg
       [1]
C Ibs
       [2]
38. Height [e_ht]
(to the nearest tenth)
Units
       [e htunit]
       [1]
  cm
39. Parameters plotted on growth chart (check all that apply)
  Height [e paramht]
   Weight [e paramwt]
   BMI [e parambmi]
   None of the above
                      [e_paramnone]
40. Recent Past Height from at least 6 months prior to today's visit (answer to the nearest tenth)
(to the nearest tenth)
Units [e prevhtunit]
c cm [1]
c in [2]
41. Date the height was measured (must be at least 6 months prior to today's visit) [e_prevhtdt]
       1
(mm/dd/yyyy)
42. Since the patient became ill with IBD, has the patient's growth decreased? (select one) [e_htdec]
○ Not at all or by <1 major channel percentile [1]</p>
By one major channel percentile (e.g., from 50th percentile to 25th percentile) [2]
C By >1 major channel percentile (e.g., from 50th percentile to 10th percentile) [3]
C Don't know
43. Mother's height [e_mothht]
Units [e_mothhtunit]
```

C cm [1]	
44. Father's height [e_fathht]	v.
Units [e_fathhtunit]	
с cm [1] с in [2]	

Email: <a href="mailto:support@clinipace.com">support@clinipace.com</a>
Voice: (919) 306-3008

PACE

Today: 2007-02-26 19:20

User: View Forms

### Measurements-Section 2 (Page 8 of 10)

[enroll08]

```
Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
Nutritional Status
45. Was the patient's Nutritional Status classified? [e_nutrstatclas]
c Yes [1]
C No [0]
C Don't know [2]
46. If the patient's Nutritional Status was classified, please indicate Nutritional Status: [e_nutrstat]
C Satisfactory [1]
C At risk [2]

← In failure [3]

47. If the Nutritional Status was not Satisfactory, is there a plan for: [e_nutrnotsatis]
                                                ← Treatment [2]
c Evaluation [1]
                                                C Neither [4]
C Both [3]
 C Don't know [5]
48. If the Nutritional Status was not Satisfactory, has a nutritional plan been initiated for: [e_nutrplan]
                                                C Treatment [2]
 C Evaluation [1]
                                                Neither [4]
 C Both [3]
 C Don't know [5]
Growth Status
49. Was the patient's Growth Status classified? [e grwstatclas]
 C Yes [1]
 C No [0]
C Don't know [2]
50. If the patient's Growth Status was classified, please indicate Growth Status: [e_grwstat]
 C Satisfactory [1]
 C At risk [2]

← In failure [3]

51. If the Growth Status was not Satisfactory, is there a plan for: [e_grwnotsatis]
                                                C Treatment [2]
 c Evaluation [1]
                                                C Neither [4]
 C Both [3]
 C Don't know [5]
 52. If the Growth Status was not Satisfactory, has a growth plan been initiated for: [e_grwplan]
                                                C Treatment [2]

← Evaluation [1]

                                                c Neither [4]
 C Both [3]
 C Don't know [5]
 53. Tanner stage (select one) [e tanstage]
                                                C 2 [2]
 C 1 [1]
 C 3 [3]
                                                r 4 [4]
                                                 C Don't know [6]
  c 5 [5]
```

54. If you assessed Tanner stage which of the following did you assess? (check all that apply)

| Breasts [e\_tanbreast]

| Pubic hair [e\_tanpubic]

| Testicular volume [e\_tantesticular]

Email: support@clinipace.com

Voice: (919) 306-3008

CLINIPACE

Today: 2007-02-26 19:21

User: View Forms

## Laboratory Evaluations (Page 9 of 10)

[enroll09]

Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
For 55-61, enter date of blood sample. [e_lbdt]
(mm/dd/yyyy)
55. Hematocrit [e_hem]
(to the nearest tenth)  Enter Hematocrit Date if different from above date. [e hemdt]
/ / / (mm/dd/yyyy)
56. Erythrocyte Sedimentation Rate (ESR) [e esr]
To Elythocyte Sedimentation Nate (ESI)
Enter ESR Date if different from above date. [e_esrdt]
/ / / jimi (mm/dd/yyyy)
57. C-Reactive Protein (CRP) [e_crp]
(to the nearest tenth)
Enter CRP Date if different from above date. [e_crpdt]
(mm/dd/yyyy)
58. White Blood Cell Count (WBC) [e_wbc]
(to the nearest tenth)
Enter WBC Date if different from above date. [e_wbcdt]
(mm/ddhnny)
(mm/dd/yyyy)
59. Albumin [e_alb]
(to the prograph to what
(to the nearest tenth)  Enter Albumin Date if different from above date. [e_albdt]
/ / / date if different from above date. [e_albdc]
(mm/dd/yyyy)
60. Alanine Amino Transferase (ALT) [e alt]

Enter ALT Date if different from above date.  / / /	e_altdt]
61. 6MP metabolites (If below level of detection 6-TGN [e_6tgn]	, enter "00")
6-MMPN [e_6mmpn]	
Enter 6-TGN/6-MMPN Date if different from about the company of the	ve date. [e_6tgnmmpndt]
62. TPMT genotype (select one) [e_tpmtgen	1
C Normal [1] C Homozygous recessive [3]	<ul><li>○ Heterozygous [2]</li><li>○ Not done [4]</li></ul>
63. TPMT phenotype (enzyme activity) (select of	ne) [e_tpmtphen]
C Normal [1] C Low [3]	<ul><li>C Intermediate [2]</li><li>C Not done [4]</li></ul>

Voice: (919) 306-3008

CLINIPACE

Today: 2007-02-26 19:21

User: View Forms

# Physician's Assessments (Page 10 of 10)

[enroll10]

Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
64. Physician's Global Assessment of current disease status (select one) [e_pga]
C Inactive [1] C Mild [2]
C Moderate [3] C Severe [4]
65. Clinical course for the last 6-12 months (select one) [e_clincourse]
<ul> <li>C Patient followed for &lt;6 months [1]</li> <li>C Quiescent (continuously asymptomatic) [2]</li> </ul>
C Mild symptoms (never requiring steroids) [3]
C Exacerbations but remissions [4] C Chronically active, moderate or severe [5]
66. For patients with Crohn's Disease ONLY, please indicate phenotype (select one):  [e phenotype]
inflammatory, non-penetrating, non-obstructive (with or without perianal fistula) [1]
penetrating (abscess or fistula other than a perianal fistula; with or without a perianal fistula) [2] obstructive (with or without perianal fistula) [3]
Obstractive (with of without policinal nectacy)
Provider First Initial [e_providerf]
Provider Last Name [e_provider1]
Type of Provider [e_providertyp]
C Physician [1] C Nurse Practicioner [2]
C Other [3]
67. Data Entered By: [e_enterid]
Additional Information: [e_additinfo]

Voice: (919) 306-3008

PACE

Today: 2007-02-26 19:22 User: View Forms

## Patient Information-Section 1 (Page 1 of 9)

[sub01]

Site ID [SiteIdentifier]	
Subject ID [SubjectIdentifier]	
Workflow ID [WorkflowIdentifier]	
1. Date of assessment [s_assessdt]	
/ / /	
2. Patient birthdate [birthdt]	
Pending	

Email: support@clinipace.com

Voice: (919) 306-3008

CLINIPACE

Today: 2007-02-26 19:23 User: View Forms

## Patient History (Page 2 of 9)

[sub02]

```
Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
Workflow ID [WorkflowIdentifier]
3. General well-being (select one) [s_wellbeing]
                                              C Slightly below par [2]
c Very Well [1]
                                              C Very Poor [4]
C Poor [3]
                                              C Don't Know [6]
 c Terrible [5]
4. Abdominal pain (select one) [s_abdpain]

← Mild [2]

 c None [1]
                                              C Severe [4]
 C Moderate [3]
 C Don't know [5]
Stools
5. Total (average number per day) [s_totstoo1]
6. Most stools are: [s moststool]
 c Formed [1]
 c Partially formed [2]
 c Liquid [3]
7. Liquid (average number per day) [s_liquidstool]
                  (enter 0 if none)
 8. Bloody (average number per day) [s_bloodstool]
                  (enter 0 if none)
 9. If blood is present, the typical amount is: [s_bldpres]
 C Small [1]
 C Large [2]
10. Nocturnal diarrhea (select one) [s_nocdia]
 c Yes [1]
 C No [0]
 C Don't know [2]
```

Email: support@clinipace.com

Voice: (919) 306-3008

CLINIPACE

Today: 2007-02-26 19:24 User: View Forms

### Physical Exam (Page 3 of 9)

[sub03]

```
Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
Workflow ID [WorkflowIdentifier]
11. Patient Global Assessment [s glob]
                 (1-10)
12. Is the patient's activity limited? [s_actlim]
C No [1]
C Occasional [2]
C Severe [3]
13. Weight (select one) [s weight]
 C Normal [1]
                                             Mild subpar [2]
← Greater than 10% loss [3]
                                             C Don't know [4]
14. Abdomen (select one) [s abdomen]
C Mass [1]
                                             C Tender [2]
C Both [3]
                                             C Neither [4]
C Don't know [5]
15. Abdominal mass (select one) [s_abdmass]
C None [1]
                                             C Dubious [2]
C Definite [3]

← Definite and tender [4]

C Don't know [5]
16. Perirectal disease (check all that apply)

    □ None or asymptomatic tags [s perinone]

Anal fissure [s perianal]
  Indolent fistula [s_periindo]
☐ Active fistula [s_periactive]
  Don't know [s_peridk]
17. Other (check all that apply)
Fever 38.5 degrees C for 3 of last 7 days [s_othfever]
  Oral aphthae [s_othoral]
Arthralgia or arthritis [s_otharth]
Uveitis [s_othuveitis]
 Abscess (at any site) [s_othabscess]
  Erythema nodosum [s_otheryth]
  Pyoderma gangrenosum [s_othpyo]
 Stricture [s_othstrict]
  None of the above [s_othnone]
   Another chronic illness or condition [s othchron]
```

If another chronic illness or condition, specify: [s\_othspec]

Email: support@clinipace.com

Voice: (919) 306-3008

PACE

Today: 2007-02-26 19:24

User: View Forms

### Current Medications (Page 4 of 9)

[sub04]

```
Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
Workflow ID [WorkflowIdentifier]
For 18-27, check all current medications:
18. Azulfidine (sulfasalazine) [s_azul]
Dose [s azuldose]
                 mg/day
(to the nearest tenth)
T 19. Pentasa (mesalamine) [s_pent]
Dose [s_pentdose]
                 mg/day
(to the nearest tenth)
7 20. Asacol (mesalamine) [s asacol]
Dose [s asadose]
                 mg/day
(to the nearest tenth)
7 21. Colazal (balsalazide) [s cola]
Dose [s coladose]
                 mg/day
(to the nearest tenth)
C 22. Prednisone [s_pred]
Dose [s_preddose]
                 mg
(to the nearest tenth)
Frequency (select one) [s predfreq]
c QOD [2]
C Other [3]
If Other Frequency, please specify: [s_predfreqothsp]
7 23. Budesonide [s_bude]
Dose [s_budedose]
                 mg/day
 (to the nearest tenth)
```

```
24. Infliximab in last 4 months [s inflix]
If YES date last given: [s_inflixdt]
     1
(mm/dd/yyyy)
Dose [s inflixdose]
                 mg
(to the nearest tenth)
  25. Methotrexate [s meth]
Dose [s_methdose]
                 mg/day
(to the nearest tenth)
Route (select one) [s methroute]
C Subcutaneous [1]
C PO [2]
26. 6MP or AZA (select one) [s 6mpaza]
6-mercaptopurine (6MP) [1]
C Azathioprine (AZA) [2]
Dose [s_6mpazadose]
                 mg/day
(to the nearest tenth)
27. Other Medications (check all that apply)
Acid suppression medication [s medacid]
   Calcium supplement [s medcalc]
   Ciprofloxacin or other antibiotic except Flagyl [s_medcipro]
   Cyclosporine or tacrolimus [s_medcyclo]
  Flagyl (metronidazole) [s medflag]
   Formula supplement (elemental or polymeric) [s medsupp]
  Hydrocortisone per rectum [s medhydro]
   Iron supplement [s mediron]
   Multiple mineral supplement [s_medmineral]
   Multiple vitamin supplement [s medvit]
  Rowasa or Canasa (mesalamine) per rectum [s medrowa]
  Tube feeding [s_medtube]
   Vitamin D supplement [s medvitd]
   Zinc supplement [s_medzinc]
   Probiotic [s medpro]
   Other IBD medications [s medoth]
If other IBD medications, specify: [s_medothsp]
```

Voice: (919) 306-3008



Today: 2007-02-26 19:24 User: View Forms

### Measurements-Section 1 (Page 5 of 9)

[sub05]

```
Site ID
        [SiteIdentifier]
Subject ID [SubjectIdentifier]
Workflow ID [WorkflowIdentifier]
28. Weight [s_wt]
(to the nearest tenth)
Units
      [s wtunit]
c kg [1]
C lbs [2]
29. Height [s_ht]
(to the nearest tenth)
Units [s_htunit]
c cm [1]
c in [2]
30. Parameters plotted on growth chart (check all that apply)
☐ Height [s paramht]
  Weight [s paramwt]
  BMI [s parambmi]
   None of the above [s_paramnone]
```

Email: support@clinipace.com

Voice: (919) 306-3008

CLINIPACE

Today: 2007-02-26 19:27 User: View Forms

### Measurements-Section 2 (Page 6 of 9)

[sub06]

```
Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
Workflow ID [WorkflowIdentifier]
Nutritional Status
31. Was the patient's Nutritional Status classified? [s_nutrstatclas]
C No [0]
C Don't know [2]
32. If the patient's Nutritional Status was classified, please indicate Nutritional Status: [s_nutrstat]
C Satisfactory [1]
C At risk [2]

← In failure [3]

33. If the Nutritional Status was not Satisfactory, is there a plan for: [s_nutrnotsatis]
                                               C Treatment [2]
 C Evaluation [1]
                                               c Neither [4]
 C Both [3]
 C Don't know [5]
34. If the Nutritional Status was not Satisfactory, has a nutritional plan been initiated for: [s_nutrplan]
                                                C Treatment [2]
 c Evaluation [1]
                                                C Neither [4]
 C Both [3]
 C Don't know [5]
Growth Status
35. Was the patient's Growth Status classified? [s grwstatclas]
C Yes [1]
C No [0]
C Don't know [2]
36. If the patient's Growth Status was classified, please indicate Growth Status: [s grwstat]
C Satisfactory [1]
C At risk [2]
C In failure [3]
37. If the Growth Status was not Satisfactory, is there a plan for: [s grwnotsatis]
                                                r Treatment [2]
 c Evaluation [1]
                                                r Neither [4]
 C Both [3]
 C Don't know [5]
38. If the Growth Status was not Satisfactory, has a growth plan been initiated for: [s grwplan]
 r Evaluation [1]
                                                r Treatment [2]
                                                r Neither [4]
 c Both [3]
 C Don't know [5]
39. Tanner stage (select one) [s tanstage]
```

C 1 [1]	C 2 [2]	
C 3 [3]	C 4 [4]	
C 5 [5]	C Don't know [6]	
40. If you assessed Tanner sta	ge which of the following did you assess? (check all that apply)	
40. If you assessed Tanner sta	ge which of the following did you assess? (check all that apply)	

Voice: (919) 306-3008

PACE

Today: 2007-02-26 19:28 User: View Forms

# Laboratory Evaluations (Page 7 of 9)

[sub07]

Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
Workflow ID [WorkflowIdentifier]
For 41-47, enter date of blood sample. [s_lbdt]
/ / /
41. Hematocrit [s_hem]
(to the nearest tenth)  Enter Hematocrit Date if different from above date. [s_hemdt]  (mm/dd/yyyy)
42. Erythrocyte Sedimentation Rate (ESR) [s_esr]
Enter ESR Date if different from above date. [s_esrdt]  / / / (mm/dd/yyyy)
43. C-Reactive Protein (CRP) [s_crp]
(to the nearest tenth)  Enter CRP Date if different from above date. [s_crpdt]  / / / (mm/dd/yyyy)
44. White Blood Cell Count (WBC) [s_wbc]
(to the nearest tenth)  Enter WBC Date if different from above date. [s_wbcdt]  / / / / / / / / / / / / / / / / / / /
45. Albumin [s_alb]
(to the nearest tenth)  Enter Albumin Date if different from above date. [s_albdt]  /

46. Alanine Amino Transferase (ALT) [s_alt]  Enter ALT Date if different from above date. [s_altdt]  / / /				
/ / / (mm/dd/yyyy)  47. 6MP metabolites (If below level of detection, enter "00")  6-TGN [s_6tgn]				
/ / / (mm/dd/yyyy)  47. 6MP metabolites (If below level of detection, enter "00")  6-TGN [s_6tgn]				
/ / / / / / / / / / / / / / / / / / /				
(mm/dd/yyyy)  47. 6MP metabolites (If below level of detection, enter "00")  6-TGN [s_6tgn]				
47. 6MP metabolites (If below level of detection, enter "00") 6-TGN [s_6tgn]				
6-TGN [s_6tgn]				
6-MMPN [s_6mmpn]				
6-MMPN [s_6mmpn]				
Enter 6-TGN/6-MMPN Date if different from above date. [s_6tgnmmpndt]				
(mm/dd/yyyy)				
48. TPMT genotype (select one) [s_tpmtgen]				
C Normal [1] C Heterozygous [2]				
C Homozygous recessive [3] C Not done [4]				
49. TPMT phenotype (enzyme activity) (select one) [s_tpmtphen]				
C Normal [1] C Intermediate [2]				
C Low [3] C Not done [4]				

Voice: (919) 306-3008

CUNIPACE

Today: 2007-02-26 19:29

User: View Forms

## Physician's Assessments (Page 8 of 9)

[sub08]

Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
Workflow ID [WorkflowIdentifier]
50. Physician's Global Assessment of current disease status (select one) [s_pga]
C Inactive [1] C Mild [2]
C Moderate [3]
51. Clinical course for the last 6-12 months (select one) [s_clincourse]
C Patient followed for <6 months [1]
C Quiescent (continuously asymptomatic) [2]
← Mild symptoms (never requiring steroids) [3]
C Exacerbations but remissions [4]
Chronically active, moderate or severe [5]
52. For Patients with Crohn's Disease ONLY, please indicate phenotype (select one):
[s_phenotype]
inflammatory, non-penetrating, non-obstructive (with or without perianal fistula) [1]
c penetrating (abscess or fistula other than a perianal fistula; with or without a perianal fistula) [2] c obstructive (with or without perianal fistula) [3]

Email: support@clinipace.com

Voice: (919) 306-3008

CLINIPACE

Today: 2007-02-26 19:30 User: View Forms

### Follow Up (Page 9 of 9)

[sub09]

```
Site ID [SiteIdentifier]
Subject ID [SubjectIdentifier]
Workflow ID [WorkflowIdentifier]
53. Since the last Visit Report the patient has: (check all that apply)
Had a relapse [s relapse]
  Been hospitalized for IBD [s hosp]
  Had surgery for IBD [s surg]
 Had an influenza vaccination [s_fluvacc01]
Don't know [s dontknow]
  None of the above [s none01]
54. Since the last Visit Report the patient has had the following tests: (check all that apply)
Upper GI small bowel series [s uppergi]
  CT [s ct]
MRI of small bowel [s mri]
  Capsule videoendoscopy [s_capsule]
r EGD [s_egd]

    □ Colonoscopy [s colon]

F PPD or CXR [s_ppdcxr]
□ DEXA Scan [s dexa]
Fye Exam [s eye]

    □ None of the above [s none02]

55. Since the last Visit Report, has the TPMT been measured? [s tpmt]
c Yes [1]
C No [0]
C Don't know [2]
If Yes, please indicate type:
56. TPMT Genotype: [s_tpmtgeno]
C Normal [1]

← Heterozygous [2]

C Homozygous [3]
57. TPMT Phenotype (enzyme activity): [s tpmtpheno]
← Normal [1]
Intermediate [2]
€ Low [3]
58. Since the last Visit Report, has the diagnosis changed (CD vs UC vs IC)? [s_diagchng]
```

```
r Yes [1]
C No [0]
59. If Yes, the diagnosis is now (select one): [s_newdiag]
Crohn's disease [1]
C UC [2]

    Indeterminate Colitis

60. If the patient has Crohn's disease, since the last Visit Report has the phenotype changed? [s_crohns]
c Yes [1]
C No [0]
61. If Yes, select one: [s phenochange]
c inflammatory, non-penetrating, non-obstructive (with or without perianal fistula)
c penetrating (abscess or fistula other than a perianal fistula; with or without a perianal fistula) [2]
  obstructive (with or without perianal fistula)
62. Since the Last Visit Report, has the extent of the disease changed? [s_extentdisease]
c Yes [1]
C No [0]
If yes, check all that apply:
[ Mouth [s mouth]
  Esophagus [s disesoph]
   Stomach [s disstom]
   Duodenum [s disduo]
Jejunum [s_disjejunum]
   Heum [s disileum]
  Right colon [s disrtcolon]
   Transverse colon [s_distranscolon]
   Left colon [s disltcolon]
 Rectum [s disrectum]
   Perianal [s disperi]
   Extra-intestinal (e.g. pancreas, liver) [s_disextra]
Provider First Initial [s_providerf]
 Provider Last Name [s_provider1]
Type of Provider [s_providertyp]
 C Physician [1]
 C Nurse Practicioner [2]
 C Other [3]
 63. Data Entered By: [s enterid]
 Additional Information: [s_additinfo]
```

		- 1
		1
	•	1
		1
		- 1
		1
Grand Control of the		

Email: <a href="mailto:support@clinipace.com">support@clinipace.com</a>
Voice: (919) 306-3008

PACE

Today: 2007-02-26 19:30 User: View Forms