CD Risk Prediction: Data Collection at Follow-up (1)

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

31. Data Recorded during Follow-up

Study Visit: ❑ 6mth ❑ 12mth ❑ 18mth ❑ 24mth ❑ 30mth ❑ 36mth ❑ Other _____

Date of Review: __ __ / __ __ __ / __ __ ____

32. Does the Patient meet the study's diagnostic definition of CD?

Update only if new diagnostic assessment was performed and indicate which of the following features have changed since enrolling in this study – also mark if "this is a new result at this visit." If new assessment has not been done, check "No" below and press "Next" twice in database for Workflow 2 to save as carried-forward from enrollment or previous follow-up. Proceed to section 33.

New Diagnostic Assessment was performed? ❑ ***No*** ❑ ***Yes***

32.1.2 Endoscopic Findings (includes capsule endoscopy): ❑ Not available by first follow-up

	Y	N	U
Discontinuous Ulcerations	❑	❑	❑
Cobblestoning	❑	❑	❑

❑This is a new result at this visit

❑This is a new result at this visit

32.1.3 Radiological Findings: ❑ Not available by first follow-up

	Y	N	U
Cobblestoning or ulceration of the mucosa	❑	❑	❑

❑This is a new result at this visit

32.1.4 Laparotomy Findings (NB: intestinal resection is an exclusion criteria for this study):

❑ Not available by first follow-up ❑ Not applicable

	Y	N	U
Typical bowel wall induration	❑	❑	❑
Mesenteric lymphadenopathy	❑	❑	❑

❑This is a new result at this visit

❑This is a new result at this visit

	Y	N	U
Serosa with creeping fat or other inflammatory changes	❑	❑	❑

❑ This is a new result at this visit

32.1.5 Histopathological Findings: ❑ Not available by first follow-up

	Y	N	U
Patchy inflammatory cell infiltrates	❑	❑	❑
Epithelial granuloma in the absence of identifiable infectious agents	❑	❑	❑

❑ This is a new result at this visit

❑ This is a new result at this visit

32.2 Does the subject meet the study's definition of CD/IBD-U? ❑ **Yes** ❑ **No**

32.3 If 'No":

If the patient does NOT fulfill the study's diagnostic definition requirements by the first follow-up visit, then it is possible that the subject is no longer eligible for participation in this study; please discuss with a Study PI.

32.3.1 Name of Study PI contacted: _____

32.3.2 Deemed Eligible for Study? ❑ **Yes** ❑ **No**

32.3.3 Comments:

CD Risk Prediction: Data Collection at Follow-up (1)

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female* **Study Visit:**
(Or affix Barcode Sticker if Available)

33. Data Recorded at Clinical Review following Diagnosis

33.1 Are these data taken from a clinic visit? ❑ Yes ❑ No ❑ No data are available on this participant for this review

If no data are available:

33.2 Has this Participant been permanently lost to follow-up? ❑ No ❑ Yes ❑ Uncertain

The remainder of this form cannot be completed, and should be submitted at this point.

If data are available:

33.3 Current Diagnostic Impression: ❑ CD ❑ IBD-U ❑ UC ❑ Not IBD

33.4 Has the diagnosis changed since the last review? ❑ Yes ❑ No

33.5 Anthropometrics:

Height (cm): _____ ❑ Clinic ❑ Self-reported Weight (kg):_____ ❑ Clinic ❑ Self-reported

Tanner Stage:

❑ Physician assessed ❑ Self-reported ❑ Not assessed Breasts: 1 2 3 4 5 Pubic Hair: 1 2 3 4 5 Genitalia: 1 2 3 4 5

34. Physician Assessment at this visit

34.1 Physician Global Assessment of Current Disease Activity:

❑ None ❑ Mild ❑ Moderate ❑ Severe *(Don't forget to complete the PCDAI or PUCAI)*

34.2 Physician Global Assessment of Disease Activity Since Last Review:

❑Quiescent ❑ Mild ❑ Moderate ❑ Chronically Severe ❑ Chronically Severe with remissions

If this is the first study follow-up visit (6 months), then complete the following questions, if not, move to section 35

34.2.1 What was the Participant's maximal clinical response to induction therapy by 3 months post diagnosis?

❑ Complete Response ❑ Partial Response ❑ No Response

For Patients who achieved a complete response (if 'No' or 'Partial' Response, leave this question blank)

34.2.2 Approximate time to that complete response:

❑ <1 week ❑ 1 to 2 weeks ❑ 2 to 4 weeks ❑4 to 8 weeks ❑ 8 to 12 weeks

CD Risk Prediction: Data Collection at Follow-up (1)

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female* **Study Visit:**

(Or affix Barcode Sticker if Available)

35. Review of Environmental and Disease Characteristics since last Review

Since Last Review, has the Patient:

35.2 Regularly smoked Cigarettes? ❑*No* ❑*Yes* **Lived with a person who regularly smoked Cigarettes?** ❑*No* ❑*Yes*

35.4 Undergone Luminal Surgery? ❑*No* ❑*Yes*

If yes, then complete the following information, if not, move to question 35.5

Date of Surgery: __ __ / __ __ __ / __ __ ____
dd mmm yyyy

	Yes	***No***
Procedure		
Diversion	❑	❑
Stricturoplasty	❑	❑
Luminal Resection	❑	❑
Indication		
Obstruction	❑	❑
Internal Penetration	❑	❑
Inflammatory Disease	❑	❑

35.5 Been Hospitalized related to IBD? ❑*No* ❑*Yes*

If yes, then complete the following section, if not, move to section 36

Date Admit	***Date Discharge***	***Comments***
__ __/__ __ __/__ __ __	__ __/__ __ __/__ __ __	
__ __/__ __ __/__ __ __	__ __/__ __ __/__ __ __	
__ __/__ __ __/__ __ __	__ __/__ __ __/__ __ __	
__ __/__ __ __/__ __ __	__ __/__ __ __/__ __ __	

36. Review of Family History for IBD since last Review

Please refer back to the subject's IBD Family History data recorded at the last assessment.

36.1 Are any further members of the family now known to have IBD? ❑*No* ❑*Yes*

If yes then indicate who on the following table, otherwise go directly to section 37

	Full Sibling	**Mother**	**Father**
Ulcerative Colitis	❑Y	❑Y	❑Y
Crohn Disease	❑Y	❑Y	❑Y
IBD-U	❑Y	❑Y	❑Y
Confirmed IBD (unaware of type)	❑Y	❑Y	❑Y

CD Risk Prediction: Data Collection at Follow-up (1)

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female* **Study Visit:**

(Or affix Barcode Sticker if Available)

37. Review of EIMs and other Medical Diagnoses for the Subject since last Review

Please refer back to the subject's EIM and Medical History data recorded at the last assessment.

37.1 Does the Subject report any new EIMs since the last review?

		Previously recognized?			Newly recognized since last review? (Leave blank if recognized previously)			
		Yes	*No*	*Unknown*	*No*	*Unknown*	*Yes*	Approx Date First Recognized
37.1.1	Small Joint Arthritis	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.1.2	Large Joint Arthritis	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.1.3	Ankylosing Spondylitis	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.1.4	Sacro-Ileitis	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.1.5	Erythema Nodosum	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.1.6	Pyoderma Gangrenosum	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.1.7	Iritis/Uveitis	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.1.8	Autoimmune Hepatitis	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.1.9	Primary Sclerosing Cholangitis	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.1.10	Pancreatitis	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)

37.2 Does the Subject report any new additional medical diagnoses of interest since the last review?

		Previously recognized?			Newly recognized since last review? (Leave blank if recognized previously)			
		Yes	*No*	*Unknown*	*No*	*Unknown*	*Yes*	Approx Date First Recognized
37.2.1	Rheumatoid Arthritis	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.2	Psoriasis	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.3	Autoimmune Thyroid Disease	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.4	Celiac Disease (Bx proven)	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.5	Atopy/Asthma	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.6	IDDM	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.7	Multiple Sclerosis	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.8	Lupus	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)

CD Risk Prediction: Disease Re-assessment Data During Follow-up (1)

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female* **Study Visit:**

(Or affix Barcode Sticker if Available)

38. Review of Disease Location and Behaviour since last Review

38.1 Has Disease Location/Behaviour been Reassessed since the last review? ❑ *No* ❑ *Yes*

If 'yes' complete the following questions, if 'no' then move to question 39.

38.2 Approximate Date of Reassessment: __ __ / __ __ __ / __ __ __
dd mmm yyyy

38.3 Summary of Imaging performed at this re-assessment:

	NP	P		NP	P
Upper Endoscopy	❑	❑	Capsule Endoscopy	❑	❑
Lower Endoscopy (of Colon)	❑	❑	Lower Endoscopy (of TI)	❑	❑
UGI Series/Followthrough	❑	❑	Ba Enema	❑	❑
Abdo Ultrasound	❑	❑	Abdo CT	❑	❑
Abdo MRI	❑	❑	WCC Labeled Scan	❑	❑

NP = not performed *P= performed*

38.4 Summary of Maximal Disease Location subsequent to the latest Re-assessment:

Please refer back to the subject's disease location data at the last assessment.

For each of the locations listed below indicate (for the current re-assessment)

1) If the location was not specifically assessed on this occasion or

2) If the level of disease involvement has increased

Tick one option only for each site. If the site was previously known to be macroscopically involved select 'unchanged'.

	NA	N	UC	Mic	Mac		NA	N	UC	Mic	Mac
Oral	❑	❑	❑	❑	❑	Cecum	❑	❑	❑	❑	❑
Esophagus	❑	❑	❑	❑	❑	Asc Col	❑	❑	❑	❑	❑
Stomach	❑	❑	❑	❑	❑	Trans Col	❑	❑	❑	❑	❑
Duodenum	❑	❑	❑	❑	❑	Desc Col	❑	❑	❑	❑	❑
Jej/Prox Ileum	❑	❑	❑	❑	❑	Sigmoid	❑	❑	❑	❑	❑
Distal Ileum/TI	❑	❑	❑	❑	❑	Rectum	❑	❑	❑	❑	❑

NA = Not Assessed *N = Normal* *UC= Un-Changed* *Mic = New Microscopic Disease only* *Mac = New Macroscopic Disease*

38.5 Stricturing/Fibrostenotic Behaviour status

Please refer back to the subject's disease behaviour data at the last assessment.

Did the participant previously exhibit Stricturing/Fibrostenotic disease behaviour? ❑ Yes ❑ No ❑ Unknown

If 'yes' then proceed to question 38.6, if 'no' or 'unknown' then answer the following question:

38.5 Does the participant now exhibit Stricturing/Fibrostenotic disease behaviou? ❑ Yes ❑ No ❑ Unknown

If 'yes' then please complete the following section, if 'no' or 'unknown' proceed to question 38.6

Approximate Date when first recognized to be present: __ __ / __ __ __ / __ __ ___
dd mmm yyyy

	Yes	No	
Features:	❑	❑	Constant luminal narrowing on DI, endo or surgery
	❑	❑	Pre-stenotic Dilatation
	❑	❑	Obstructive signs/symptoms

38.6 Internally Penetrating Behaviour status

Please refer back to the subject's disease behaviour data at the last assessment.

Did the participant previously exhibit internally penetrating disease behaviour? ❑ Yes ❑ No ❑ Unknown

If 'yes' then proceed to section 39, if 'no' or 'unknown' then answer the following question:

Does the participant now exhibit Internally Penetrating disease behaviour? ❑ Yes ❑ No ❑ Unknown

If 'yes' then please complete the following section, if 'no' or 'unknown' proceed to section 39

Approximate Date when first recognized to be present: __ __ / __ __ __ / __ __ ___
dd mmm yyyy

	Yes	No	
Features:	❑	❑	Entero-enteric or entero-vesicular fistula/e
	❑	❑	Entero-cutaneous fistula/e
	❑	❑	Intra-abdominal abscess/es
	❑	❑	Intestinal Perforation

38.7 Comments Regarding Disease Location and Behaviour Data:

CD Risk Prediction: Disease Re-assessment Data During Follow-up (2)

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female* **Study Visit:**

(Or affix Barcode Sticker if Available)

39. Update of Perianal Disease History since last Reveiw

Was it possible to obtain accurate information regarding perianal disease at this review? ❑ *No* ❑ *Yes*

If 'yes' complete the following section, if 'no' then move to section 40.

Please refer back to the subject's Perianal Disease data recorded at the last assessment.

Approximate Date of the current Perianal Review: __ __ / __ __ __ / __ __ ____
dd mmm yyyy

	Previously Recognized?			Newly Recognized Disease Since Last Review (Leave blank if previously recognized)		
	Yes	No	Unknown	Yes	No	Unknown
Large Skin Tags	❑	❑	❑	❑	❑	❑
Ulcers	❑	❑	❑	❑	❑	❑
Fissure/s	❑	❑	❑	❑	❑	❑
Isolated Abscess	❑	❑	❑	❑	❑	❑
Multiple Abscesses	❑	❑	❑	❑	❑	❑
Perianal Fistula/e	❑	❑	❑	❑	❑	❑
Recto-vaginal Fistula/e	❑	❑	❑	❑	❑	❑
Ano-vaginal Fistula/e	❑	❑	❑	❑	❑	❑

CD Risk Prediction: PCDAI Data at Follow-up

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female* **Study Visit:**
(Or affix Barcode Sticker if Available)

40.1 Data Recorded at Clinical Review

How was this data collected? ❑ Clinic Visit ❑ Telephone Interview ❑ Assessment not done

Date of Assessment ___ ___ / ___ ___ ___ / ___ ___ ___ ___ **Comments:**
dd **mmm** **yyyy**

Which Activity Index Tool was used? ❑ PCDAI ❑ PUCAI

40.2 History (Recall over past 7 days)

Most Severe Abdominal Pain
❑ None ❑ Mild: Brief, does not interfere with activities ❑ Mod/Severe: Daily, longer lasting, affects activities, nocturnal

Stools (per day)
❑ 0-1 liquid stools, no blood ❑ Upto 2 semi-formed + small blood, or 2-5 liquid +/- blood ❑ Gross bleeding, or >/= 6 liquid, or nocturnal diarrhea

Patient Functioning, General Well-being
❑ No limitation of activities, well ❑ Occasional difficulty in maintaining age appropriate activities, below par ❑ Frequent, limitation of activity very poor

40.3 Examination

Weight
❑ Weight gain or voluntary weight stable/loss ❑ Involuntary weight stable, weight loss 1-9% ❑ Weight loss >/= 10%

Height
Height approximately 12 months ago: Date Taken: __ __ / __ __ __ / __ __ __ __ (d d / m m m / y y y y) Height (cm) _____

❑ < 1 channel decrease in Ht OR Ht Vel z-score <= -1 ❑ >= 1 and < 2 channel decrease in Ht OR Ht Vel z-score -1 to <-2
❑ > 2 channel decrease in Ht OR Ht Vel z-score >= -2

Abdomen

	Yes	*No*		*Yes*	*No*		*Yes*	*No*
Tenderness	❑	❑	Mass	❑	❑	Involuntary guarding	❑	❑

Perirectal Disease

	Yes	*No*		*Yes*	*No*		*Yes*	*No*
Asymptomatic tags	❑	❑	Fissure	❑	❑	Active Fistula or abscess	❑	❑
Inflamed tags	❑	❑	Indolent fistula	❑	❑	Drainage or Tenderness	❑	❑

Extra-Intestinal Manifestations

	Yes	*No*		*Yes*	*No*		*Yes*	*No*
Fever >/= 38.5oC for 3 days over past week	❑	❑	Uveitis	❑	❑	E Nodosum	❑	❑
Oral Ulcers	❑	❑	Definite Arthritis	❑	❑	P. gangrenosum	❑	❑

40.4 Investigations Required to complete Index *(Values obtained within the last week)*

	Requested	**Collected/Performed**	**Not Available**	**(Record result under "Core Investigations")**
HCT (%):	❑	❑	❑	
ESR (mm/hr):	❑	❑	❑	
Albumin (g/dL):	❑	❑	❑	

Comments:

CD Risk Prediction: PUCAI© at Diagnosis

DISREGARD this entire page if completing PCDAI form

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

40.1. a. Disease Activity Data Recorded at diagnosis

How was this data collected? ❑ Clinic Visit ❑ Telephone Interview ❑ Assessment not done

Date of Assessment ___ ___ / ___ ___ ___ / ___ ___ ___ ___
dd **mmm** **yyyy** **Comments:**

40.1.b. History (Last 24 hours)

Abdominal Pain
❑ No Pain ❑ Pain can be ignored ❑ Pain cannot be ignored

Rectal Bleeding
❑ None ❑ Small amount only, in less than 50% of stools

❑ Small amount with most stools ❑ Large amount (>50% of the stool content)

Stool Consistency of most stools
❑ Formed ❑ Partially Formed ❑ Completely unformed

Number of stools per 24 hours
❑ 0 – 2 ❑ 3 - 5 ❑ 6 – 8 ❑ > 8

Nocturnal stools (any episode causing wakening)
❑No ❑ Yes

Activity Level
❑ No limitation of activity ❑ Occasional limitation of activity ❑ Severely restricted activity

Comments:

CD Risk Prediction: Treatment & Investigation Data at Follow-up (1)

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female* **Study Visit:**

(Or affix Barcode Sticker if Available)

41 Summary of Treatment since Last Review

Treatment	**Received Since Last Review?** *No*	*Yes*	**Start Date**	**Dose (mg)**	**Still Ongoing?** *No*	**Stop Date**	*Yes*	**Current Dose** **Current Daily Dose (mg)**
Supplements etc								
Probiotic	❑	❑	_____	XXXXXX	❑	_____	❑	XXXXXXXXXXXX
Omega-3	❑	❑	_____	XXXXXX	❑	_____	❑	XXXXXXXXXXXX
Oral 5-ASA								
Sulfasalazine	❑	❑	_____	_____	❑	_____	❑	_____
Mesalazine	❑	❑	_____	_____	❑	_____	❑	_____
Olsalazine	❑	❑	_____	_____	❑	_____	❑	_____
Antibiotics								
Metronidazole (Flagyl)	❑	❑	_____	_____	❑	_____	❑	_____
Ciprofloxacin	❑	❑	_____	_____	❑	_____	❑	_____
Rifaxamin (Xifaxin)	❑	❑	_____	_____	❑	_____	❑	_____
Corticosteroids								
MethylPrednisone	❑	❑	_____	_____	❑	_____	❑	_____
Hydrocortisone IV	❑	❑	_____	_____	❑	_____	❑	_____
Prednisone or Prednisolone	❑	❑	_____	_____	❑	_____	❑	_____
Oral Budesonide	❑	❑	_____	_____	❑	_____	❑	_____
Immunomodulators								
Azathioprine	❑	❑	_____	_____	❑	_____	❑	_____
6-Mercaptopurine	❑	❑	_____	_____	❑	_____	❑	_____
Tacrolimus	❑	❑	_____	_____	❑	_____	❑	_____
Cyclosporin	❑	❑	_____	_____	❑	_____	❑	_____

	Received Since Last Review? *No*	*Yes*	**Start Date**	**Dose (mg)**	**Freq**	**Still Ongoing?** *No*	**Stop Date**	*Yes*	**Change Dose or Frequency?** *No*	*Yes*	**Date**	**Dose(mg)**	**Freq**
Methotrexate (SC/IM)	❑	❑	_____	_____	_____	❑	_____	❑	❑	❑	_____	_____	____
Methotrexate (Oral)	❑	❑	_____	_____	_____	❑	_____	❑	❑	❑	_____	_____	____
Biologic Agent													
Adalimumab	❑	❑	_____	_____	_____	❑	_____	❑	❑	❑	_____	_____	____
									❑	❑	_____	_____	____
									❑	❑	_____	_____	____
									❑	❑	_____	_____	____
Certolizumab	❑	❑	_____	_____	_____	❑	_____	❑	❑	❑	_____	_____	____
									❑	❑	_____	_____	____
									❑	❑	_____	_____	____

	Received Since Last Review? *No*	*Yes*	**Start Date**	**Dose (mg)**	**Still Ongoing?** *No*	*Yes*	**Date Received**	**Dose(mg)**
Infliximab	❑	❑	_____	_____	❑	❑	_____	_____
							_____	_____
							_____	_____
							_____	_____
Natalizumab	❑	❑	_____	_____	❑	❑	_____	_____
Comments:							_____	_____

CD Risk Prediction: Treatment & Investigation Data at Follow-up (2)

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female* **Study Visit:**

(Or affix Barcode Sticker if Available)

42. Summary of Enteral Therapy since Last Review

	Received Since Last Review?				**Still Ongoing?**			**Change Dose?**			
Treatment	*No*	*Yes*	**Start Date**	**Est Cal/day**	*No*	**Stop Date**	*Yes*	*No*	*Yes*	**Date**	**Est. Cal/day)**
Exclusive											
Nutren Junior	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Vital Junior	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Pediasure	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Ensure	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Modulen	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Peptamen	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Other:											
	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Supplemental											
Nutren Junior	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Vital Junior	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Pediasure	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Ensure	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Modulen	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Peptamen	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____
Other:											
	❑	❑	_____	_____	❑	_____	❑	❑	❑	_____	_____

43. Summary of Core Laboratory Investigations at Follow-up Visit

Date of Blood Draw ____ ____ /____ ____ ____/ ____ ____ ____ ____ **Lab Used** _____

dd **mo** **yr**

	Performed			**Result**		**Performed**			**Result**
Hemoglobin (g/dL)	❑Y	❑N	❑U	_____	*CRP* (mg/L)	❑Y	❑N	❑U	_____
HCT (%)	❑Y	❑N	❑U	_____	*Albumin* (g/dL)	❑Y	❑N	❑U	_____
Platelet Count (10^9/L)	❑Y	❑N	❑U	_____	*Urea (mmol/L)*	❑Y	❑N	❑U	_____
White Cell Count (10^9/L)	❑Y	❑N	❑U	_____	*Creatinine (micromol/L)*	❑Y	❑N	❑U	_____
Neutrophil (10^9/L)	❑Y	❑N	❑U	_____	*AST (U/L)*	❑Y	❑N	❑U	_____
Lymphocytes (10^9/L)	❑Y	❑N	❑U	_____	*ALT (U/L)*	❑Y	❑N	❑U	_____
Eosinophil (10^9/L)	❑Y	❑N	❑U	_____	*Alk Phos (U/L)*	❑Y	❑N	❑U	_____
ESR (mm/hr)	❑Y	❑N	❑U	_____	*GGT (U/L)*	❑Y	❑N	❑U	_____

Y= Yes, N= No, U=Unknown

44. Study Specific Investigations/Procedures to be completed this visit

Only collected at the following reviews: **12 month** **24 month** **36 month**

Serology:

❑ *Will not be collected* ❑ *Requested* ❑ *Collected/performed*

Date Collected (dd/mmm/yyyy): _____ Sample ID: _____ (Barcode Identity)

DNA:

❑ *Will not be collected* ❑ *Requested* ❑ *Collected/performed*

Date Collected (dd/mmm/yyyy): _____ Sample ID: _____ (Barcode Identity)

PCDAI USER'S GUIDE

This guide is intended to help nurse coordinators and physicians complete the PCDAI in order to assess disease activity in children with Crohn's disease participating in clinical trials.

HISTORY

All calculations are based upon a 1 week (7 day) history recall of symptoms. The history recall should be solicited from the patient and/or caregiver.

1. **Abdominal pain**

The descriptions in the PCDAI of "mild" and "moderate/severe" should be used to guide in scoring the pain. Note that duration, effect on activities, and nocturnal occurrence separate moderate/severe from mild. If pain varies in severity during the week, patient should be scored according to the most severe pain. However, mild pain should be present on at least two days to score 5 points rather than 0 points.

2. Stools

The intent is to score the stool pattern during the preceding week.
To facilitate scoring, first categorize the patient as having blood in the stool or not.
If there is **no blood** in the stool, score as follows:

Formed stools or up to 1 loose stool daily = 0
2-5 liquid or very loose stools on 1 or more days = 5
6 or more liquid or very loose stools on 1 or more days or any nocturnal diarrhea = 10

If **blood** is present in the stool on any day during the past week, score as follows:

Small amounts of blood in stool (on toilet paper or small spots in stool, etc.) = 5
Any gross bleeding (large amounts on stool or colors the water in the toilet, etc.) = 10

3. Patient functioning, general well-being

If there is variation during the week, patient should be scored according to the most significant limitation of activity, even if only one day of the week, as long as likely due to Crohn's disease and not to an intercurrent illness.

PHYSICAL EXAMINATION

4.Weight (The intent is to assess the ability to normally maintain or gain weight)
Voluntary weight stable/loss means patient maintaining or losing weight on purpose.
Involuntary weight stable means patient wants to gain weight but cannot.
To calculate percentage weight loss use formula:

$$\frac{\text{Historic weight} - \text{Current weight}}{\text{Historic weight}} \times 100 = \%\ \text{weight loss}$$

Take historic weight as maximal weight attained within preceding 4-6 months, excluding any value that reflects excess weight due to corticosteroid use.

5. Height The intent is to assess the normalcy vs impairment of the patient's recent linear growth. Note that post-pubertal patients will score 0 points. For patients still growing, there are two options for scoring. Method (a) is preferred. Method (b) to be used if data required for (a) are unavailable.

a) Height velocity (cm/year), the most sensitive parameter, should be used if reliable height measurements are available from the preceding 6 to 12 months.
Convert height increment during preceding 6 to 12 months into velocity (cm/year) as follows:

$$\frac{\text{Present height} - \text{Height 6} - \text{12 months previously}}{\text{Interval (months) between heights}} \times 12 = \text{Height velocity (cm/year)}$$

Using height velocity chart, which accompanies PCDAI, determine centile for height velocity.
Height velocity should ideally be plotted according to bone age rather than chronologic age. However, if maturity is appropriate for age (not delayed or advanced) it is reasonable to plot and score height velocity according to chronologic age.
In follow-up visits of short-term clinical trials less than 4 months duration, score height velocity the same as the initial score unless there has been an actual height gain.

b) If reliable height measurements from 6 to 12 months previously are lacking (often the case with newly diagnosed patients), use any earlier heights to assess previous height centile and compare with current height centile. Score according to degree of decrease in height centile.

PCDAI: *see instructions previous page re: scoring items marked *

HISTORY (Recall; 1 week)*

Abdominal pain:* None _____(0)
Mild – Brief, does not interfere with activities _____ (5)
Mod / severe - daily, longer lasting, affects activities, nocturnal _____ (10)

Stools*: (per day)
Formed stools or up to 1 liquid stool, no blood _____ (0)
Up to 2 semi-formed with small blood, or 2-5 liquid with or without small blood _____ (5)
Any gross bleeding, or ≥ 6 liquid, or nocturnal diarrhea _____ (10)

Patient Functioning* – General Well-Being

No limitation of activities, well _____ (0)
Occasional difficulty in maintaining appropriate activities, below par _____ (5)
Frequent limitation of activity, very poor _____ (10)

LABORATORY (values obtained within the past week)

HCT (%)	< 10 yrs :	>33	____ (0)
		28-32	____ (2.5)
		< 28	____ (5)
	Males 11-14yrs	>35	____ (0)
		30-34	____ (2-5)
		< 30	____ (5)
	Males 15-19yrs:	≥37	____ (0)
		32-36	____ (2.5)
		< 32	____ (5)
	Females 11-19yrs	≥ 34	____ (0)
		29-33	____ (2.5)
		< 29	____ (5)
ESR (mm/hr)		< 20	____ (0)
		20-50	____ (2.5)
		> 50	____ (5)
ALBUMIN (g/dL)		≥ 3.5	____ (0)
		3.1-3.4	____ (5)
		≤ 3.0	____ (10)

TOTAL SCORE _____

EXAMINATION

Weight*
Weight gain or voluntary weight stable/loss _____ (0)
Involuntary weight stable, weight loss 1-9% _____ (5)
Weight loss ≥ 10% _____ (10)

Height* Score using (a) criteria when possible

a) Height velocity ≥ -1SD _____ (0)
Height velocity < - 1SD, >-2SD _____ (5)
Height velocity ≤ - 2SD _____ (10)

OR

b) < 1 channel decrease _____ (0)
≥1, < 2 channel decrease _____ (5)
> 2 channel decrease _____ (10)

Abdomen

No tenderness, no mass _____ (0)
Tenderness, or mass without tenderness _____ (5)
Tenderness, involuntary guarding, definite mass _____ (10)

Perirectal disease

None, asymptomatic tags _____ (0)
Inflamed tags or 1-2 indolent fistula(e) or fissure(s), scant drainage, no tenderness _____ (5)
Active fistula, drainage, tenderness, or abscess _____ (10)

Extra-intestinal Manifestations

(Fever ≥ 38.5 for 3 days over past week, oral ulcers definite arthritis, uveitis, E.nodosum, P. gangrenosum)
None _____ (0)
One _____ (5)
≥ Two _____ (10)