

CRONOGRAM A (DC or UC patients receiving Infliximab)

Information to be collected	Infliximab															
	Induction period			Maintenance period - data collection time points (24-month follow up)												
	Day1 or basal	W2	W6	W14	W22	W30	W38	W46	W54	W62	W70	W78	W86	W94	W102	Or completion of Fup ³
Date of birth	X ⁴															
Sex	X ⁴															
Height	X ⁴	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
BMI	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Smoking status	X ⁴															
Medical history	X ⁴															
Comorbidities	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Disease presentation	X ⁴															
Diagnosis (UC or CD) – location, steroid behavior, prognostic classification)	X ⁴															
Clinical activity (PUCAI / PCDAI)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Dose of IFX administered	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant therapies	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Routine laboratory parameters	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Serum IFX levels ¹	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Anti-IFX antibodies ¹	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Fecal sample (calprotectin levels) ²	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

The data collection time points during maintenance with infliximab are expected every 8 weeks (or every 6 weeks, if required) until completing the 24-month follow up period.

¹ Blood sample to be collected prior to each infusion of IFX at the scheduled appointment (approximately every 8 weeks). Sample will be analyzed by Central Laboratory.

² Stool sample to be collected prior to each infusion of IFX at the scheduled appointment (approximately every 8 weeks). Sample will be analyzed by Central Laboratory

³ Patients in maintenance with infliximab at study inclusion will be followed every 8 weeks until completing the 24-month follow up period;

⁴ Basal data to be collected, regardless of the patient's treatment phase at study inclusion.

W = week; IFX = infliximab; PUCAI – pediatric ulcerative colitis activity index; PCDAI – pediatric Crohn's disease activity index.