

USTEKINUMAB TROUGH LEVELS AND THEIR IMPACT ON CLINICAL AND ANALYTICAL RESULTS IN CROHN'S DISEASE

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Background and importance

Ustekinumab is an effective treatment for moderate to severe Crohn's disease (CD). However, limited data exist correlating ustekinumab serum levels with clinical remission, and its therapeutic range remains unclear.

Aim and objectives

To analyze the relationship between trough ustekinumab concentrations at maintenance and clinical and analytical response of patients with CD.

Material and methods



Observational, retrospective, multicenter study
April 2019 - May 2024

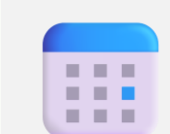


Serum levels → ELISA assay

Efficacy endpoints →

Clinical remission
Clinical response
Normalization of FCP and CRP

Variables collected



Demographics Age, BMI

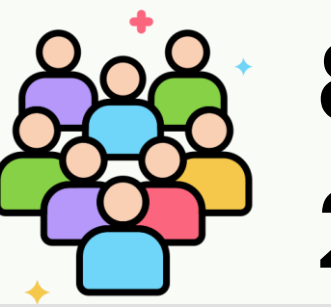


Biomarkers Serum levels, CRP, FCP at 0, 6, 12, and 24 months



Treatment Persistence, Clinical Response & Remission at 6, 12, 24 months

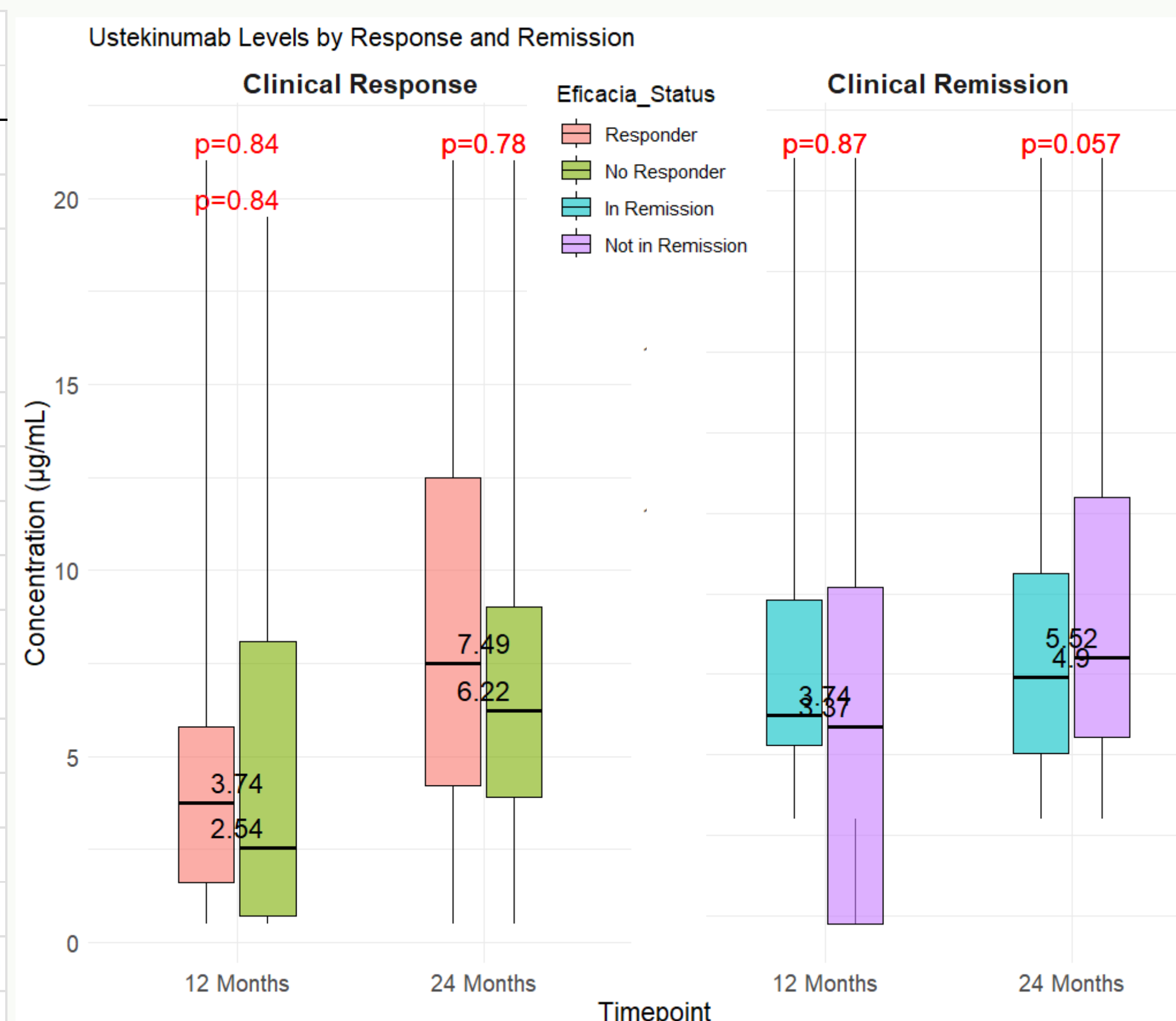
Results



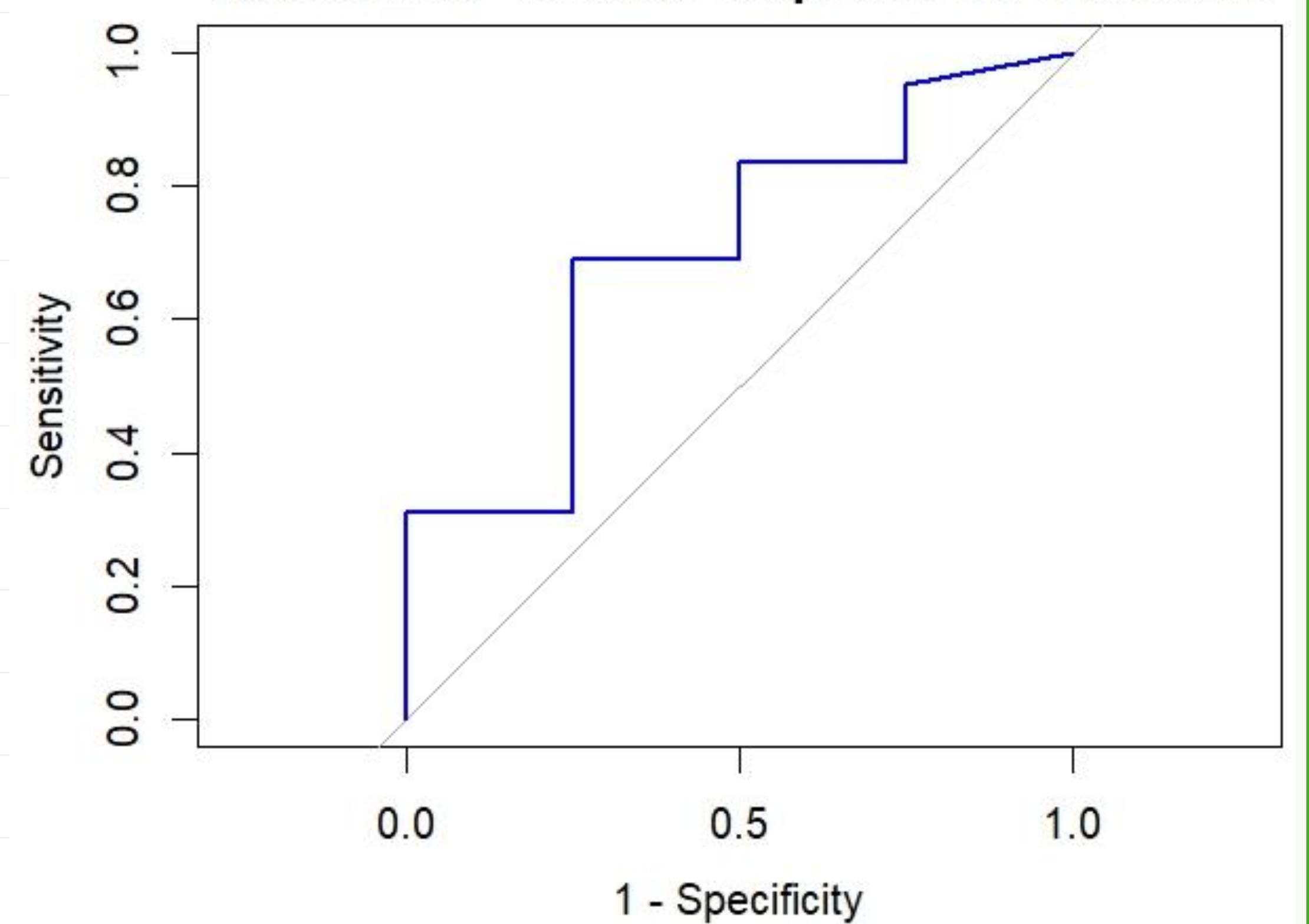
89 patients
232 determinations

Table 1. Baseline characteristics of the study population

Variables	Total, N=232
Age, median (IQR)	44,5 (23,5)
Sex, n (%)	
Female	107 (46,1%)
BMI, median (IQR)	25,15 (8,29)
Age at diagnosis, n (%)	
<16 years	28 (12,1%)
16-40 years	166 (71,6%)
>40 years	38 (16,4%)
Disease location, n (%)	
L1: ileal	110 (47,4%)
L2: colonic	22 (9,5%)
L3: ileocolonic	100 (43,1%)
Disease behavior, n (%)	
B1: non-stricturing and non-penetrating	122 (52,6%)
B2: stricturing	85 (36,6%)
B3: penetrating	25 (10,8%)
Family history of IBD, n (%)	
No family history	199 (85,8%)
First degree	15 (6,5%)
Second degree	18 (7,8%)
Extraintestinal manifestations, n (%)	
No manifestations	134 (57,8%)
Presence of manifestations	98 (42,2%)
Persistence, median (IQR)	42 (27,5)
Periodicity, n (%)	
Every 12 weeks	2 (0,9%)
Every 8 weeks	91 (39,2%)
Every 6 weeks	52 (22,4%)
Every 4 weeks	87 (37,5%)



ROC Curve - Clinical response at 24 months



Conc (µg/mL)	Sensitivity (%)	Specificity (%)	AUC
2.20	69.04	75.00	0.70

Timepoint	Clinical Response % (n)	Clinical Remission % (n)
Month 12	80.8% (59)	50.7% (37)
Month 24	90.2% (37)	34.1% (14)

Conclusion and relevance

Higher trough concentrations seem to be associated with greater clinical response. A larger cohort will be needed to test the robustness of the results.

