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Title:
Long-term use of subcutaneous infliximab biosimilar CT-P13 in patients with inflammatory bowel disease in clinical practice

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DOI: 10.17235/reed.2026.11727/2025
Link: PubMed (Epub ahead of print)

Please cite this article as:
Huguet José María, Martí Romero Lidia, Boscá-Watts Marta Maia, Ramirez José J., Sanchis Artero Laura, Paredes José M., Cambralla María, Ruiz Lucía, Alemany Pérez Gloria, Garrido Alejandro, Pastor Miguel A., Iborra Marisa. Long-term use of subcutaneous infliximab biosimilar CT-P13 in patients with inflammatory bowel disease in clinical practice. Rev Esp Enferm Dig 2026. doi: 10.17235/reed.2026.11727/2025.

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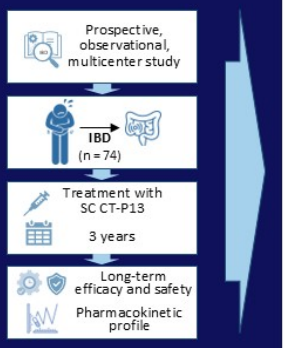
Study Design & Patients



Results

Table 2. Changes in inflammatory markers and SC CT-P13 plasma levels.

	All patients (n = 74)		p-value
	Baseline	Follow-up*	
CRP (mg/dL), mean ± SD	0.71 ± 1.20	1.00 ± 1.98	0.3
FC (µg/g), mean ± SD	238.58 ± 475.05	231.08 ± 393.78	>0.9
SC CT-P13 levels (µg/mL), mean ± SD	8.15 ± 5.93	15.89 ± 7.99	<0.001

* Follow-up: up to 3 years.

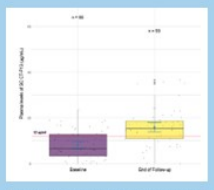


Figure 1. Distribution of plasma levels of CT-P13 at baseline (after switching from IV to SC) and at the end of follow-up, with 12 µg/mL used as a reference level.

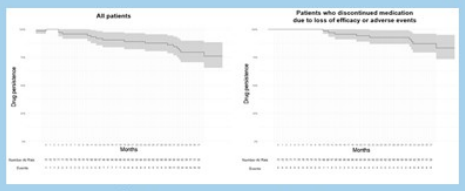


Figure 2. Drug persistence at 3 years.

Abbreviations:
CRP, C-reactive protein; CT-P13, infliximab biosimilar; FC, fecal calprotectine; IBD, inflammatory bowel disease; IV, intravenous; SC, subcutaneous; SD, standard deviation.

Conclusions

In this prospective multicenter real-world cohort, switching from IV to SC IFX biosimilar CT-P13 was associated with sustained treatment persistence, stable disease control, and favorable pharmacokinetics over a 3-years.

Overall, these data support SC CT-P13 as an effective and convenient long-term maintenance option in IBD in routine clinical practice.

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J.M.H. was involved in the conception and design of the study and in writing and preparing the manuscript. All authors contributed to data collection and interpretation, and all authors contributed to review the manuscript and approved the final version.

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Abbreviations list

IFX: infliximab

UC: ulcerative colitis

CD: Crohn's disease

IV: intravenous

IBD: inflammatory bowel disease

IM: Immunomodulatory therapy

SC: subcutaneous

CRP: C-reactive protein

FC: fecal calprotectin

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ABSTRACT

Background: Subcutaneous (SC) infliximab biosimilar CT-P13 has shown comparable efficacy and safety to the intravenous (IV) formulation in inflammatory bowel disease (IBD). However, long-term real-world data remain limited. This study assessed the three-year effectiveness, safety, and pharmacokinetics profile of SC CT-P13 in IBD patients switched from IV infliximab.

Methods: Prospective, observational, multicenter study conducted in eight hospitals (Valencian Community, Spain). Adult patients with ulcerative colitis (UC) or Crohn's disease (CD) receiving IV infliximab were switched to SC CT-P13 and followed for up to 3 years. Clinical activity, inflammatory biomarkers, adverse events, treatment persistence, and infliximab trough levels were assessed, including analyses according to immunomodulatory therapy (IM) use and dosing intensities.

Results: Seventy-four patients were included (43% UC, 57% CD). Mean SC CT-P13 trough levels increased significantly from baseline to 3 years (8.15 ± 5.93 to 15.89 ± 7.99 µg/mL, $p<0.001$), with consistent results across disease type, intensified dosing, and perianal CD subgroups. Inflammatory markers (CRP, calprotectin) remained stable throughout follow-up. Concomitant IM use decreased from 51% at baseline to 26.3% at study end, without changes in pharmacokinetics, clinical outcomes, or biomarkers. Treatment persistence at 3 years was 80% overall and 88% when considering only discontinuations due to loss of efficacy or adverse events. Fourteen patients (19%) experienced adverse events, predominantly mild.

Conclusions: Switching from intravenous to subcutaneous infliximab biosimilar CT-P13 was associated with sustained treatment persistence, stable disease control, favorable pharmacokinetics, and good tolerability over 3 years. These real-world findings support SC CT-P13 as a convenient long-term maintenance option in routine clinical practice.

Keywords: CT-P13. Inflammatory bowel disease. Infliximab biosimilar. Long-term. Subcutaneous.

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Lay Summary

Inflammatory bowel disease (IBD), including Crohn's disease and ulcerative colitis, often requires long-term treatment with biologic medicines such as infliximab. Traditionally, infliximab is given by intravenous (IV) infusion in hospital day-care units, but a subcutaneous (SC) form now allows patients to self-inject at home, offering greater comfort and independence.

This study followed 74 patients with IBD who switched from IV infliximab to the SC biosimilar CT-P13 and were observed for up to three years across eight hospitals in Spain. Treatment remained effective and well tolerated throughout the study, with most patients maintaining stable disease control. Infliximab blood levels increased and remained stable over time, while inflammatory markers showed no relevant changes.

Adverse events were uncommon and mostly mild, and only a small number of patients discontinued treatment due to side effects. Many patients were also able to stop immunomodulatory medications without worsening of their disease.

Overall, 88% of patients continued SC CT-P13 after three years, supporting its long-term effectiveness, safety, and convenience as a maintenance treatment for Crohn's disease and ulcerative colitis.

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Key Points

What was previously known about the topic of the paper?

- SC infliximab biosimilar CT-P13 shows short-term efficacy, safety, and stable pharmacokinetics after switching from IV in IBD.

What the study contributes?

- This 3-year real-world study confirms sustained efficacy, favorable safety, and high persistence with SC CT-P13.
- Stable trough levels and reduced need for immunomodulators support long-term treatment optimization.

How the results will influence clinical practice?

- SC CT-P13 offers a convenient, well-tolerated maintenance option that may improve adherence in routine IBD care.

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INTRODUCTION

Tumor necrosis factor (TNF) inhibitors, including infliximab (IFX), have significantly improved inflammatory bowel disease (IBD) management, both as monotherapy and in combination with immunomodulatory (IM) (1). The intravenous (IV) IFX biosimilar CT-P13 has demonstrated comparable efficacy, safety and immunogenicity to originator IFX, in real-life and randomized studies (2,3), and switching between products is safe and effective (4).

The EMA subsequently approved a subcutaneous (SC) formulation of CT-P13, distinct from the IV formulation, for adult indications including ulcerative colitis (UC) and Crohn's disease (CD) (5-8). Switching from IV to SC CT-P13 has shown favorable efficacy, safety, treatment persistence, low immunogenicity, and good patient acceptance at 12 months (9,10).

Our group previously reported short-term outcomes of SC CT-P13 at 3 and 6 months (11). Given the chronic nature of IBD, we planned long-term follow-up. The primary objective was to evaluate the efficacy and safety of SC CT-P13 in clinical practice after 3 years of switching from IV to SC administration. Secondary objectives included assessments of pharmacokinetics and their relationship with clinical outcomes.

METHODS

Study Design

This prospective, observational, multicenter study was conducted in eight hospitals in Valencia (Spain), and included patients with IBD treated with CT-P13 as a part of clinical practice. Data were prospectively collected from medical records from SC CT-P13 initiation until treatment discontinuation or last follow-up. The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Consorcio Hospital General Universitario de Valencia (approval number 142/2021, 8 April 2021). All participants provided written informed consent.

Study Population

Patients with UC or CD receiving IV IFX who were switched to SC CT-P13 120 mg according to standard clinical protocols were eligible. Reasons for switching included

patient comfort/desire and poor venous access. Patients with primary or secondary IFX failure, IFX allergy or intolerance, or contraindications to IFX were excluded.

Data Collection

Collected variables included demographic and disease characteristics, treatment history, concomitant IM or steroid use, and clinical activity indices (Harvey-Bradshaw index [HBI] for CD, and partial Mayo score [PMS] for UC). Biomarkers (CRP, FC), SC CT-P13 trough levels, and treatment discontinuation and causes were also recorded. All available data were systematically collected at baseline and during routine follow-up visits (at least twice annually) for up to three years.

SC CT-P13 persistence and effectiveness measurements

Treatment persistence was defined as the time from SC CT-P13 initiation to discontinuation for any reason. Discontinuation included lack of efficacy, adverse events, or patient or physician decision. Biochemical remission was defined as CRP <0.5 mg/dL and FC <250 µg/g (12,13). IV IFX was considered intensified when dosing differed from 5 mg/kg every 8 weeks, either by dose escalation or interval shortening.

Safety

Adverse events were classified as mild or moderate based on their impact on daily activities. Serious adverse events were defined as events that were fatal or life-threatening, required hospitalization or prolonged hospitalization, cause persistent disability or incapacity, or result in congenital anomalies or birth defects. The causal relationship between SC CT-P13 and each adverse event was evaluated by the investigator according to predefined criteria (14).

Statistical Analysis

Although this was a prospective observational study with a limited time frame for data collection, a sample size of 50 patients was considered appropriate based on previously published studies.

Analyses were primarily descriptive. Categorical variables are presented as number (percentage) and compared using chi-square or Fisher's exact test. Continuous variables are summarized as mean ± standard deviation (SD) or median (interquartile range, IQR), and compared using the Wilcoxon test, as appropriate.

Persistence was estimated using the Kaplan–Meier method with 95% confidence intervals (CI). A parsimonious Cox proportional hazards regression model was fitted including prespecified covariates: disease type (UC/CD), prior IV IFX intensification (yes/no), and concomitant IM use at baseline (yes/no). An adjusted linear regression model assessed determinants of SC CT-P13 trough levels, including diagnosis, prior IV IFX intensification, IM use, and age.

Sensitivity analyses excluded patients who discontinued IM therapy or received intensified dosing. Missing data were handled using available-case analyses for descriptives and complete-case analyses for adjusted models, without imputation. Statistical significance was set at $p < 0.05$. Analyses were performed using R® software version 4.3.2.

RESULTS

Patient characteristics

A total of 74 patients were included in the study, with a mean age of 42 years, and 53% of patients were males. The main reasons for IFX IV initiation were failure to conventional treatment in 45% of cases. **Table 1** shows the baseline characteristics of the study patients.

Changes in inflammatory markers and SC CT-P13 levels

Changes in inflammatory markers and SC CT-P13 levels between baseline and the end of follow-up are summarized in **Table 2**. The only significant change was an increase in trough levels of SC CT-P13 at the end of follow-up (**Fig. 1**), With similar results in UC and CD subgroups. Clinical activity remained stable throughout follow-up, with most patients maintaining remission (85% for UC and 97% for CD).

Concomitant IM use decreased from 38 patients (51.3%) at baseline to 15 (26.3%) at the end of follow-up. According to IM withdrawal status, no significant differences

were observed in inflammatory markers or SC CT-P13 concentrations.

SC CT-P13 trough levels increased significantly from baseline to follow-up in both patients receiving standard dosing (6.28 ± 5.31 to 16.22 ± 8.38 µg/mL, p <0.001) and those previously intensified (10.08 ± 6.00 to 15.58 ± 7.74 µg/mL, p = 0.003).

In the adjusted linear regression model, patients receiving concomitant IM therapy at baseline had higher SC CT-P13 trough levels during follow-up (β 4.8 µg/mL; 95% CI 0.66–8.9; p = 0.024), while increasing age was associated with lower trough concentrations (β −0.21 µg/mL per year; 95% CI −0.36 to −0.06; p = 0.008). Diagnosis (UC vs CD) and prior IFX intensification were not significantly associated with trough levels.

SC CT-P13 persistence

Drug persistence at 3 years was 80% overall and 88% when considering only discontinuations due to loss of efficacy or adverse events (**Fig. 2**). Reasons for SC CT-P13 withdrawal included loss of effectiveness (6.7%), adverse events (5.4%), patient's decision to return to IV (5.4%), patient's decision to stop treatment (4.0%), and lost to follow-up (1.3%).

In the adjusted Cox proportional hazards model, no baseline clinical variable was independently associated with treatment discontinuation. Compared with UC, CD was not associated with a significantly different risk of discontinuation (HR 0.69; 95% CI 0.24–1.99; p =0.50). Prior IV IFX intensification (HR 0.92; 95% CI 0.33–2.54; p =0.90) and baseline IM use (HR 0.41; 95% CI 0.14–1.26; p =0.12) were also not significantly associated with persistence. These analyses were based on a limited number of discontinuation events.

Sensitivity analyses

Sensitivity analyses yielded results consistent with the primary analyses. Excluding patients who discontinued IM therapy during follow-up, neither diagnosis nor prior intensification was significantly associated with treatment persistence or trough levels; the IM variable was omitted due to lack of variability.

Similarly, exclusion of patients who received intensified dosing did not materially alter the results of adjusted Cox or linear regression models. Associations between IM use, age, and trough levels were consistent in direction and magnitude with those observed in the main analysis.

Missing data

Missing data were low to moderate across variables. Clinical activity indices (PMS for UC and HBI for CD) were complete for all patients. Missing values affected IFX trough levels (12% at baseline and 20% at follow-up), FC (13.5%), and CRP (1.4%). Descriptive analyses used available-case data, and adjusted models were based on complete cases, without imputation. Given the extent and distribution of missingness, a major systematic bias is unlikely.

Safety

A total of 14 patients (19%) experienced at least one adverse event (**Table 3**). No significant differences in safety outcomes were observed between UC and CD subgroups.

DISCUSSION

This multicenter, prospective, real-world study provides the first 3-year treatment persistence data for SC IFX biosimilar CT-P13 in patients with IBD who switched from IV IFX. Over a 3-year follow-up, patients maintained clinical benefit with favorable pharmacokinetics and high treatment persistence, supporting SC CT-P13 as a viable long-term maintenance therapy in routine clinical practice. To our knowledge, this represents the longest prospective cohort of patients switched from IV to SC IFX.

Our findings are consistent with and extend previous evidence from clinical trials and real-world studies. The ENEIDA registry identified an optimal SC IFX trough levels of 12–13 µg/mL associated with clinical remission and reported 1-year persistence of 92% (15). In the LIBERTY open-label extensions, 2-year persistence rates were approximately 75–80%, with stable high trough concentrations (~20 µg/mL) and a positive exposure–response relationship (16-21). Similarly, the REMSWITCH-LT real-

world study reported a 2-year persistence of 72% in patients switched from intensified IV IFX, with an increase in trough levels from ~6–8 to ~17–20 µg/mL and a significant association between higher concentrations and remission (22,23).

In our cohort, 3-year persistence was slightly higher (80%, and 88% when excluding discontinuations unrelated to efficacy or safety), with a comparable increase in SC CT-P13 trough levels(from 8.15 ± 5.93 to 15.89 ± 7.99 µg/mL). Across studies, safety outcomes were favorable, with low rates of mostly mild adverse events and no new safety concerns, reinforcing the long-term tolerability of SC IFX.

We also observed a reduction in concomitant IM use over follow-up without an apparent impact on clinical outcomes, inflammatory biomarkers, or CT-P13 trough levels, in line with previous real-world data suggesting that SC monotherapy may be feasible in selected patients (24). This finding is clinically relevant given the increased risk of infections and malignancies associated with combination therapy (25). However, IM withdrawal was not randomized and reflected individual clinical decisions. Although no statistically significant differences were observed between patients who discontinued IM and those who maintained it, there was a numerical trend toward withdrawal in patients with higher trough levels (11.54 ± 6.23 vs. 8.00 ± 4.66 µg/mL). These observations should therefore be interpreted as associative rather than causal and do not support systematic IM withdrawal.

Safety findings were consistent with previous studies, showing low rates of mostly mild adverse events and no new safety signals(9,11,26,27). These results align with earlier real-world reports, including the 12- and 24-week data published by Argüelles et al. (28), further supporting the favorable long-term safety profile of SC CT-P13.

Several limitations should be acknowledged. As an observational real-world study, treatment strategies were not randomized, and clinical decisions (including IM withdrawal) were based on physician judgment, introducing potential selection bias. Assessments were performed according to routine clinical practice rather than a standardized study protocol, which may have contributed to variability and missing data. In addition, the relatively small size of some subgroups and the limited number of discontinuation events reduced statistical power. Despite these limitations, this study represents the first prospective, multicenter, real-world cohort with 3-year

follow-up after switching from IV to SC IFX, providing robust long-term data with pharmacokinetic monitoring and clinically relevant subgroup analyses

Conclusions

In this prospective multicenter real-world cohort, switching from IV to SC IFX biosimilar CT-P13 was associated with sustained treatment persistence, stable disease control, and favorable pharmacokinetics over a 3-years. Treatment was well tolerated, with no new safety signals identified. Although a reduction in concomitant IM use was observed, this finding should be interpreted cautiously due to the observational design. Overall, these data support SC CT-P13 as an effective and convenient long-term maintenance option in routine clinical practice.

Acknowledgements

The authors thank all the participants, the investigators and site staff at each of the participating centers. Medical writing support, under the guidance of the authors, was provided by Esther Pellicer, PhD.

Funding

This work was supported by Kern Pharma, S.L. under its Program Grants for Research Program. The funding source had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and the decision to submit the manuscript for publication.

Conflict of Interest

J.M.H. has participated in educational activities, research projects, scientific meetings or advisory boards sponsored by Abbvie, Biogen, Faes Farma, Ferring, Janssen, Kern Pharma, Lilly, Merck Sharp Dohme (MSD), STADA, Sandoz, Takeda, and Vifor Pharma.
M.M.B. has participated in educational activities, research projects, scientific meetings and advisory boards sponsored by Abbvie, Biogen, Ferring, Janssen, MSD, and Takeda.

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M.I. has reported grants and personal fees from Abbvie, Alfasigma, Chiesi, Jonsson & Jonsson, Kern Pharma, MSD, and Otsuka.

L.M., J.J.R., L.S., M.C., L.R., G.A., and M.A.P declare no conflicts of interest.

Ethical Considerations

The study was conducted in 8 centers in Spain, according to the ethical principles of the Declaration of Helsinki, International Council for Harmonization Good Clinical Practice guidelines, and the corresponding laws and requirements. The study was approved by the Ethics Committee of Consorcio Hospital General Universitario de Valencia on 8 April 2021, and the reference number is 142/2021), and subsequently by all Ethics Committees of the participating hospitals. Written informed consent was obtained from all subjects participating in the study prior to the initiation of any study procedures.

Data availability

Data supporting the study findings are available from the corresponding author upon request.

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Table 1. *Baseline characteristics of patients switched to SC CT-P13*

	All patients (n = 74)	**UC (n = 32)**	**CD (n = 42)**
Age (y), mean ± SD	42.47 ± 13.14	45.09 ± 13.84	40.41 ± 12.36
Sex			
Male	39 (53%)	18 (56%)	21 (50%)
Female	35 (47%)	14 (44%)	21 (50%)
Weight (Kg), mean ± SD	70.34 ± 15.34	67.61 ± 12.70	72.73 ± 17.08
Years from diagnosis, mean ± SD	10.38 ± 7.54	9.35 ± 5.52	11.32 ± 8.98
Reasons for starting IV IFX			
Failure to conventional treatment	33 (45%)	14 (44%)	19 (45%)
Corticosteroid dependence	14 (18.7%)	12 (37.2%)	2 (4.8%)
Corticosteroid resistance	7 (9.5%)	5 (16%)	2 (4.8%)
Perianal disease	5 (6.7%)	0 (0%)	5 (11.9%)
Others	15 (20.3%)	1 (3.1%)	14 (34%)
Perianal-CD			
No	26 (70%)	0 (0%)	26 (70%)
Yes	11 (30%)	0 (0%)	11 (30%)
Months with IV IFX treatment, mean ± SD	35.84 ± 34.13	34.68 ± 36.11	36.83 ± 32.81
Dose of IV IFX			

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	All patients (n = 74)	UC (n = 32)	CD (n = 42)
Standard dose*	36 (48.6%)	17 (53.1%)	19 (45.2%)
Intensified dose†	38 (51.4%)	15 (46.9%)	23 (54.8%)
CRP (mg/dL), mean ± SD	0.71 ± 1.20	0.54 ± 0.78	0.85 ± 1.45
FC (µg/g), mean ± SD	238.58 ± 475.05	304.36 ± 579.13	187.42 ± 375.93
Baseline IV IFX (µg/mL), mean ± SD	8.15 ± 5.93	8.20 ± 6.21	8.11 ± 5.79
Associated IM	38 (51%)	20 (62%)	18 (42%)
AZA/6MP	34 (89%)	19 (95%)	15 (83%)
MTX	4 (11%)	1 (5.0%)	3 (17%)
Corticosteroids			
No	72 (97%)	31 (97%)	41 (98%)
Yes	2 (2.7%)	1 (3.1%)	1 (2.4%)

Values are n (%), unless otherwise indicated. Percentages for disease-specific variables and treatment subcategories are calculated using the corresponding subgroup denominator. * Patients on standard dose (5 mg/kg every 8 weeks). † Patients on intensified dose (> 5 mg/kg every 8 weeks).

AZA: azathioprine; CD: Crohn's disease; CRP: C-reactive protein; CT-P13: infliximab biosimilar; FC: fecal calprotectine; IV: intravenous; IFX: infliximab; 6MP: mercaptopurine; IM: immunomodulator therapy; MTX: methotrexate; SC: subcutaneous; SD: standard deviation; UC: ulcerative colitis.

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Table 2. *Changes in in inflammatory markers and SC CT-P13 plasma levels*

	All patients (n = 74)		**p-value**
Within-group changes from baseline to end of follow-up			
Variable	**Baseline**	**Follow- up***	
CRP (mg/dL), mean ± SD	0.71 ± 1.20	1.00 ± 1.98	0.30
FC (µg/g), mean ± SD	238.58 ± 475.05	231.08 ± 393.78	>0.90
SC CT-P13 (µg/mL), mean ± SD	8.15 ± 5.93	15.89 ± 7.99	<0.001
Between-group comparisons according to IM withdrawal status			
Variable	**IM withdrawn**	**IM continued**	
CRP (mg/dL), mean ± SD			
Baseline	0.86 ± 1.45	0.40 ± 0.47	0.60
Follow-up*	1.33 ± 2.84	0.77 ± 0.76	0.50
FC (µg/g), mean ± SD			
Baseline	332.52 ± 638.00	231.36 ± 408.85	0.70
Follow-up*	284.81 ± 573.43	157.80 ± 232.93	0.80
SC CT-P13 (µg/mL), mean ± SD			
Baseline	11.54 ± 6.23	8.00 ± 4.66	0.20
Follow-up*	18.35 ± 7.93	16.51 ± 9.37	0.40

* Follow-up: up to 3 years.

CRP: C-reactive protein; CT-P13: infliximab biosimilar; FC: fecal calprotectine; IM: immunomodulator therapy; SC: subcutaneous; SD: standard deviation.

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Table 3. *Adverse events during SC CT-P13*

	Adverse events	Serious adverse events	Related to SC CT-P13	SC CT-P13 discontinuation
Infection	5 (6.7%)	2 (2.7%)	2 (2.7%)	1 (1.3%)
Drug-induced psoriasis	2 (2.7%)	0 (0%)	2 (2.7%)	0 (0%)
Asthenia	2 (2.7%)	0 (0%)	0 (0%)	0 (0%)
Drug-induced lupus	1 (1.3%)	0 (0%)	1 (1.3%)	1 (1.3%)
Headache	1 (1.3%)	0 (0%)	1 (1.3%)	0 (0%)
Others	4 (5.4%)	0 (0%)	1 (1.3%)	2 (2.7%)

Values are n (%). Percentages are calculated using the total study population (n = 74) as the denominator.

CT-P13: infliximab biosimilar; SC: subcutaneous.

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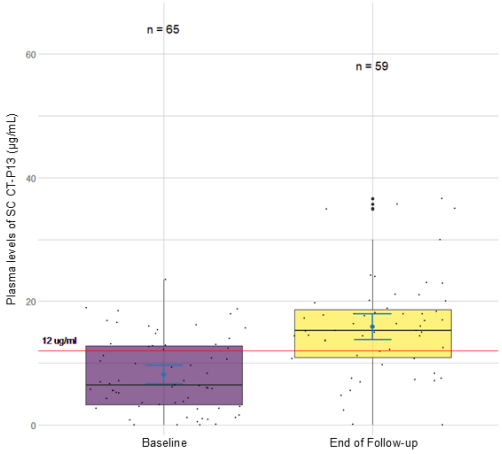

Fig. 1. Distribution of plasma levels of CT-P13 at baseline (after switching from IV to SC) and at the end of follow-up, with 12 µg/mL used as a reference level. CT-P13: infliximab biosimilar; IV: intravenous; SC: subcutaneous.

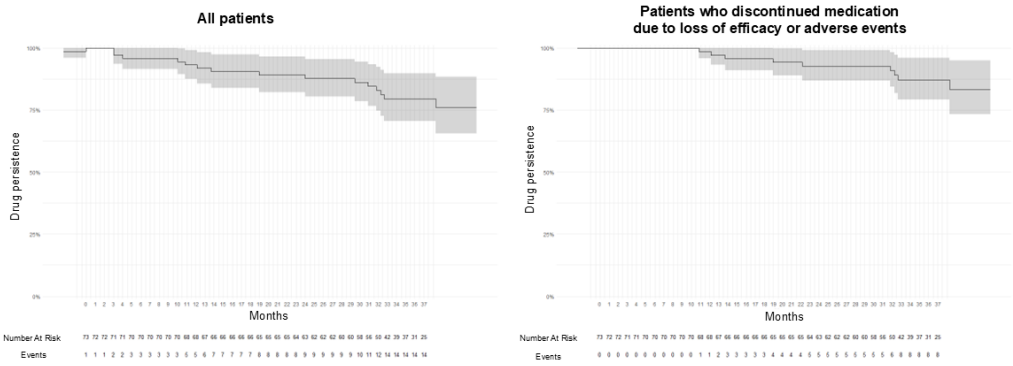

Fig. 2. Drug persistence at 3 years.