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# Patient Satisfaction and Experience with CT-P17 Following Transition from Reference Adalimumab or Another Adalimumab Biosimilar: Results from the Real-World YU-MATTER Study

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## Abstract

**Background and Objectives** Biosimilars are cost-effective alternatives to reference products for patients with inflammatory bowel diseases (IBD) and chronic inflammatory rheumatic diseases (CIRD), but patient beliefs can affect adherence to the transition. This study aimed to explore patient experience and satisfaction after switching to CT-P17, a high-concentration (100 mg/mL), citrate-free adalimumab biosimilar.

**Patients and Methods** This observational, multicenter, prospective French study included adult patients with IBD or CIRD who switched to CT-P17 from reference adalimumab (R-ADA; 100 mg/mL) or a low-concentration adalimumab biosimilar (ADA-BioS; 50 mg/mL). Patients completed online questionnaires to assess treatment perceptions, satisfaction, and tolerance at study inclusion (under previous treatment) and over 3 months of CT-P17 treatment. The primary criterion was overall patient satisfaction, which was assessed with the question, “What is your global satisfaction with the CT-P17 injection?”, using a 7-point Likert scale. Multivariate logistic regression analysis was performed to identify factors associated with increased treatment satisfaction after switching to CT-P17.

**Results** The total analysis population included 232 patients (IBD 72.0%, CIRD 28.0%). Median patient age was 57.0 years (interquartile range [IQR] 46.0–63.0), 50.4% were men, and median disease duration was 9 years (IQR 5–16). Approximately half of the cohort (51.2%) switched to CT-P17 from an ADA-BioS (including 19.4% from an ADA-BioS with citrate) and half (48.7%) from R-ADA. The proportion of patients who were satisfied with treatment was stable between baseline (under previous treatment) and 3 months (under CT-P17). More patients reported increased satisfaction after switching to CT-P17 from an ADA-BioS (22.7% vs 8.0% when switching from R-ADA;  $p = 0.002$ ), or from an ADA-BioS containing citrate (28.9% vs 12.3% when switching from a citrate-free ADA-BioS;  $p = 0.008$ ). Independent prognostic factors for increased satisfaction were previous treatment with an ADA-BioS (odds ratio [OR] 2.88 [95% confidence interval 1.17–7.08];  $p = 0.021$ ) and pain at the injection site under previous treatment (OR 1.26 [1.08–1.47];  $p = 0.004$ ). Significantly fewer patients reported pain, redness, itching, and hematoma after 3 months of CT-P17 treatment versus baseline ( $p < 0.001$ ).

**Conclusions** The majority of patients had stable or increased treatment satisfaction after switching from R-ADA or an ADA-BioS to CT-P17. In particular, switching to CT-P17 from a low-concentration ADA-BioS or an ADA-BioS containing citrate was associated with increased patient satisfaction. An improvement in overall tolerance with CT-P17 versus previous adalimumab treatment was also reported.

**Trial Registration** ClinicalTrials.gov identifier NCT05427942, registered June 22, 2022.

## Key Points

This real-world study aimed to evaluate patient satisfaction after switching to CT-P17 from reference adalimumab (R-ADA) or a low-concentration adalimumab biosimilar (ADA-BioS) in patients with immune-mediated inflammatory diseases.

Data from this study suggest that patient satisfaction and overall tolerance may be improved by switching to CT-P17 from R-ADA or another ADA-BioS.

Patient education and shared decision making when switching to biosimilars are important to limit treatment dissatisfaction, non-adherence, and loss of therapeutic benefit.

## 1 Introduction

Treatment with biologics has dramatically improved outcomes for patients with immune mediated inflammatory diseases such as inflammatory bowel diseases (IBD) and chronic inflammatory rheumatic diseases (CIRD). Considering that the high cost of such drugs can limit treatment access, biosimilars have been developed as cost-effective alternatives to reference products [1, 2]. In Europe, both the European Crohn's and Colitis Organisation (ECCO) and the European Alliance of Associations for Rheumatology (EULAR) have stated that switching from a reference biologic to a biosimilar is acceptable when not contraindicated [3, 4].

Adalimumab (Humira<sup>®</sup>) is the first fully human monoclonal antibody directed against tumor necrosis factor and has demonstrable efficacy and tolerability in patients with a wide range of inflammatory conditions, including IBD and CIRD [5]. Following positive results from a phase III trial in patients with rheumatoid arthritis [6], CT-P17 (Yuflyma<sup>®</sup>; Celltrion Inc.), a high-concentration and citrate-free biosimilar of reference adalimumab (R-ADA), was approved in Europe in February 2021 for the same indications as R-ADA [7]. With an approved dose of 100 mg/mL (i.e., similar to R-ADA), CT-P17 became the first high-concentration adalimumab biosimilar (ADA-BioS) available in France [8].

Patient preferences and experience can generally impact medication adherence, which in turn is linked to sustained disease remission. This may be challenged when switching to a biosimilar [9] due to potential nocebo factors such as patient fears, beliefs, and expectations [10, 11], as well as

poor awareness about biosimilars [12, 13]. A lack of training about the use of new biosimilar injection devices may also explain poor treatment adherence [14, 15]. In addition, patients have reported impaired experiences following transition from R-ADA (100 mg/mL) to a low-concentration ADA-BioS (50 mg/mL), with more pain and bruising [16, 17]. This may be explained by the volume to be injected and the presence of citrate in some biosimilar formulations [18, 19].

In light of the potentially favorable characteristics of CT-P17 (i.e., high concentration of 100 mg/mL, absence of citrate), it was of interest to explore patient perceptions and experience before and after switching from R-ADA (100 mg/mL) or ADA-BioS (50 mg/mL) to CT-P17. This question is in line with the increasing importance of real-world data and patient-reported outcome measures (PROMs), as recommended by French, European, and US Health Authorities, to measure patient perceptions and provide valuable insights into treatment benefits and quality of care [20–22]. This study aimed to evaluate patient satisfaction after switching to CT-P17 compared with their previous experience with R-ADA or ADA-BioS, both overall and according to their inflammatory disease (IBD or CIRD). In addition, patient expectations about CT-P17 and their perceptions of the shared medical decision to switch were studied, as well as patient satisfaction with the information provided about CT-P17, tolerance at injection site, and adherence to treatment. Patient beliefs about medicines and health literacy were also explored.

## 2 Methods

### 2.1 Study Design

YU-MATTER (ClinicalTrials.gov identifier NCT05427942) was a non-interventional, multicenter, prospective study conducted in 17 gastroenterology and 11 rheumatology private practices and hospital centers throughout France. The study was conducted in compliance with the ethical standards of the 1964 Helsinki Declaration and its later amendments, deontology guidelines and Good Epidemiology Practices, and French regulations on prospective non-interventional studies. All patients were informed about the study content before enrollment and had no objections to their data being shared. The study protocol was approved on June 2, 2022, by the independent Ethics Committee of 'Nord Ouest 3' France (reference number: 2022-A00448-35).

Patients aged  $\geq 18$  years, with stable disease (i.e., remission, non-active disease, or low disease activity, per physician discretion) and treated for  $\geq 3$  months with either R-ADA (100 mg/mL) or an ADA-BioS (50 mg/mL) for IBD (Crohn's disease or ulcerative colitis) or CIRD

(rheumatoid arthritis, ankylosing spondylitis, axial spondyloarthritis without radiographic evidence, or psoriatic arthritis), were enrolled at the time of switching to CT-P17 as part of routine management. As the study objectives focused on the perceptions of patients treated after the first prescription of CT-P17, additional eligibility criteria included an available internet connection for the completion of electronic PROMs (ePROMs) by patients, and a mobile phone number for patient reminders during follow-up (3–4 months after inclusion).

At inclusion (i.e., upon prescription of CT-P17), data describing patient and disease characteristics, previous R-ADA or ADA-BioS, concomitant treatments for IBD or CIRD, and CT-P17 prescription (i.e., dose, frequency, and form [syringe or pen]) were collected by physicians. Figure 1 describes the different ePROMs completed by patients at the time of CT-P17 prescription (T0), after the first CT-P17 injection (T1; 14–21 days after inclusion), and then monthly over 3 months of follow-up (T2, T3, and T4).

The patient questionnaires used validated PROMs and additional survey items to evaluate patient perceptions of switching to CT-P17, treatment satisfaction, tolerance at the injection site, patient beliefs, and health literacy. Patient beliefs were assessed using the 18-item Beliefs about Medicines Questionnaire (BMQ) [23]; BMQ-Specific domain scores could range from –20 to +20 (with positive scores indicating that the perceived necessity of treatment exceeded potential concerns), while BMQ-General domain scores could range from 8 to 40 (with higher values indicating stronger beliefs). The health literacy of patients was measured using the Health Literacy Survey Europe (HLS-EU-Q16) [24], comprising 16 items (rated on a 4-point Likert scale) that assessed the three domains of health care, disease prevention, and health promotion. After dichotomizing the responses, HLS-EU-Q16 total scores could range from 0 to 16, with scores of 0–8 indicating insufficient health literacy, 9–12 indicating limited health literacy, and 13–16 indicating adequate health literacy. Additional questionnaire items were developed in collaboration with patient associations and tested before the study via in-depth, sociologist-led interviews with four patients receiving R-ADA or ADA-BioS treatment for IBD or CIRD. In particular, overall patient satisfaction with treatment (primary criterion) was assessed with the question, “What is your global satisfaction with the CT-P17 injection?”, using a 7-point Likert scale (extremely dissatisfied, somewhat dissatisfied, a little dissatisfied, neither satisfied nor dissatisfied, a little satisfied, somewhat satisfied, and extremely satisfied; Supplementary Fig. 1, see electronic supplementary material [ESM]). Patient expectations of CT-P17, perceptions of the shared medical

decision to switch to CT-P17, and tolerance at the injection site were assessed as shown in Supplementary Table 1 (see ESM).

## 2.2 Statistical Analysis

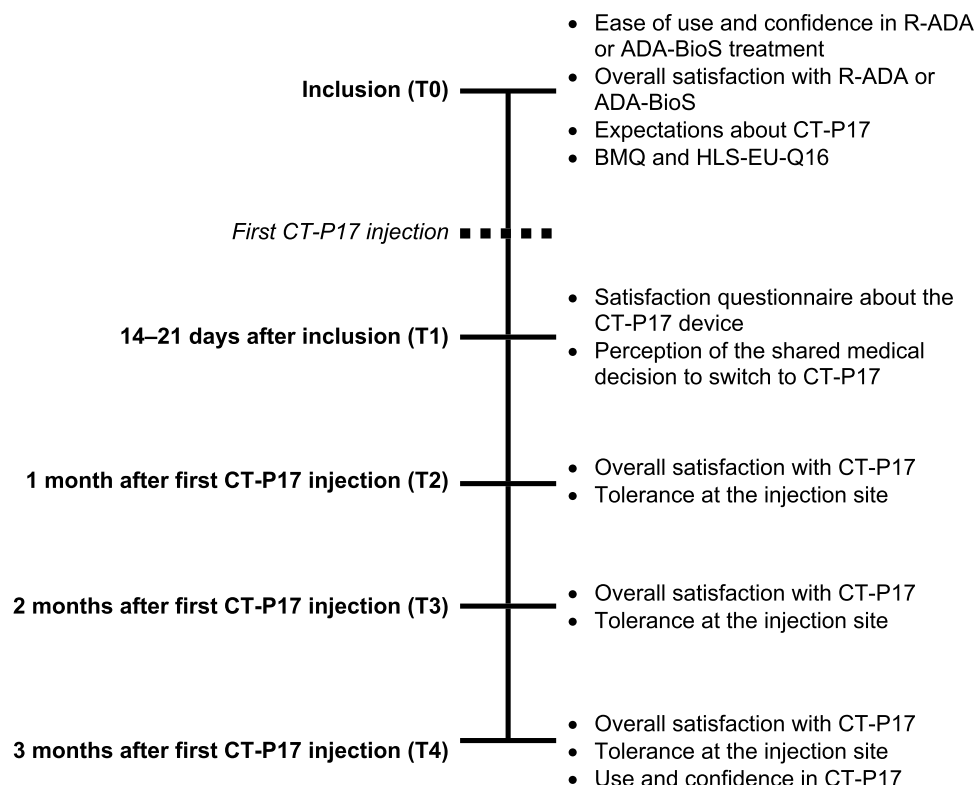
Sample size calculations were based on the width of the two-sided 95% confidence interval (CI). Based on the experience of experts in the study scientific committee, we hypothesized that 75% of patients would be satisfied with CT-P17. To estimate this proportion with an accuracy of 5–6% (i.e., the half-width of the two-sided 95% CI, based on the Wilson method), 300 patients were required, assuming that approximately 25% would be non-evaluable for the primary criterion (patient satisfaction based on completed ePROMs).

Data were described at each time point using standard descriptive statistics, both in the total analysis population (i.e., patients who met all the selection criteria, completed ePROMs at T0, and received at least one CT-P17 injection after inclusion) and according to the type of inflammatory disease (IBD or CIRD). Associated 95% CIs were provided when relevant. Most parameters were also described according to the characteristics of the previous ADA administered (i.e., R-ADA or ADA-BioS, citrate-free or with citrate).

The overall patient satisfaction to treatment (primary criterion) was described at each time point between T0 (under the previous R-ADA or ADA-BioS) and T4 (3 months after the first CT-P17 injection). Based on the 7-point Likert scale, satisfied patients were those who were extremely, somewhat or a little satisfied; increased satisfaction over T0–T4 was defined as an increase of  $\geq 2$  points, no change in satisfaction as a maximal change of 1 point, and decreased satisfaction as a decrease of  $\geq 2$  points. Last Observation Carried Forward was used to replace missing data at T4 in the total analysis population [25]; sensitivity analyses were also carried out in patients with ePROMs completed and analyzable at T4 (evaluable population). Increased satisfaction was compared between subgroups (IBD or CIRD, previous R-ADA or ADA-BioS, and previous ADA-BioS with or without citrate) using Chi-square tests.

Factors associated with increased satisfaction at T4 were identified using multivariate logistic regression models. Univariate analyses were firstly performed based on data available at inclusion (patient and disease characteristics, previous R-ADA or ADA-BioS and patient experience, shared medical decision to switch, expectations about CT-P17, and BMQ and HLS-EU-Q16 scores). After selection of variables (based on  $p < 0.10$ ), backward selection with a significance level of 0.05 was applied. Statistical analyses were carried out using SAS<sup>®</sup> version 9.4 (SAS Institute, Cary, NC, USA) and R version 4.3.2.

**Fig. 1** Patient-reported outcome measures collected at each study time point. *ADA-BioS* adalimumab biosimilar, *BMQ* Beliefs about Medicines Questionnaire, *HLS-EU-Q16* Health Literacy Survey Europe—16 questions, *R-ADA* reference adalimumab



## 3 Results

### 3.1 Study Population

Among 316 patients enrolled between June 2022 and March 2023, 232 (73.4%) entered the total analysis population (Fig. 2). Among those, 167 patients (72.0%) had IBD and 65 (28.0%) had CIRD. Overall, 193 patients (83.2%) completed the study. Of the 39 non-completers, 27 patients were lost to follow-up and 12 (i.e., 5.2% of the total analysis population) discontinued CT-P17 treatment due to patient request ( $n = 8$ ) or physician recommendation ( $n = 4$ ). Among those who completed the study, questionnaires at T4 were analyzable in 81.5% of patients (evaluable population,  $n = 189$ ; IBD,  $n = 142$  [75.1%]; CIRD,  $n = 47$  [24.9%]). No significant differences in baseline patient and disease characteristics, and previous R-ADA or ADA-BioS treatment, were observed between the total analysis and evaluable populations (data not shown).

Patient and disease characteristics of the total analysis population are presented in Table 1. Most patients with IBD had a diagnosis of Crohn's disease ( $n = 136$  [81.4%]), and 53.8% of those with CIRD had ankylosing spondylitis ( $n = 35$ ). Patients with IBD were younger than patients with CIRD (median 38.0 vs 57.0 years, respectively), while similar disease durations were observed at inclusion (median 9 years for both patient groups). Regardless of IBD or CIRD

diagnosis, most patients (72.2–82.1%) were in remission or had non-active disease at the time of the switching to CT-P17.

Regarding treatment prior to CT-P17, approximately half of all patients were treated with an ADA-BioS (51.3%); this proportion was higher among patients with CIRD (63.1% vs 46.7% in IBD; Table 1). Overall, the majority of patients (80.6%) were receiving a citrate-free ADA-BioS before switching to CT-P17 (CIRD 70.8%; IBD: 84.4%).

### 3.2 Patient Expectations of CT-P17

Prior to the switch, more patients with CIRD had positive expectations of CT-P17 than patients with IBD (easier to use in 64.6% vs 48.0% of patients, respectively; more comfortable in 61.5% vs 51.0%; less painful in 80% vs 60.5%; Supplementary Table 2, see ESM). For each of these expected benefits, more patients who received an ADA-BioS prior to CT-P17 had positive expectations than patients previously treated with R-ADA (62.2% vs 42.5%, 58.0% vs 49.6%, and 76.4% vs 54.8%, respectively). Expected benefits were also more frequently observed among the 45 patients who previously received an ADA-BioS containing citrate, when compared with the 187 patients who received a citrate-free ADA-BioS (80.0% vs 46.0%, 68.9% vs 50.3%, and 82.2% vs 62.0%, respectively). A minority of patients had negative

expectations of CT-P17 (0–11.0% across expectations and patient subgroups).

### 3.3 Overall Patient Satisfaction with CT-P17

In the total analysis population, the high proportion of patients who were extremely, somewhat, or a little satisfied with treatment at T0 (under previous R-ADA or ADA-BioS; 78.4% [95% CI 72.7–83.3]) remained stable at T4 (under CT-P17; 75.4% [69.5–80.5]). Similar proportions at T0 and T4 were also observed for patients neither satisfied nor dissatisfied with treatment (4.3% [2.4–7.8] and 4.7% [2.7–8.3], respectively) and for those who were extremely, somewhat, or a little dissatisfied (17.2% [12.9–22.6] and 19.8% [15.2–25.4]). In the evaluable population, the proportion of patients satisfied with treatment at T0 and T4 was also stable (79.4% [73.0–84.5] and 76.2% [69.6–81.7], respectively). Figure 3 illustrates patient satisfaction between T0 and T4.

Overall, 80.6% (95% CI 75.0–85.2) of patients in the total analysis population had the same or an increased level of treatment satisfaction between T0 and T4 (evaluable population, 81.0% [74.8–85.9]). More patients reported increased satisfaction after switching from an ADA-BioS to CT-P17 (22.7% vs 8.0% when switching from R-ADA;  $p = 0.002$ ), or from an ADA-BioS containing citrate to CT-P17 (28.9% vs 12.3% when switching from a citrate-free ADA-BioS;  $p = 0.008$ ; Fig. 4). A numerically greater proportion of patients who switched from R-ADA reported decreased satisfaction at T4 versus those who

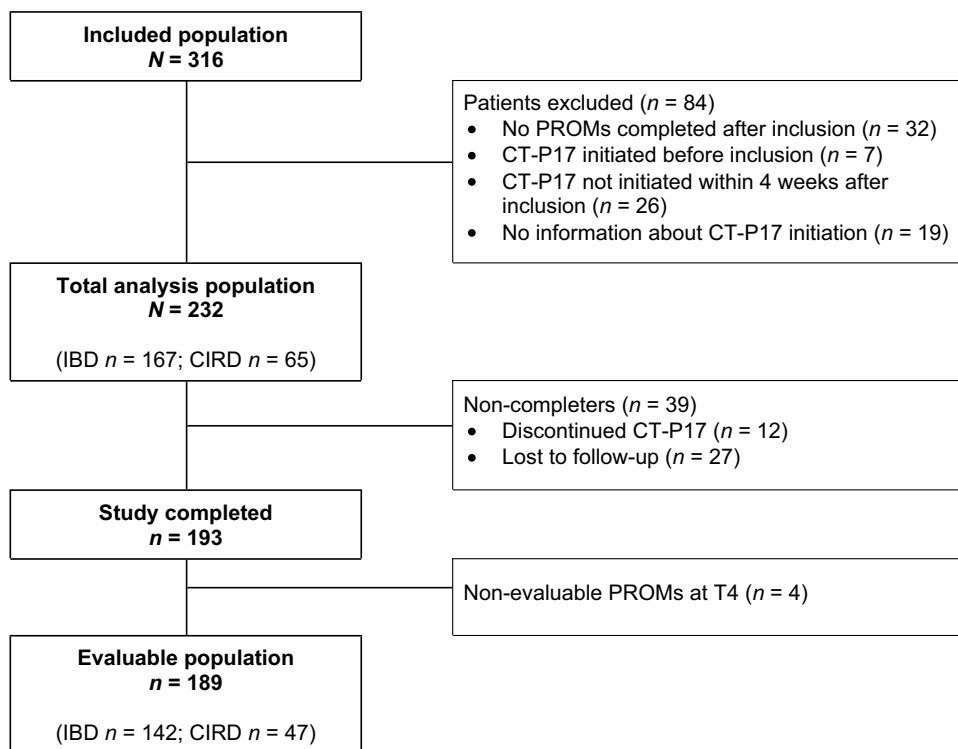
switched from an ADA-BioS (22.1% vs 16.8%, respectively;  $p = 0.306$  vs patients with increased/same satisfaction). Among those who switched from a citrate-free ADA-BioS, the proportion of patients with decreased satisfaction at T4 were comparable with those who switched from an ADA-BioS containing citrate (19.3% vs 20.0%, respectively;  $p = 0.909$  vs patients with increased/same satisfaction). Changes in treatment satisfaction from T0 to T4 were also similar between IBD and CIRD subgroups (increased treatment satisfaction in 15.6% and 15.4% of patients, respectively;  $p = 0.972$ ).

The results of univariate analyses are presented in Supplementary Table 3 (see ESM). On the basis of selected variables, multivariate analysis found that the use of an ADA-BioS prior to CT-P17 was an independent prognostic factor for increased treatment satisfaction between T0 and T4 (odds ratio [OR] vs R-ADA, 2.88 [95% CI 1.17–7.08];  $p = 0.021$ ), as well as pain at the injection site with previous R-ADA or ADA-BioS (OR per unit of a 0–10 numeric rating scale [NRS], 1.26 [1.08–1.47];  $p = 0.004$ ).

### 3.4 Perceptions of the Shared Medical Decision to Switch and Satisfaction with CT-P17 Information

Overall, at least 70% of patients felt they had been involved in the medical decision to switch to CT-P17 (i.e., received information about the treatment, understood the reason for

**Fig. 2** Patient disposition. *CIRD* chronic inflammatory rheumatic disease, *IBD* inflammatory bowel disease, *PROMs* patient-reported outcome measures



**Table 1** Baseline patient and disease characteristics

	Total analysis population <i>N</i> = 232	IBD subgroup <i>n</i> = 167	CIRD subgroup <i>n</i> = 65
Age (years), median (IQR)	43.0 (30.5–56.0)	38.0 (28.0–51.0)	57.0 (46.0–63.0)
Female sex, <i>n</i> (%)	115 (49.6)	82 (49.1)	33 (50.8)
BMI (kg/m <sup>2</sup> ), median (IQR)	24.5 (22.0–27.4)	23.7 (21.0–25.8)	26.7 (23.7–29.8)
Inflammatory disease, <i>n</i> (%)			
Crohn's disease	136 (58.6)	136 (81.4)	-
Ulcerative colitis	31 (13.4)	31 (18.6)	-
Ankylosing spondylitis	35 (15.1)	-	35 (53.8)
Rheumatoid arthritis	17 (7.3)	-	17 (26.2)
Axial spondyloarthritis without radiographic evidence	7 (3.0)	-	7 (10.8)
Psoriatic arthritis	6 (2.6)	-	6 (9.2)
Disease duration (years), median (IQR)	9 (5–16)	9 (5–15)	9 (5–18)
Remission or non-active disease <sup>a</sup> , <i>n</i> (%)			
Crohn's disease ( <i>n</i> = 132)	-	106 (80.3)	-
Ulcerative colitis ( <i>n</i> = 28)	-	23 (82.1)	-
Ankylosing spondylitis or axial spondyloarthritis without radiographic evidence ( <i>n</i> = 37)	-	-	30 (81.1)
Rheumatoid arthritis or psoriatic arthritis ( <i>n</i> = 18)	-	-	13 (72.2)
Patients with ≥1 concomitant treatment, <i>n</i> (%)	-	10 (6.0)	31 (47.7)
Azathioprine	-	4 (2.4)	-
Oral 5-ASA	-	3 (1.8)	-
Oral corticosteroids	-	2 (1.2)	-
Methotrexate	-	2 (1.2)	24 (36.9)
Biotherapy	-	1 (0.6)	-
NSAIDs	-	-	7 (10.8)
Prednisone	-	-	3 (4.6)
Sulfasalazine	-	-	1 (1.5)
Previous R-ADA treatment, <i>n</i> (%)	113 (48.7)	89 (53.3)	24 (36.9)
Humira <sup>®</sup> 40 mg	94 (40.5)	70 (41.9)	24 (36.9)
Humira <sup>®</sup> 80 mg	19 (8.2)	19 (11.4)	0
Previous ADA-BioS treatment, <i>n</i> (%)	119 (51.3)	78 (46.7)	41 (63.1)
Amgevita <sup>®</sup>	46 (19.8)	31 (18.6)	15 (23.1)
Hulio <sup>®</sup>	22 (9.5)	16 (9.6)	6 (9.2)
Imraldi <sup>®</sup>	20 (8.6)	7 (4.2)	13 (20.0)
Idacio <sup>®</sup>	16 (6.9)	12 (7.2)	4 (6.2)
Hyrimoz <sup>®</sup>	14 (6.0)	11 (6.6)	3 (4.6)
Amsparity <sup>®</sup>	1 (0.4)	1 (0.6)	0
Previous citrate-free ADA-BioS treatment, <i>n</i> (%)	187 (80.6)	141 (84.4)	46 (70.8)
Duration of last adalimumab treatment before CT-P17 (months), median (IQR)	35.0 (13.5–60.0)	31.0 (14.0–64.0)	36.0 (13.0–49.0)
Patients with >1 previous adalimumab treatment, <i>n</i> (%)	139 (59.9%)	99 (59.3%)	40 (61.5%)
Cumulative duration of all previous adalimumab treatments (months) <sup>b</sup> , median (IQR)	47.0 (24.0–83.0)	48.0 (25.0–81.0)	44.0 (21.0–96.0)
Prescribed CT-P17 dosage, <i>n</i> (%)			
40 mg/0.4 mL	198 (85.3)	133 (79.6)	65 (100)
80 mg/0.8 mL	34 (14.7)	34 (20.4)	0
Prescribed CT-P17 device, <i>n</i> (%)			
Pre-filled pen	197 (84.9)	144 (86.2)	53 (81.5)
Pre-filled syringe	35 (15.1)	23 (13.8)	12 (18.5)
BMQ scores, median (IQR)			
BMQ necessity subscore	20.0 (18.0–22.0)	20.0 (18.0–22.0)	21.0 (19.0–23.0)

**Table 1** (continued)

	Total analysis population <i>N</i> = 232	IBD subgroup <i>n</i> = 167	CIRD subgroup <i>n</i> = 65
BMQ concern subscore	15.0 (13.0–17.5)	15.0 (13.0–17.0)	16.0 (14.0–19.0)
BMQ-Specific score	5.0 (3.0–7.0)	5.0 (3.0–7.0)	5.0 (2.0–8.0)
BMQ-General score	19.5 (16.0–23.0)	19.0 (16.0–23.0)	21.0 (17.0–23.0)
HLS-EU-Q16 scores, <i>n</i> (%)			
Insufficient health literacy (score 0–8)	35 (15.1)	24 (14.4)	11 (16.9)
Limited health literacy (score 9–12)	84 (36.2)	61 (36.5)	23 (35.4)
Adequate health literacy (score 13–16)	113 (48.7)	82 (49.1)	31 (47.7)

<sup>a</sup>Remission or non-active disease was defined according to current recommendations, using specific evaluations for each pathology: Harvey-Bradshaw Index (HBI) <4 for Crohn's disease, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) <4 for ankylosing spondylitis and axial spondyloarthritis without radiographic evidence, Mayo score ≤1 for ulcerative colitis, and Disease Activity Score-28 (DAS-28) <2.6 for rheumatoid arthritis and psoriatic arthritis

<sup>b</sup>The cumulative duration of previous adalimumab treatment includes all periods of previous treatment, regardless of the adalimumab agent received

5-ASA 5-aminosalicylic acid, *ADA-BioS* adalimumab biosimilar, *BMI* body mass index, *BMQ* Beliefs about Medicines Questionnaire, *CIRD* chronic inflammatory rheumatic disease, *HLS-EU-Q16* Health Literacy Survey Europe—16 questions, *IBD* inflammatory bowel disease, *IQR* interquartile range, *NSAID* nonsteroidal anti-inflammatory drug, *R-ADA* reference adalimumab

the switch, were involved in the decision to change treatment, had their treatment preferences taken into account, and felt listened to by their physician). In addition, patients were highly satisfied with the information provided about CT-P17 prior to their first injection (median score 8.0 based on a 0–10 NRS; interquartile range [IQR] 7–10), with no differences according to their inflammatory disease (CIRD or IBD), previous treatment (R-ADA or ADA-BioS), or the presence of citrate in their previous ADA-BioS.

### 3.5 Tolerance of CT-P17 at the Injection Site

In the evaluable population, switching to CT-P17 was associated with improved tolerance at the injection site versus previous treatment. Compared with R-ADA or ADA-BioS treatment at T0, fewer patients reported pain ( $p < 0.0001$ ), redness ( $p < 0.0001$ ), itching ( $p = 0.0003$ ), and hematoma ( $p < 0.0001$ ) with CT-P17 treatment at T4 (Table 2). In addition, the proportion of patients with good overall tolerance at the injection site was 29.1% under previous treatment at T0, which significantly increased 3 months after the first injection of CT-P17 (57.7% at T4;  $p < 0.0001$ ). In the total analysis population, improvements in tolerance from T0 to T4 were higher in patients previously treated with an ADA-BioS versus R-ADA (26.9% to 60.4% vs 31.0% to 54.8%, respectively), and in those previously treated with an ADA-BioS with citrate versus without (20.0% to 63.9% vs 31% to 56.2%). No differences were observed between patients with CIRD and IBD.

### 3.6 Patient Beliefs and Health Literacy

Based on BMQ-Specific scores (assessing patient perceptions about prescribed treatment at T0), perceived beliefs outweighed perceived concerns as the median differential between necessity and concern subscores was positive (5.0 [IQR 2.0–8.0]). The necessity-concerns differential was higher at T0 in patients satisfied with CT-P17 at T4 when compared with neutral or dissatisfied patients (6.0 vs 3.0;  $p = 0.001$ ). The median BMQ-General score (assessing general beliefs about medicine) was 19.5 (IQR 16–23), and was lower in patients satisfied with CT-P17 versus neutral or dissatisfied patients (19.0 vs 21.0;  $p = 0.024$ ).

Using the HLS-EU-Q16, 48.7% of patients had adequate health literacy at T0, 36.2% had limited health literacy, and 15.1% had insufficient health literacy (Table 1). There were no differences in health literacy scores based on patients' level of satisfaction with CT-P17 at T4 (median 47.0 vs 45.0 in satisfied vs neutral/dissatisfied patients, respectively;  $p = 0.124$ ). The median necessity-concerns differential increased from 2.0 in patients with insufficient health literacy to 7.0 in those with adequate health literacy ( $p < 0.001$ ).

## 4 Discussion

In light of the recent development of biosimilars, it was of interest to explore patient perceptions and experiences after switching from R-ADA or low-concentration ADA-BioS to CT-P17, a new citrate-free, high-concentration ADA-BioS. The results of this French prospective real-world study (YU-MATTER), conducted in a large population of adults treated



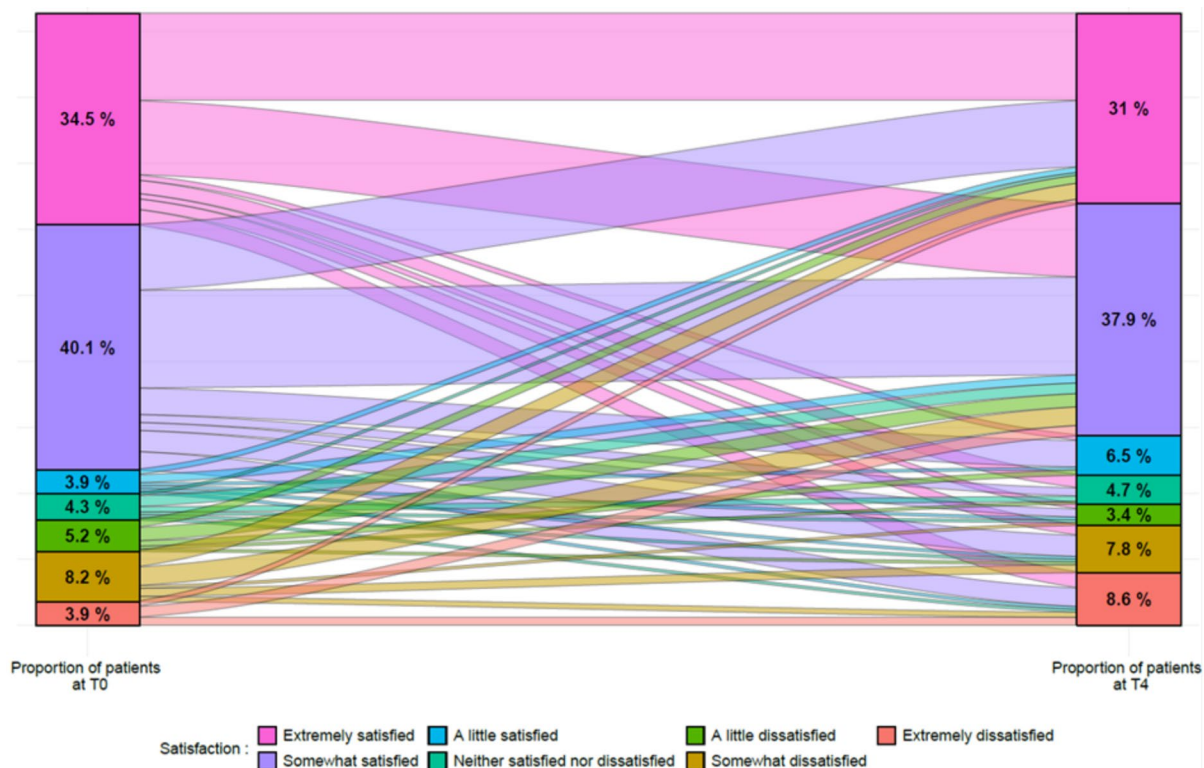
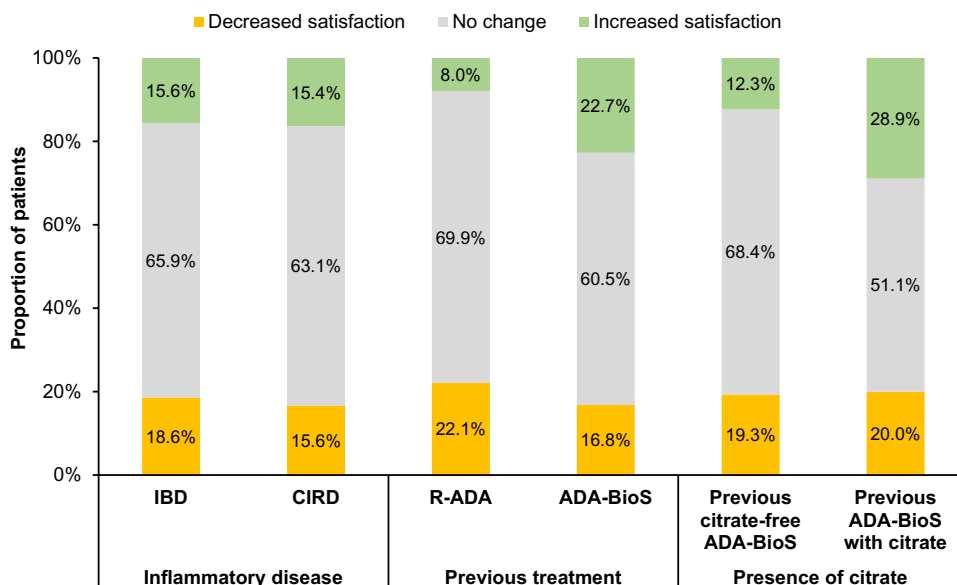


Fig. 3 Flow diagram of patient satisfaction from T0 (under previous adalimumab treatment) to T4 (3 months after first CT-P17 injection)

Fig. 4 Change in patient satisfaction from T0 (under previous adalimumab treatment) to T4 (3 months after first CT-P17 injection) in key subgroups of interest. *ADA-BioS* adalimumab biosimilar, *CIRD* chronic inflammatory rheumatic disease, *IBD* inflammatory bowel disease, *R-ADA* reference adalimumab. Analyses were based on the total analysis population ( $N = 232$ ). Increased satisfaction was defined as an increase of  $\geq 2$  points on the 7-point Likert scale, no change was defined as a maximal change of 1 point, and decreased satisfaction was defined as a decrease of  $\geq 2$  points



with R-ADA or ADA-BioS for IBD or CIRD, showed that the level of treatment satisfaction was stable after switching to CT-P17 (78.4% and 75.4% of patients were satisfied before and after the switch, respectively; 80.6% of patients had the same or increased level of satisfaction after the switch). However, significantly more patients treated with

an ADA-BioS (vs R-ADA) and/or an ADA-BioS containing citrate (vs citrate-free ADA-BioS) reported increased satisfaction after switching to CT-P17. Although a greater proportion of patients who switched from R-ADA reported decreased satisfaction versus those who switched from an ADA-BioS, a greater proportion of these patients also

**Table 2** Tolerance at the injection site (evaluable population)

	Under previous adalimumab treatment (T0) <i>n</i> = 189	Three months after first CT-P17 injection (T4) <i>n</i> = 189	<i>p</i> -Value
Pain (NRS range 0–10), mean (SD)	3.1 (2.4)	1.8 (2.6)	<0.0001
Redness, <i>n</i> (%)			
None	87 (46.0)	132 (69.8)	<0.0001
Mild	61 (32.3)	47 (24.9)	
Moderate	32 (16.9)	7 (3.7)	
Severe	9 (4.8)	3 (1.6)	
Itching (NRS range 0–10), mean (SD)	1.6 (2.4)	1.0 (2.1)	0.0003
Hematoma, <i>n</i> (%)			
None	109 (57.7)	150 (79.4)	<0.0001
Small (<1 cm <sup>2</sup> )	67 (35.5)	34 (18.0)	
Large (>1 cm <sup>2</sup> )	13 (6.9)	5 (2.6)	
Overall good tolerance to injections <sup>a</sup> , <i>n</i> (%) [95% CI]			
Yes	55 (29.1) [23.1–35.9]	109 (57.7) [50.5–64.5]	<0.0001
No	134 (70.9) [64.1–76.9]	80 (42.3) [35.5–49.5]	

<sup>a</sup>Overall good tolerance to injections was defined as pain and itching NRS scores <4, plus no redness and no hematoma  
*CI* confidence interval, *NRS* numeric rating scale, *SD* standard deviation

reported no change in satisfaction after switching to CT-P17. Increased levels of patient satisfaction after switching from an ADA-BioS (and stable satisfaction after switching from R-ADA) may be explained by the high-concentration, citrate-free formulation of CT-P17, contrary to what has been previously reported following transition from R-ADA to other low-concentration ADA-BioS agents [15, 16]. These favorable characteristics may also account for the low proportion of patients who discontinued CT-P17 over 3 months of follow-up (5.2%).

Pain at the injection site under previous treatment and previous use of ADA-BioS (vs R-ADA) were independent prognostic factors for increased treatment satisfaction after switching to CT-P17. This finding is consistent with data that low-concentration ADA-BioS agents are more often associated with pain and bruising than R-ADA [15, 16]. In practice, positive expectations of CT-P17 were realized with less pain, redness, itching, and hematoma at the injection site, as well as a higher overall tolerance of CT-P17 in patients previously treated with an ADA-BioS.

Our univariate regression analysis additionally found that higher body mass index (BMI) was associated with increased treatment satisfaction after switching to CT-P17 (OR 2.373 for BMI  $\geq 25$  vs  $< 25$  kg/m<sup>2</sup>; *p* = 0.0476; Supplementary Table 3, see ESM). The reasons for this finding are unclear; however, data from previous studies suggest that increased BMI may be associated with less pain sensitivity on areas with excess subcutaneous fat [26]. Alternatively, increased treatment satisfaction with CT-P17 may be

attributed to injection volume, since 57.7% of patients with BMI  $\geq 25$  kg/m<sup>2</sup> in our study previously received an ADA-BioS (with a higher injection volume than CT-P17), while 53.3% of patients with BMI  $< 25$  kg/m<sup>2</sup> previously received R-ADA (with the same injection volume as CT-P17).

We observed that patients who were convinced of the necessity of treatment (rather than potential concerns) were more often satisfied after the switch to CT-P17 compared with other patients. As previously reported [10, 11], patient fears and beliefs are important and should be taken into account, because concerns about biosimilars may lead to dissatisfaction, non-adherence, and loss of therapeutic benefit. In addition, less-than-adequate health literacy when switching to CT-P17 (which accounted for approximately half of the patients in this study) translated to less awareness of treatment necessity over concerns, which further highlights the importance of patient education and shared decision making when switching to biosimilars in clinical practice.

Our research has potential limitations. Patients were asked to complete questionnaires online and without physician involvement, which was consistent with the study objectives and in line with current French, European, and US recommendations [20–22]. Physicians did not administer or collect questionnaires during follow-up; consequently, this may have increased the number of non-responders over the course of the study. To mitigate this, all efforts were made to ensure that patients completed their surveys, including developing adapted questionnaires in collaboration with patient associations and a sociologist, and sending regular

reminders via mobile phone during follow-up. As a result, 284/316 patients enrolled in this study (89.9%) completed their questionnaire at T0, 232/284 (81.7%) had evaluable questionnaires at T0 (i.e., total analysis population), 205/232 (88.4%) completed all required questionnaires over the study period, and 189/232 patients (81.5%) had evaluable questionnaires at both T0 and T4 (i.e., evaluable population). No significant differences in baseline characteristics were observed between the total analysis and evaluable populations, and sensitivity analyses found that levels of patient satisfaction were comparable between these groups, thereby suggesting a low risk of attrition bias. In addition, available data from recent real-world studies of patients treated with an ADA-BioS for IBD or CIRD showed similar characteristics to those analyzed in the present YU-MATTER study [27, 28]. Finally, the potential selection bias related to having an internet connection, which was necessary for patient participation, was limited as 93% of French people have access to the internet [29].

## 5 Conclusions

This real-world prospective study showed that the global experience of patients after switching to CT-P17, a high-concentration and citrate-free biosimilar of adalimumab, was positive with no decrease in treatment satisfaction and improvements in overall injection tolerance. Switching from a low-concentration ADA-BioS (vs R-ADA) and pain at injection site under previous treatment were identified as independent prognostic factors for a successful patient experience with CT-P17. Patients convinced of the necessity of treatment were more often satisfied after switching to CT-P17, suggesting that patient education and shared decision making during the transition to biosimilars are important to limit treatment dissatisfaction, non-adherence, and loss of therapeutic benefit.

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## Declarations

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**Availability of data and material** The datasets supporting the conclusions of this article are available from the corresponding author upon reasonable request.

**Ethics approval** The study protocol was approved on June 2, 2022, by the independent Ethics Committee of “Nord Ouest 3” France (reference number: 2022-A00448-35), which covers all participating centers. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and all applicable local regulations.

**Consent to participate** All patients in this study provided written informed consent to participate.

**Consent for publication** Not applicable.

**Code availability** Not applicable.

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