Symptom listed on MDHAQ/MEDI60	DMARD naïve N=149 (28%)	DMARD treated N=379 (72%)	Methotrexate N=153 (29%)
Headache	28%	36%	36%
Unusual fatigue	31%	33%	34%
Anxiety	23%	27%	
Cough	16%	18%	
Dizziness	14%	18%	20%
Hair loss	10%	17%	19%
Nausea	11%	13%	18%
Skin rash or hives	11%	14%	13%
Stomach pain/cramps	9%	16%	15%
Eye problems	9%	13%	14%
Anorexia/weight loss	10%	16%	17%
Diarrhea	5%	9%	8%
Fever	5%	8%	7%
Mouth sores	3%	7%	8%

stomach pain or cramps, eye problems, and/or weight loss; and 5-10% diarrhea, fever, and/or mouth sores (Table). Similar proportions were seen for Mtx-treated patients, although anxiety and cough were not listed as specific adverse events.

Conclusion: The MDHAQ symptom checklist may prove valuable to detect adverse events of high-risk medications, including on an electronic MDHAQ, which could be completed at home for 12 weeks after initiation of a new medication as a cost-effective approach for early detection of adverse events.

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Dr. Pincus holds a copyright and trademark on MDHAQ and RAPID3 for which he receives royalties and license fees from profit-making organizations, all of which are used to support further development of quantitative clinical measures for patients and health professionals.

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FRI0518

BIOSIMILAR INFlixIMAB THERAPY IN RHEUMATOID ARTHRITIS, SPONDYLOARTHRITIS AND PSORIATIC ARTHRITIS: A LONG-TERM FOLLOW-UP STUDY

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Background:

Objectives: REFLECT study has been carried out to assess in real life the use of CT-P13, the first monoclonal antibody biosimilar to infliximab (IFX) approved in France. Long-term real-life data on CT-P13 use are limited in patients (pts) suffering from rheumatic diseases and inflammatory bowel diseases.

Methods: REFLECT is a multicenter, prospective, observational study conducted in France which aims to describe characteristics of pts' receiving CT-P13 and to assess its safety and effectiveness in real-life conditions. Eligible pts for inclusion were pts (≥ 6 years old) with RA, axSpA, PsA, and inflammatory bowel disease treated with CT-P13. IFX naïve pts (IFX-N) or those having switched from IFX originator to CT-P13 were enrolled (IFX-S). An intermediate result in pts with rheumatic diseases using descriptive statistical analyses from inclusion after 18-month-follow-up period are described below.

Results: From 19 October 2016 to 31 January 2019, 1321 pts were included by 70 centres, and 616 pts with rheumatic diseases were analysed: 132 RA (25.0% males; mean age: 61.5 ± 10.5 ; median time since diagnosis: 12.9 years), 398 axSpA (59.0%; 48.0 ± 13.1 years; 10.7 years, respectively), and 86 PsA (41.9%; 53.0 ± 14.1 years; 10.3 years). Previous bDMARDs other than IFX were reported in 40.1%, 42.1% and 47.4% of RA, axSpA and PsA pts, respectively. More than 1/3 of pts switched from the IFX originator to CT-P13 (40.2% of RA, 42.7% of axSpA and 35.5% of PsA). At the first administration of CT-P13, the majority of IFX-N pts had active disease (92.0% of RA, 76.4% of axSpA and 55.0% of PsA) compared to IFX-S pts (39.5% of RA, 23.1% of axSpA and 26.3% of PsA). At the first infusion of CT-P13, the median DAS28 scores were 4.8 and 2.4 for RA pts in IFX-N and IFX-S pts, and 4 and 2.2 for PsA pts, respectively. In axSpA pts, the median BASDAI at baseline were 5.6 and 2.4 and the median BASFI was 5.3 and 2.8 in IFX-N and IFX-S pts, respectively. From the first administration of CT-P13 to 18 months follow-up the median DAS 28 decreased (-1 point) in both IFX-N pts and IFX-S for RA pts; for axSpA pts the BASFI and BASDAI scores decreased by -2 and -1, respectively in IFX-N and remained stable in IFX-S.

The analysis of pts suffering from PsA has not been reported due to the small number of patients with a follow-up at 18 months (4 IFX-N pts and 1 IFX-S pts).

Table 1. Reasons for treatment withdrawing

	RA		Ax Spa		PsA	
IFX pts (N)	IFXn (N=16)	IFXs (N=9)	IFXn (N=28)	IFXs (N=30)	IFXn (N=5)	IFXs (N=6)
Missing	0	0	1	0	0	0
Remission	0 (0.0%)	2 (22.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Therapeutic failure	9 (56.3%)	3 (33.3%)	18 (56.3%)	19 (63.3%)	3 (60.0%)	4 (66.7%)
Intolerance	2 (12.5%)	1 (11.1%)	3 (11.1%)	2 (6.7%)	0 (0.0%)	0 (0.0%)
Other	5 (31.3%)	3 (33.3%)	6 (22.2%)	9 (30.0%)	2 (40.0%)	2 (33.3%)

Table 2. Safety data

	RA (N=132)	ax Spa (N=398)	PsA (N=86)
Patients with at least one adverse event (AE)	49 (37.1%)	141 (35.4%)	25 (29.1%)
Patients with at least one serious AE	11 (8.3%)	19 (4.8%)	1 (1.2%)
Patients with at least one allergic infusion reaction†	3 (2.3%)	9 (2.3%)	-
Patients with at least one infection‡	3 (2.3%)	4 (1.0%)	1 (1.2%)

† Including acute and delayed hypersensitivity reactions

‡ Including severe infections, tuberculosis, opportunistic infections, hepatitis.

78.8%, 82.9% and 87.2% remain on treatment with CT-P13 in RA, AxSpA and PsA pts respectively. The reasons for treatment withdrawing are reported in table 1.

The safety data are presented in Table 2.

Conclusion: The results from this long-term follow-up period show that CT-P13 was effective in inducing and maintaining remission in both naïve and switched patients. This real-life study did not highlight any new safety concerns.

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FRI0519

IMPROVING RHEUMATOID ARTHRITIS COMPARATIVE EFFECTIVENESS RESEARCH USING THE TARGET TRIAL EMULATION FRAMEWORK: A SYSTEMATIC REVIEW

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Background: Methods used in observational comparative effectiveness research (CER) are highly variable. Target trial emulation is an intuitive design approach that encourages researchers to formulate their question as a hypothetical randomised controlled trial (RCT), or the "target trial". Using observational data to emulate the target trial helps avoid common biases and has been shown to better align results with actual RCTs.

Objectives: We systematically reviewed observational CER studies in rheumatoid arthritis to provide examples of design issues that might have been avoided by using target trial emulation.

Methods: We searched for head-to-head effectiveness comparisons of biologic DMARDs in RA. Study designs were reviewed for components of target trial emulation: 1) eligibility criteria, 2) treatment strategies, 3) assignment procedures, 4) follow-up period, 5) outcome, 6) causal contrasts of interest (i.e., intention-to-treat or per-protocol effect), and 7) analysis plan. Reported methods were taken as the "emulation" of a corresponding target trial, to assess design issues that might introduce bias.

Results: We found 31 CER studies, the majority of which had one design issue belonging to one of the 7 protocol components (Table 1). The most common issues were: 1) 17 out of 31 studies used post-baseline information to define baseline eligibility (e.g. requiring ≥ 1 follow-up), which can bias results; 2) 26 out of 31 studies did not declare their causal contrast of interest, which is often made difficult by issue 1 and impacts data analysis and interpretation; and 3) 9 out of 31 studies used statistical selection of confounders rather than pre-defining them, which can also introduce bias (e.g. through adjustment of collider or intermediate variables).