Treat 2 Target: differerenti prospettive medico paziente

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IXEVOLUTION
un passo avanti nella gestione delle spondiloartriti

Improving patients' participation in health decision-making

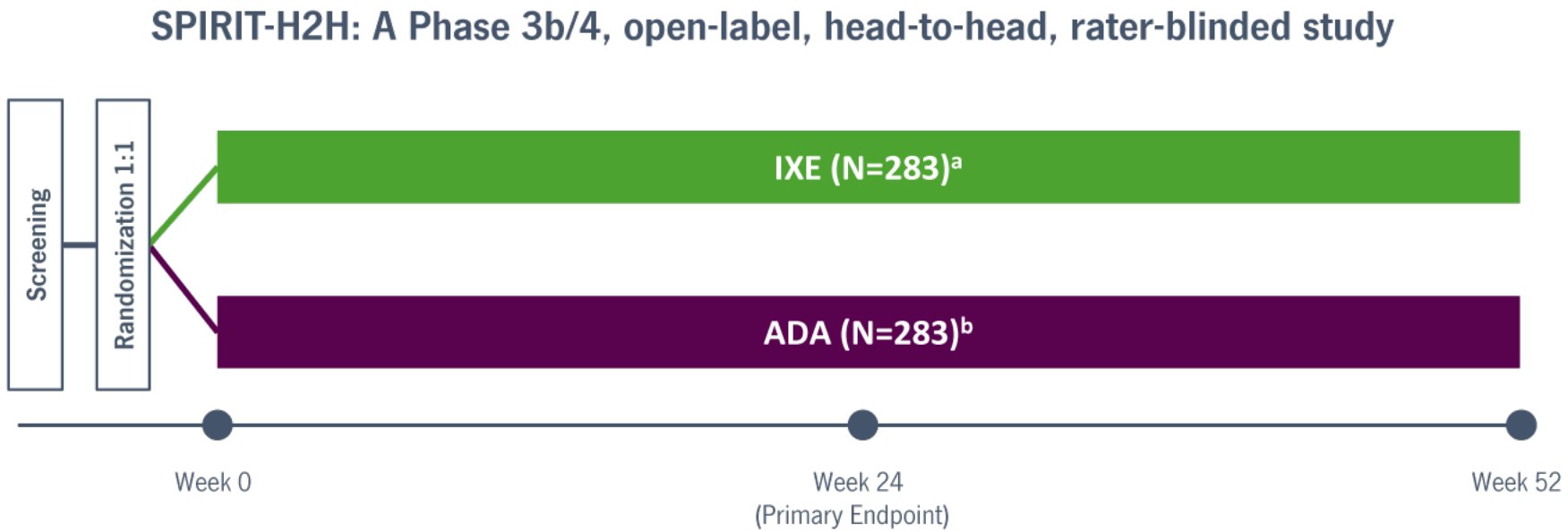
Quali valori sono indici di benessere per il paziente e quali per lo specialista?

- Challenges for Patients and Patients' Organisations in Times of the Pandemic
- Understand the impact of desease on patients with chronic inflammatory rheumatic conditions

[a]All patients administered IXE received a 160 mg starting dose at Week 0. Patients who met criteria for moderate-to-severe PsO received 80 mg IXE Q2W from Week 2 to Week 12, and Q4W thereafter. Patients without moderate-to-severe PsO received 80 mg IXE Q4W from Week 4. [b]Patients administered ADA who met criteria for moderate-to-severe PsO received an 80 mg starting dose, followed by 40 mg Q2W starting at Week 1. Patients administered ADA who did not meet criteria for moderate-to-severe PsO received a 40 mg starting dose, followed by 40 mg Q2W starting at Week 2. [c]No changes in MTX dose were allowed during Weeks 0-24 except for safety reasons.

Smolen JS, et al. Rheumatol Ther. 2020;7(4):1021-1035.

SPIRIT H2H: Study design



- Randomization was stratified by concomitant use of csDMARDs and the presence/absence of moderate-to-severe plaque PsO (defined in the study as BSA ≥10% + PASI ≥12 + sPGA ≥3 at baseline)
- Dosing was based on the presence/absence of moderate-to-severe PsO at baseline[a,b]
- MTX (10-25 mg/week; oral or parenteral), when included, must have been used for ≥12 weeks (and as a stable dose for ≥8 weeks) prior to randomization[c]

[a]All patients administered IXE received a 160 mg starting dose at Week 0. Patients who met criteria for moderate-to-severe PsO received 80 mg IXE Q2W from Week 2 to Week 12, and Q4W thereafter. Patients without moderate-to-severe PsO received 80 mg IXE Q4W from Week 4. [b]Patients administered ADA who met criteria for moderate-to-severe PsO received an 80 mg starting dose, followed by 40 mg Q2W starting at Week 1. Patients administered ADA who did not meet criteria for moderate-to-severe PsO received a 40 mg starting dose, followed by 40 mg Q2W starting at Week 2. [c]No changes in MTX dose were allowed during Weeks 0-24 except for safety reasons.

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SPIRIT H2H: Study endpoints and statistical analyses

EFFICACY

Endpoints were assessed in subgroups defined by the presence or absence of concomitant MTX use at baseline

ENDPOINTS AT WEEK 52

- ACR50 + PASI 100
- ACR20/50/70
- SPARCC Enthesitis Index=0; LEI=0
- LDI-B=0
- mCPDAI ≤5 (LDA or remission)
- PASI 75/90/100
- NAPSI=0
- DLQI (0,1)
- MDA
- DAPSA ≤4 (remission); ≤14 (LDA or remission)
- VLDA
- HAQ-DI ≤0.5

SAFETY

TEAEs; SAEs; deaths; discontinuations due to AEs; AESI: infections, serious infections, malignancies, major adverse, MACE, IBD, ISRs, depression, hepatic laboratory changes, cytopenia, and neutropenia.

STATISTICAL NOTES

Post-hoc analyses of efficacy and QoL outcomes were performed through Week 52 in the ITT population, consisting of all randomized patients by treatment assigned at Week 0

Treatment group differences were evaluated within each MTX subgroup using Fisher's exact test

Missing data were imputed using NRI

Any p-value <.05 was considered statistically significant

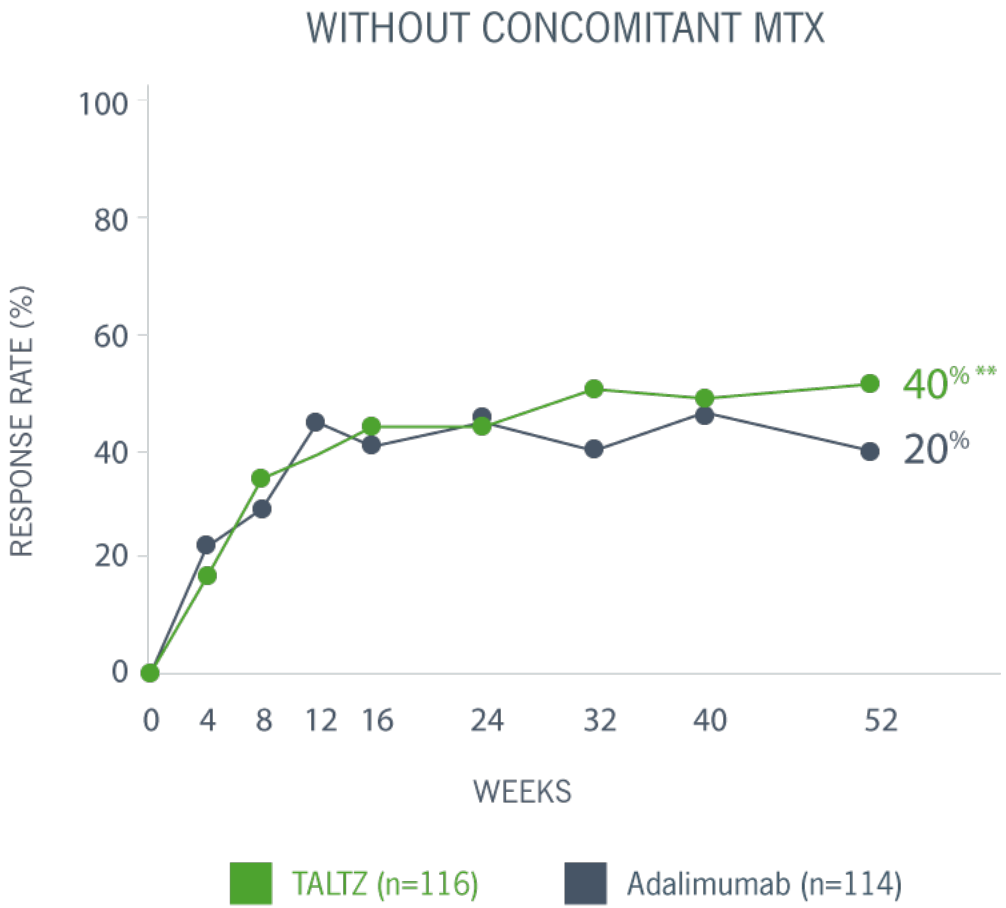
The study was not powered to perform statistical comparison of safety data between two treatment arms

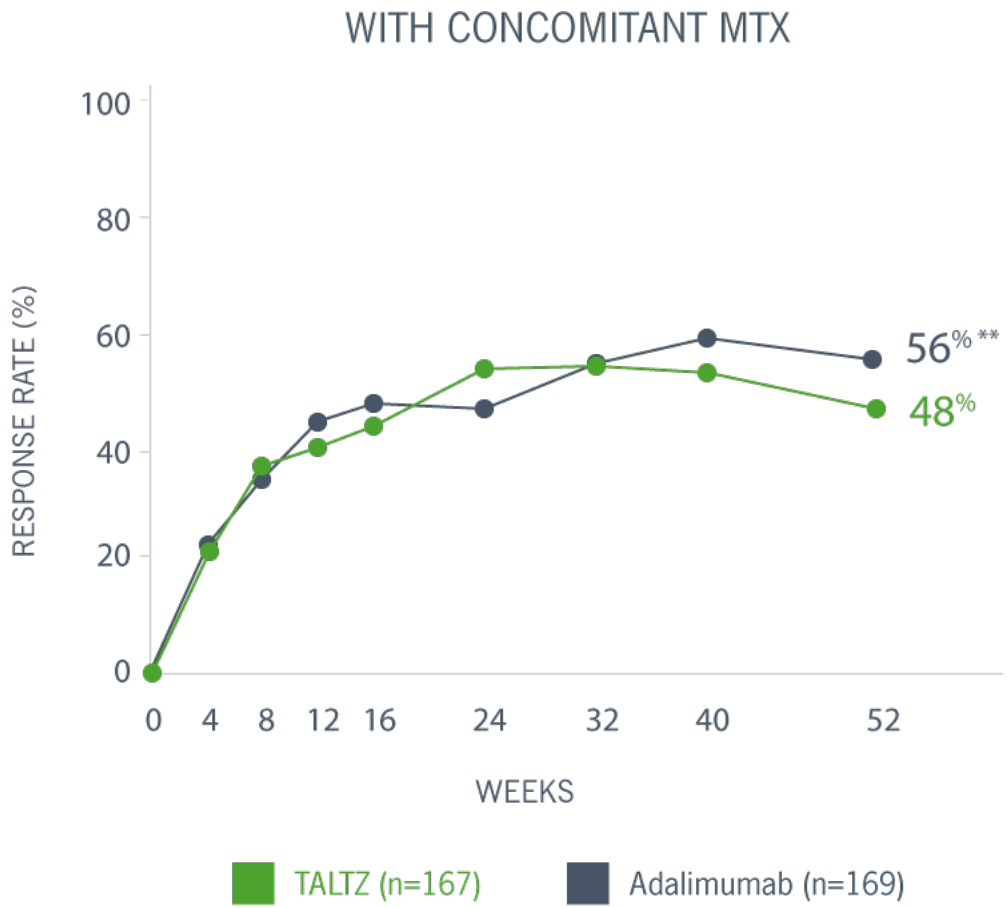
Descriptive statistics were performed on the safety population, defined as all randomized patients who received ≥1 dose of the study treatment

Note: Rates of simultaneous achievement of ACR50 and PASI100 in patients with and without concomitant MTX were prespecified but not type-I error-controlled at week 24 and weeks 28-52 were post hoc analysis.
Smolen JS, et al. Rheumatol Ther. 2020;7(4):1021-1035.

ACR50 response by treatment week, NRI

ITT population, without concomitant MTX and with concomitant MTX (SPIRIT-H2H)



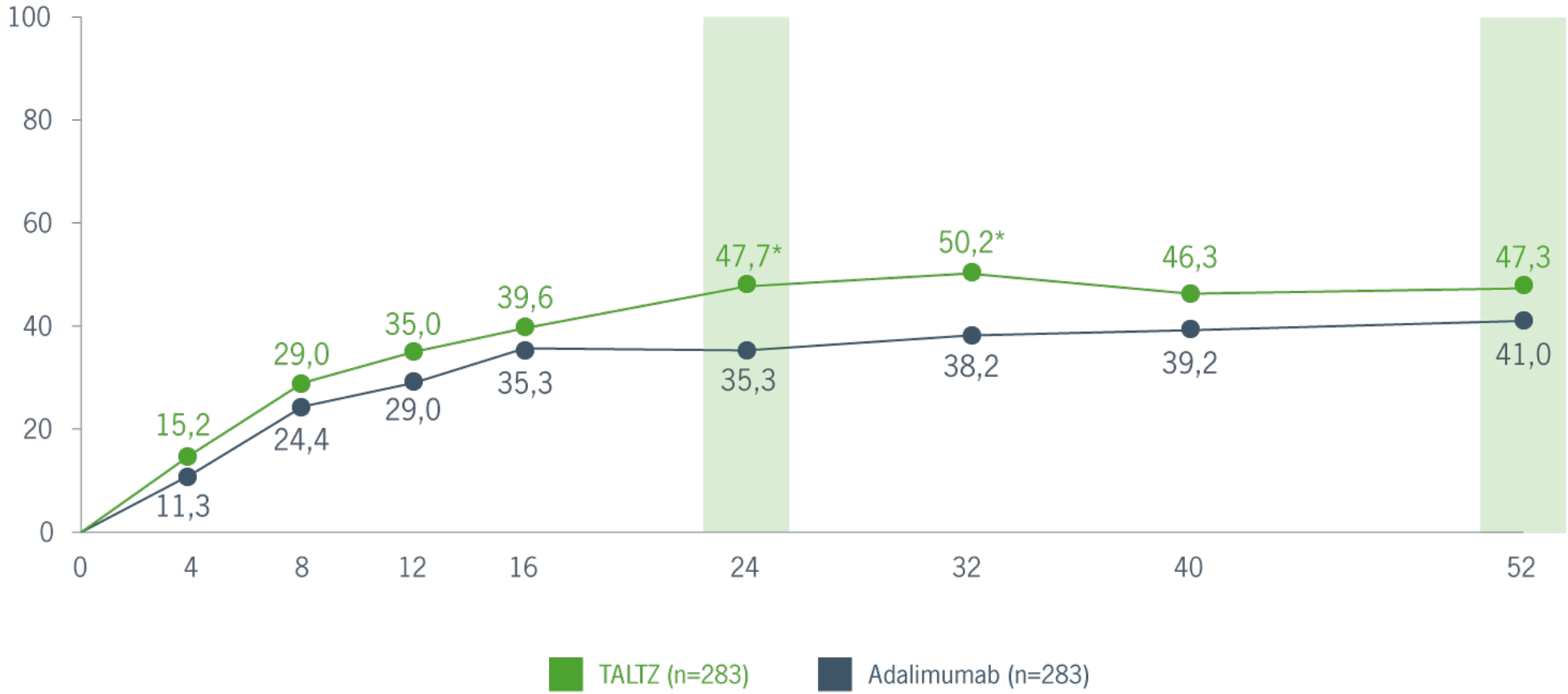


vs. ADA: *p<.05, **p≤.01, ***p≤.001.

Smolen JS, et al. Rheumatol Ther. 2020;7(4):1021-1035.

Minimal disease activity (MDA) by treatment week, NRI

ITT Population (SPIRIT-H2H)

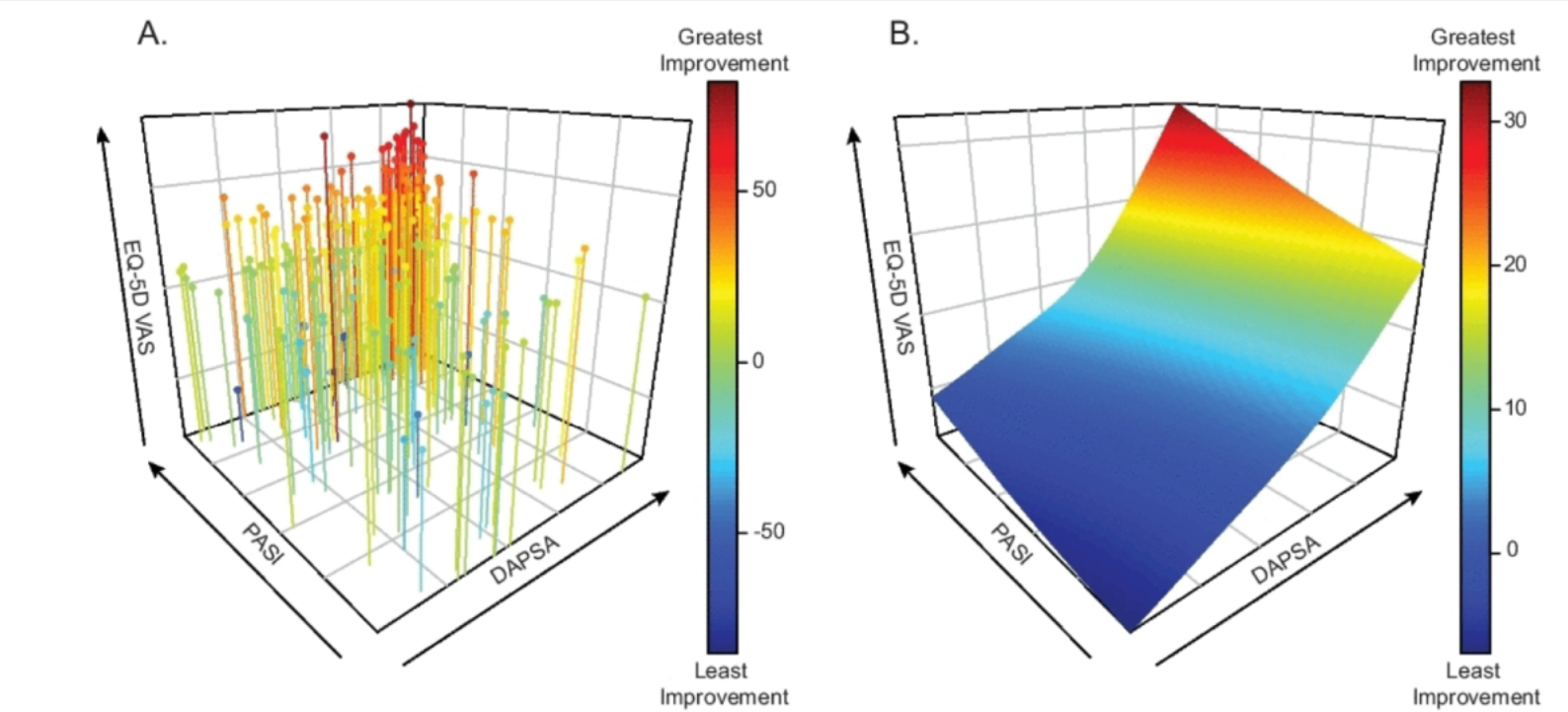


*p<.01 vs. ADA.

Smolen JS, et al. Ann Rheum Dis. 2020; doi:10.1136/annrheumdis-2020-217372 (Ahead of print).

QoL rispetto alla salute
(post hoc analisis SPIRIT-P1,P2)

The greatest improvements in HRQoL were achieved when patients achieved clinically significant improvements in both joint and skin symptoms, particularly with respect to the mental aspects of the disease

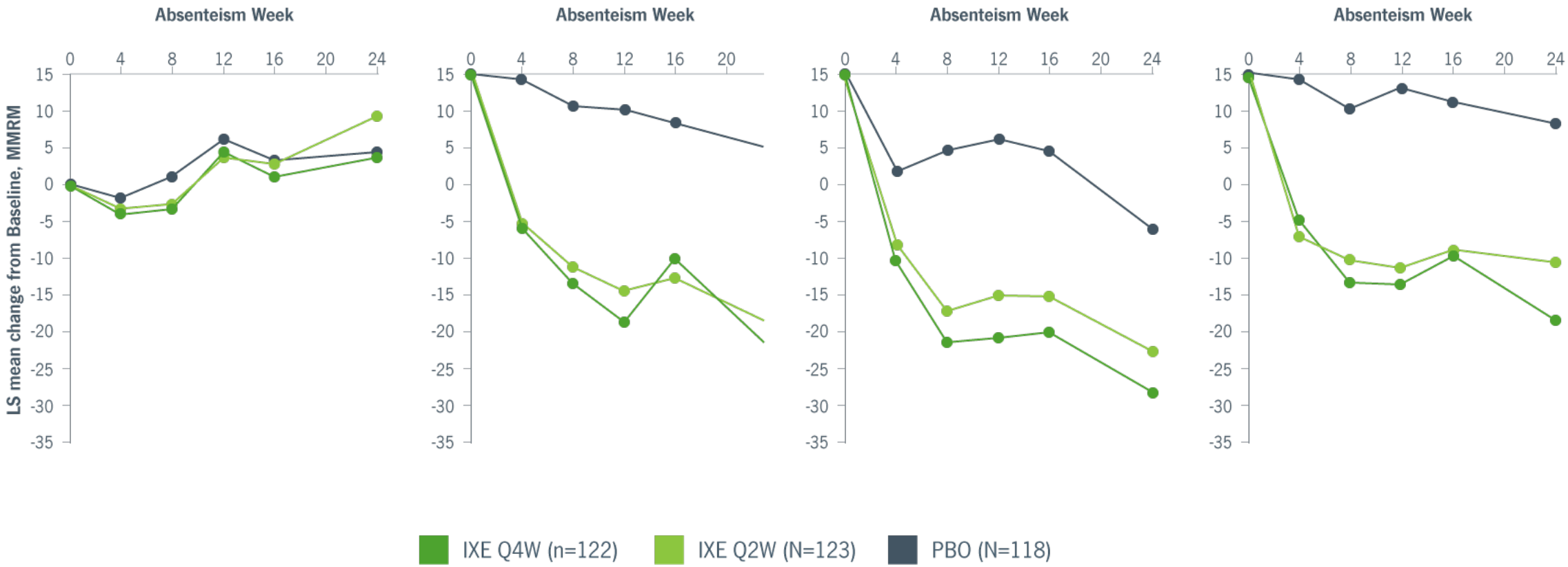


Regressione secondo il modello analitico smoothing spline modelling degli score di malattia relativi ad articolazioni e pelle, migliorando la HRQoL.

Kavanaugh A, et al. Ann Rheum Dis 2019;0:1–5.

Work productivity & activity index

Post hoc analisis SPIRIT-P2



vs. ADA: *p<.05, **p≤.01, ***p≤.001.

Kavanaugh A et al. Clin Exp Rheumatol. 2019 Jul-Aug;37(4):566-574

Product information

Classe H - Medicinale soggetto a prescrizione medica limitativa, vendibile al pubblico su prescrizione di centri ospedalieri o di specialisti - internista, reumatologo, dermatologo (RRL).

TALTZ 80 mg soluzione iniettabile in penna preriempita – 2 penne preriempite - AIC n° 044863025/E
Prezzo al pubblico: € 3.518,73 Prezzo ex-factory: € 2.132,00

TALTZ 80 mg soluzione iniettabile in siringa preriempita – 2 siringhe preriempite - AIC n° 044863052/E
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Clicchi qui per RCP Taltz

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