Χαράσσοντας την πορεία TREAT-TO-TARGET στη Ρευματολογία: Αποτελέσματα διαρκείας με το Tofacitinib

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Disclosures

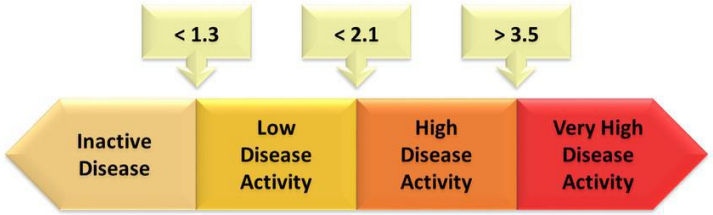
Speaker/Honoraria Fees last 2 years: Janssen, UCB, Lilly, Abbvie, Boehringer

“Η Pfizer έχει ελέγξει το περιεχόμενο ώστε να ανταποκρίνεται στις ειδικές προδιαγραφές της αλλά δεν έχει επιβεβαιώσει ότι οι βιβλιογραφικές παραπομπές έχουν παρατεθεί ορθά”

“Για όλα τα φαρμακευτικά προϊόντα που αναφέρονται παρακαλείσθε να συμβουλεύεσθε τις εγκεκριμένες Περιλήψεις Χαρακτηριστικών των Προϊόντων”

Case 1

Γυναίκα 40 ετών με ΑΣ



Καπνίστρια, ΑΥ, φλεγμονώδης οσφυαλγία από 10ετίας

09/2023
- Αυχεναλγία
- Οσφυαλγία
- Οστικό οίδημα Θ11-Θ12-Ο1
- HLA B27 (+)
- Αυξημένη CRP, ΤΚΕ

ASDAS 4,3 | BASDAI:3,4

Διάγνωση ΑΣ

Έναρξη IV infliximab

09/2024
- Έξαρση νοσήματος
- Οσφυαλγία
- Αυξημένη CRP, ΤΚΕ

Αλλαγή σε ΥΔ adalimumab

Βελτίωση πόνου και δυσκαμψίας
Αρνητική CRP

02/2025
- Έξαρση νοσήματος
- Φλεγμονώδης πόνος ΣΣ
- Αρθρίτιδα ΔΕ και ΑΡ ώμου και ΠΧΚ
- Επώδυνος περιορισμός ΘΜΣΣ, ΟΜΣΣ

ASDAS 5,6 | BASDAI:9,4

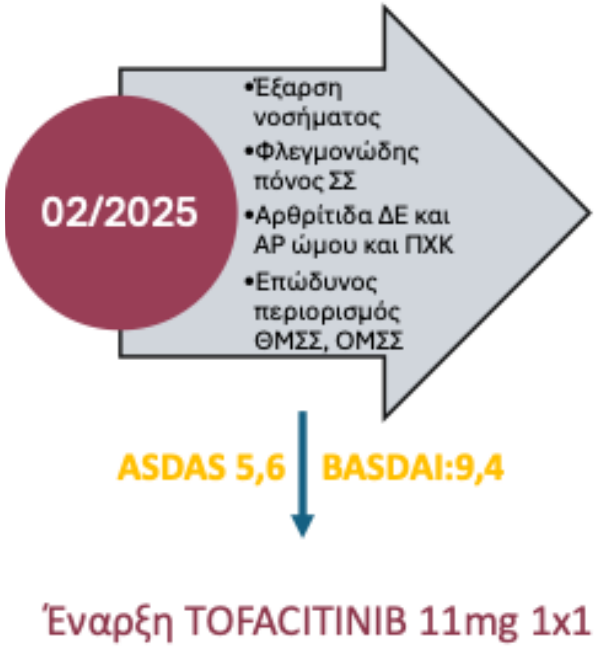
Έναρξη TOFACITINIB 11mg 1x1

«Πραγματικό προφίλ ασθενή από προσωπικό αρχείο»

Case 1

Γυναίκα 40 ετών με ΑΣ

Καπνίστρια, ΑΥ, φλεγμονώδης οσφυαλγία από 10ετίας



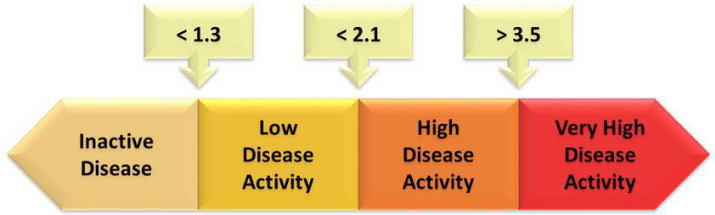
07/2025:

Βελτίωση πόνου και δυσκαμψίας ΣΣ

Πλήρης αποδρομή της περιφερικής αρθρίτιδας

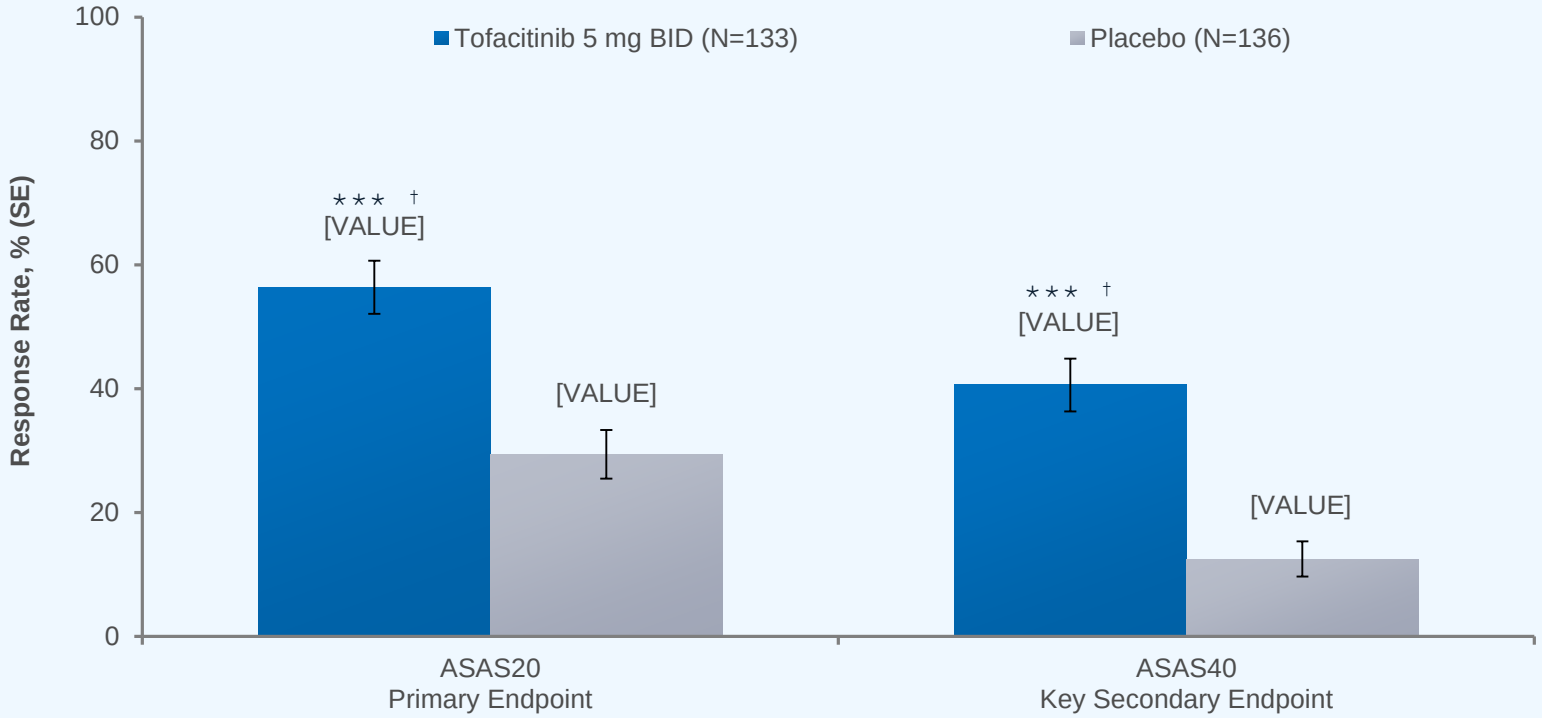
ASDAS:2,1

BASDAI: 3



«Πραγματικό προφίλ ασθενή από προσωπικό αρχείο»

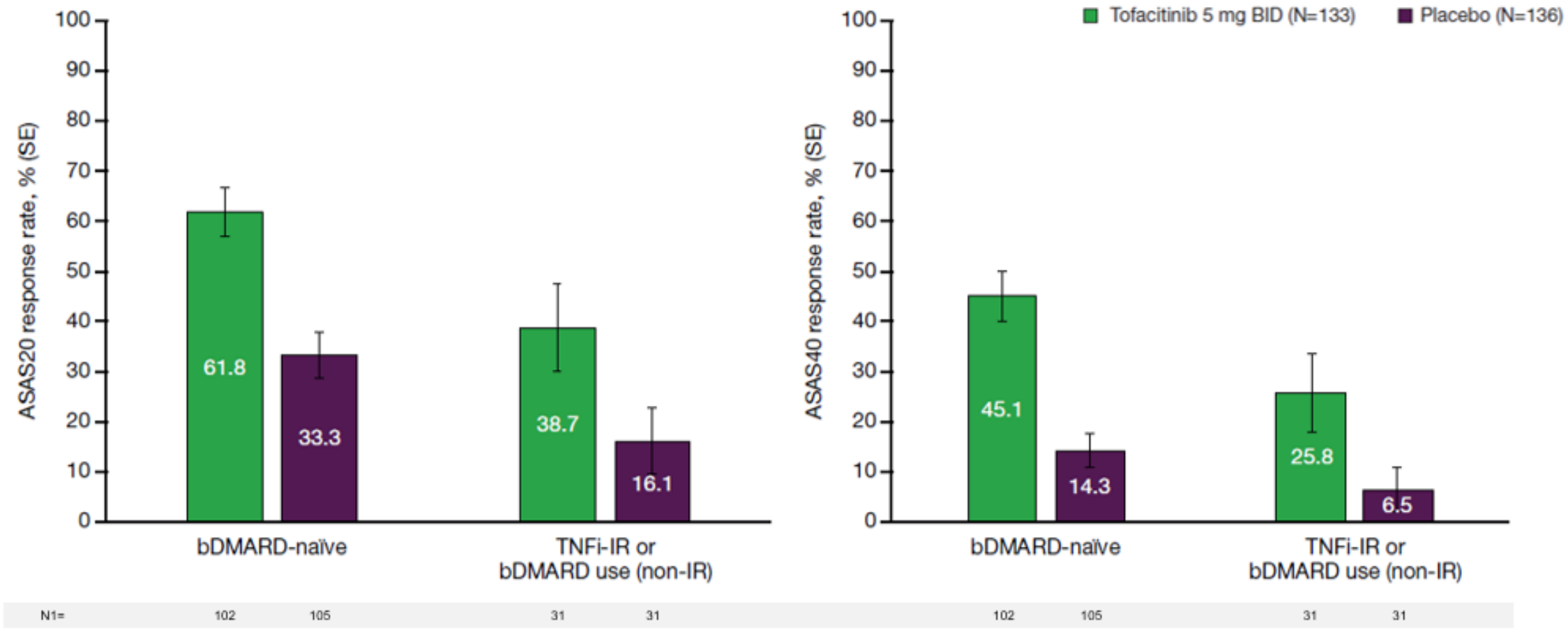
ASAS20 and ASAS40 Response Rates Were Significantly Greater in Tofacitinib Treated Patients Compared to Placebo[1]



Cochran-Mantel-Haenszel normal approximation, full analysis set, missing response = non-response. Results based on Week 16 data cutoff 19 December 2019; data snapshot 29 January 2020.
****P*<0.001 for comparing tofacitinib 5 mg BID versus placebo. †*P*≤0.05 for comparing tofacitinib 5 mg BID versus placebo, according to the prespecified step-down testing procedure for global type I error control.

1. Deodhar A, et al. *Ann Rheum Dis.* 2021;80:1004–1013.

ASAS20 and ASAS40 Response Rates[a] at Week 16 Stratified by bDMARD Treatment History[b]



Data are from the Week 16 analysis: data cutoff 19 December 2019; data snapshot 29 January 2020. [a]Normal approximation was used. Missing response was considered as non-response. [b]bDMARD treatment history was derived from the clinical database. ASAS=Assessment of SpondyloArthritis International Society; bDMARD=biologic disease-modifying antirheumatic drug; BID=twice daily; BL=baseline; IR=inadequate response or intolerance; N=number of patients in full analysis set; N1=number of patients in full analysis set, stratified by bDMARD treatment history; SE=standard error; TNFi=tumor necrosis factor inhibitor.

Deodhar A, et al. *Ann Rheum Dis*. 2021;0:1-10. doi:10.1136/annrheumdis-2020-219601.

PROs from Study 1120

Methods: PROs Assessed in Several Domains

The domains assessed in this analysis included:[1,2]

Pain

Fatigue

HRQoL

Work Productivity

Physical Functioning

The domains that were assessed are in line with recommendations from ASAS and OMERACT regarding the measurement of PROs in clinical trials.[3,4]

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253. 2. Deodhar A, et al. *Ann Rheum Dis*. 2021;80:1004–1013. 3. van der Heijde D, et al. *Ann Rheum Dis*. 2017;76(6):978–991. 4 Navarro-Compán V, et al. *Semin Arthritis Rheum*. 2021;51(6):1342–1349.

PROs from Study 1120

Pain

Patient-reported pain was measured using the following outcomes:

Total Back Pain[1]

- Total pain in the spine due to AS reported by the patient
- Patients mark their level of pain on a 0-10 numerical rating scale (NRS) anchored by 0 for “No Pain” to 10 for “Most Severe Pain”

Nocturnal Spinal Pain[1]

- Pain in the spine at night due to AS reported by the patient
- Patients mark their level of pain on a 0-10 NRS anchored by 0 for “No Pain” to 10 “Most Severe Pain”

BASDAI Overall Spinal Pain[1-3]

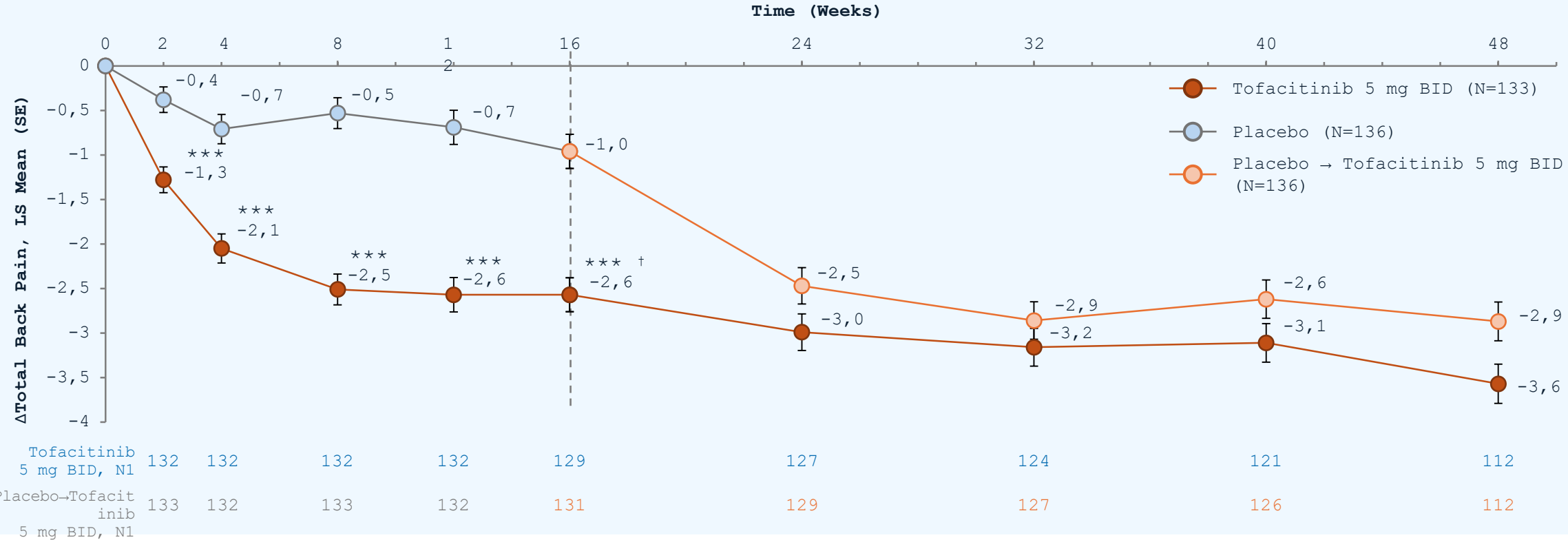
- Question 2 of the BASDAI: “How would you describe the overall level of AS neck, back, or hip pain you have had?” (during the past week)
- Patients rate their pain using an NRS from 0 (none) to 10 (very severe)

1. Deodhar A, et al. *Ann Rheum Dis*. 2021;80:1004-1013. 2. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253. 3. Sieper J, et al. *Ann Rheum Dis*. 2009;68(Suppl 2):ii1-ii44.

PROs from Study 1120

Pain: Total Back Pain Up to Week 48[1]

Note: these data were originally published in the primary Study 1120 manuscript (Deodhar et al. 2021)

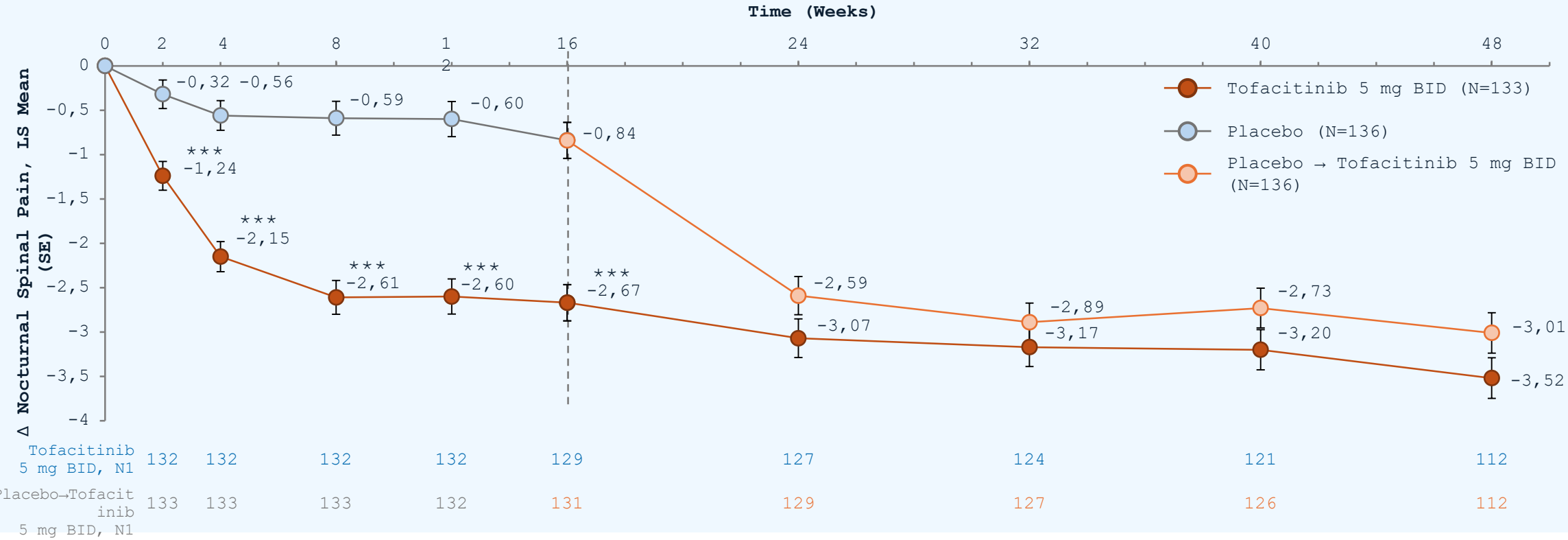


***P<0.001 for comparing tofacitinib 5 mg BID vs placebo up to week 16. P values are reported without adjustment for multiple comparisons. †P≤0.05 for comparing tofacitinib 5 mg BID vs placebo, according to the prespecified step-down testing procedure for type I error control of ASAS components

Patients receiving placebo advanced to tofacitinib 5 mg BID at week 16 (dashed line). Week 16 results are based on MMRM including all postbaseline data to week 16 (data cut-off 19 December 2019; data snapshot 29 January 2020); week 48 results based on another MMRM including all postbaseline data to week 48

1. Deodhar A, et al. *Ann Rheum Dis.* 2021;80:1004–1013.

Pain: Nocturnal Spinal Pain Up to Week 48[1]

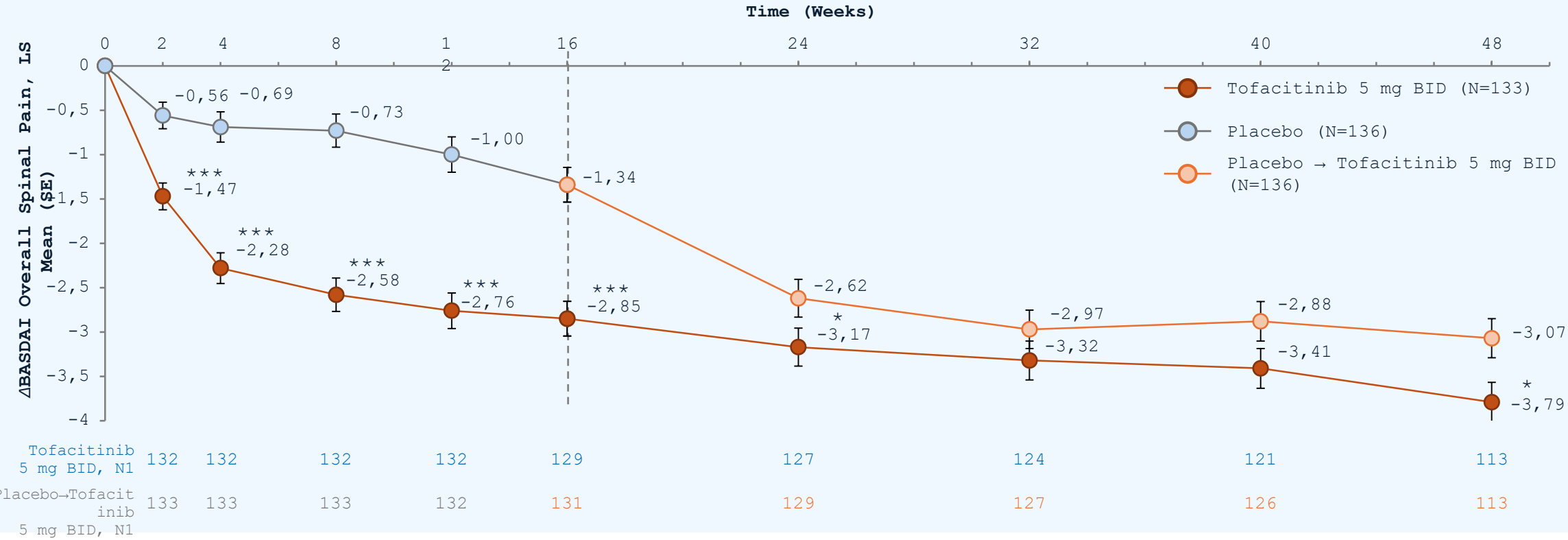


***P<0.001 for comparing tofacitinib 5 mg BID vs placebo (up to week 16) or placebo→tofacitinib 5 mg BID (up to week 48). P values are reported without adjustment for multiple comparisons.
Patients receiving placebo advanced to tofacitinib 5 mg BID at week 16 (dashed line). Results up to week 16, based on MMRM, include all postbaseline data to week 16 (data cut-off 19 December 2019; data snapshot 29 January 2020); results after week 16 are based on another MMRM including all postbaseline data to week 48 (reporting results after week 16 only).

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.

PROs from Study 1120

Pain: BASDAI Overall Spinal Pain Up to Week 48[1]



*$P \leq 0.05$, ***$P < 0.001$ for comparing tofacitinib 5 mg BID vs placebo (up to week 16) or placebo→tofacitinib 5 mg BID (up to week 48). *P* values are reported without adjustment for multiple comparisons. Patients receiving placebo advanced to tofacitinib 5 mg BID at week 16 (dashed line). Results up to week 16, based on MMRM, include all postbaseline data to week 16 (data cut-off 19 December 2019; data snapshot 29 January 2020); results after week 16 are based on another MMRM including all postbaseline data to week 48 (reporting results after week 16 only).

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.

PROs from Study 1120

Pain: Summary of Results[1]

	Baseline, mean (SD) [N1] (range)		Week 16, LS mean Δ (SE) [N1]		Week 48, LS mean Δ (SE) [N1]	
	Tofacitinib 5 mg BID (N=133)	Placebo (N=136)	Tofacitinib 5 mg BID (N=133)	Placebo (N=136)	Tofacitinib 5 mg BID (N=133)	Placebo→ Tofacitinib 5 mg BID (N=136)[a]
Total back pain (NRS 0-10)[b,c]	6.9 (1.5) (1–10)	6.9 (1.6) (2–10)	−2.57 (0.19)*** [129]	−0.96 (0.19) [131]	−3.57 (0.22)* [113]	−2.87 (0.22) [112]
Nocturnal spinal pain (NRS 0-10)[c]	6.8 (1.9) (0–10)	6.8 (1.9) (1–10)	−2.67 (0.20)*** [129]	−0.84 (0.20) [131]	−3.52 (0.23) [112]	−3.01 (0.23) [112]
BASDAI overall spinal pain (Question 2; NRS 0-10)[c]	7.3 (1.7) (2–10)	7.3 (1.6) (2–10)	−2.85 (0.20)*** [129]	−1.34 (0.20) [131]	−3.79 (0.22)* [113]	−3.07 (0.22) [113]

Δ, change from baseline; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BID, twice daily; LS mean, least squares mean; MMRM, mixed model for repeated measures; N, number of patients in full analysis set; N1, number of patients with observation at visit if different from the full analysis set; NRS, numerical rating scale; SD, standard deviation; SE, standard error.

*$P \leq 0.05$, ***$P < 0.001$ vs placebo (week 16) or placebo→tofacitinib 5 mg BID (week 48). For endpoints not pre-specified for type I error control, *P* values are reported without multiple comparison adjustment

[a]Patients receiving placebo advanced to tofacitinib 5 mg BID at week 16

[b]Change from baseline at week 16 was a type I error-controlled secondary endpoint

[c]Week 16 results are based on MMRM including all postbaseline data to week 16 (data cut-off 19 December 2019; data snapshot 29 January 2020); week 48 results based on another MMRM including all postbaseline data to week 48

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.

PROs from Study 1120

Fatigue

Patient-reported fatigue was measured using the following outcomes:

FACIT-F[1-3]

- 13 items measuring fatigue and its effect on functioning and daily activities in the last 7 days
- Answered on a 5 point scale (0-4) for a total score of 0-52, with lower scores representing more fatigue
- 2 domains:
  - Experience (range 0-20)
  - Impact (range 0-32)

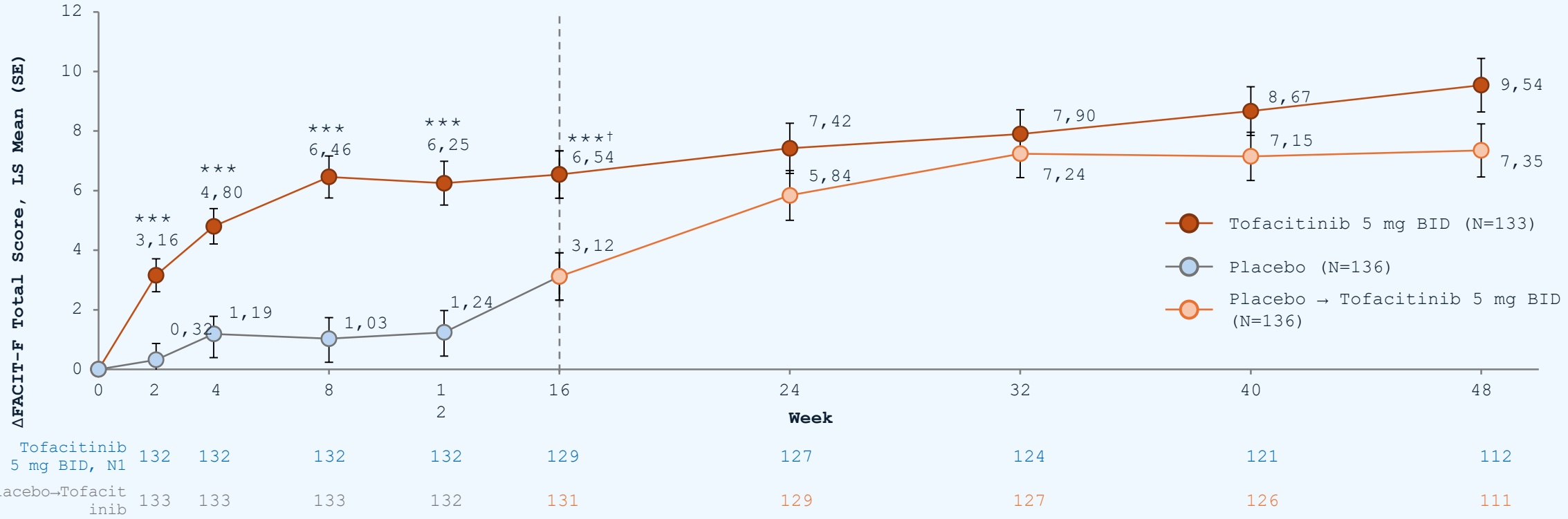
BASDAI Fatigue[1,2,4]

- Question 1 of the BASDAI: “How would you describe the overall level of fatigue/tiredness you have experienced?” (during the past week)
- Measured using an NRS with values 0 (none) to 10 (very severe) with higher values indicating worse fatigue

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253. 2. Deodhar A, et al. *Ann Rheum Dis*. 2021;80:1004–1013. 3. Cella D, et al. *Support Care Cancer*. 2011;19(9):1441–1450. 4. Sieper J, et al. *Ann Rheum Dis*. 2009;68(Suppl 2):ii1–ii44.

Fatigue: FACIT-F Total Score Up to Week 48[1]

Note: these data were originally published in the primary Study 1120 manuscript (Deodhar et al. 2021)

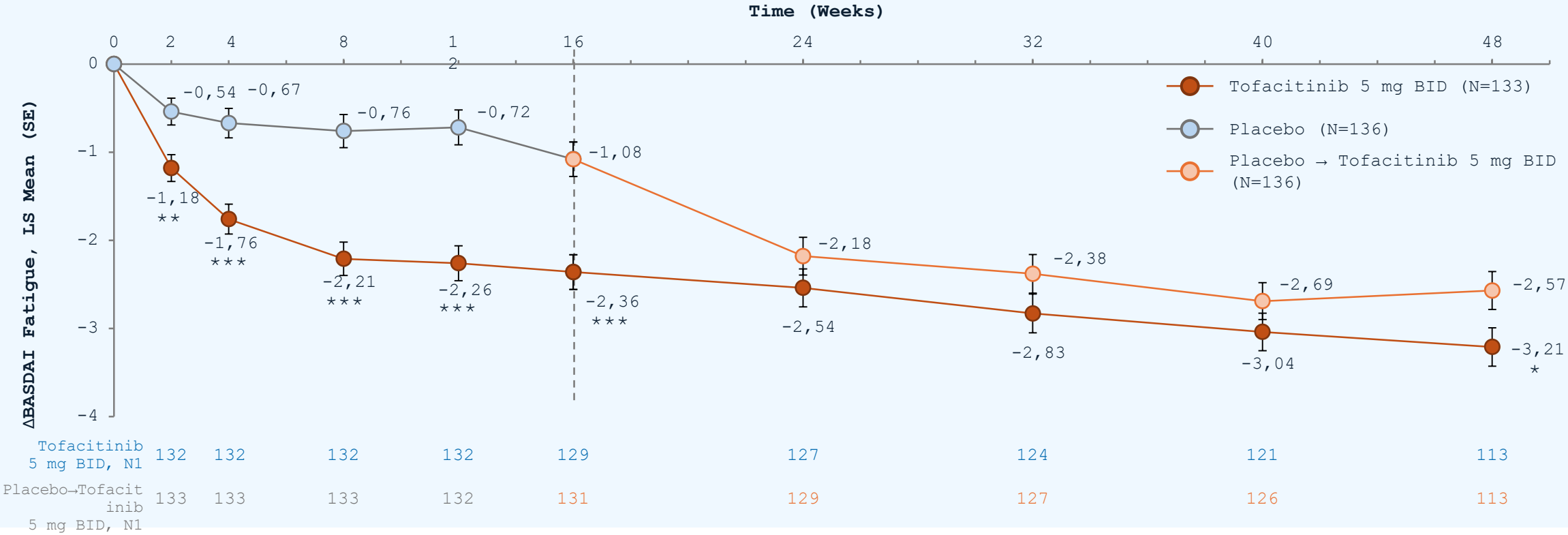


***P<0.001 for comparing tofacitinib 5 mg BID vs placebo up to week 16. P values are reported without adjustment for multiple comparisons. †P≤0.05 for comparing tofacitinib 5 mg BID vs placebo, according to the prespecified step-down testing procedure for global type I error control.
Patients receiving placebo advanced to tofacitinib 5 mg BID at week 16 (dashed line). Week 16 results are based on MMRM including all postbaseline data to week 16 (data cut-off 19 December 2019; data snapshot 29 January 2020); week 48 results based on another MMRM including all postbaseline data to week 48

1. Deodhar A, et al. *Ann Rheum Dis.* 2021;80:1004–1013.

PROs from Study 1120

Fatigue: BASDAI Fatigue Up to Week 48[1]



*$P \leq 0.05$, **$P < 0.01$, ***$P < 0.001$ for comparing tofacitinib 5 mg BID vs placebo (up to week 16) or placebo→tofacitinib 5 mg BID (up to week 48). *P* values are reported without adjustment for multiple comparisons. Patients receiving placebo advanced to tofacitinib 5 mg BID at week 16 (dashed line)

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.

PROs from Study 1120

Fatigue: Summary of Results[1]

	Baseline, mean (SD) [N1] (range)		Week 16, LS mean Δ (SE) [N1]		Week 48, LS mean Δ (SE) [N1]	
	Tofacitinib 5 mg BID (N=133)	Placebo (N=136)	Tofacitinib 5 mg BID (N=133)	Placebo (N=136)	Tofacitinib 5 mg BID (N=133)	Placebo→ Tofacitinib 5 mg BID (N=136)[a]
FACIT-F[c]						
Total score (0–52)[b]	27.2 (10.7) (4–52)	27.4 (9.3) (1–46)	6.54 (0.80)*** [129]	3.12 (0.79) [131]	9.54 (0.90) [112]	7.35 (0.89) [111]
Experience domain score (0–20)	8.9 (4.3) (0–20)	8.7 (4.0) (0–17)	2.85 (0.36)*** [129]	1.29 (0.36) [131]	4.22 (0.40) [112]	3.40 (0.40) [111]
Impact domain score (0–32)	18.3 (6.9) (4–32)	18.8 (5.9) (1–30)	3.68 (0.49)** [129]	1.81 (0.49) [131]	5.32 (0.54)* [112]	3.95 (0.54) [111]
BASDAI fatigue (Question 1; NRS 0–10)[c]	6.8 (1.5) (2–10)	6.8 (1.7) (2–10)	−2.36 (0.20)*** [129]	−1.08 (0.20) [131]	−3.21 (0.22)* [113]	−2.57 (0.22) [113]

Δ, change from baseline; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BID, twice daily; FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; LS mean, least squares mean; MMRM, mixed model for repeated measures; N, number of patients in full analysis set; N1, number of patients with observation at visit if different from the full analysis set; NRS, numerical rating scale; SD, standard deviation; SE, standard error.

*$P \leq 0.05$, **$P < 0.01$, ***$P < 0.001$ vs placebo (week 16) or placebo→tofacitinib 5 mg BID (week 48). For endpoints not pre-specified for type I error control, *P* values are reported without multiple comparison adjustment

[a]Patients receiving placebo advanced to tofacitinib 5 mg BID at week 16

[b]Change from baseline at week 16 was a global type I error-controlled endpoint

[c]Week 16 results are based on MMRM including all postbaseline data to week 16 (data cut-off 19 December 2019; data snapshot 29 January 2020); week 48 results based on another MMRM including all postbaseline data to week 48

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.

PROs from Study 1120

HRQoL

Patient-reported HRQoL was measured using the following outcomes:

ASQoL[1,2]

- 18-item questionnaire assessing the amount of restriction the patient is experiencing in daily activities, level of pain and fatigue, and the impact on the patient's emotional state
- Each item is scored as 0 (no impact) or 1 (yes – impact), and a total score is calculated by summing the items
- Scores range from 0 to 18, with higher values indicating more impaired HRQoL

SF-36v2[1,2]

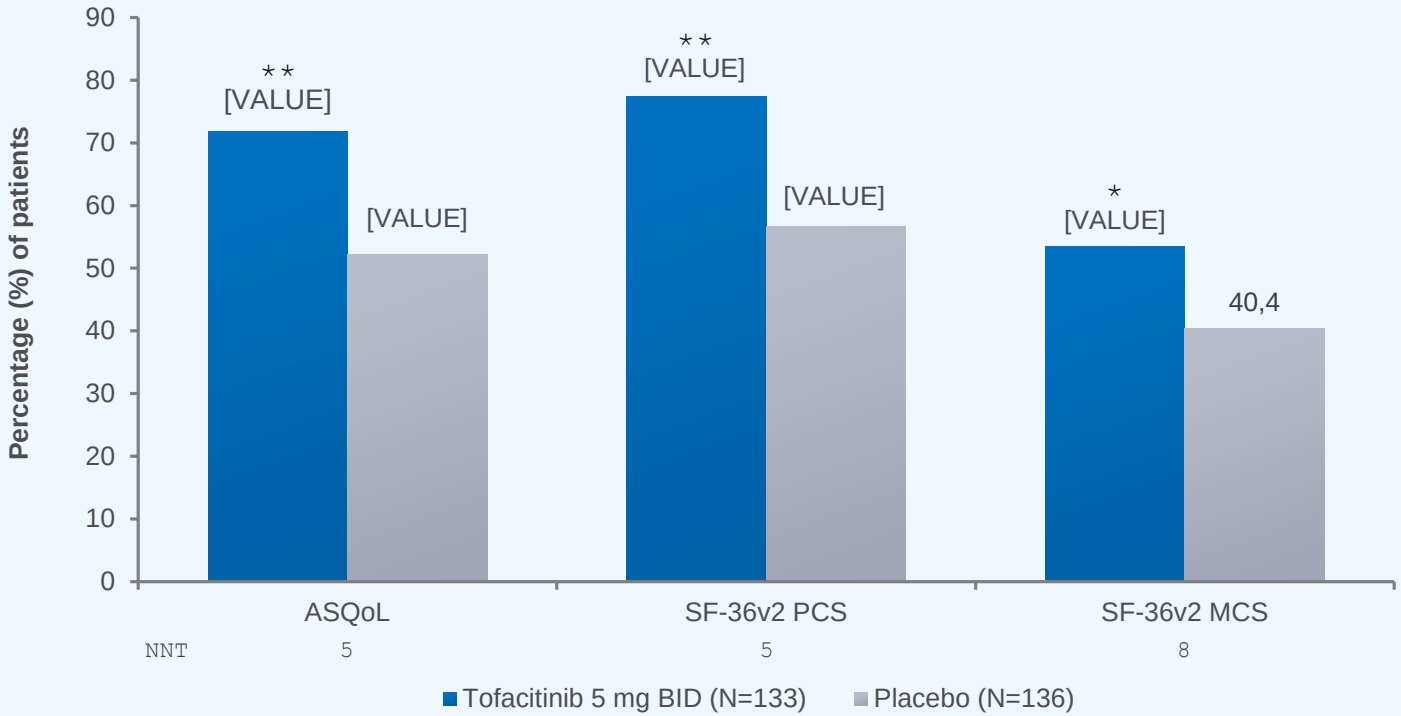
- A generic health status measure that contains 36 items grouped into 8 domains, each scored 0-100, with higher scores indicated better health status:
  - Physical functioning
  - Role-physical
  - Bodily pain
  - General health
  - Vitality
  - Social functioning
  - Role-emotional
  - Mental health
- Scores can be combined into a physical component summary (PCS) and mental component summary (MCS)

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253. 2. Deodhar A, et al. *Ann Rheum Dis*. 2021;80:1004–1013.

PROs from Study 1120

HRQoL: Improvements ≥MCID and NNTs at Week 16[1]

ASQoL and SF-36v2 PCS & MCS



MCID Cut-offs

- **ASQoL**: decrease of ≥1.8 points from baseline
- **SF-36v2 PCS**: increase of ≥2.5 points from baseline
- **SF-36v2 MCS**: increase of ≥2.5 points from baseline

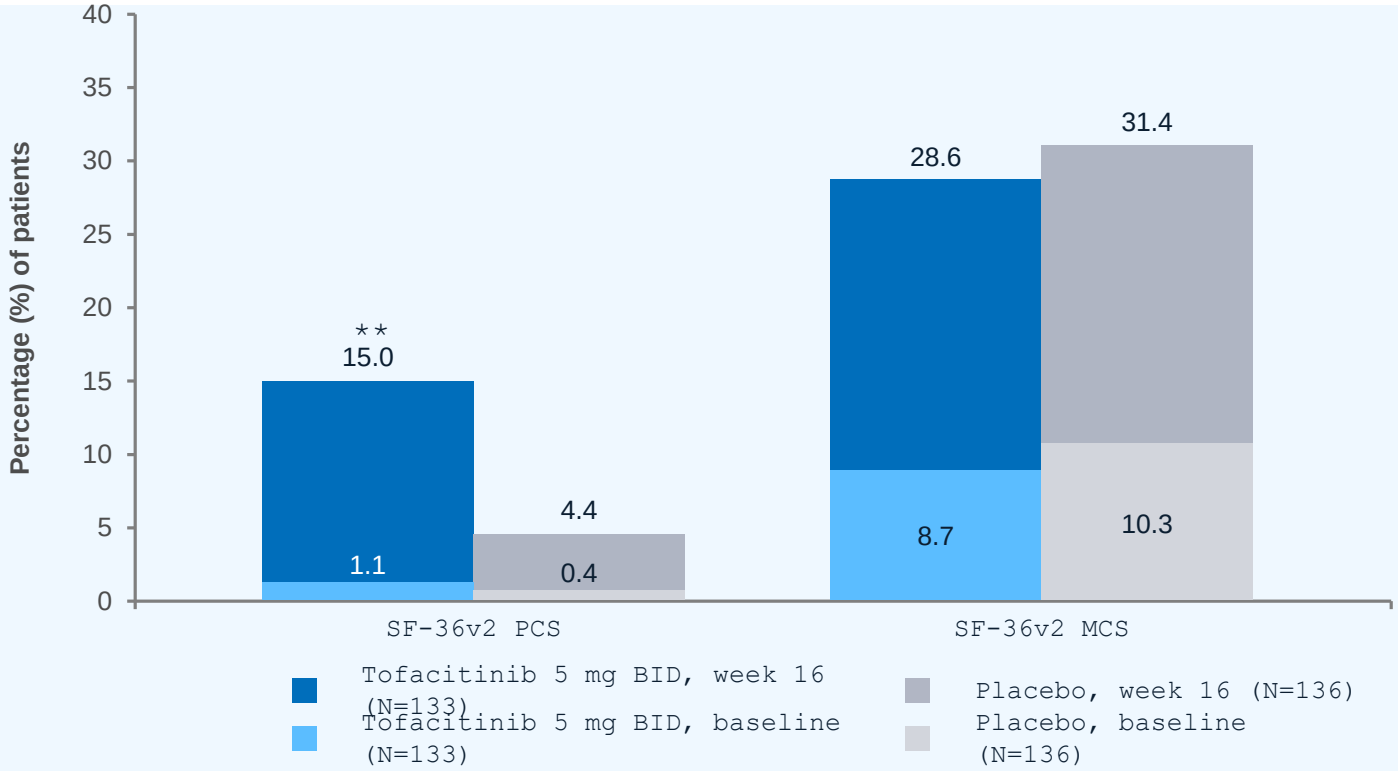
Data are from the week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Missing response was considered as non-response. *P* values are nominal
*$P \leq 0.05$, **$P < 0.01$ for comparing tofacitinib 5 mg BID vs placebo at week 16; Cochran-Mantel-Haenszel approach adjusting for stratification factor (bDMARD-naïve vs TNFi-IR or bDMARD use [non-IR])

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.

PROs from Study 1120

HRQoL: SF-36v2 PCS & MCS Scores ≥Normative Values[1]

SF-36v2 PCS & MCS



Normative Values

- **SF-36v2 PCS:** ≥50
- **SF-36v2 MCS:** ≥50

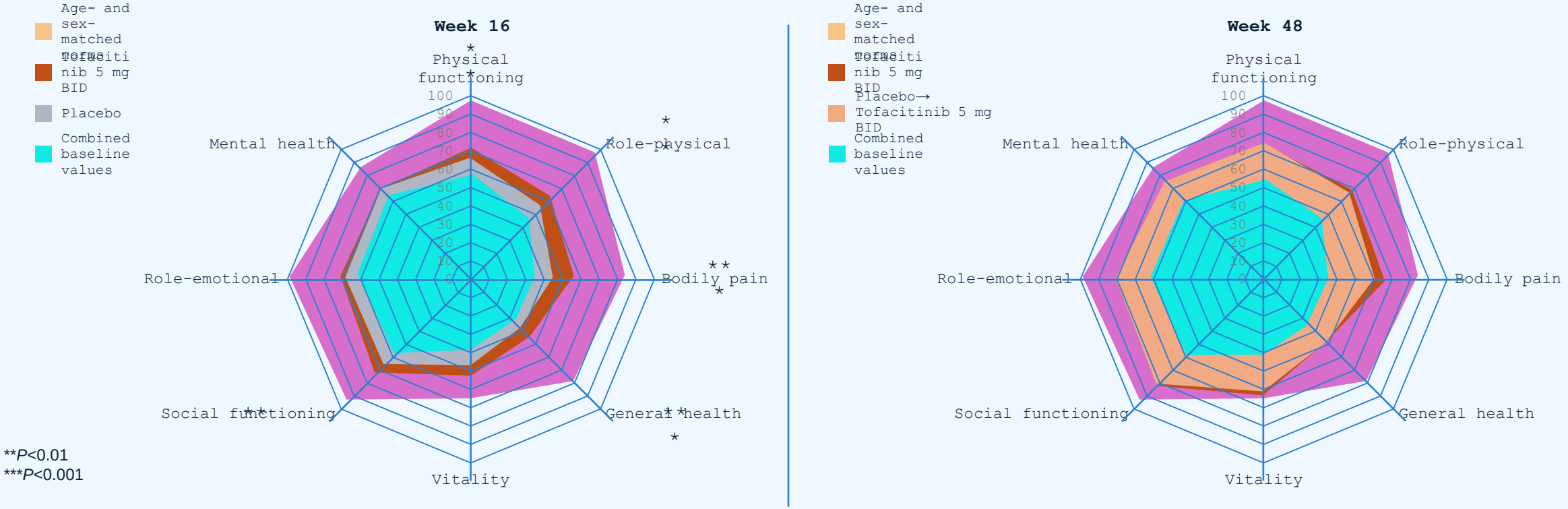
Data are from the week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Missing response was considered as non-response. *P* values are nominal.
***P*<0.01 for comparing tofacitinib 5 mg BID vs placebo at week 16; Cochran-Mantel-Haenszel approach adjusting for stratification factor (bDMARD-naïve vs TNFi-IR or bDMARD use [non-IR])

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.

PROs from Study 1120

HRQoL: SF-36v2 Versus Age- and Sex-matched Norms[1]

Spydergrams of SF-36v2 Domains from Baseline to Week 16 and Week 48



Week 16 data cut-off 19 December 2019; data snapshot 29 January 2020. Spydergrams were based on sample means generated using domain 0–100 scores. US age-sex norms were matched to the protocol population. Spydergrams are for illustrative purposes only. ***P*<0.01, ****P*<0.001 for tofacitinib 5 mg BID vs placebo (week 16) without adjustment for multiple comparisons. *P* values at week 16 were generated using ANCOVA, including data at week 16 for comparisons with placebo based on LS mean changes from baseline in domain norm-based scores to week 16

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.

PROs from Study 1120

Work Productivity

Patient-reported work productivity was measured using the following outcome:

WPAI: Spondyloarthritis[1-3]

- 6 questions about the impact of AS on the patient's ability to work and perform regular activities during the past 7 days
- Results are presented as a percentage of impairment in 4 domains:
  - Percentage of absenteeism
  - Percentage of presenteeism
  - Percentage of overall work impairment
  - Percentage of activity impairment

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253. 2. Deodhar A, et al. *Ann Rheum Dis*. 2021;80:1004–1013. 3. Reilly MC, et al. *Rheumatology (Oxford)*. 2010;49(4):812–819.

PROs from Study 1120

Work Productivity: Summary[1]

	Baseline, mean (SD) [N1] (range)		Week 16, LS mean Δ (SE) [N1]		Week 48, LS mean Δ (SE) [N1]	
	Tofacitinib 5 mg BID (N=133)	Placebo (N=136)	Tofacitinib 5 mg BID (N=133)	Placebo (N=136)	Tofacitinib 5 mg BID (N=133)	Placebo→ Tofacitinib 5 mg BID (N=136)[a]
WPAI[e]						
Activity Impairment, %	56.5 (23.4) (0–90)	56.0 (21.4) (0–100)	−19.03 (1.97)*** [129]	−5.63 (1.97) [131]	−27.37 (2.34)** [112]	−19.77 (2.31) [112]
Absenteeism (work time missed), %	9.9 (22.4) [81] (0–100)	11.5 (24.6) [88] (0–100)	−3.65 (2.66) [74]	0.88 (2.62) [81]	−8.10 (2.14) [61]	−5.79 (2.05) [70]
Presenteeism, (impairment while working), %	48.4 (26.3) [79] (0–100)	49.6 (22.2) [85] (0–90)	−19.83 (2.27)*** [71]	−6.94 (2.30) [77]	−25.35 (2.77) [58]	−23.00 (2.66) [70]
Overall Work Impairment, %	50.8 (27.4) [79] (0–100)	53.5 (23.1) [85] (0–100)	−21.49 (2.51)*** [71]	−7.64 (2.56) [76]	−27.63 (3.01) [58]	−23.22 (2.90) [69]

**$P<0.01$, ***$P<0.001$ vs placebo (week 16) or placebo→tofacitinib 5 mg BID (week 48). For endpoints not pre-specified for type I error control, P values are reported without multiple comparison adjustment.

[a]Patients receiving placebo advanced to tofacitinib 5 mg BID at week 16

[e]Week 16 results based on ANCOVA including all postbaseline data at week 16 (data cut-off 19 December 2019; data snapshot 29 January 2020); week 48 results based on MMRM including all postbaseline data to week 48

Note: no MCID or normative values were available for WPAI

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.

PROs from Study 1120

Physical Functioning

Patient-reported physical functioning was measured using the following outcomes:

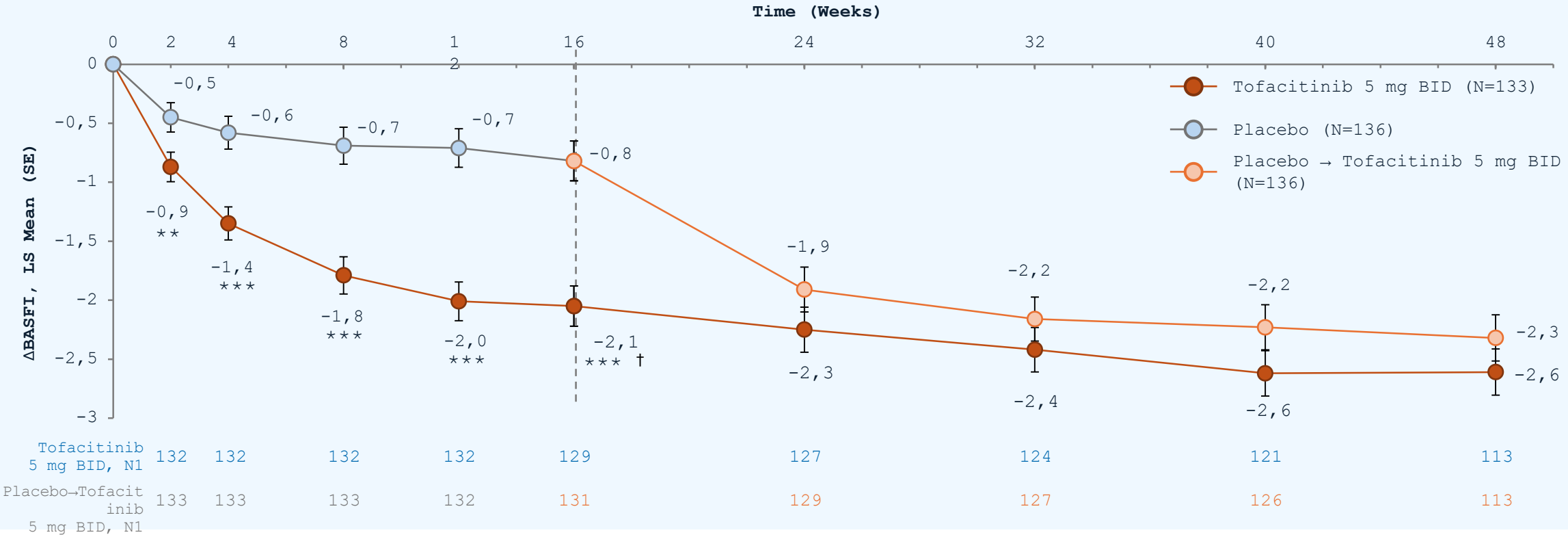
Bath Ankylosing Spondylitis Functional Index (BASFI)[1]

- 10 questions designed to determine the degree of functional limitation in patients with AS, including activities related to functional anatomy and the ability to cope with everyday life
- Patients answer using an NRS from 0 (easy) to 10 (impossible)

1. Deodhar A, et al. *Ann Rheum Dis.* 2021;80:1004–1013.

Physical Functioning: BASFI Up to Week 48[1]

Note: these data were originally published in the primary Study 1120 manuscript (Deodhar et al. 2021)



**P<0.01, ***P<0.001. †P≤0.05 for the comparison with placebo for type I error-control, according to the prespecified step-down testing procedure for the ASAS components
Patients receiving placebo advanced to tofacitinib 5 mg BID at week 16 (dashed line). Week 16 results are based on MMRM including all postbaseline data to week 16 (data cut-off 19 December 2019; data snapshot 29 January 2020); week 48 results based on another MMRM including all postbaseline data to week 48

1. Deodhar A, et al. *Ann Rheum Dis.* 2021;80:1004–1013.

PROs from Study 1120

Correlation Analysis for Related PROs of Interest At Week 16[1]

Tofacitinib 5 mg BID (*N*=133)

Endpoint 1	Endpoint 2	N1	Correlation Coefficient Value
Total back pain	SF-36v2, bodily pain	129	−0.76***
Nocturnal spinal pain	SF-36v2, bodily pain	129	−0.69***
FACIT-F total score	BASDAI fatigue	128	−0.66***
SF-36v2, physical functioning	BASFI	129	−0.76***
SF-36v2, mental health	EQ-5D-3L anxiety/depression	129	−0.69***

Placebo (*N*=136)

Endpoint 1	Endpoint 2	N1	Correlation Coefficient Value
Total back pain	SF-36v2, bodily pain	131	−0.66***
Nocturnal spinal pain	SF-36v2, bodily pain	131	−0.65***
FACIT-F total score	BASDAI fatigue	130	−0.60***
SF-36v2, physical functioning	BASFI	131	-0.71***
SF-36v2, mental health	EQ-5D-3L anxiety/depression	131	-0.64***

Data are from the week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020.

****P*<0.001, based on Student's t distribution (N1-2 degree of freedom) to test the null hypothesis of no correlation. Correlation coefficient values of ≤0.3, >0.30–≤0.60, and >0.60 were regarded as weakly, moderately, and highly correlated, respectively

For SF-36v2 domains, norm-based scores were used.

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.

Key Takeaways

Conclusions of the Study[1]

Week 16

- In patients with active AS, patients treated with tofacitinib 5 mg BID achieve clinically meaningful improvements vs placebo up to week 16 across a wide range of PROs including:
  - Pain
  - Fatigue
  - HRQoL
  - Work productivity

Week 48

- Improvements with tofacitinib 5 mg BID were maintained at week 48 or continued to increase up to week 48
- In patients who switched from placebo to tofacitinib 5 mg BID at week 16, PROs improved to levels near the tofacitinib 5 mg group

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.

Case 2

Γυναίκα 25 ετών με JIA - Enthesitis related

2015
- JIA
- Ολιγοαρθρίτιδα ενθεσίτιδα, ιερολαγονίτιδα

→ Έναρξη MTX

→ Προσθήκη etanercept

2018
- Ιερολαγονίτιδα
- Ολιγοαρθρίτιδα άκρων χειρών
- Ενθεσίτιδα

→ Έναρξη Adalimumab

→ Ύφεση και διακοπή το 2021

2022
- Αρθρίτιδα άκρων χειρών
- Αρθρίτιδα ΠΔΚ και γονάτων
- Οσφυαλγία, τροχαντηρίτιδα

→ Έναρξη Certolizumab (Αλλεργική αντίδραση στην 1η ένεση)

2023
- Διαρροϊκές κενώσεις
- Ελκώδης κολίτιδα
- Ενθεσίτιδα

→ Επανέναρξη Adalimumab ΑΣΤΟΧΙΑ

«Πραγματικό προφίλ ασθενή από προσωπικό αρχείο»

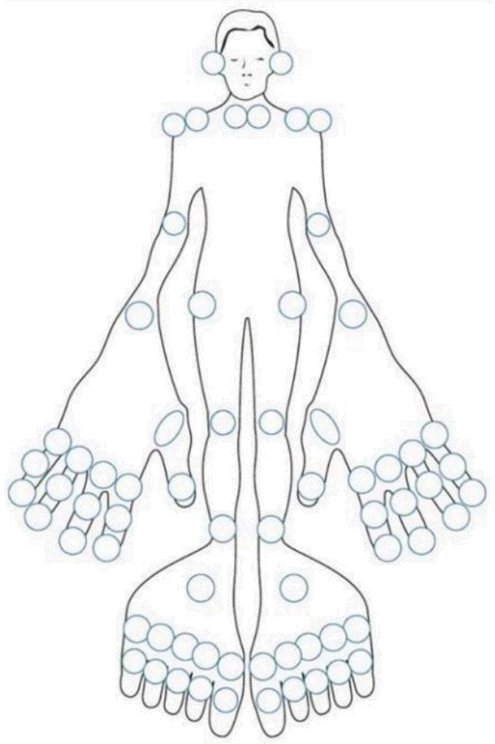
Case 2

Γυναίκα 25 ετών με JIA

2024

- JIA-Πολυαρθρίτιδα
- Ελκώδης κολίτιδα
- Ιερολαγονίτιδα

TOFACITINIB 11mg/day



07/2025

Χωρίς ενεργό αρθρίτιδα

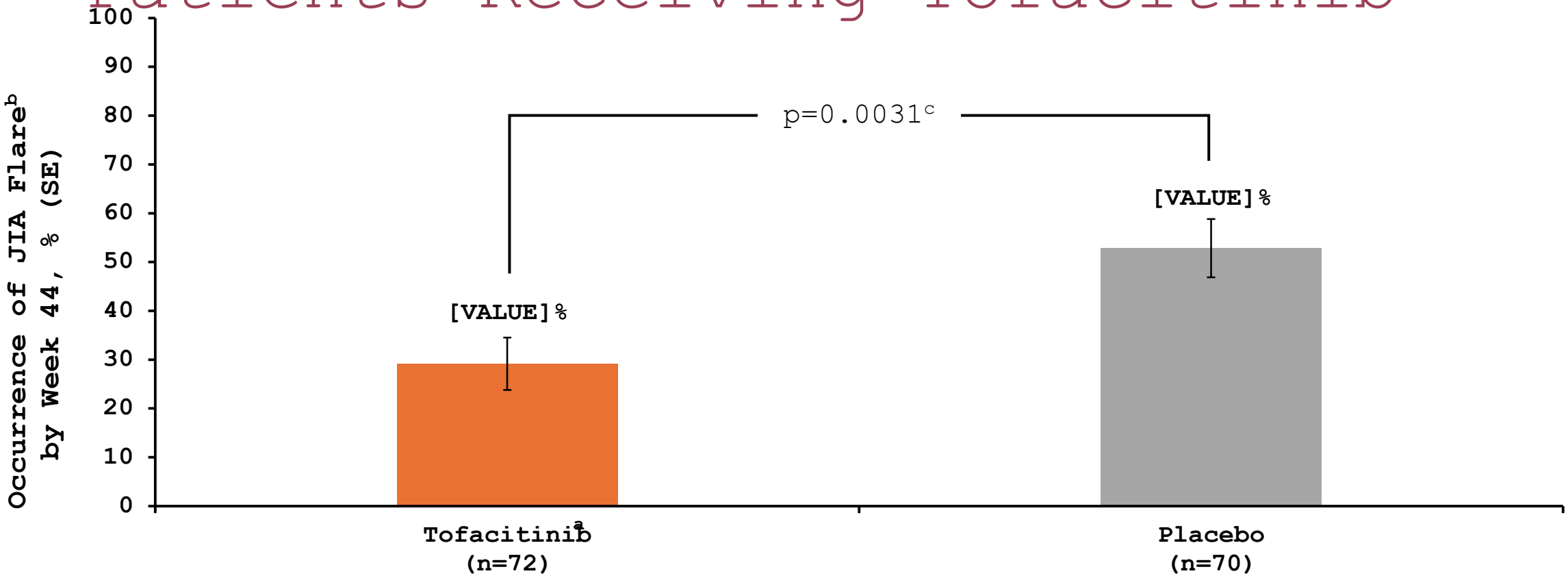
Χωρίς διαρροϊκές κενώσεις

Χωρίς οσφυαλγία

Τροχαντηρίτιδα ετερόπλευρη

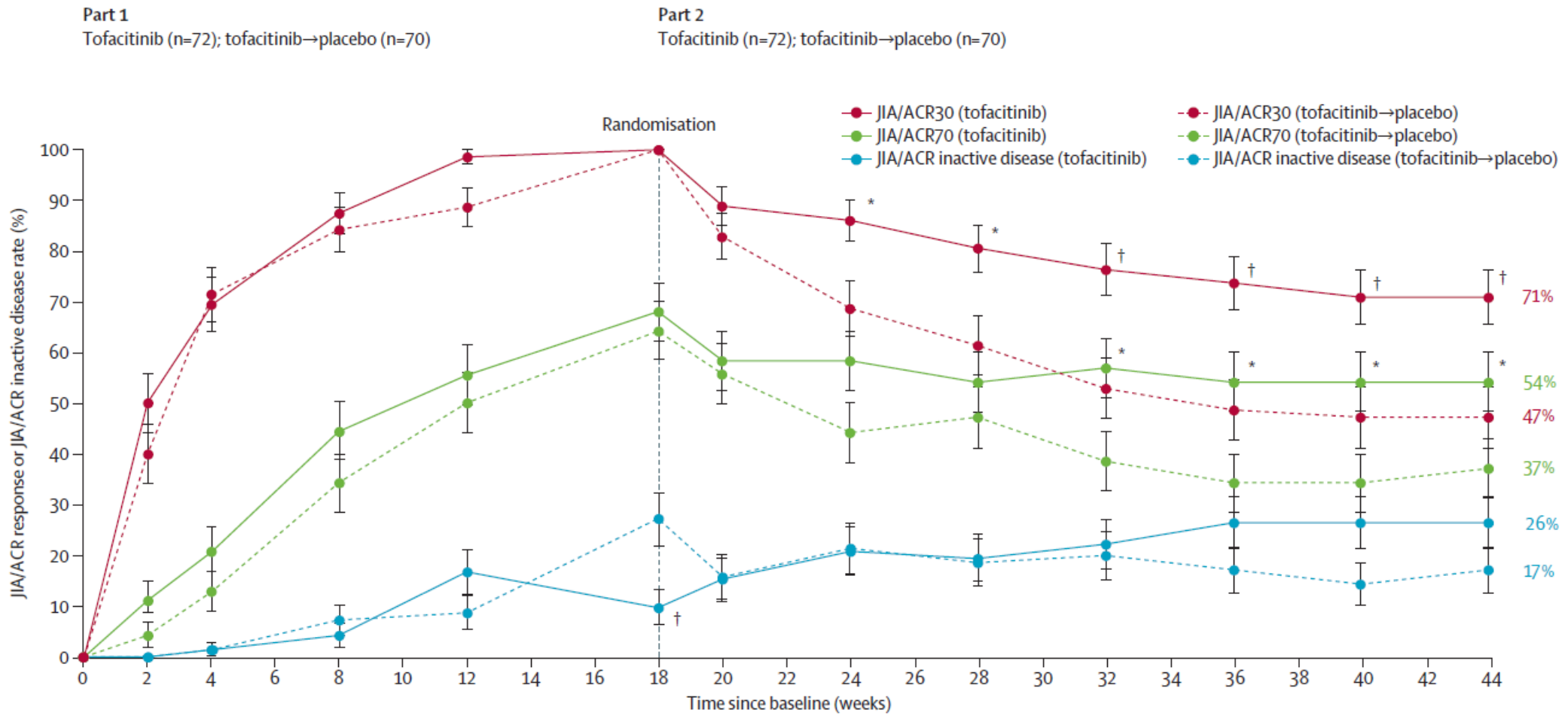
«Πραγματικό προφίλ ασθενή από προσωπικό αρχείο»

Occurrence of JIA Flare in Double-blind Phase was Lower in Patients Receiving Tofacitinib



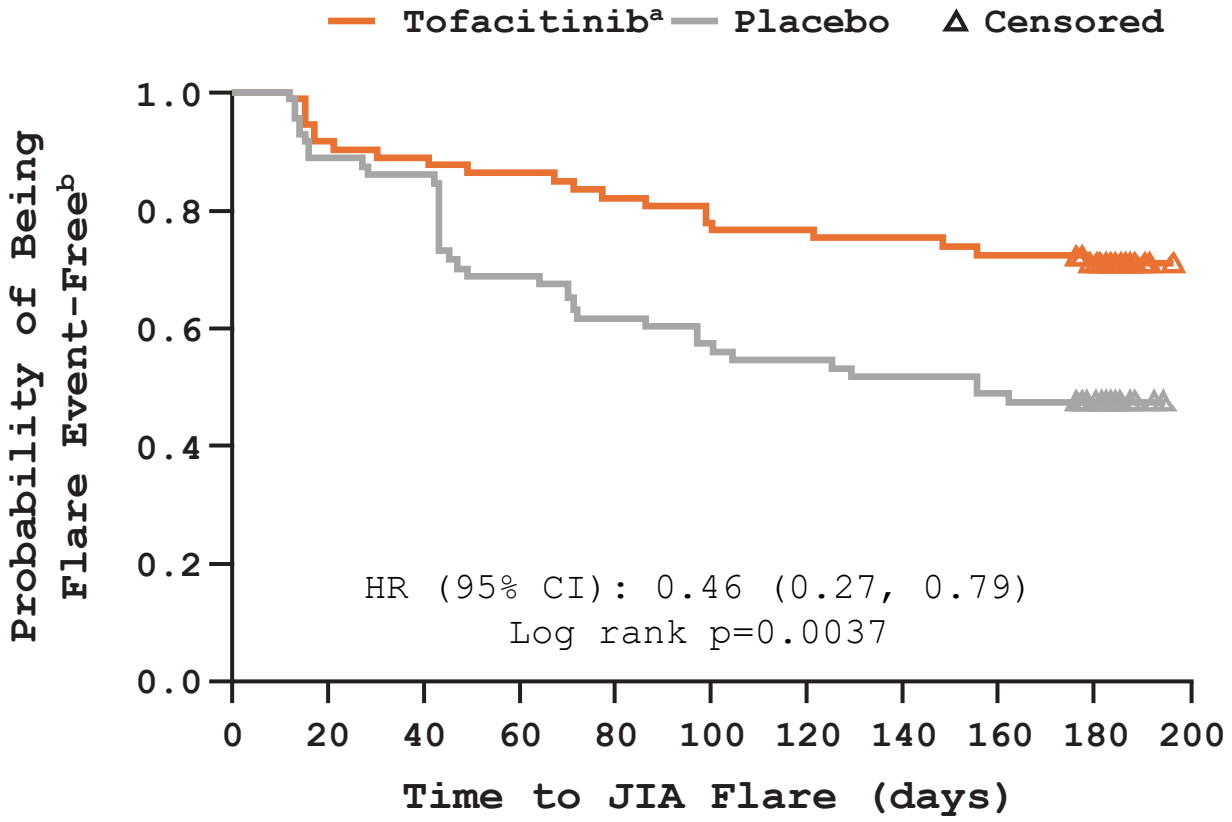
a. Tofacitinib 5 mg BID or equivalent weight-based lower dose in patients <40 kg.
b. Flare is defined as a worsening of ≥30% in ≥3 out of 6 JIA core set variables, with ≤1 variable improving by ≥30% (Brunner HI et al. *J Rheumatol* 2002; 29: 1058-1064).
c. Normal approximation approach for binomial proportions.
pcJIA, polyarticular course juvenile idiopathic arthritis; SE, standard error.
Ruperto N, et al. *Lancet.* 2021; 398(10315):1984-1996.

JIA/ACR30/70 Response Rates at Week 44 Were Higher With Tofacitinib vs Placebo



Error bars represent standard error. *p<0.05. †p<0.01.
ACR, American College of Rheumatology; JIA, juvenile idiopathic arthritis; pcJIA, polyarticular course juvenile idiopathic arthritis.
Ruperto N, et al. *Lancet*. 2021; 398(10315):1984-1996.

Time to Disease Flare in Double-blind Phase Was Greater With Tofacitinib vs Placebo (pcJIA)



Tofacitinib (N=72)
Events: 21
Median time to flare: cannot be calculated

Placebo (N=70)
Events: 37
Median time to flare (95% CI): 155 (86.0,-) days

a. Tofacitinib 5 mg BID or equivalent weight-based lower dose in patients <40 kg.
b. Flare is defined as a worsening of ≥30% in ≥3 out of 6 JIA core set variables, with ≤1 variable improving by ≥30% (Brunner HI et al. J Rheumatol 2002; 29: 1058-1064).
CI, confidence interval; HR, hazard ratio; pcJIA, polyarticular course juvenile idiopathic arthritis; SE, standard error.
Ruperto N, et al. *Lancet*. 2021; 398(10315):1984-1996.

Adverse Events (pcJIA/jPsA/ERA)

Patients with events, n (%)	Open-label (0-18 weeks)	Double-blind (18-44 weeks)	
	Tofacitinib [a] N=225	Tofacitinib [a] N=88	Placebo N=85
AEs	153 (68.0)	68 (77.3)	63 (74.1)
Serious AEs	7 (3.1)	1 (1.1)	2 (2.4)
Permanent discontinuations due to AEs	26 (11.6)	16 (18.2)	29 (34.1)
Temporary dose reductions or temporary hold due to AEs	20 (8.9)	9 (10.2)	8 (9.4)
Most common AEs by preferred term (≥10% of any treatment group)			
Upper respiratory tract infection	24 (10.7)	13 (14.8)	9 (10.6)
Disease progression	5 (2.2)	8 (9.1)	13 (15.3)
JIA exacerbation	6 (2.7)	3 (3.4)	12 (14.1)

a. Tofacitinib 5 mg BID or equivalent weight-based lower dose in patients <40 kg.
AE, adverse event; ERA, enthesitis-related arthritis; jPsA, juvenile psoriatic arthritis; pcJIA, polyarticular course juvenile idiopathic arthritis.
Ruperto N, et al. *Lancet*. 2021; 398(10315):1984-1996.

AEs of Special Interest (pcJIA/jPsA/ERA)

Patients with events, n (%)	Open-label (Weeks 0-18) Tofacitinib[a] N=225	Double-blind (Weeks 18-44) Tofacitinib[a] N=88	Double-blind (Weeks 18-44) Placebo N=85
Death	0	0	0
Gastrointestinal perforation[b]	0	0	0
Hepatic events[b]	3 (1.3)	0	0
Herpes zoster[b,c]	2 (0.9)	0	0
Interstitial lung disease[b]	0	0	0
Major adverse cardiovascular events[b]	0	0	0
Malignancy (excluding NMSC)[b]	0	0	0
Macrophage activation syndrome[b]	0	0	0
Opportunistic infections[b]	0	0	0
Serious infections	3 (1.3)	1 (1.1) [d]	1 (1.2)
Thrombotic events (DVT, PE,[b] or ATE)	0	0	0
Tuberculosis[b]	0	0	0

a. Tofacitinib 5 mg BID or equivalent weight-based lower dose in patients <40 kg. b. Adjudicated events. c. Both mild and monodermatomal, and neither met opportunistic infection criteria. d. One serious AE of pilonidal cyst repair was coded to surgical procedures instead of infections and was inadvertently not identified as a serious infection. Following adjudication, it was determined that the serious AE did not meet opportunistic infection criteria; it is included in the table as a serious infection.
AE, adverse event; ATE, arterial thromboembolism; DVT, deep vein thrombosis; NMSC, non-melanoma skin cancer; PE, pulmonary embolism.
Ruperto N, et al. [Abstract: OP0291]. *Ann Rheum Dis* 2020; 79(S1): 180-181.

Adverse Events-Long Term-48w (pcJIA/jPsA/ERA)

Paediatric rheumatology

CLINICAL SCIENCE

Safety and efficacy of tofacitinib for the treatment of patients with juvenile idiopathic arthritis: preliminary results of an open-label long-term extension study

Hermine I Brunner ,[1] Jonathan D Akikusa,[2] Eslam Al-Abadi ,[3] John F Bohnsack,[4] Alina Lucica Boteanu,[5] Gaelle Chedeville,[6] Ruben Cuttica,[7] Wendy De La Pena,[8] Lawrence Jung,[9] Ozgur Kasapcopur,[10] Katarzyna Kobusinska,[11] Grant S Schulert ,[1] Claudia Neiva,[12] Rafael Rivas-Chacon,[13] Juan Cruz Rizo Rodriguez,[14] Monica Vazquez-Del Mercado ,[15] Linda Wagner-Weiner,[16] Jennifer E Weiss,[17] Carine Wouters,[18] Holly Posner,[19] Ann Wouters,[19] Cheng Chang,[20] Claire White,[21] Keith Kanik,[20] Shixue Liu,[22] Alberto Martini,[23] Daniel J Lovell ,[1] Nicolino Ruperto ,[24] the Paediatric Rheumatology International Trials Organisation (PRINTO) and Pediatric Rheumatology Collaborative Study Group (PRCSG)

Table 2 Summary of safety during the LTE study in the overall cohort treated with tofacitinib

	Overall cohort (N=225)*
Patients with AEs, n (%)	201 (89.3)
Total number of AEs	1213
Patients with SAEs, n (%)	34 (15.1)
Total number of SAEs	39†
Patients who permanently discontinued due to AEs, n (%)	29 (12.9)
Patients who temporarily discontinued or had dose reduced due to AEs, n (%)	83 (36.9)
Most common AEs (≥5% by MedDRA Preferred Term), n (%)	
Upper respiratory tract infection	48 (21.3)
JIA exacerbation	28 (12.4)
Nasopharyngitis	27 (12.0)
Arthralgia	22 (9.8)
Viral infection	22 (9.80)
Urinary tract infection	21 (9.3)
Headache	20 (8.9)
Fever	20 (8.9)
Cough	19 (8.4)
Vomiting	19 (8.4)
Abdominal pain	19 (8.4)
Sinusitis	17 (7.6)
Influenza	17 (7.6)
SARS-CoV-2 test positive	16 (7.1)
COVID-19	15 (6.7)
Oropharyngeal pain	15 (6.7)
Arthritis	14 (6.2)
Nausea	14 (6.2)
Disease progression	13 (5.8)
Pharyngitis	13 (5.8)
Bronchitis	12 (5.3)
Ear infection	12 (5.3)
AEs of special interest, n (%); IR‡ (95% CI)	
Deaths	0; 0.00 (0.00 to 0.53)
Active uveitis§	2 (0.9); —
Serious infections	10 (4.4); 1.44 (0.69 to 2.65)
Renal events	8 (3.6); 1.16 (0.50 to 2.29)
Herpes zoster (non-serious and serious)¶	4 (1.8); 0.58 (0.16 to 1.47)
Adjudicated opportunistic infections (excluding tuberculosis)**	2 (0.9); 0.29 (0.04 to 1.03)
Adjudicated tuberculosis	0; 0.00 (0.00 to 0.53)
Adjudicated gastrointestinal perforation	0; 0.00 (0.00 to 0.53)
Adjudicated hepatic events	0; 0.00 (0.00 to 0.53)
Adjudicated MAS††	0; 0.00 (0.00 to 15.72)
Adjudicated interstitial lung disease	0; 0.00 (0.00 to 0.53)
Adjudicated malignancies (excluding NMSC)	0; 0.00 (0.00 to 0.53)
Adjudicated NMSC	0; 0.00 (0.00 to 0.53)
Adjudicated MACE	0; 0.00 (0.00 to 0.53)
Adjudicated DVT	0; 0.00 (0.00 to 0.53)
Adjudicated PE	0; 0.00 (0.00 to 0.53)
ATE	0; 0.00 (0.00 to 0.53)
Laboratory test abnormalities, n (%)‡‡	
Haemoglobin <0.8× LLN	9 (4.0)
Lymphocytes	
<0.8× LLN	23 (10.2)
≥1.2× ULN	3 (1.3)
AST >3.0× ULN	0
ALT >3.0× ULN	6 (2.7)
Cholesterol >1.3× ULN‡‡	5 (2.3)
Creatine kinase >2.0× ULN	28 (12.4)

The safety analysis set included all patients with pcJIA, jPsA or ERA.
Safety assessments were reported from LTE baseline through to data cut-off. AEs and SAEs were assessed up to 365 days after the last dose of tofacitinib. Laboratory abnormalities were recorded up until the patient stopped treatment or the lag time expired.
*Mean total duration of tofacitinib treatment (median; range) was 36.7 (41.6; 1–103) months.
†By MedDRA System Organ Class, these were: gastrointestinal disorders (n=4); general disorders and administration site conditions (n=3); hepatobiliary disorders (n=2); infections and infestations (n=10); injury, poisoning and procedural complications (n=1); musculoskeletal and connective tissue disorders (n=5); nervous system disorders (n=2); pregnancy, puerperium and perinatal conditions (n=2); psychiatric disorders (n=8); renal and urinary disorders (n=1); reproductive system and breast disorders (n=1); and skin and subcutaneous tissue disorders (n=1).
‡Number of patients with first event per 100 patient-years. For IRs, only patients with events during the risk period were included in the numerator. The risk period extended from the patient's first dose of tofacitinib until the date of last dose of tofacitinib plus 28 days, last contact date or data cut-off, whichever occurred first.
§One patient had active uveitis at month 12; one patient had uveitis at month 27.
¶Three patients with serious cases and one patient with a non-serious case.
**Two serious cases of herpes zoster were adjudicated as opportunistic infections.
††Applicable to patients with sJIA without active systemic features only (N=11).
‡‡Cholesterol was evaluated in 221 patients.
AEs, adverse events; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ATE, arterial thromboembolism; DVT, deep vein thrombosis; ERA, enthesitis-related arthritis; IR, incidence rate (patients with events per 100 patient-years); JIA, juvenile idiopathic arthritis; jPsA, juvenile psoriatic arthritis; LLN, lower limit of normal; LTE, long-term extension; MACE, major adverse cardiovascular event(s); MAS, macrophage activation syndrome; MedDRA, Medical Dictionary for Regulatory Activities; n, number of patients with events; N, number of patients evaluated; NMSC, non-melanoma skin cancer; pcJIA, polyarticular course juvenile idiopathic arthritis; PE, pulmonary embolism; SAEs, serious adverse events; sJIA, systemic juvenile idiopathic arthritis; ULN, upper limit of normal.

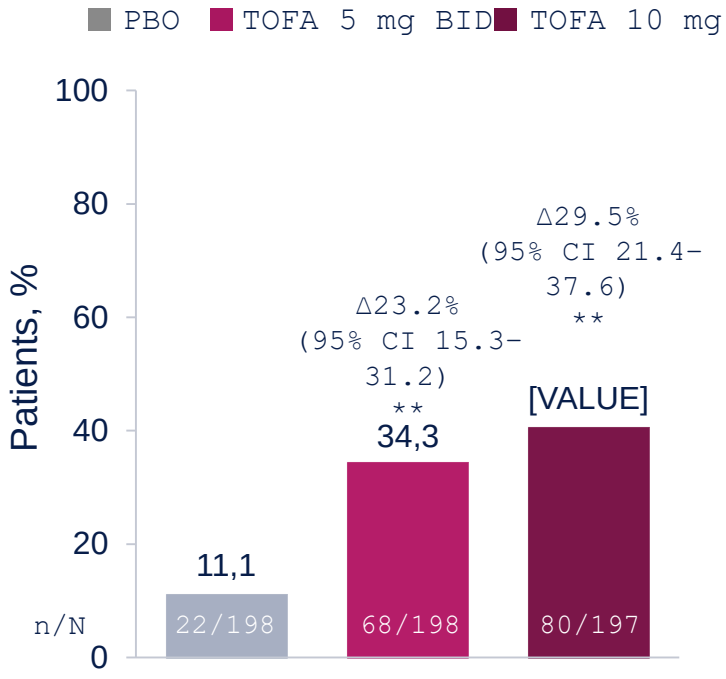
Safety and efficacy of tofacitinib for the treatment of patients with juvenile idiopathic arthritis: preliminary results of an open-label, long-term extension study, (Brunner HI et al. An n Rheum Dis ;2024 ;0:1-11)

Tofacitinib στην Ελκώδη Κολίτιδα
Κλινική ύφεση και βελτίωση συμπτωμάτων

OCTAVE Sustain[†2]

Primary endpoint: Week 52

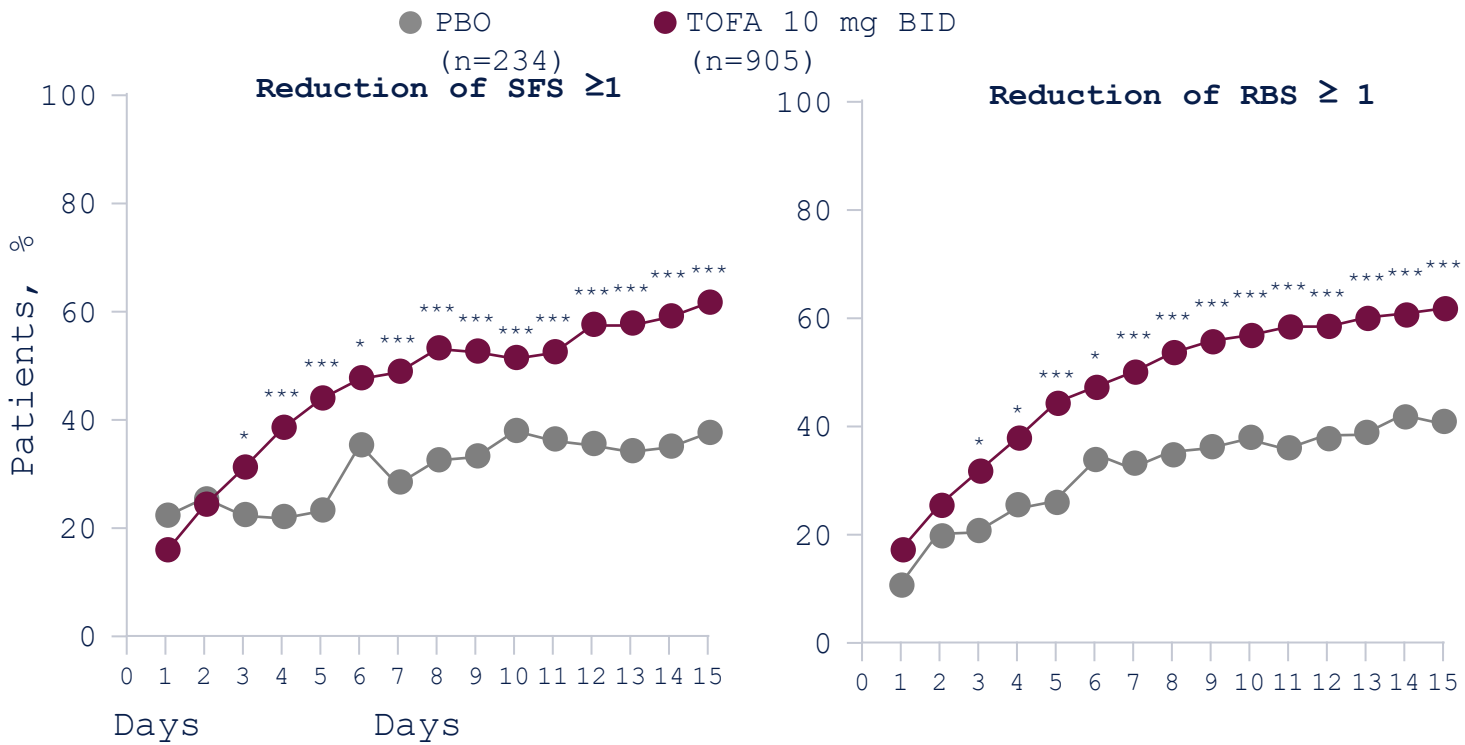
Clinical remission per full Mayo Clinic Score



OCTAVE I and II[1]

***Post-hoc* analysis**

Symptomatic improvement of SFS and RBS scores over first 15 days of therapy



Symptomatic improvement: Reduction from baseline Mayo SFS of ≥1 or RBS ≥1.

Clinical remission: Total Mayo Clinic Score ≤2 with no individual subscore >1 and RBS of 0.

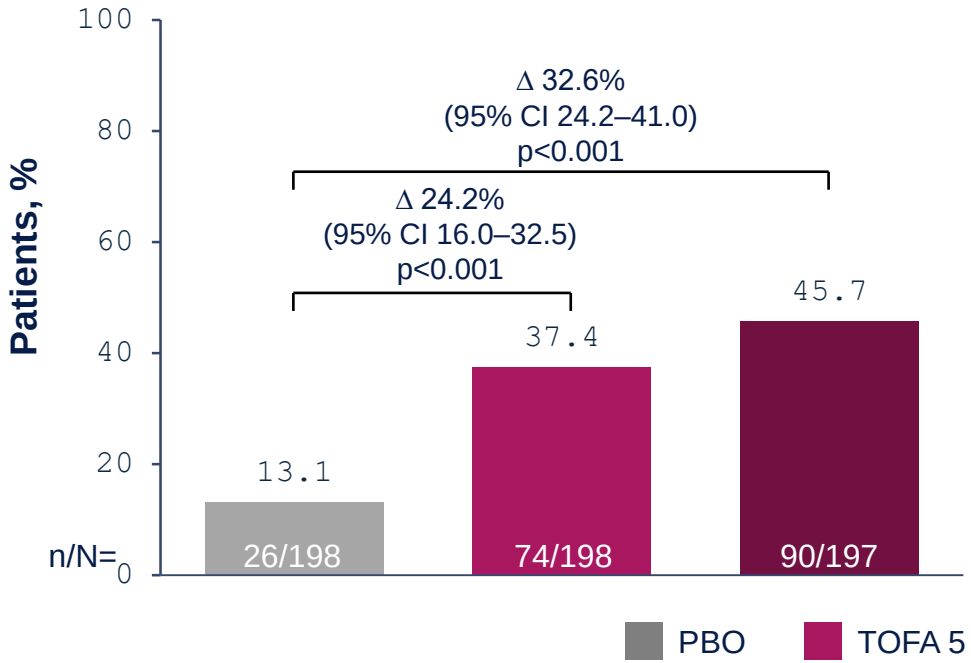
*p≤0.01, **p<0.001 and ***p≤0.0001 vs PBO.

BID, twice daily; CI, confidence interval; JAKi, Janus kinase inhibitor; PBO, placebo; RBS, rectal bleeding score; SFS, stool frequency score; TOFA, tofacitinib.

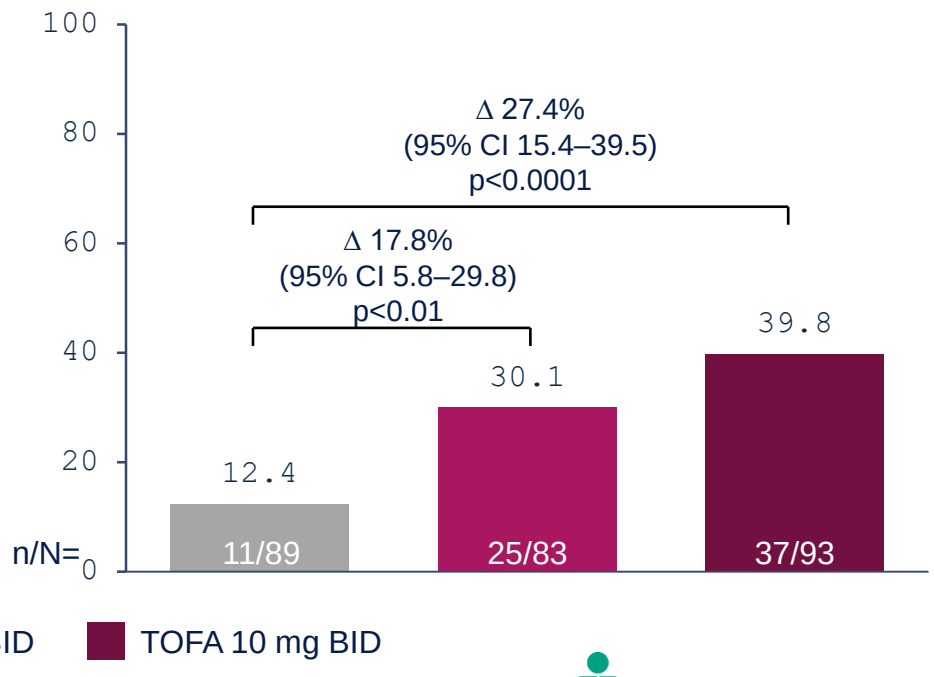
Hanauer S, et al. *Clin Gastroenterol Hepatol*. 2019;17:139–47; 2. Sandborn W, et al. *N Engl J Med*. 2017;376:1723–36.

Tofacitinib στην Ελκώδη Κολίτιδα
Ενδοσκοπική ανταπόκριση

Endoscopic improvement†‡[1]
Key secondary endpoint: Week 52
Overall patient population



Endoscopic improvement†‡[2]
Secondary endpoint: Week 52
Patients with prior anti-TNF failure



PBO TOFA 5 mg BID TOFA 10 mg BID

Endoscopic improvement†: MES ≤1.

1. Sandborn WJ, et al. *N Engl J Med*. 2017;376:1723–36; 2. Sandborn WJ, et al. *Clin Gastroenterol Hepatol*. 2022;20:591–601.
†Termed mucosal healing in the original OCTAVE protocols.[2] ‡MES ≤1.
BID, twice daily; CI, confidence interval; MES, Mayo Endoscopic Subscore; PBO, placebo; TNF, tumor necrosis factor; TOFA, tofacitinib.

Systematic review and meta-analysis of real-world UC studies

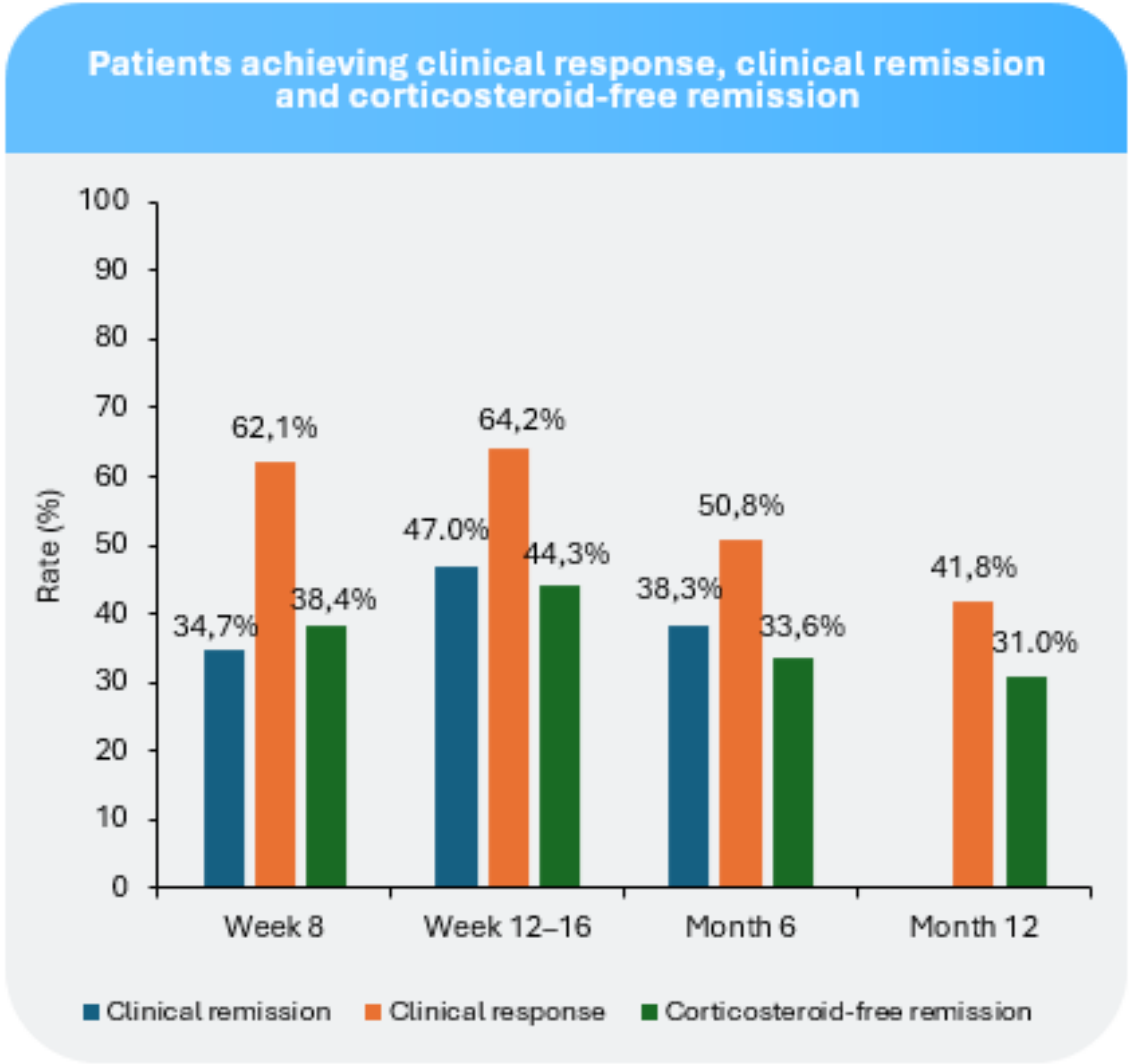
Tofa
N=1162

- 1162 ασθενείς με ΕΚ που έλαβαν tofacitinib

- 14 μελέτες ανέφεραν κλινική ανταπόκριση (n=797)
  - Week 8 - ανταπόκριση **62.1%** (95% CI: 55.0–69.1)
  - 1 έτος – ανταπόκριση **41.8%** (95% CI: 31.8–51.8)

- 11 μελέτες ανέφεραν κλινική ύφεση (n=755)
  - Week 8 – Ύφεση **34.7%** (95% CI: 24.4–45.1),
  - Week 12 - **47.0%** (95% CI: 40.3–53.6)
  - 6 μήνες - **38.3%** (95% CI: 29.2–47.5)

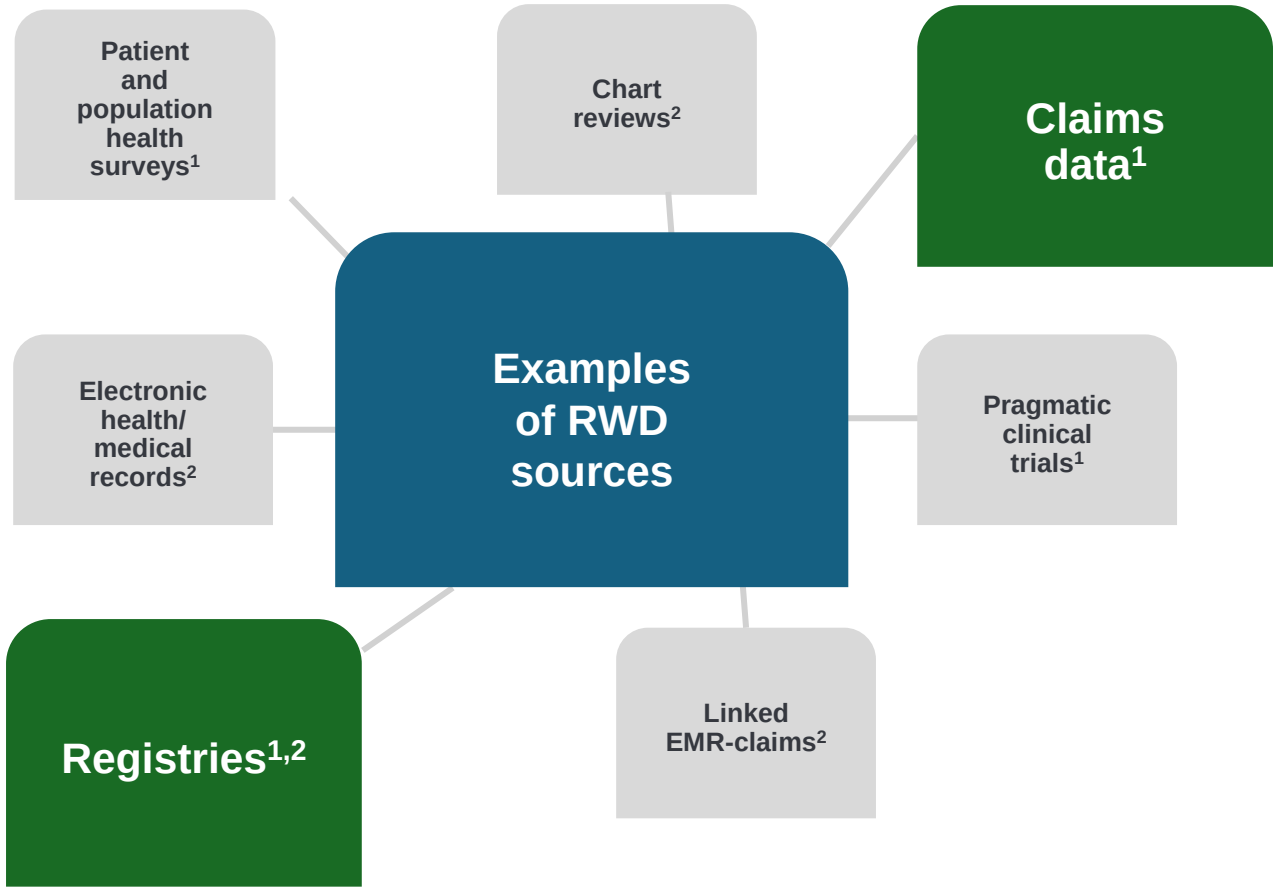
- Corticosteroid-free remission (n=301) **33.6%** στους 6 μήνες (95% CI: 24.5 – 42.7)



Taxonera C, et al. Inflamm Bowel Dis 2022;28(1):32–40.
Study independently funded.

Real World Data (RWD)

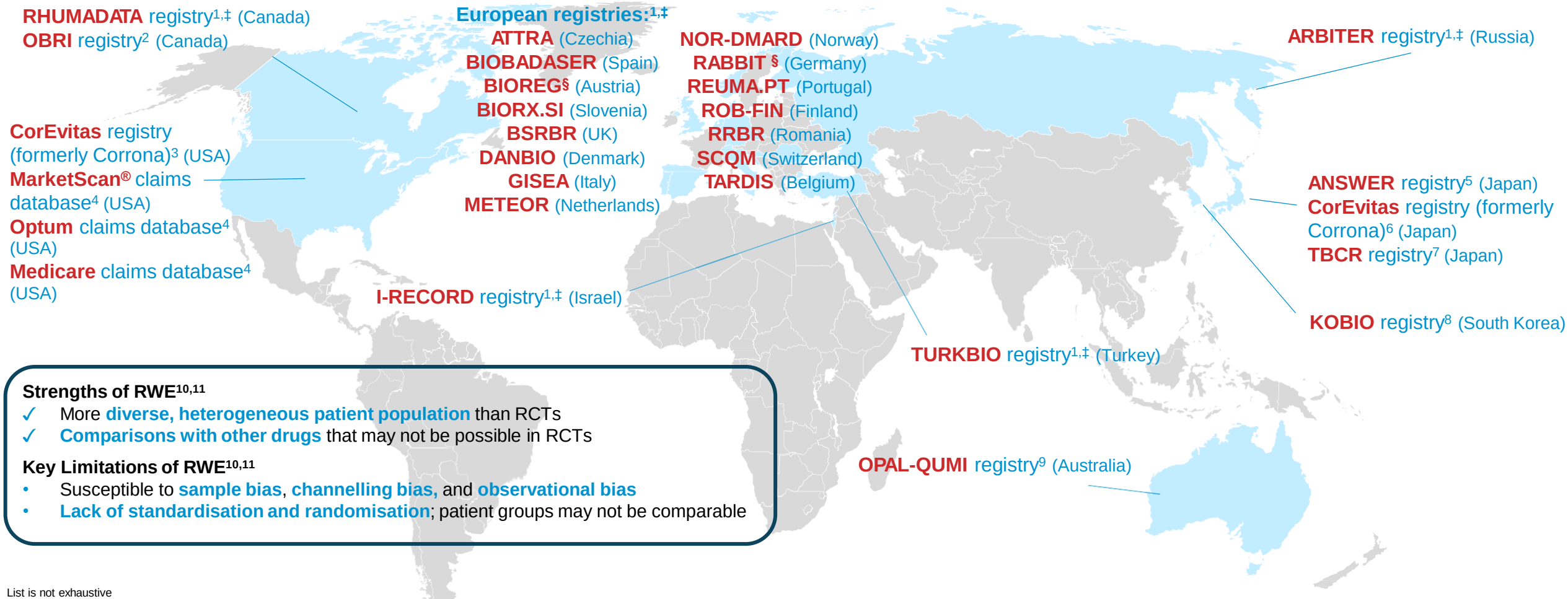
- Μπορούμε να τα «εξάγουμε» από δεδομένα της καθημερινής κλινικής πρακτικής
- Συλλέγονται εύκολα και με συστηματικό τρόπο καθώς οι βάσεις δεδομένων είναι ηλεκτρονικές
- Αντιπροσωπεύουν την εφαρμογή των θεραπειών στον «πραγματικό κόσμο» ασθενών και ιατρών



EMR, electronic medical record; HCP, healthcare professional; RCT, randomized controlled trial; RWD, real-world data.

1. Katkade VB, et al. J Multidiscip Healthc. 2018;11:295-304.
2. Curtis MD, et al. Health Serv Res. 2018;53:4460-4476.

JAKis and Real-World Evidence (RWE)



Strengths of RWE[10,11]

- ✓ More **diverse, heterogeneous patient population** than RCTs
- ✓ **Comparisons with other drugs** that may not be possible in RCTs

Key Limitations of RWE[10,11]

- Susceptible to **sample bias**, **channelling bias,** and **observational bias**
- **Lack of standardisation and randomisation**; patient groups may not be comparable

List is not exhaustive

‡Part of the JAK-POT international collaboration of registries. §Registries planning to participate in future studies but not included yet.

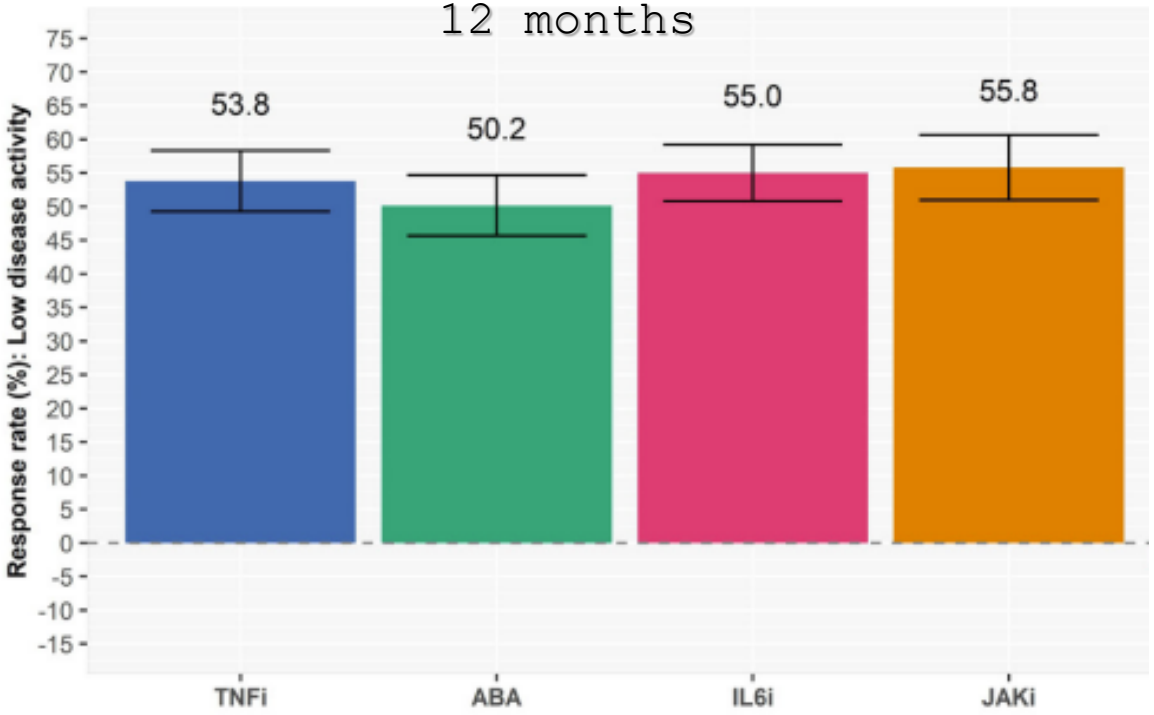
ATTRA=Appropriate Technology Transfer for Rural Areas; BIOREG=Biologica Register; BSRBR=British Society for Rheumatology Biologics Register for Rheumatoid Arthritis; Corrona=Consortium of Rheumatology Researchers of North America, Inc; DANBIO=Danish National Patient Registry; GISEA=Gruppo Italiano Studio Early Arthritis; JAK=Janus kinase; METEOR=Measurement of Efficacy of Treatment in the 'Era of Outcome' in Rheumatology; NOR-DMARD=The Norwegian Antirheumatic Drug Register; OBRI=Ontario Best Practices Research Initiative; OPAL=Oral Psoriatic Arthritis Trial; QUMI=Quality Use of Medicines Initiative; RA=rheumatoid arthritis; RABBIT=Rheumatoid Arthritis– Observation of Biologic Therapy; REUMA.PT=Rheumatic Diseases Portuguese Register; ROB-FIN=Finnish Register of Biological Treatment; RRBR=Romanian Registry of Rheumatic Diseases; RWE=real-world evidence; SCQM=Swiss Clinical Quality Management.

1. Lauper K, et al. [abstract]. Presented at: Annual Meeting of the European League Against Rheumatism. Virtual Congress, June, 2020. **2.** Movahedi M, et al. Presented at: Annual Meeting of the European League Against Rheumatism. Virtual Congress, June, 2020. **3.** Kremer JM, et al. *ACR Open Rheumatol*. 2021;3(3):173-184. **4.** Desai RJ, et al. *Rheumatology (Oxford)*. 2021; doi:10.1093/rheumatology/keab294. **5.** Ebina K, et al. *Clin Rheumatol*. 2021; doi:10.1007/s10067-021-05609-7. **6.** Tanaka Y, et al. [abstract] Presented at: Annual Meeting of the American College of Rheumatology. Virtual Congress, November, 2020. **7.** Takahashi N, et al. *Sci Rep* 2020;10:21907. **8.** Min HK, et al. *Clin Rheumatol*. 2021; doi: 10.21203/rs.3.rs-32790/v1. **9.** Bird P, et al. *Clin Rheumatol*. 2020;39(9):2545-2551. **10.** Katkade VB, et al. *J Multidiscip Healthc.* 2018;11:295-304. **11.** Camm AJ, et al. *Open Heart.* 2018;5(1):e000788. Full references for this slide available at the end of the presentation. References available on request.

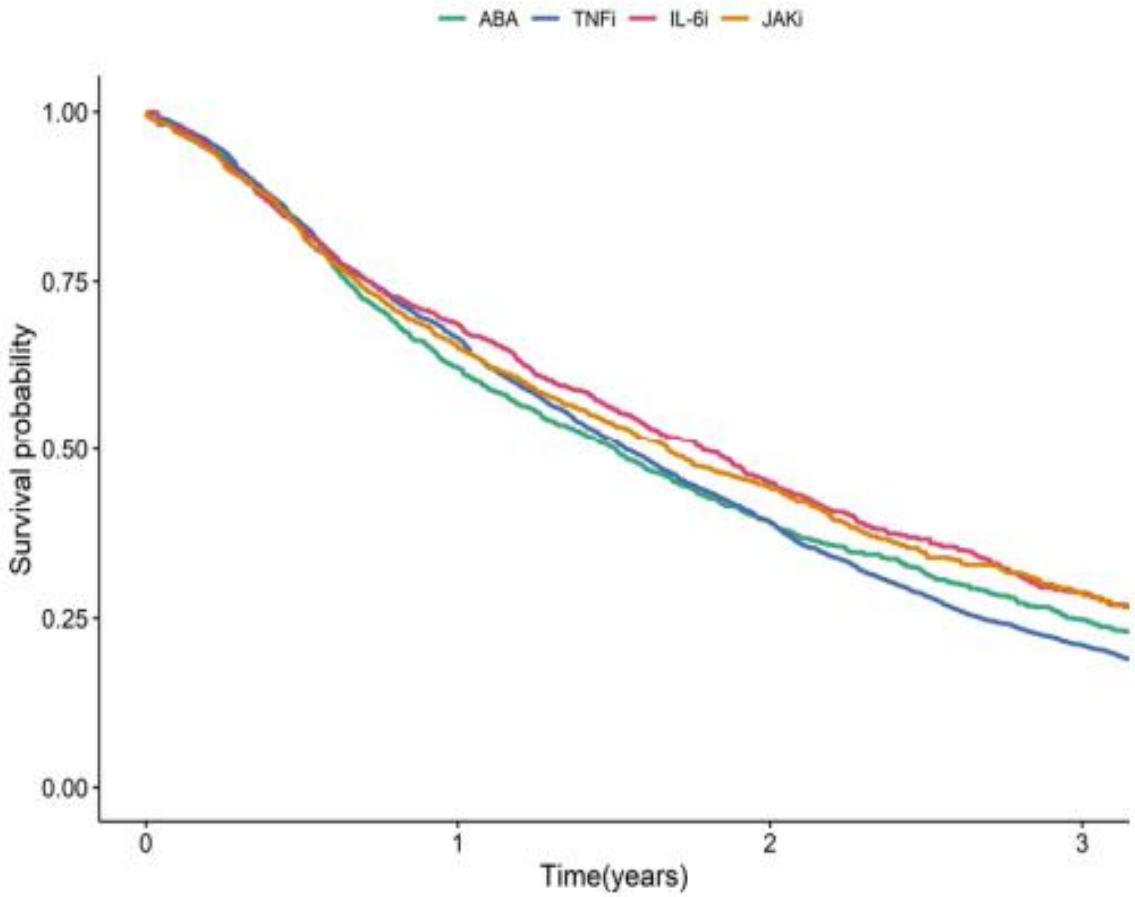
JAK-POT collaboration: efficacy and drug survival in RWE

n=31,846 treatment courses
Real world data from registries of 19 countries

Adjusted CDAI low disease activity at 12 months



Drug survival

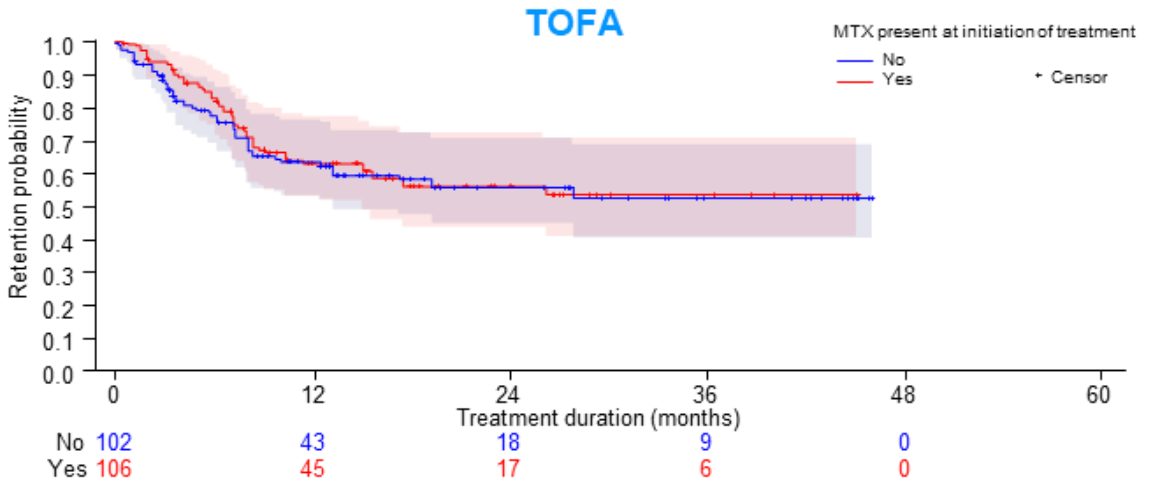


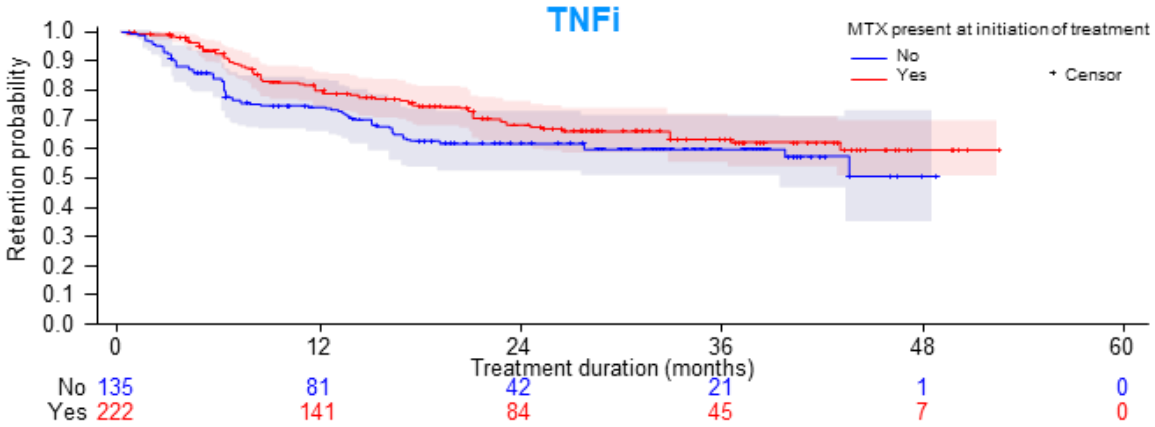
Lauper K et al. Ann Rheum Dis 2022;81:1358-1366

Tofacitinib monotherapy vs combination therapy

Tofacitinib Retention With and Without MTX
Data from the OBRI registry

Propensity score weighted KM survival curves for time to discontinuation of tofacitinib or TNFi with MTX and without MTX[1]





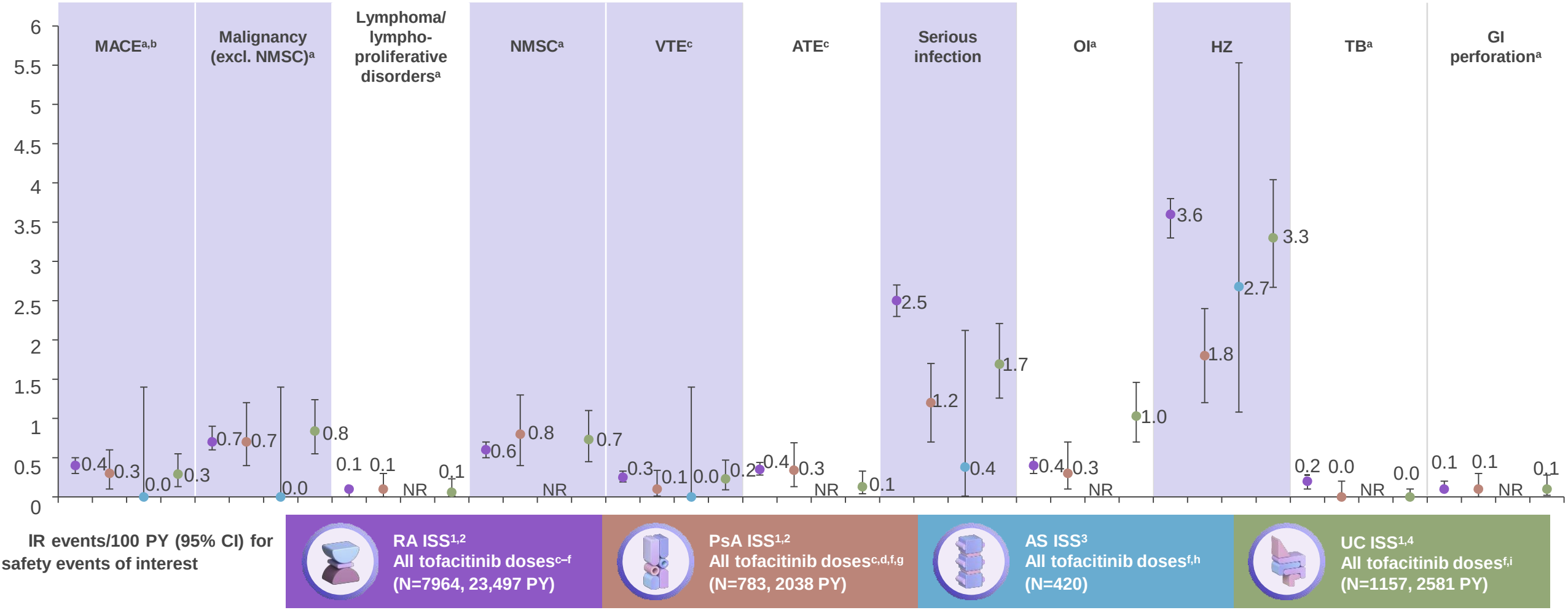
Tofa n=208[1]

Retention on tofacitinib therapy is similar with or without csDMARDs

CDAI, Clinical Disease Activity Index; JAKi, Janus Kinase inhibitor; KM, Kaplan-Meier; MTX, methotrexate; OBRI, Ontario Best Practices Research Initiative; csDMARDs; conventional synthetic disease modifying antirheumatic drugs, TNFi, tumour necrosis factor inhibitor.

1. Movahedi M, et al. BMJ Open 2023;13:e063198. doi:10.1136/bmjopen-2022-063198.

AESIs in the tofacitinib clinical trial programmes in RA, PsA, AS, and UC[1–4]



The approved dose of XELJANZ (tofacitinib citrate) for RA, AS, and PsA is 5 mg BID, and for UC is 10 mg BID for induction and 5 mg BID for maintenance.[5] Figure adapted from Burmester GR, et al. 2021,[1] Mease P, et al. 2020,[2] Deodhar A, et al. 2022,[3] and Sandborn WJ, et al. 2023.[4]
[a]Adjudicated events.[1,4] [b]MACE is defined as a composite of any myocardial infarction, stroke, or cardiovascular death.[1,3] [c]Drug exposures for RA and PsA were VTE: 24064.6 PY and 2098.4 PY, and ATE: 23957.1 PY and 2086.4 PY, respectively.[2] [d]Final data for the RA and PsA cohorts are from 18 April 2019 and 31 July 2019, respectively.[1,4] AESI, adverse event of special interest; AS, ankylosing spondylitis; ATE, arterial thromboembolism; BID, twice daily; CI, confidence interval; GI, gastrointestinal; HZ, herpes zoster; ISS, integrated safety summary; LTE, long-term extension; MACE, major adverse cardiovascular event;
MR, modified release; NMSC, nonmelanoma skin cancer; NR, not reported; OI, opportunistic infections; OLE, open-label extension; PsA, psoriatic arthritis; PY, patient-years; QD, once daily; RA, rheumatoid arthritis; TB, tuberculosis; UC, ulcerative colitis; VTE, venous thromboembolism.

1. Burmester GR, et al. *RMD Open*. 2021;7:e001595. 2. Mease P, et al. *Ann Rheum Dis*. 2020;79:1400–1413. 3. Deodhar A, et al. *Ann Rheum Dis*. 2022;81(S1):394–395. 4. Sandborn WJ, et al. *J Crohns Colitis*. 2023;17:338–351 and supplementary appendix.

5. XELJANZ TOFACITINIB SmPC 3/2025.

Το XELJANZ διατίθεται σε 4 από στόματος χορηγούμενες μορφές στις ενδείξεις του[1]

Δισκία	Δισκίο παρατεταμένης αποδέσμευσης	Πόσιμο διάλυμα
 5 mg  10 mg	 11 mg	 Δοσολογία με βάση το σωματικό βάρος

Μη πραγματικό μέγεθος.

Εγκεκριμένες μορφές και δοσολογίες ανά ένδειξη[1]

- **ΡΑ, ΨΑ και ΑΣ:** δισκία 5 mg και δισκία 11 mg παρατεταμένης αποδέσμευσης
- **ΝΙΑ:** δισκία 5 mg και πόσιμο διάλυμα
- **ΕΚ:** δισκία 5 mg και δισκία 10 mg

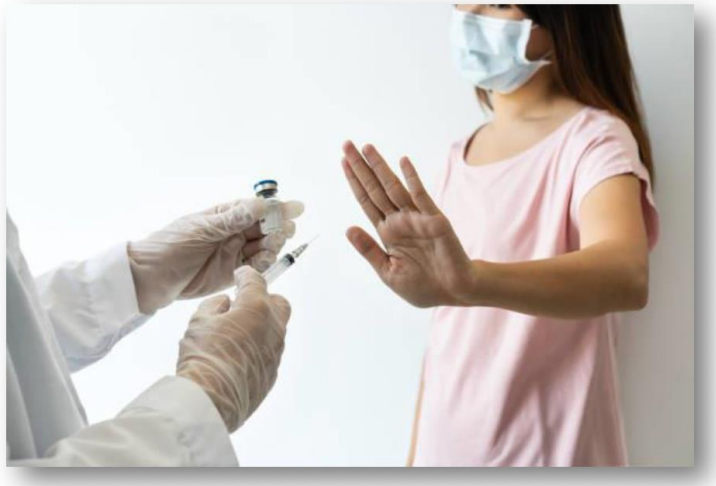
Για το πλήρες κείμενο των ενδείξεων, της δοσολογίας και του τρόπου χορήγησης συμβουλευτείτε την Περίληψη Χαρακτηριστικών του Προϊόντος.

ΡΑ=ρευματοειδής αρθρίτιδα, ΨΑ=ψωριασική αρθρίτιδα, ΑΣ=αγκυλοποιητική σπονδυλίτιδα, ΝΙΑ=νεανική ιδιοπαθής αρθρίτιδα,, ΕΚ=ελκώδης κολίτιδα.

1.XELJANZ Περίληψη Χαρακτηριστικών του Προϊόντος, 03/2025.

Long story short

- ✓ Ευκολία & ευελιξία στη χρήση
- ✓ Μη απαραίτητη εκπαίδευση
- ✓ Συμμόρφωση;
- ✓ Συνήθως οι ασθενείς λαμβάνουν και άλλα χάπια…



Το tofacitinib

- Υψηλή αποτελεσματικότητα
- Αποτελεσματικό σε ασθενείς με προηγούμενη έκθεση σε βιολογικούς παράγοντες
- Έχει ταχεία δράση
- Είναι ασφαλές

Nash, P., et al. (2025). Expert consensus statement on the treatment of immune-mediated inflammatory diseases with Janus kinase inhibitors: 2024 update. Annals of the Rheumatic Diseases. doi.org/10.1016/j.ard.2025.01.032.

Aymon. et al. “Incidence of Major Adverse Cardiovascular Events in Patients with Rheumatoid Arthritis Treated with JAK Inhibitors Compared With Biologic Disease-Modifying Antirheumatic Drugs: Data From an International Collaboration of Registries.ARTHRITIS & RHEUMATOLOGY, vol. 77, No. 9, September 2025, pp 1194-1204. doi: 10.1002/art.43188

Ευχαριστώ...

OPEN ACCESS

CLINICAL SCIENCE

Tofacitinib for the treatment of ankylosing spondylitis: a phase III, randomised, double-blind, placebo-controlled study

Atul Deodhar [1], Paula Sliwinska-Stanczyk [2], Huji Xu [3], Xenofon Baraliakos [4], Lianne S Gensler [5], Dona Fleishaker [6], Lisy Wang [6], Joseph Wu [6], Sujatha Menon [6], Cunshan Wang [6], Oluwaseyi Dina [7], Lara Fallon [8], Keith S Kanik [6], Désirée van der Heijde [9]

Patients with events, n (%)	Up to Week 16 (double-blind phase)		Up to Week 48 (double-blind and open-label phases)	
	Tofacitinib 5 mg BID (N=133)	Placebo (N=136)	Tofacitinib 5 mg BID (N=133)	Placebo → Tofacitinib 5 mg BID (N=136)
IBD	0	0	0	0
Uveitis	1 (0.8)	3 (2.2)	2 (1.5)	4 (2.9)

- All patients who experienced uveitis had a history of uveitis
- All cases of uveitis were mild or moderate in severity; none were SAEs
- No patients discontinued study drug due to uveitis

Deodhar A, et al. Ann Rheum Dis 2021;80:1004–1013

Incidence of Uveitis in Patients With Axial Spondylarthritis Treated With Biologics or Targeted Synthetics: A Systematic Review and Network Meta-Analysis

Anti-TNF mAbs				
0.75 (0.18; 3.10)	Anti-IL17			
0.76 (0.10; 6.12)	1.01 (0.15; 6.86)	ETN		
1.01 (0.13; 7.56)	1.33 (0.21; 8.42)	1.32 (0.12; 14.31)	JAKi	
0.32 (0.10; 1.04)	0.43 (0.19; 0.98)	0.42 (0.08; 2.38)	0.32 (0.06; 1.67)	Placebo

44 trials included:

- 17 anti-TNF mAb (1,004 PEY),
- 9 etanercept (180 PEY),
- 13 anti–IL-17 (1,834 PEY), and
- 6 JAKi (331 PEY)

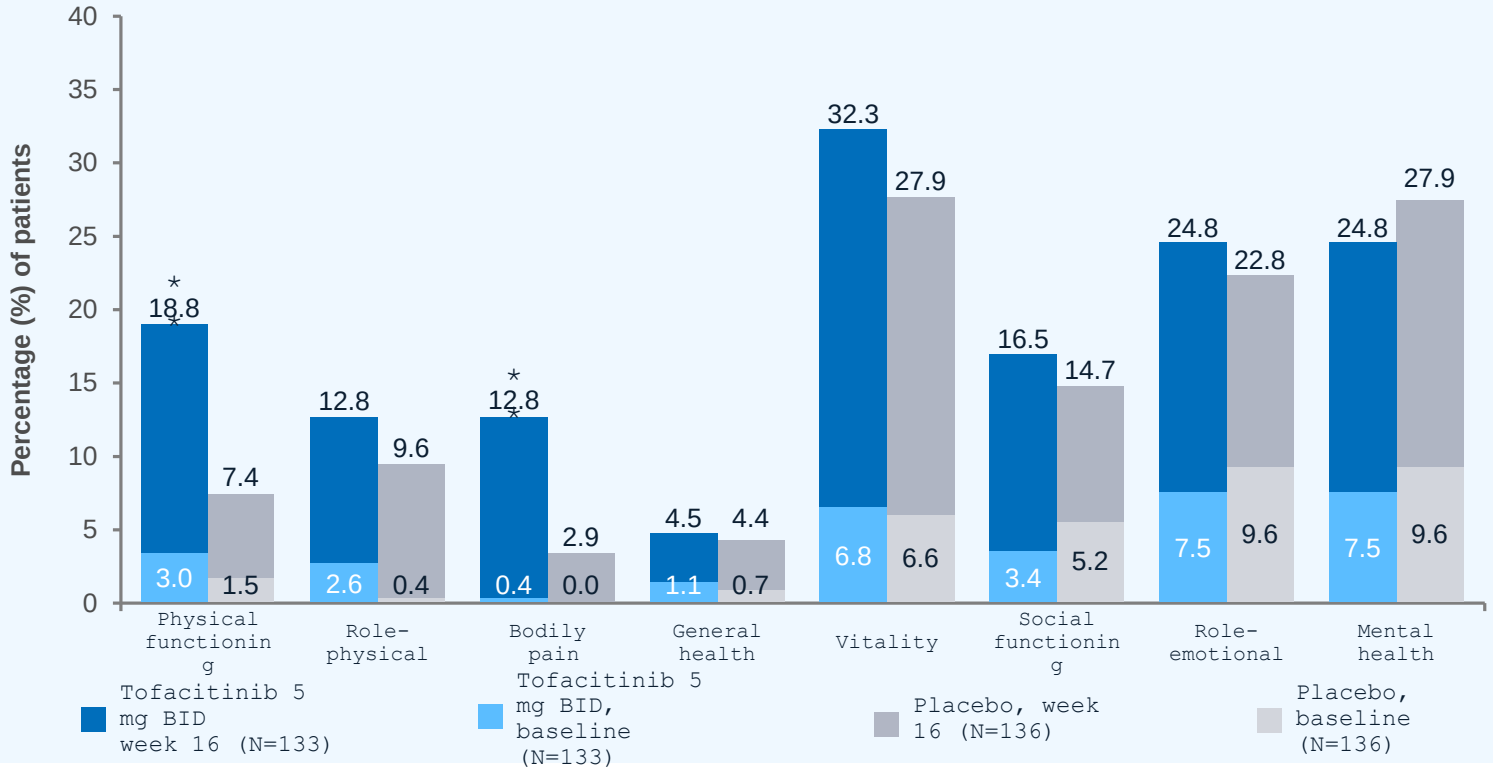
Uveitis incidence between TNFi , JAKi and IL-17i

Bechman K. et al., Arthritis & Rheumatology, Vol. 76, No. 5, May 2024, pp 704–714

PROs from Study 1120

HRQoL: SF-36v2 Domain Scores ≥Normative Values[1]

SF-36v2 Domain Scores



Normative Values

- **Physical functioning:** ≥88.23
- **Role-physical:** ≥87.96
- **Bodily pain:** ≥76.81
- **General health:** ≥73.00
- **Vitality:** ≥60.55
- **Social functioning:** ≥87.66
- **Role-emotional:** ≥91.04
- **Mental health:** ≥76.70

Domain-specific cutoffs were calculated as the study protocol's age- and sex-distributed means matched to the 1998 US population norms on the raw scale with a range of 0–100.
Data are from the week 16 analysis: data cut-off 19 December 2019; data snapshot 29 January 2020. Missing response was considered as non-response. *P* values are nominal.
***P*<0.01 for comparing tofacitinib 5 mg BID vs placebo at week 16; Cochran-Mantel-Haenszel approach adjusting for stratification factor (bDMARD-naïve vs TNFi-IR or bDMARD use [non-IR])

1. Navarro-Compán V, et al. *RMD Open*. 2022;8(2):e002253.