# SUPPLEMENTARY MATERIALS

## Inclusion criteria

Patients were eligible to be included in the study only if all of the following criteria applied:

1. Age ≥18 years at the time of signing informed consent.
2. Meets ACR/EULAR 2010 RA Classification Criteria with a duration of RA disease of ≥6 months at time of screening and participant not diagnosed before 16 years of age.
3. Must have active disease at both screening and baseline, as defined by having both:
    - ≥6/68 TJC
    - ≥6/66 SJC.

   If surgical treatment of a joint has been performed, that joint cannot be counted in the TJC or SJC for enrolment purposes.
4. Must have a hsCRP measurement ≥3 mg/L at screening.
5. Must meet Class I, II or III of the ACR 1991 Revised Criteria for Global Functional Status in RA.
6. Must have at least 1 bone erosion present on hand/wrist or foot radiographs confirmed by central reading at screening.
7. *ContRAst 1*: Must have inadequate response, despite currently taking MTX: weekly 15-25 mg oral or injected, for at least 12 weeks at the maximum tolerated dose prior to Day 1, with no change in route of administration in this time. MTX dose must be stable and tolerated for at least 8 weeks prior to Day 1. A lower dose of ≥7.5 mg/week is acceptable if reduced for reasons of intolerance to MTX, for example, nausea/vomiting, hepatic or haematologic toxicity, or per local requirement (there must be clear documentation in the medical record). Exception: A lower dose of 6 mg/week is allowed if the minimum locally approved or recommended dose is lower than 7.5 mg/week.

   *ContRAst 2*: Must have inadequate response, despite currently taking at least one and at most two concomitant csDMARDs for at least 12 weeks prior to Day 1, from the following:



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- MTX: weekly 15-25 mg oral or injected, for at least 12 weeks at the maximum tolerated dose prior to Day 1, with no change in route of administration in this time. A lower dose of ≥7.5 mg/week is acceptable if reduced for reasons of intolerance to MTX, for example, nausea/vomiting, hepatic or haematologic toxicity, or per local requirement (there must be clear documentation in the medical record). Exception: A lower dose of 6 mg/week is allowed if the minimum locally approved or recommended dose is lower than 7.5 mg/week.
- Hydroxychloroquine up to 400 mg/day or chloroquine up to 250 mg/day.
- Sulfasalazine up to 3000 mg/day.
- Leflunomide up to 20 mg/day. Note: concomitant use of leflunomide and MTX is not allowed, for safety reasons.
- Bucillamine up to 100 mg/day (or up to 300 mg/day if permitted per local requirements).
- Iguratimod up to 50 mg/day.

NOTE: The dose of csDMARD(s) must be stable and tolerated for at least 8 weeks prior to Day 1 and should remain stable throughout the study from screening to end of treatment period, except adjustment for safety reasons. In addition, patients with prior bDMARD exposure: Prior exposure to one or more bDMARDs is permitted. Prior bDMARD exposure may have been with or without combination with a csDMARD. Prior bDMARD therapy must be discontinued before randomisation per **Supplementary Table 2**.

8. Body weight ≥40 kg
9. Male or female patients are eligible to participate so long as they meet and agree to abide by the contraceptive criteria
10. Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form and in the protocol.
11. *ContRAst 1:* Willing to continue or initiate treatment with oral folic acid (at least 5 mg/week) or equivalent and be treated during the entire study (mandatory co-medication for MTX treatment).



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*ContRAst 2:* For patients on MTX: Must be willing to continue or initiate treatment with oral folic acid (at least 5 mg/week) or equivalent and be treated during the entire study (mandatory co-medication for MTX treatment).

**Exclusion criteria**

A participant will not be eligible for inclusion in this study if any of the following criteria apply:

1. Active infections (including localised infections), or history of recurrent infections (excluding recurrent fungal infections of the nail bed), or has required management of acute or chronic infections, as follows:
   - Currently taking any suppressive anti-infective therapy for a chronic infection (such as pneumocystis, cytomegalovirus, herpes simplex virus, herpes zoster and atypical mycobacteria) OR
   - Hospitalisation for treatment of infection within 26 weeks of Day 1 OR
   - Use of parenteral (intravenous) or intramuscular antimicrobials (antibacterials, antivirals, antifungals, or antiparasitic agents) within 26 weeks of Day 1 or oral antimicrobials (apart from isonicotinic acid hydrazide use for latent TB treatment) within 14 days of Day 1.
2. Symptomatic herpes zoster within 3 months prior to screening.
3. Hereditary or acquired immunodeficiency disorder, including immunoglobulin deficiency.
4. Known infection with human immunodeficiency virus or positive test at screening.
5. History of infected joint prosthesis at any time, with the prosthesis still in situ. History of chronic leg ulcers, permanent in-dwelling catheters, chronic sinusitis, recurrent chest infections or recurrent urinary tract infections.
6. Any baseline symptomatology that in the investigator's opinion would confound the early detection of PAP based upon clinical features, such as persistent cough (CTC Grade ≥2) or persistent dyspnoea (dyspnoea scale Grade ≥2).
7. Current unstable liver or biliary disease per investigator assessment defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminaemia, oesophageal or gastric varices, persistent jaundice, or cirrhosis.
8. Current acute or chronic Hepatitis B and/or Hepatitis C.

9. Current or history of renal disease or estimated glomerular filtration rate by Chronic Kidney Disease Epidemiology Collaboration equation calculation <60 mL/min/1.73m2 at screening.
10. Breast cancer within the past 10 years or lymphoma, leukaemia, or any other malignancy within the past 5 years except for cervical carcinoma in situ that has been resected with no evidence of recurrence or metastatic disease, or basal cell or squamous epithelial cancers of the skin that have been resected with no evidence of recurrence or metastatic disease for at least 3 years.
11. History of any lymphoproliferative disorder, such as Epstein-Barr Virus related lymphoproliferative disorder, or signs and symptoms suggestive of current lymphatic disease.
12. History or presence of significant other concomitant illness according to Investigator judgment such as, but not limited to cardiovascular (including Stage III or IV cardiac failure according to New York Heart Association classification, myocardial infarction within 3 months, unstable angina pectoris, uncontrolled hypertension, uncontrolled hypercholesterolemia, uncontrolled diabetes mellitus, VTE requiring anticoagulation), neurological, endocrinological, gastrointestinal (including diverticulitis), hepatic disease, metabolic, lymphatic disease, or previous renal transplant that would adversely affect the participant's participation in the study.
13. Any condition or contraindication as addressed in the local product information or local clinical practice for tofacitinib that would preclude the participant from participating in the study. For all patients, investigators should carefully review potential risk factors related to VTE, including DVT and PE and review the risk of infection in patients older than 65 years of age.
14. History of other inflammatory rheumatologic or systemic autoimmune disorder, other than Sjögren's syndrome secondary to RA, that may confound the evaluation of the effect of the study intervention such as mixed connective tissue disease, psoriatic arthritis, juvenile chronic arthritis, spondyloarthritis, Felty syndrome, systemic lupus erythematosus, scleroderma, Crohn's disease, ulcerative colitis, or vasculitis.
15. Presence of fibromyalgia that, in the investigator's opinion, would make it difficult to appropriately assess RA activity for the purposes of the study.

16. Undergone any major surgery within 8 weeks prior to study entry or will require major surgery during the study that, in the opinion of the investigator in consultation with the medical monitor, would pose an unacceptable risk to the participant.
17. Current or previous active *Mycobacterium tuberculosis* regardless of treatment.
18. Evidence of latent TB (as documented by a positive QuantiFERON-TB Gold plus test or T-SPOT.TB test at screening, no findings on medical history or clinical examination consistent with active TB, and a normal chest radiograph) except for patients that either:
    - Are willing to complete at least 4 weeks of anti-TB therapy as per World Health Organisation or national guidelines prior to randomisation and agree to complete the remainder of treatment while in the study OR
    - Are documented as having evidence of satisfactory anti-TB treatment as per WHO or national guidelines within the last 5 years following review by a
    - physician specialising in TB.
19. Previous close contact with a person with active TB and did not receive satisfactory anti-TB treatment as per WHO or national guidelines.
20. Significant allergies to humanised monoclonal antibodies.
21. Clinically significant multiple or severe drug allergies or severe post-treatment hypersensitivity reactions (including, but not limited to, erythema multiforme major, linear immunoglobulin A dermatosis, toxic epidermal necrolysis, and exfoliative dermatitis).
22. Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.
23. Any prior treatment antagonising GM-CSF or its receptor.
24. Any prior treatment with JAKi(s) (either experimental or approved) including, but not limited to tofacitinib, baricitinib, upadacitinib, filgotinib and peficitinib.
25. *ContRAst 1:* Any prior treatment with a biologic DMARD (either experimental or approved) which has been discontinued due to an IR.
26. Patients who are expected to be non-compliant with restrictions on medications and vaccinations prior to the study, during the study or during the 8-week safety follow-up of the study. See **Supplementary Table 3** for details of prohibited medications/treatments.

27. Current enrolment or past participation within the last 42 days before randomisation in any other clinical study involving an investigational study treatment or any other type of medical research.
28. ALT or aspartate transaminase (AST) >1.5 x upper limit of normal (ULN).
29. Bilirubin >1.5 x ULN (isolated bilirubin >1.5 x ULN is acceptable if bilirubin is fractionated and direct bilirubin <35%).
30. Has a positive test for hepatitis B virus (HBV) defined as either:
    - Positive for hepatitis B surface antigen OR
    - Positive for hepatitis B core antibody and positive for HBV deoxyribonucleic acid.
31. Positive test for hepatitis C antibody at screening. Patients with positive Hepatitis C antibody due to prior resolved disease can be enrolled, only if a confirmatory negative hepatitis C RNA test is obtained.
32. Haemoglobin ≤9 g/dL; white blood cell count ≤3.0 x 109/L; platelet count ≤100 x 109/L; absolute neutrophil count <1.0 x 109/L; lymphocyte count ≤0.75 x 109/L at screening.
33. Abnormal chest radiograph within 12 weeks of screening judged by the investigator as clinically significant.
34. Pregnant or lactating, or women planning to become pregnant or initiating breastfeeding.
35. Current drug or alcohol abuse or dependence, or a history of drug or alcohol abuse or dependence within a year prior to Day 1.
36. History of sensitivity to any of the study treatments, or components thereof or a history of drug or other allergy that, in the opinion of the investigator or Medical Monitor, contraindicates their participation.



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## Supplementary methods

*mTSS*

The images from all time points for a specific patient and read campaign were evaluated in a single session. The readers were presented with all the time points to be read for a given patient, displayed side-by-side and blinded to the chronological order of the visits. The same approach will be used for both primary readers as well as the adjudicators. During image analysis, readers will be blinded to treatment assignment, to clinical information, and to the results of image evaluations by the other central readers.

There was an adjudication for results that show a large discrepancy between the two independent readers for the efficacy assessment. The adjudication process involved reading by a third independent reader who was blinded to the results of first two readers.

Cases that required adjudication were identified once the two primary independent readings were completed, according to the following criteria:

Change in mTSS from screening in different directions (one positive, one negative) that differ by 5 or more score points

Change in mTSS from screening in the same direction (both positive or both negative) that differ by 5 or more score points; a score of 0 change was considered to be in the same direction as the change assessed by the second reader

Cases read by one independent reader and set as un-readable by the other independent reader.



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*Handling of missing data*

Intermittent missing data (i.e. between two non-missing assessments) for the ACR20 response were imputed under a missing at random (MAR) assumption.

If a participant experienced any of the intercurrent (post-randomisation) events (IEs*) but efficacy data continued to be collected, their data were analysed as if they were still on the original randomised intervention.

Study withdrawal before the completion of the trial created missing outcome data. This could occur concurrently or after the IE.

Missing data for the ACR20 response resulting from study withdrawal were imputed using one of three possible multiple imputation (MI) models depending on the availability of off-treatment data (i.e. data that were collected post discontinuation of study intervention), using principles introduced by Roger et al.[1]

**1. MI using off-treatment data within randomised treatment arm:**

If there was sufficient off-treatment data within a randomised treatment arm (i.e. at least 3 participants per arm per visit), then missing data were imputed conditional on the participant's observed outcomes, using off-treatment data within randomised treatment arm. The use of this MI model assumed that missing outcomes resulting from participants withdrawing from the study would behave in a similar way to other participants who discontinued study intervention, were randomised to the same treatment arm, and continued providing data post-discontinuation of study intervention.

**2. MI using off-treatment data across all treatment arms:**

If there was insufficient off-treatment data within a randomised treatment arm (i.e. failure of the imputation model in option 1) but there was sufficient off-treatment data across all treatment arms combined (i.e. at least 3 participants per visit), then missing data were imputed conditional on the participant's observed outcomes, using off-treatment data across all treatment arms. The use of this MI model assumed that missing outcomes resulting from participants withdrawing from the study would behave in a similar way to other participants who discontinued study intervention and



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continued providing data post-discontinuation of study intervention regardless of randomised treatment arm.

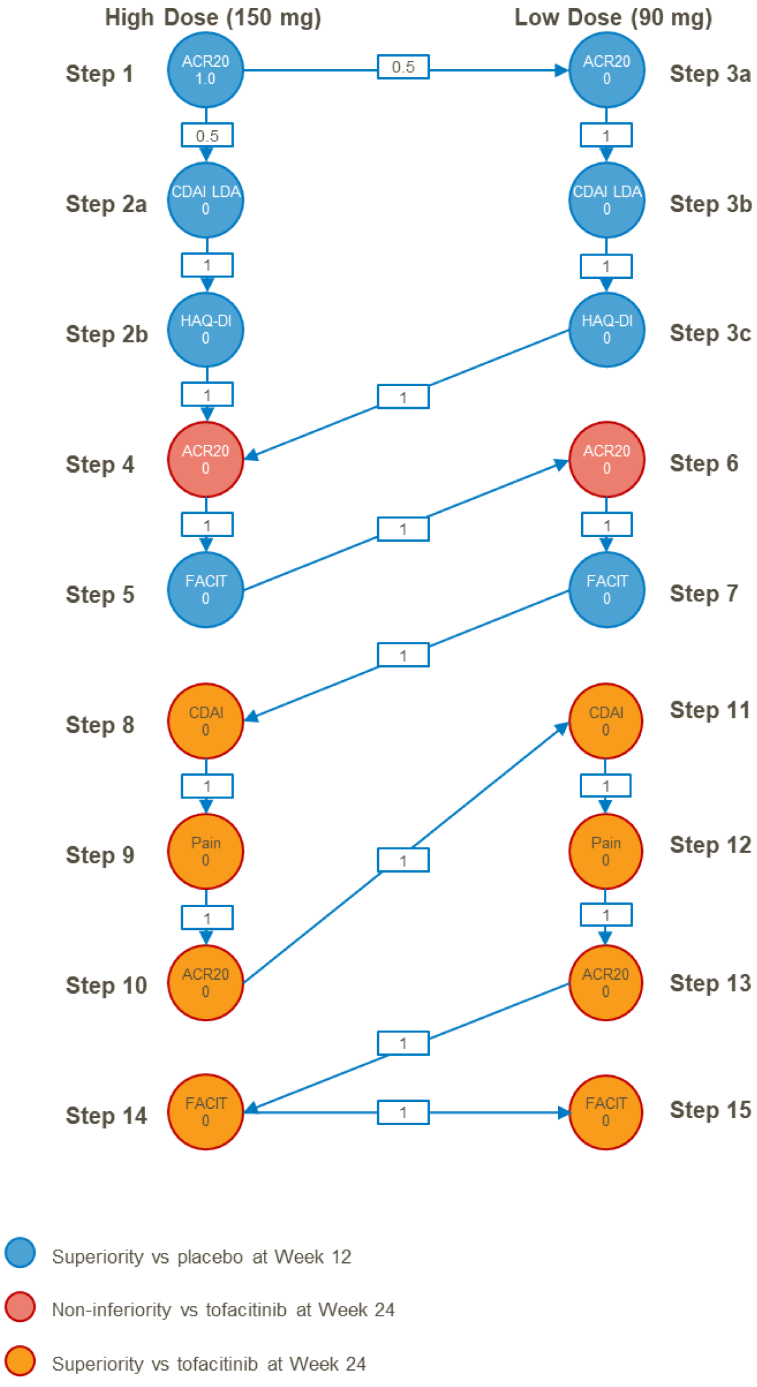
**3. MI under MAR assumption:**

If there was insufficient off-treatment data (i.e. neither option 1 nor 2 is feasible) then all missing data were imputed under a MAR assumption. This MI model uses all available data collected on- and off-treatment within randomised treatment arm, and assumed missing outcomes resulting from participants withdrawing from the study would behave in a similar way to participants who were randomised to the same treatment arm and had data collected in the study, with no adjustment for values before or after intercurrent events.
Note: Week 1 data were not included in any imputation models due to the unavailability of off-treatment data at this visit by design of the study.

*The IEs anticipated to impact on the interpretation of the treatment effect for the primary objective were: discontinuation of study intervention for any reason; use of prohibited medication and change in stable dose of background medication.

1. Roger JH, Bratton DJ, Mayer B, et al. Pharm Stat. 2019;18:85–95.

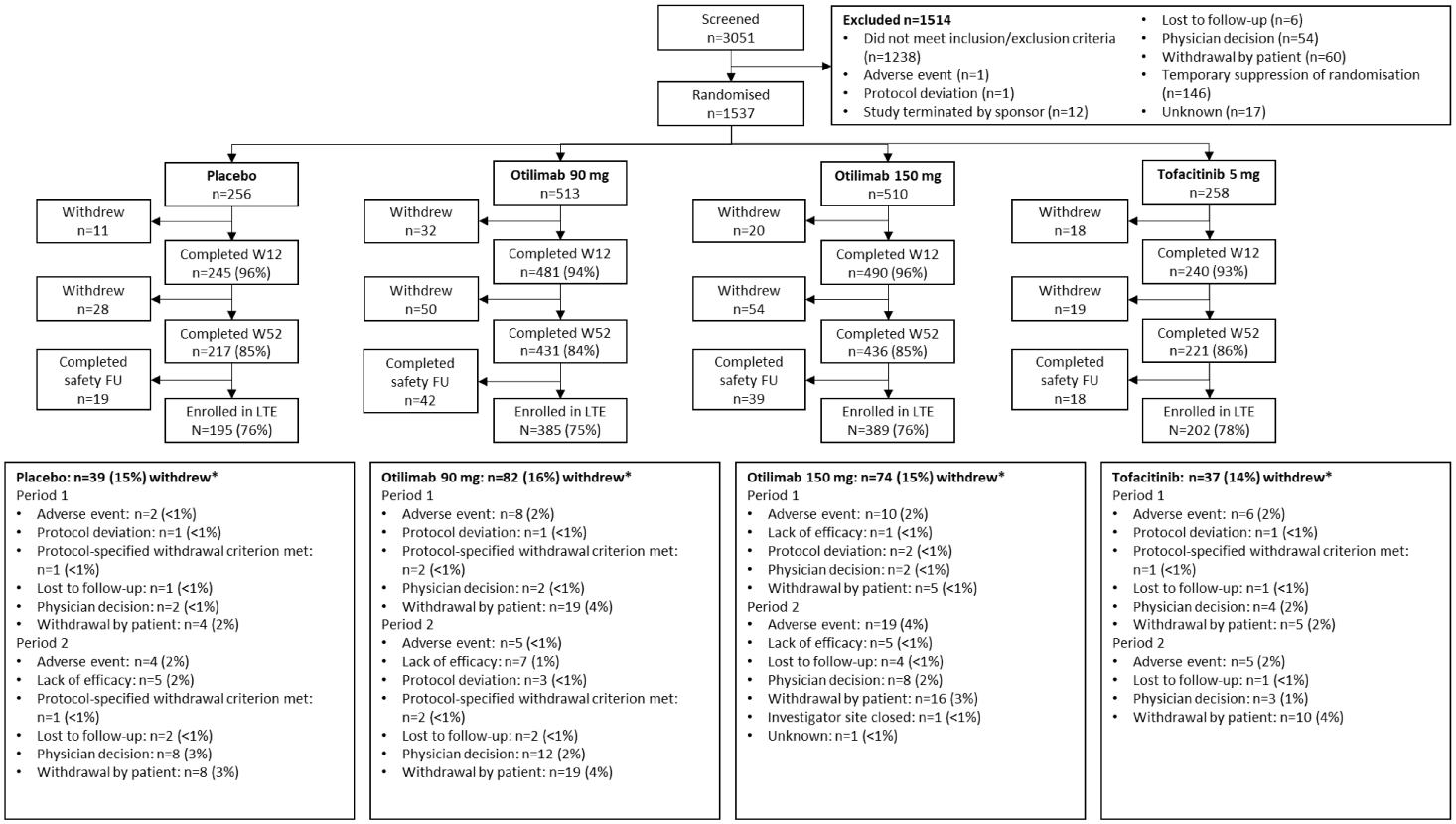
**Supplementary Figure 1.** Step-down multiple testing procedure for contRAst 1 and contRAst 2




The numbers in the circles refer to the initial weighting of alpha. The numbers along the arrows refer to the weighting of alpha that is passed along to the next test. ACR,

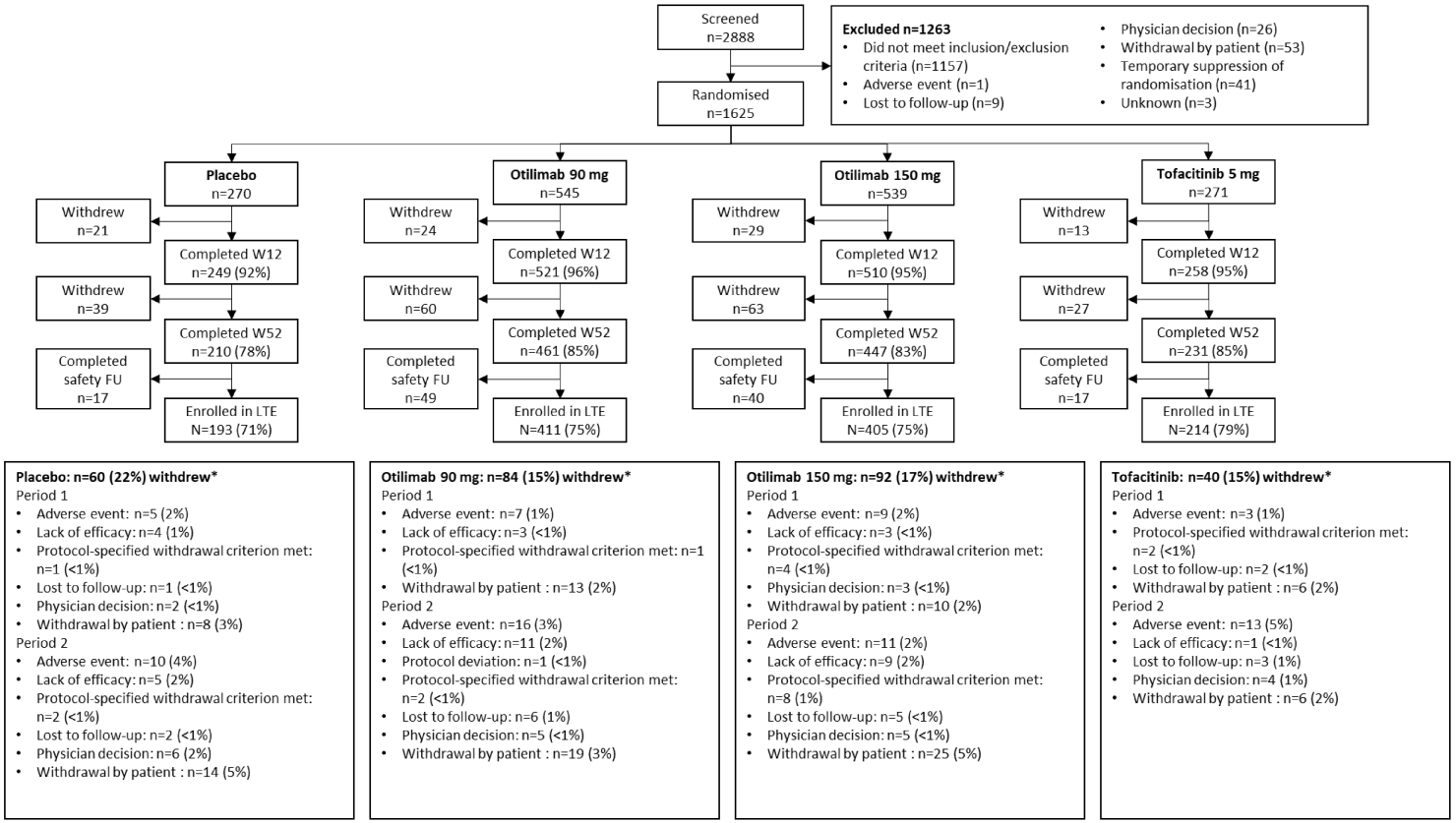
American College of Rheumatology; CDAI, Clinical Disease Activity Index; HAQ-DI, Health Assessment Questionnaire-Disability Index; LDA, low disease activity.

**Supplementary Figure 2A.** Patient disposition for contRAst 1



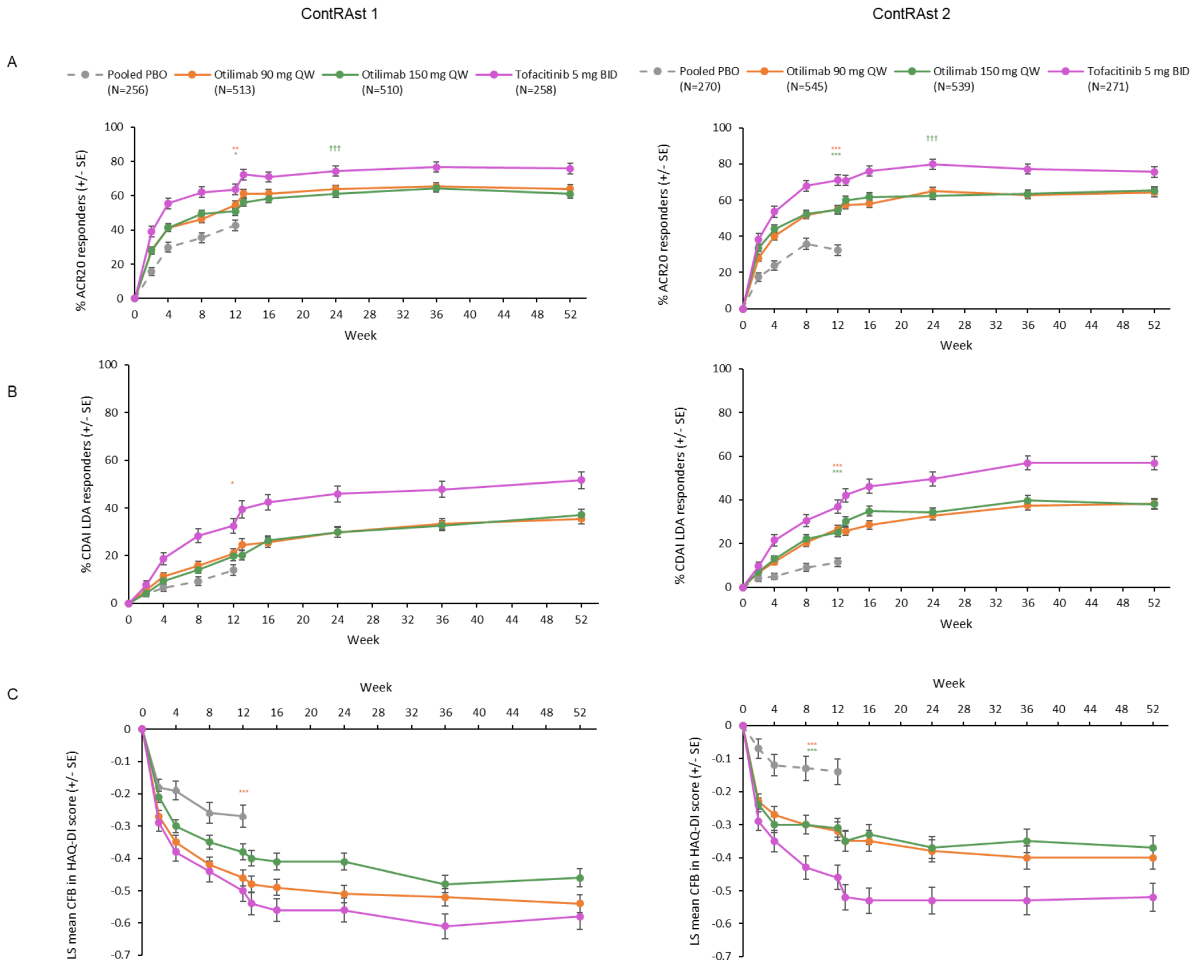

*Only one primary reason for treatment discontinuation permitted. Period 1 defined as time from randomisation to Week 12, Period 2 defined as time from first dose post-Week 12 until date of study completion/withdrawal/treatment withdrawal plus FU, whichever is earlier. FU, follow-up; LTE, long-term extension; W, week.

**Supplementary Figure 2B.** Patient disposition for contRAst 2




*Only one primary reason for treatment discontinuation permitted. Period 1 defined as time from randomisation to Week 12, Period 2 defined as time from first dose post-Week 12 until date of study completion/withdrawal/treatment withdrawal plus FU, whichever is earlier. FU, follow-up; LTE, long-term extension; W, week.

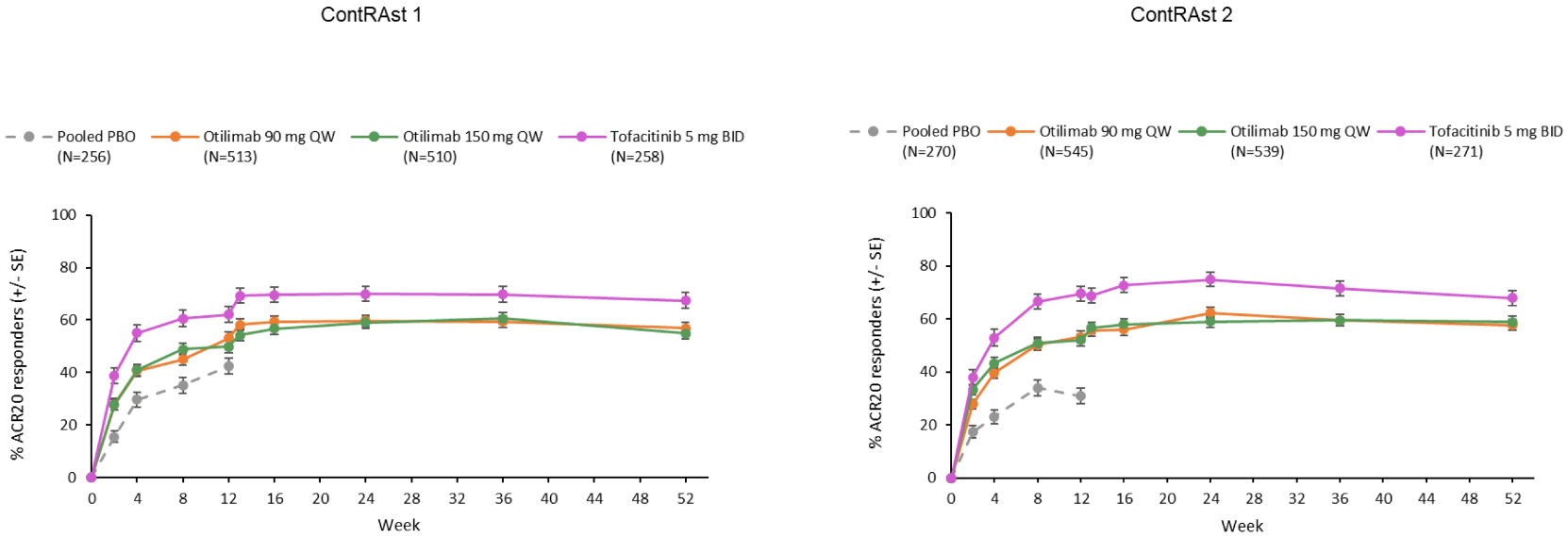
**Supplementary Figure 3.** Proportion of A) ACR20 responders and B) CDAI-LDA responders and C) LS mean CFB in HAQ-DI Score at each assessment visit




*P<0.05; **P<0.01; ***P<0.001 for otilimab vs placebo per SAP; ††† P<0.001 for otilimab vs tofacitinib per SAP. Comparison of tofacitinib vs placebo was not included in the SAP; however, statistical data are provided in the data tables.

ACR, American College of Rheumatology; BID, twice daily; CDAI, clinical disease activity index; CFB, change from baseline; LDA, low disease activity; LS, least squares; PBO, placebo; QW, once weekly; SAP, statistical analysis plan.

**Supplementary Figure 4.** Supplementary analysis* of the proportion of patients achieving ACR20 at each assessment visit (non-responder imputation)




*This supplementary analysis was not included in the multiple testing hierarchy, therefore P values are not provided. ACR, American College of Rheumatology; BID, twice daily; PBO, placebo; QW, once weekly; SE, standard error.



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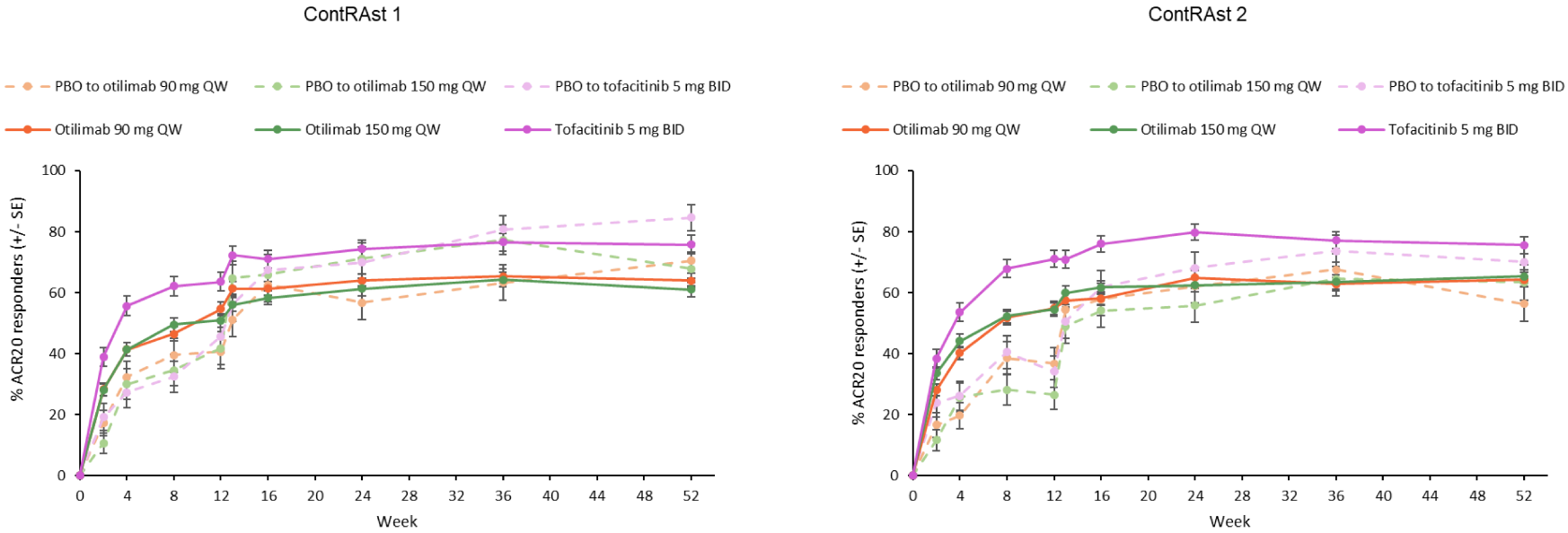
**Supplementary Figure 5.** Supplementary analysis* of the proportion of patients achieving ACR20 at each assessment visit, splitting out pooled placebo arm

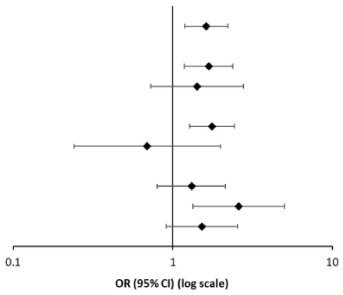



*This supplementary analysis was not included in the multiple testing hierarchy, therefore P values are not provided. ACR, American College of Rheumatology; BID, twice daily; PBO, placebo; QW, once weekly; SE, standard error.

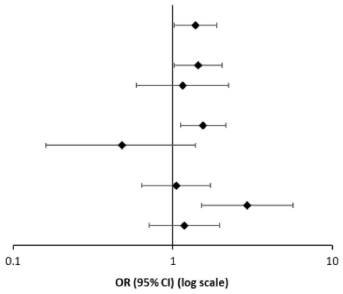
**Supplementary Figure 6.** Subgroup analysis of ACR20 for A) otilimab vs placebo at Week 12 and B) otilimab vs tofacitinib at Week 24 in contRAst 1

A

| Otilimab 90 mg | Pooled PBO responders, % (SE) N=256 | Otilimab 90 mg QW responders, % (SE) N=513 | OR (95% CI) |
|---|---|---|---|
| **Overall** | 42.7 (3.15) | 54.7 (2.31) | 1.62 (1.19, 2.21) |
| **Sex** | | | |
| Female (n=603) | 41.7 (3.55) | 54.4 (2.60) | 1.68 (1.18, 2.38) |
| Male (n=166) | 46.7 (6.84) | 55.8 (4.85) | 1.42 (0.73, 2.77) |
| **Both RF- and Anti CCP antibody-** | | | |
| No (n=686) | 42.1 (3.28) | 56.1 (2.44) | 1.76 (1.27, 2.44) |
| Yes (n=79) | 52.9 (11.51) | 43.5 (6.72) | 0.69 (0.24, 1.99) |
| **Duration of RA** | | | |
| ≤5 years (n=309) | 50.3 (5.08) | 57.0 (3.59) | 1.31 (0.80, 2.14) |
| >5–10 years (n=186) | 30.9 (6.03) | 53.5 (4.53) | 2.58 (1.33, 5.00) |
| >10 years (n=274) | 42.4 (5.18) | 52.8 (3.88) | 1.52 (0.91, 2.54) |

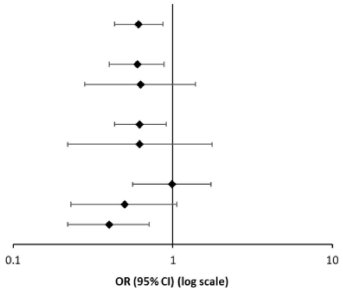



| Otilimab 150 mg | Pooled PBO responders, % (SE) N=256 | Otilimab 150 mg QW responders, % (SE) N=510 | OR (95% CI) |
|---|---|---|---|
| **Overall** | 42.7 (3.15) | 50.9 (2.27) | 1.39 (1.02, 1.89) |
| **Sex** | | | |
| Female (n=601) | 41.7 (3.55) | 50.8 (2.57) | 1.44 (1.02, 2.04) |
| Male (n=165) | 46.7 (6.84) | 51.3 (4.82) | 1.15 (0.59, 2.24) |
| **Both RF- and Anti CCP antibody-** | | | |
| No (n=686) | 42.1 (3.28) | 53.1 (2.40) | 1.55 (1.12, 2.15) |
| Yes (n=76) | 52.9 (11.51) | 35.5 (6.66) | 0.48 (0.16, 1.39) |
| **Duration of RA** | | | |
| ≤5 years (n=300) | 50.3 (5.08) | 51.4 (3.66) | 1.05 (0.64, 1.72) |
| >5–10 years (n=186) | 30.9 (6.03) | 56.7 (4.49) | 2.93 (1.51, 5.66) |
| >10 years (n=280) | 42.4 (5.18) | 46.5 (3.75) | 1.18 (0.71, 1.96) |

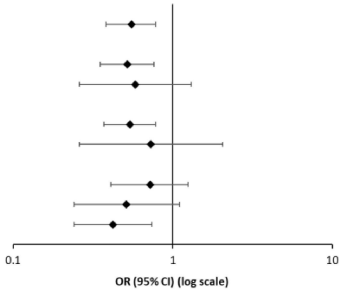



B

| Otilimab 90 mg | Tofacitinib 5 mg BID responders, % (SE) N=258 | Otilimab 90 mg QW responders, % (SE) N=513 | OR (95% CI) |
|---|---|---|---|
| **Overall** | 74.4 (2.95) | 63.9 (2.29) | 0.61 (0.43, 0.87) |
| **Sex** | | | |
| Female (n=610) | 74.1 (3.28) | 63.2 (2.59) | 0.60 (0.40, 0.88) |
| Male (n=161) | 75.3 (6.46) | 66.6 (4.61) | 0.63 (0.28, 1.39) |
| **Both RF- and Anti CCP antibody-** | | | |
| No (n=682) | 75.4 (3.07) | 65.5 (2.39) | 0.62 (0.43, 0.91) |
| Yes (n=83) | 61.1 (10.66) | 50.2 (6.93) | 0.62 (0.22, 1.76) |
| **Duration of RA** | | | |
| ≤5 years (n=307) | 71.1 (4.90) | 71.1 (3.35) | 0.99 (0.56, 1.74) |
| >5–10 years (n=182) | 76.0 (6.14) | 60.9 (4.56) | 0.50 (0.23, 1.06) |
| >10 years (n=282) | 76.6 (4.37) | 57.9 (3.88) | 0.40 (0.22, 0.71) |




| Otilimab 150 mg | Tofacitinib 5 mg BID responders, % (SE) N=258 | Otilimab 150 mg QW responders, % (SE) N=510 | OR (95% CI) |
|---|---|---|---|
| **Overall** | 74.4 (2.95) | 61.3 (2.27) | 0.55 (0.38, 0.78) |
| **Sex** | | | |
| Female (n=608) | 74.1 (3.28) | 60.2 (2.56) | 0.52 (0.35, 0.76) |
| Male (n=160) | 75.3 (6.46) | 65.5 (4.71) | 0.58 (0.26, 1.30) |
| **Both RF- and Anti CCP antibody-** | | | |
| No (n=682) | 75.4 (3.07) | 62.2 (2.39) | 0.54 (0.37, 0.78) |
| Yes (n=80) | 61.1 (10.66) | 53.4 (7.03) | 0.73 (0.26, 2.06) |
| **Duration of RA** | | | |
| ≤5 years (n=298) | 71.1 (4.90) | 63.8 (3.55) | 0.72 (0.41, 1.25) |
| >5–10 years (n=182) | 76.0 (6.14) | 61.7 (4.45) | 0.51 (0.24, 1.10) |
| >10 years (n=288) | 76.6 (4.37) | 58.5 (3.79) | 0.42 (0.24, 0.74) |

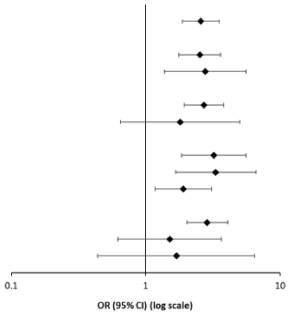


ACR, American College of Rheumatology; BID, twice daily; CCP, cyclic citrullinated peptide; CI, confidence interval; OR, odds ratio; PBO, placebo; QW, once weekly; RA, rheumatoid arthritis; RF, rheumatoid factor; SE, standard error.

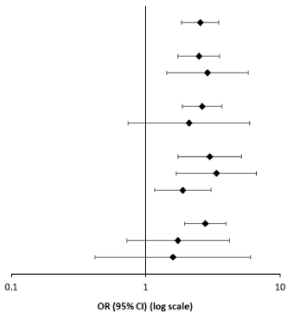
**Supplementary Figure 7.** Subgroup analysis of ACR20 for A) otilimab vs placebo at Week 12 and B) otilimab vs tofacitinib at Week 24 in contRAst 2

A

| Otilimab 90 mg | Pooled PBO responders, % (SE) N=270 | Otilimab 90 mg QW responders, % (SE) N=545 | OR (95% CI) |
|---|---|---|---|
| **Overall** | 32.5 (2.96) | 54.9 (2.21) | 2.57 (1.87, 3.53) |
| **Sex** | | | |
| Female (n=645) | 32.2 (3.32) | 54.7 (2.46) | 2.52 (1.76, 3.61) |
| Male (n=170) | 33.5 (6.42) | 55.7 (4.89) | 2.78 (1.38, 5.58) |
| **Both RF- and Anti CCP antibody-** | | | |
| No (n=707) | 31.8 (3.08) | 56.0 (2.39) | 2.72 (1.94, 3.81) |
| Yes (n=100) | 40.0 (10.87) | 49.4 (5.79) | 1.80 (0.65, 5.00) |
| **Duration of RA** | | | |
| ≤5 years (n=260) | 30.7 (4.84) | 57.5 (3.94) | 3.21 (1.85, 5.58) |
| >5–10 years (n=215) | 26.0 (5.76) | 54.4 (4.18) | 3.32 (1.67, 6.59) |
| >10 years (n=340) | 37.7 (4.74) | 53.4 (3.41) | 1.90 (1.17, 3.08) |
| **Prior failed DMARD** | | | |
| csDMARD only (n=644) | 33.6 (3.31) | 58.9 (2.43) | 2.86 (2.02, 4.07) |
| 1 bDMARD (n=112) | 30.4 (7.92) | 41.3 (6.00) | 1.51 (0.62, 3.67) |
| >1 bDMARD (n=59) | 24.1 (10.59) | 36.2 (8.02) | 1.69 (0.44, 6.46) |

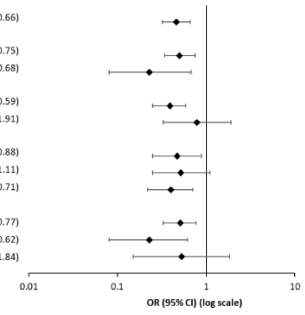



| Otilimab 150 mg | Pooled PBO responders, % (SE) N=270 | Otilimab 150 mg QW responders, % (SE) N=539 | OR (95% CI) |
|---|---|---|---|
| **Overall** | 32.5 (2.96) | 54.5 (2.21) | 2.55 (1.85, 3.50) |
| **Sex** | | | |
| Female (n=644) | 32.2 (3.32) | 54.0 (2.47) | 2.49 (1.74, 3.56) |
| Male (n=165) | 33.5 (6.42) | 56.3 (4.92) | 2.88 (1.43, 5.81) |
| **Both RF- and Anti CCP antibody-** | | | |
| No (n=710) | 31.8 (3.08) | 54.8 (2.39) | 2.63 (1.87, 3.68) |
| Yes (n=91) | 40.0 (10.87) | 53.3 (6.11) | 2.10 (0.74, 5.93) |
| **Duration of RA** | | | |
| ≤5 years (n=271) | 30.7 (4.84) | 56.4 (3.78) | 3.00 (1.74, 5.18) |
| >5–10 years (n=206) | 26.0 (5.76) | 55.0 (4.35) | 3.35 (1.68, 6.68) |
| >10 years (n=332) | 37.7 (4.74) | 52.7 (3.46) | 1.89 (1.16, 3.07) |
| **Prior failed DMARD** | | | |
| csDMARD only (n=642) | 33.6 (3.31) | 58.1 (2.46) | 2.77 (1.95, 3.94) |
| 1 bDMARD (n=108) | 30.4 (7.92) | 44.2 (6.06) | 1.73 (0.72, 4.20) |
| >1 bDMARD (n=59) | 24.1 (10.59) | 34.6 (7.62) | 1.59 (0.42, 6.04) |

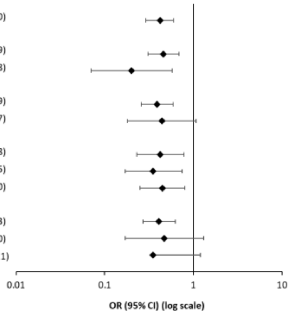



B

| Otilimab 90 mg | Tofacitinib 5 mg BID responders, % (SE) N=271 | Otilimab 90 mg QW responders, % (SE) N=545 | OR (95% CI) |
|---|---|---|---|
| **Overall** | 79.8 (2.65) | 65.0 (2.15) | 0.46 (0.32, 0.66) |
| **Sex** | | | |
| Female (n=660) | 78.5 (2.93) | 65.5 (2.39) | 0.50 (0.34, 0.75) |
| Male (n=156) | 86.8 (5.64) | 63.3 (4.76) | 0.23 (0.08, 0.68) |
| **Both RF- and Anti CCP antibody-** | | | |
| No (n=692) | 82.1 (2.74) | 65.1 (2.33) | 0.39 (0.25, 0.59) |
| Yes (n=117) | 67.6 (7.84) | 63.3 (5.70) | 0.79 (0.33, 1.91) |
| **Duration of RA** | | | |
| ≤5 years (n=258) | 78.8 (4.51) | 64.7 (3.84) | 0.47 (0.25, 0.88) |
| >5–10 years (n=218) | 80.4 (5.13) | 69.0 (3.93) | 0.52 (0.25, 1.11) |
| >10 years (n=340) | 80.2 (4.07) | 62.6 (3.35) | 0.40 (0.22, 0.71) |
| **Prior failed DMARD** | | | |
| csDMARD only (n=644) | 80.3 (2.96) | 67.9 (2.35) | 0.51 (0.33, 0.77) |
| 1 bDMARD (n=112) | 80.5 (6.80) | 50.5 (6.13) | 0.23 (0.08, 0.62) |
| >1 bDMARD (n=50) | 72.2 (10.31) | 59.6 (8.13) | 0.53 (0.15, 1.84) |

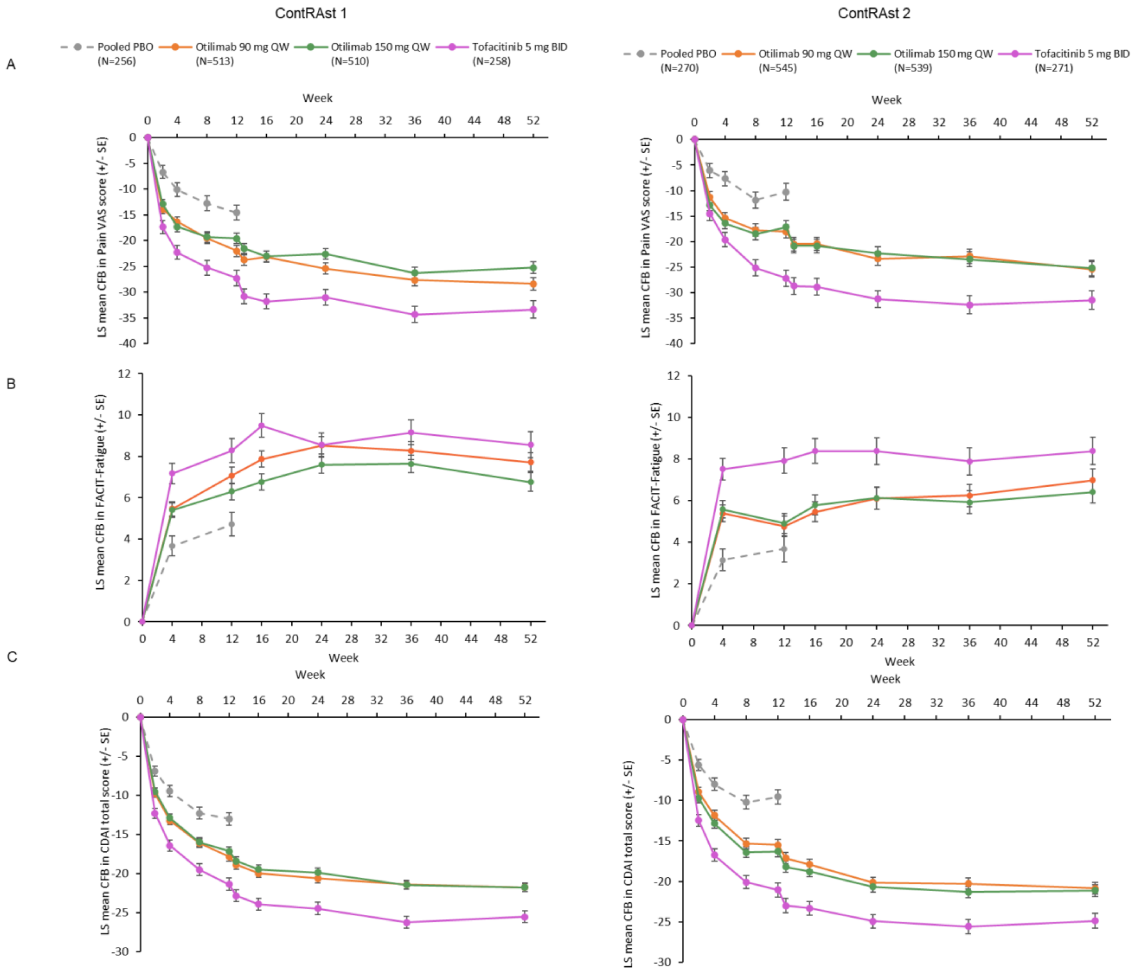



| Otilimab 150 mg | Tofacitinib 5 mg BID responders, % (SE) N=271 | Otilimab 150 mg QW responders, % (SE) N=539 | OR (95% CI) |
|---|---|---|---|
| **Overall** | 79.8 (2.65) | 62.5 (2.21) | 0.42 (0.29, 0.60) |
| **Sex** | | | |
| Female (n=659) | 78.5 (2.93) | 63.2 (2.46) | 0.46 (0.31, 0.69) |
| Male (n=151) | 86.8 (5.64) | 59.8 (4.87) | 0.20 (0.07, 0.58) |
| **Both RF- and Anti CCP antibody-** | | | |
| No (n=695) | 82.1 (2.74) | 64.8 (2.35) | 0.39 (0.26, 0.59) |
| Yes (n=108) | 67.6 (7.84) | 48.8 (6.22) | 0.44 (0.18, 1.07) |
| **Duration of RA** | | | |
| ≤5 years (n=269) | 78.8 (4.51) | 62.0 (3.79) | 0.42 (0.23, 0.78) |
| >5–10 years (n=209) | 80.4 (5.13) | 61.0 (4.32) | 0.35 (0.17, 0.75) |
| >10 years (n=332) | 80.2 (4.07) | 63.9 (3.38) | 0.45 (0.25, 0.80) |
| **Prior failed DMARD** | | | |
| csDMARD only (n=642) | 80.3 (2.96) | 63.0 (2.44) | 0.41 (0.27, 0.63) |
| 1 bDMARD (n=108) | 80.5 (6.80) | 66.5 (5.88) | 0.47 (0.17, 1.30) |
| >1 bDMARD (n=60) | 72.2 (10.31) | 49.7 (8.43) | 0.35 (0.10, 1.21) |



ACR, American College of Rheumatology; b/csDMARD, biologic/conventional synthetic disease-modifying anti-rheumatic drug; BID, twice daily; CCP, cyclic citrullinated peptide; CI, confidence interval; OR, odds ratio; PBO, placebo; QW, once weekly; RA, rheumatoid arthritis; RF, rheumatoid factor; SE, standard error.

**Supplementary Figure 8.** LS mean CFB in A) pain VAS, B) FACIT-Fatigue and C) CDAI at each assessment visit




Due to the step-down multiple testing approach, statistical significance was not assessed, or cannot be claimed, for otilimab vs placebo for these endpoints, however, statistical data are provided in the data tables.

BID, twice daily; CDAI, clinical disease activity index; CFB, change from baseline; FACIT, Functional Assessment of Chronic Illness Therapy; LS, least squares; PBO, placebo; QW, once weekly; SE, standard error; VAS, visual analogue scale.



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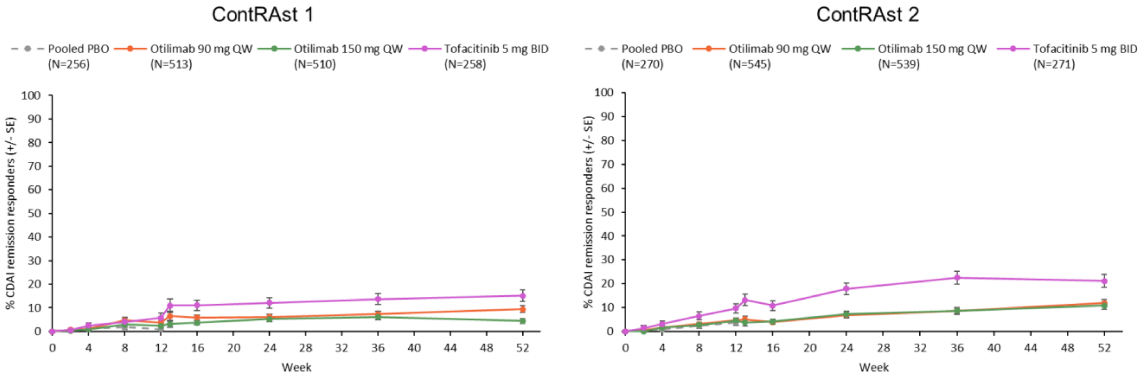
**Supplementary Figure 9.** Proportion of patients achieving CDAI remission (CDAI ≤2.8) at each assessment visit




Due to the step-down multiple testing approach, statistical significance was not assessed, or cannot be claimed, for otilimab vs placebo for these endpoints, however, statistical data are provided in the data tables.

BID, twice daily; CDAI, clinical disease activity index; PBO, placebo, QW, once weekly; SE, standard error.



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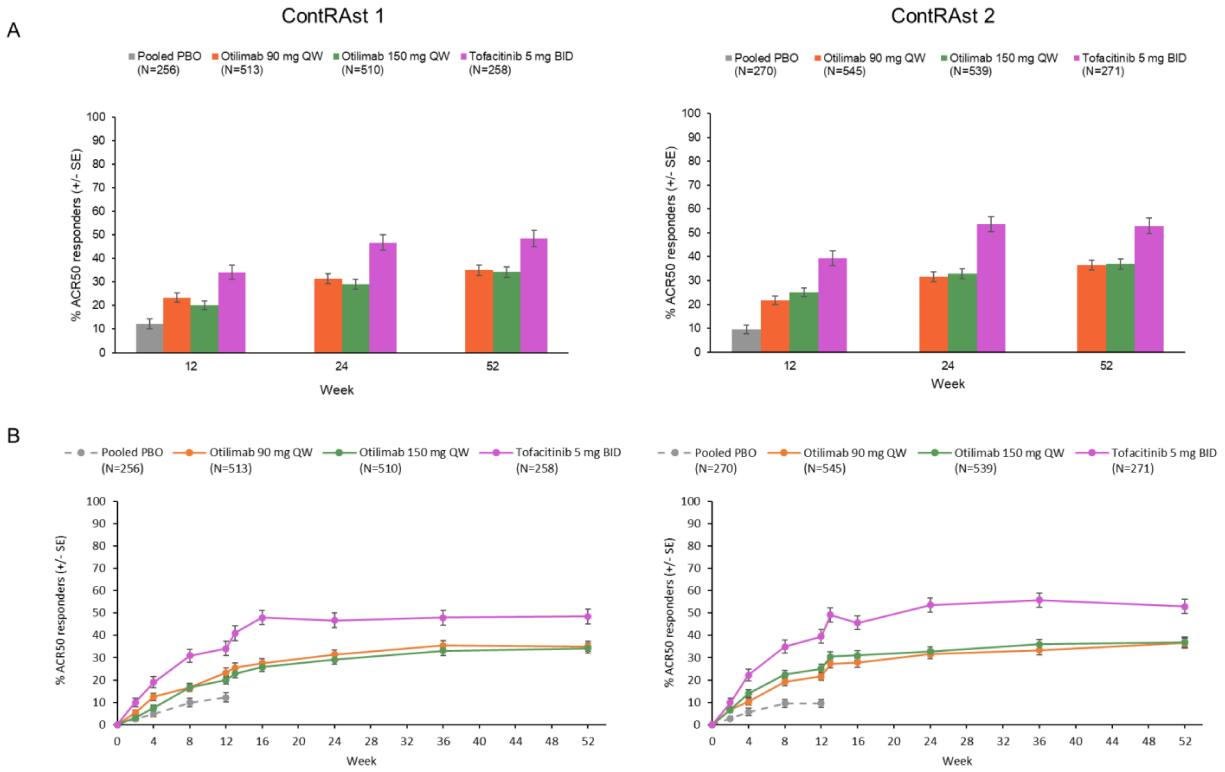
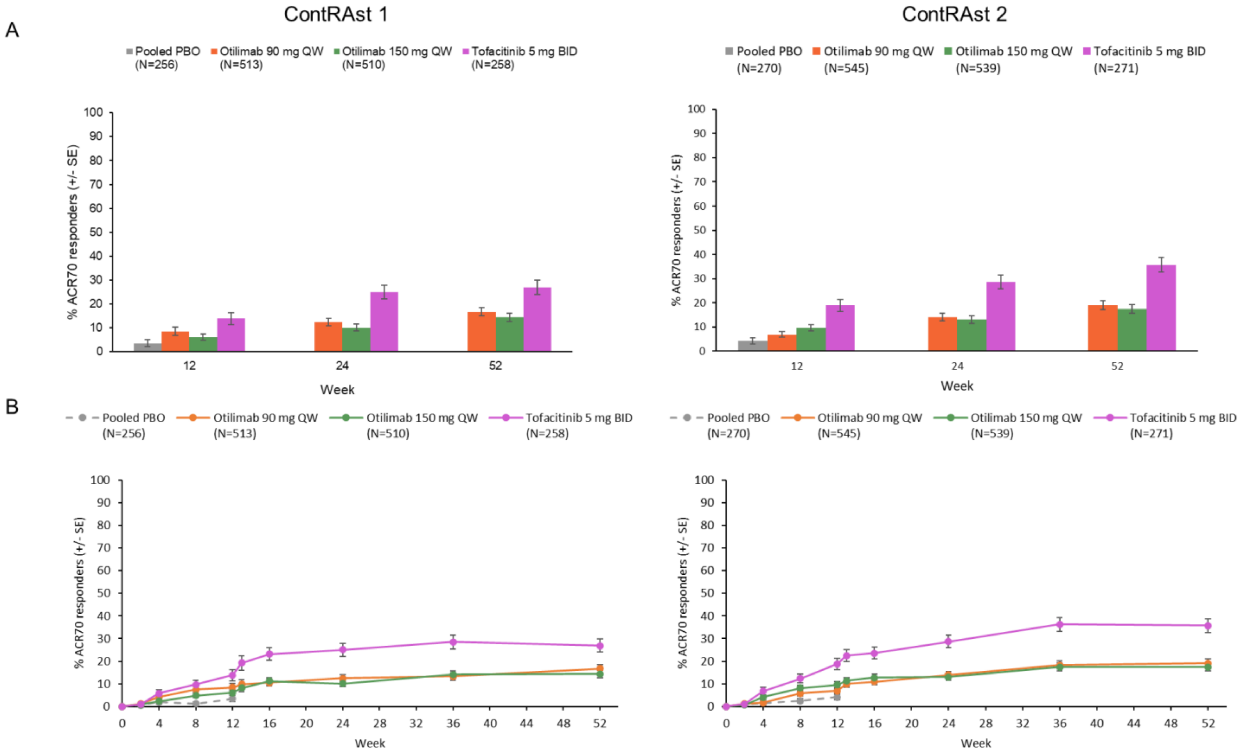
**Supplementary Figure 10.** Proportion of patients achieving ACR50 at A) Week 12, 24 and 52 and B) each assessment visit




Due to the step-down multiple testing approach, statistical significance was not assessed, or cannot be claimed, for otilimab vs placebo for these endpoints; however, statistical data are provided in the data tables.

ACR, American College of Rheumatology; BID, twice daily; PBO, placebo; QW, once weekly; SE, standard error.

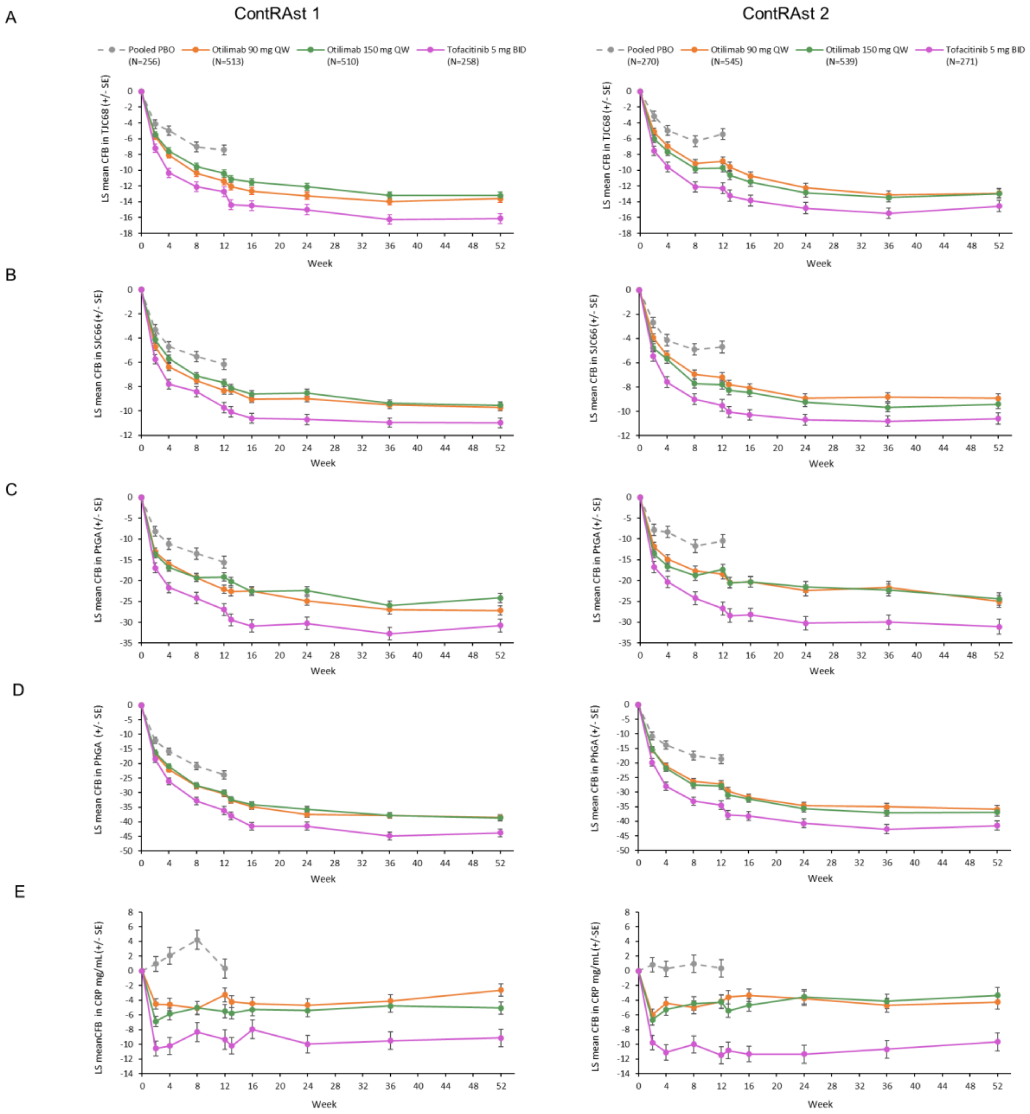
**Supplementary Figure 11.** Proportion of patients achieving ACR70 at A) Week 12, 24 and 52 and B) each assessment visit




Due to the step-down multiple testing approach, statistical significance was not assessed, or cannot be claimed, for otilimab vs placebo for these endpoints; however, statistical data are provided in the data tables.

ACR, American College of Rheumatology; BID, twice daily; PBO, placebo; QW, once weekly; SE, standard error.

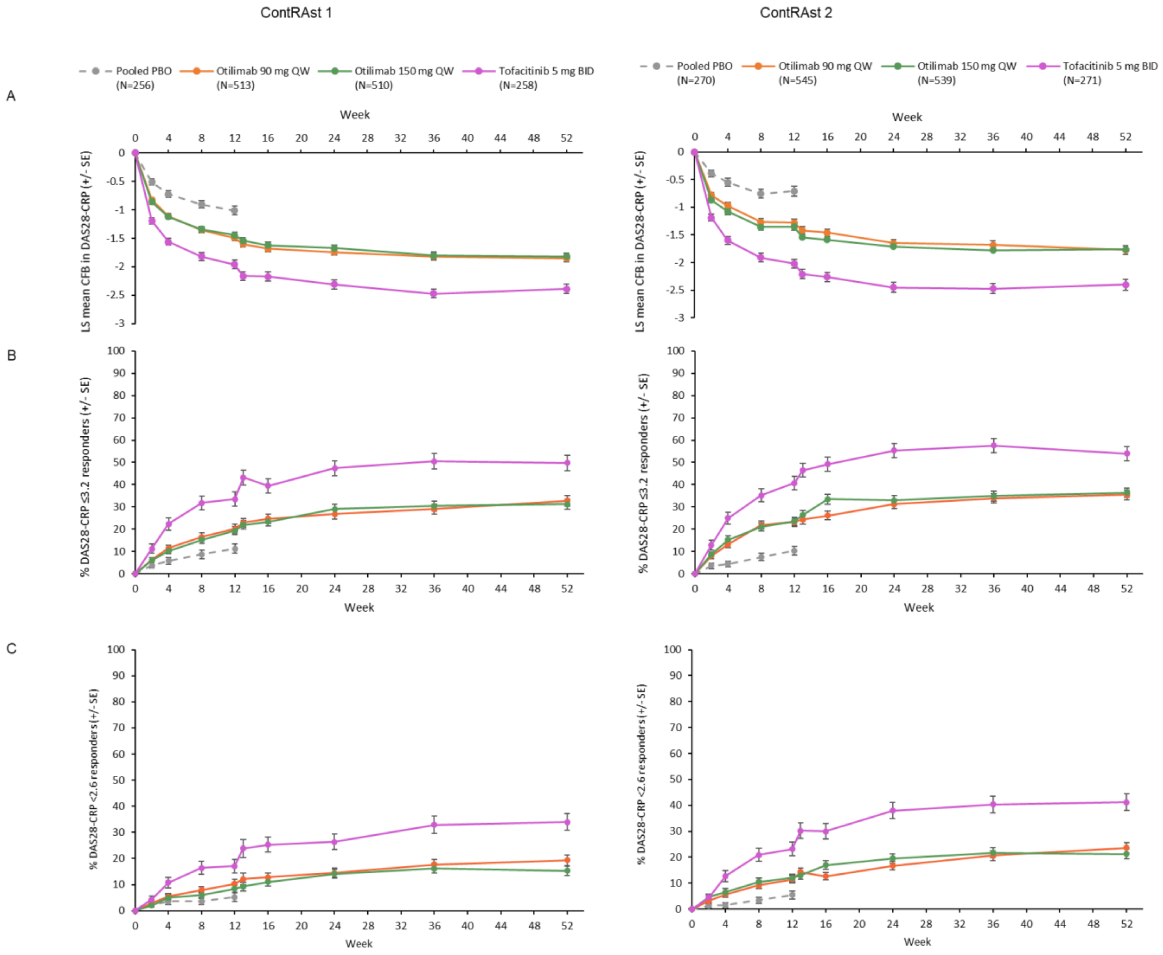
**Supplementary Figure 12.** LS mean CFB in A) TJC68, B) SJC66, C) PtGA, D) PhGA and E) CRP




Due to the step-down multiple testing approach, statistical significance was not assessed, or cannot be claimed, for otilimab vs placebo for these endpoints, however, statistical data are provided in the data tables.

BID, twice daily; CFB, change from baseline; CRP, C-reactive protein; LS, least squares, PBO, placebo; PhGA, physician's global assessment; PtGA, patient's global assessment; QW, once weekly; SE, standard error; SJC, swollen joint count; TJC, tender joint count.

**Supplementary Figure 13.** A) LS mean CFB in DAS28-CRP and proportion of patients achieving B) DAS-28 CRP ≤3.2 and C) DAS28-CRP <2.6




Due to the step-down multiple testing approach, statistical significance was not assessed, or cannot be claimed, for otilimab vs placebo for these endpoints; however, statistical data are provided in the data tables.

BID, twice daily; CFB, change from baseline; CRP, C-reactive protein; DAS28, disease activity score-28 joints; LS, least squares; PBO, placebo; QW, once weekly; SE, standard error.



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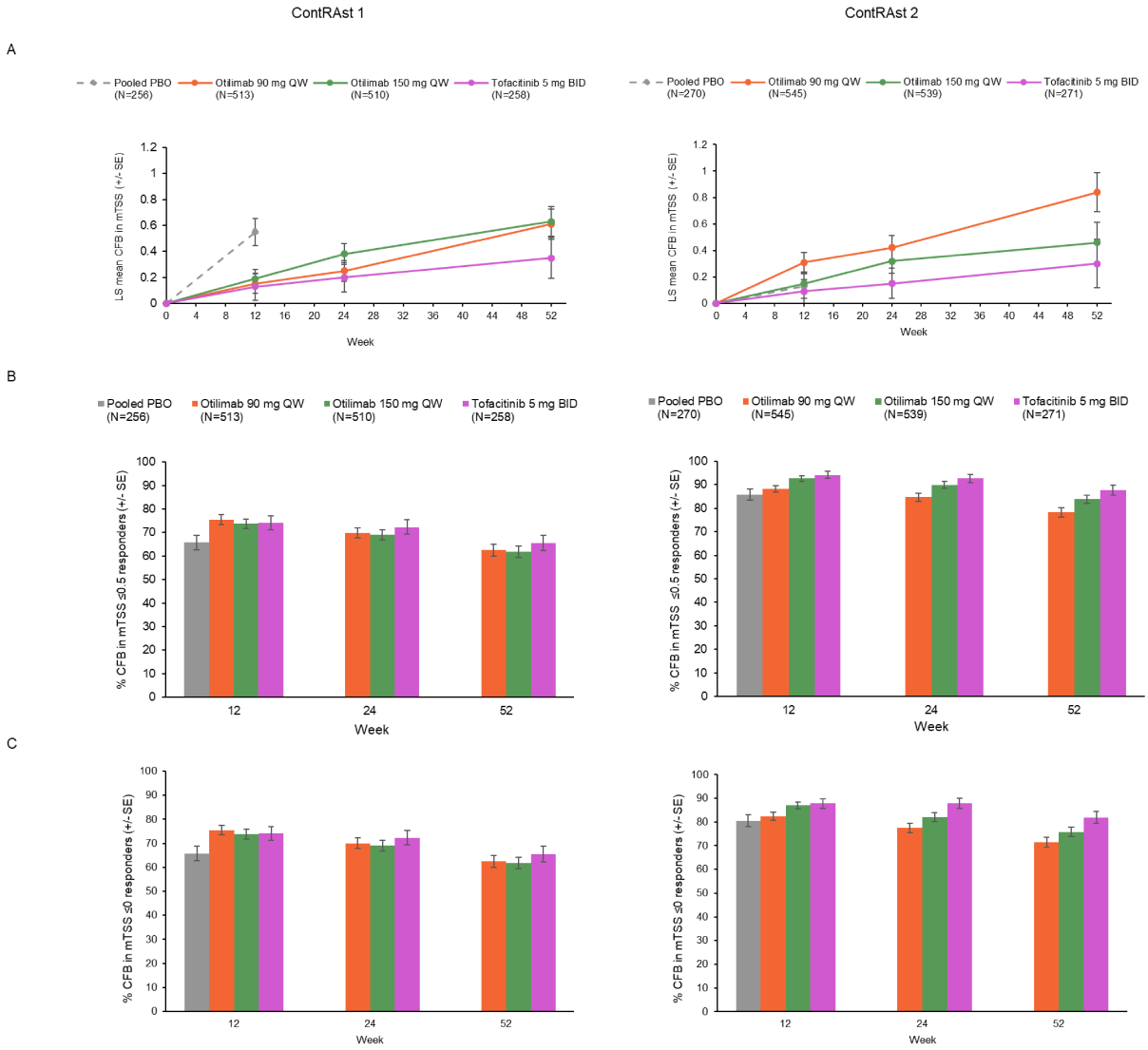
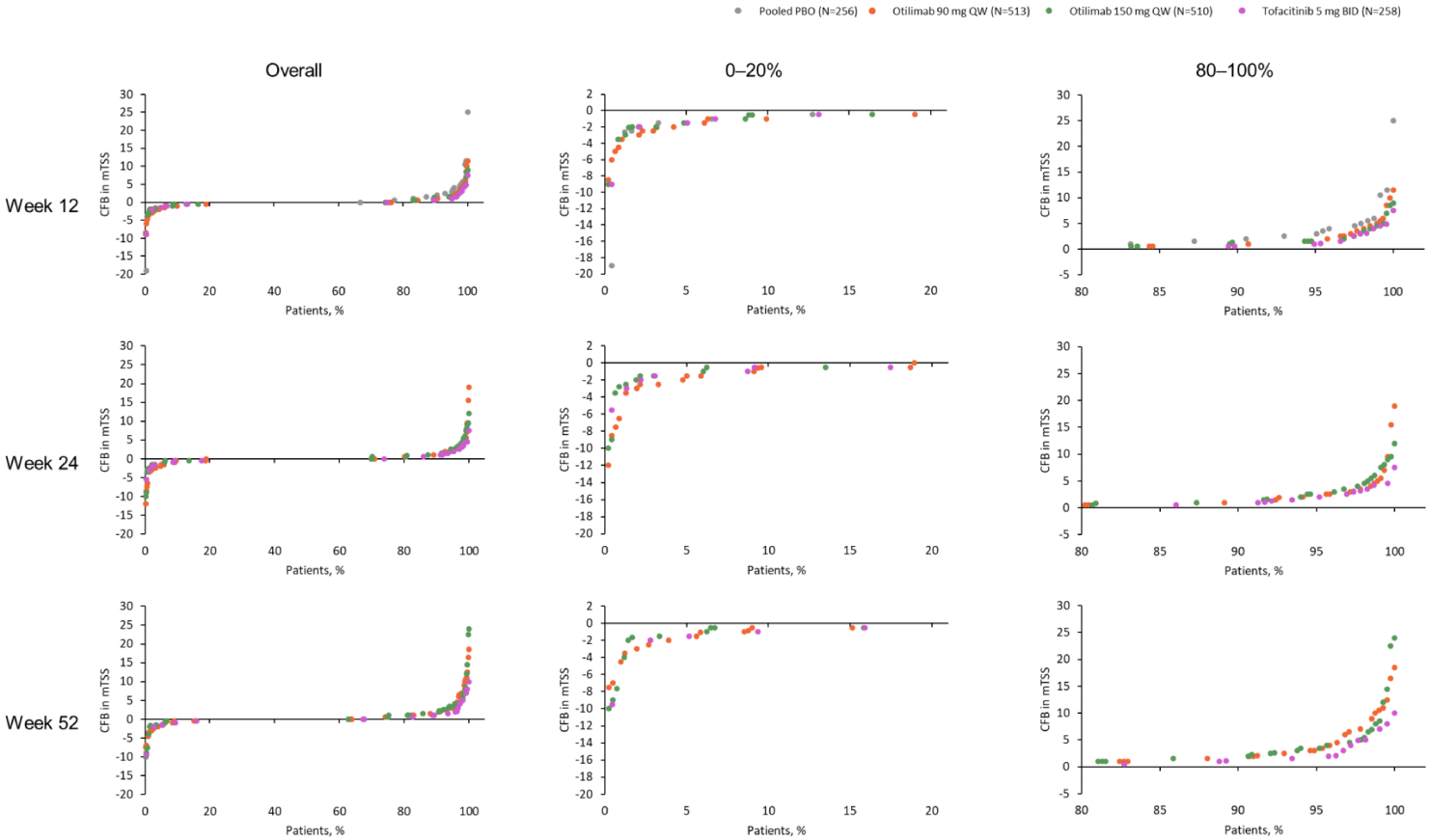
**Supplementary Figure 14.** A) LS mean CFB in mTSS, and proportion of patients with a LS mean CFB in mTSS of B) ≤0.5 and C) ≤0



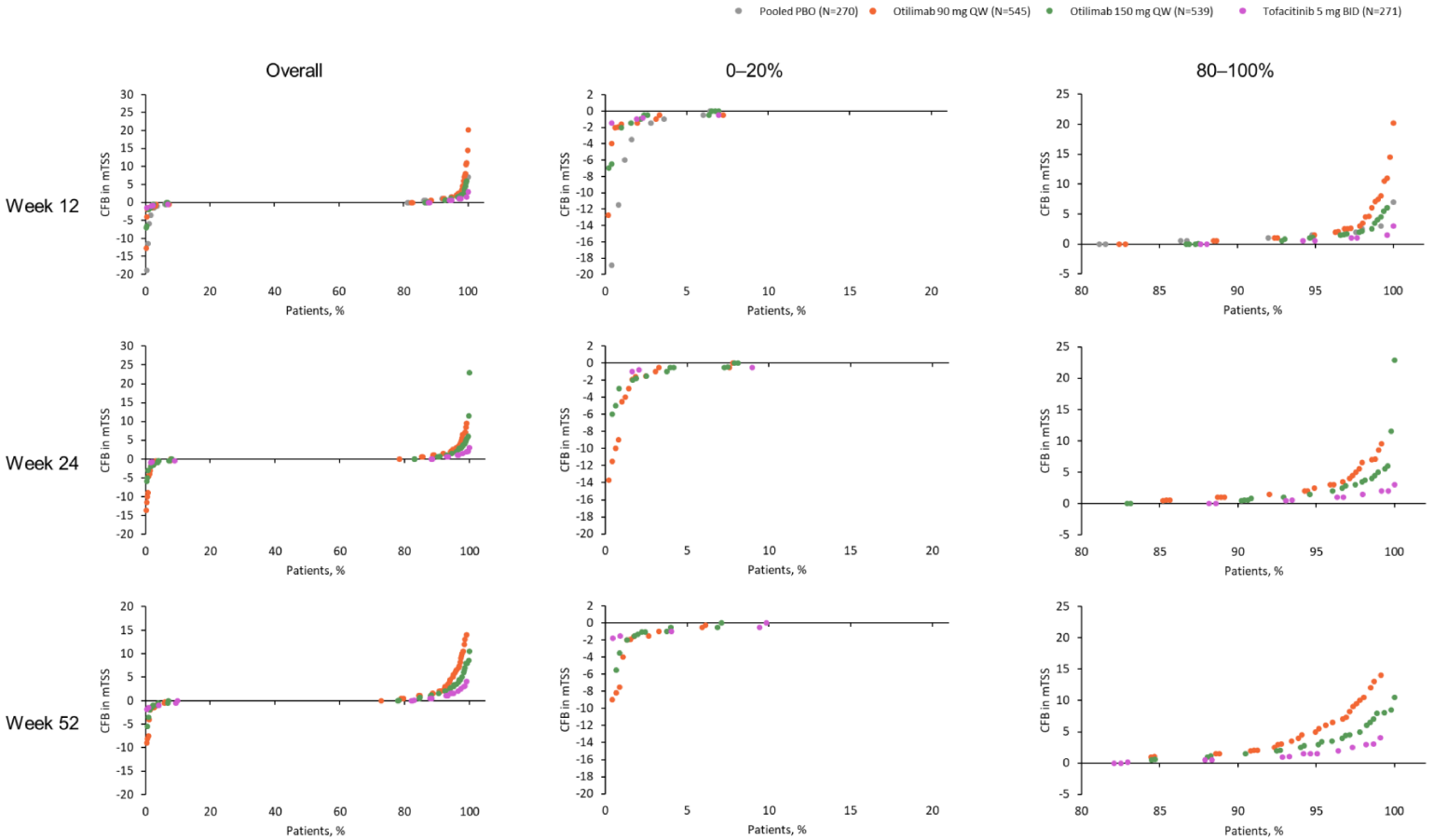

BID, twice daily; CFB, change from baseline; LS, least squares; mTSS, van der Heijde modified total Sharp score; PBO, placebo; QW, once weekly; SE, standard error.

**Supplementary Figure 15.** Cumulative probability plots of individual CFB in mTSS at Week 12, 24 and 52 in contRAst 1



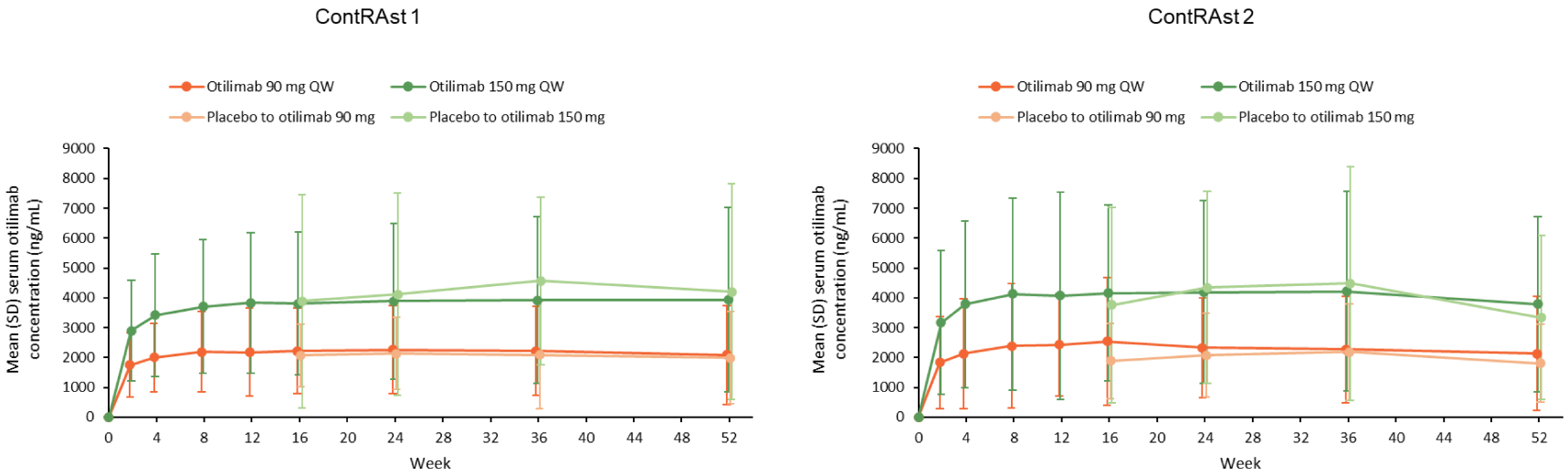

BID, twice daily; CFB, change from baseline; mTSS, van der Heijde modified total Sharp score; PBO, placebo; QW, once weekly.

**Supplementary Figure 16.** Cumulative probability plots of individual CFB in mTSS at Week 12, 24 and 52 in *contRAst 2*




BID, twice daily; CFB, change from baseline; mTSS, van der Heijde modified total Sharp score; PBO, placebo; QW, once weekly.

**Supplementary Figure 17.** Mean serum otilimab concentrations over time

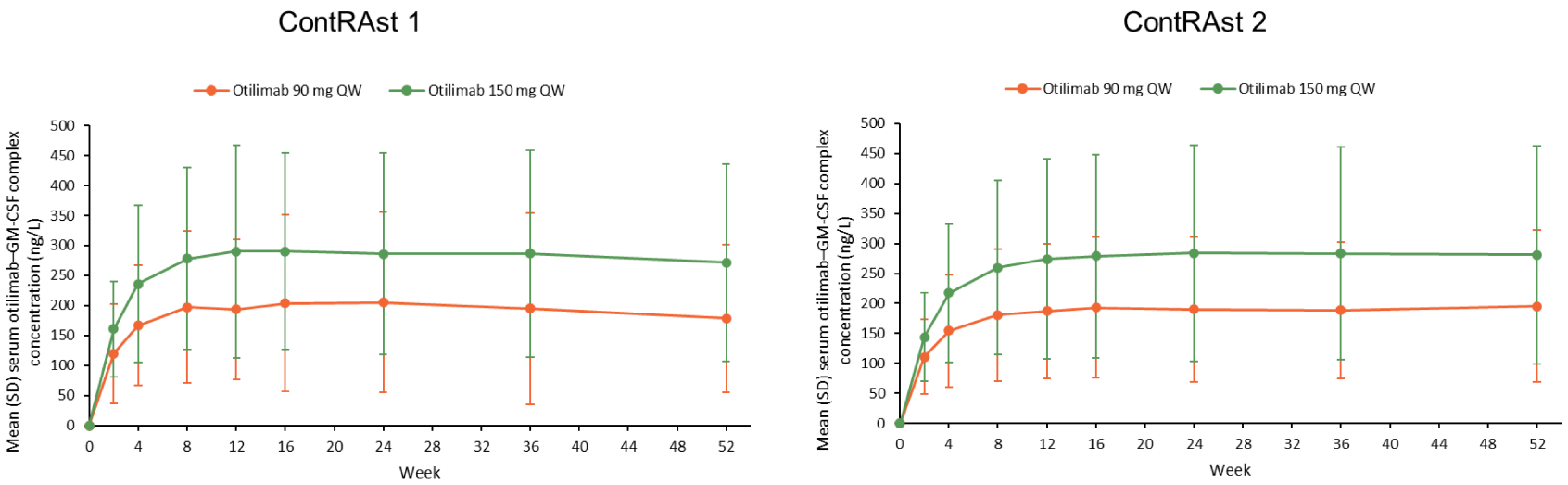



QW, once weekly; SD, standard deviation



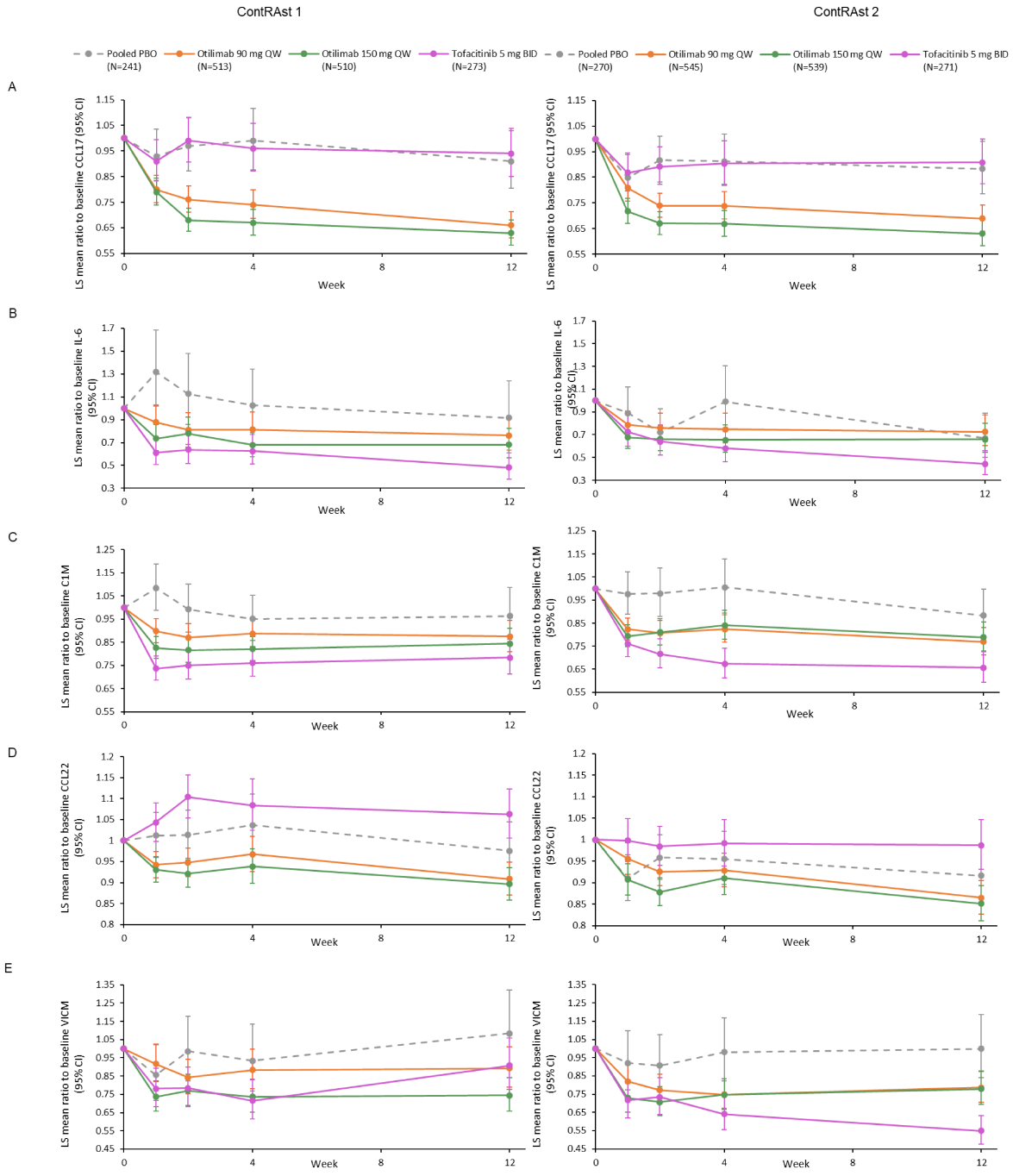
Fleischmann RM, *et al. Ann Rheum Dis* 2023; 82:1516–1526. doi: 10.1136/ard-2023-224482

**Supplementary Figure 18.** Serum otilimab–GM-CSF complex accumulation over time




GM-CSF, granulocyte-macrophage colony-stimulating factor; QW, once weekly; SD, standard deviation

**Supplementary Figure 19.** CFB in biomarkers up to Week 12

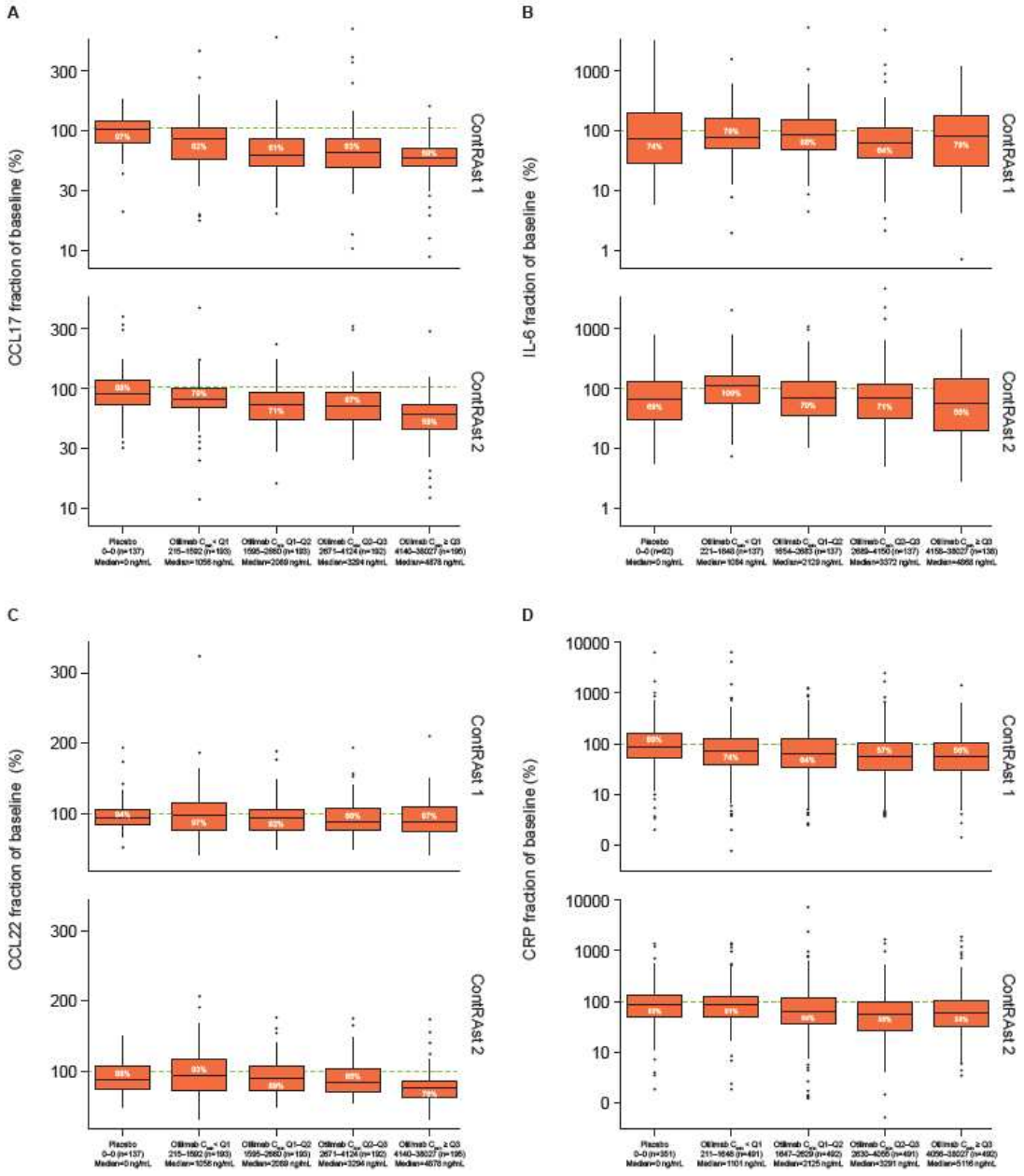



BID, twice daily; C1M, matrix-metalloprotease-degraded Type I collagen, CCL17/22, chemokine (C-C motif) ligand 17/22; CI, confidence interval; CFB, change from baseline; IL-6, interleukin 6; LS, least squares; QW, once weekly; VICM, citrullinated and MMP-degraded vimentin.



Fleischmann RM, *et al. Ann Rheum Dis* 2023; 82:1516–1526. doi: 10.1136/ard-2023-224482

**Supplementary Figure 20.** CFB in A) CCL17, B) IL-6, C) CCL22 and D) CRP at Week 12 versus otilimab $C_{min}$ quartile




CCL17/22, chemokine (C-C motif) ligand 17/22; CI, confidence interval; CFB, change from baseline; CRP, C-reactive protein; IL-6, interleukin 6.

**Supplementary Table 1.** List of study sites and IEC/IRB

| Description and address of research facility/hospital/institution | Name and address of IEC/IRB |
|---|---|
| **ContRAst 1** | |
| **Argentina** | |
| Hospital Privado Centro Medico de Cordoba S.A, Parque Velez Sarsfield, Avenue Naciones Unidas 346, Cordoba, Córdova, X5016KEH, Argentina | Consejo de Evaluación Ética de la Investigación en Salud, Avenue Velez Sarfield 2311, Area Marron, Oficina 3, Cordoba, Cordoba, 5000, Argentina |
| CEMIC, Av Galvan 4102, Ciudad Autonoma de Buenos Aires, Buenos Aires, C1431FWO, Argentina | Comité de Ética en Investigación de CEMIC, Galván 4102, Capital Federal, C1431FWO, Ciudad Autonoma de Buenos Aires, Buenos Aires, 1111, Argentina |
| Clinica Adventista Belgrano, Estomba 1710, Ciudad Autonoma Buenos Aires, Buenos Aires, C1430EGF, Argentina | Comite Independiente De Etica Luis Maria Zieher, J .E Uriburu 774, Ciudada Autonoma de Buenos Aires, Buenos Aires, 1111, Argentina |
| Hospital Militar Central " Cirujano Mayor Dr. Cosme Argerich", Reumatologia, Piso 4 Cons 418, Avenue Luis M. Campos 726, Ciudad Autónoma de Buenos Aires, C1426BOR, Argentina | CIREC, A. Luis Maria Campos 726, Ciudad Autonoma de Buenos Aires, Ciudad Autonoma Buenos Aires, C1426BOR, Argentina |
| Mind Out Research, Jose Pedro Varela - 3901/3954, Ciudad Autonoma Buenos Aires, Buenos Aires, C1417, Argentina | Comite Independiente De Etica Luis Maria Zieher, J .E Uriburu 774, Ciudada Autonoma de Buenos Aires, Buenos Aires,1111, Argentina |
| Hospital Italiano de La Plata, Calle 51 1725 entre 29 y 30, La Plata, Buenos Aires, B1900AXI, Argentina | Administración Nacional de Medicamentos, Alimentos y Tecnologia Médica (Argentina), Avenida de Mayo 869, Ciudad Autónoma de Buenos Aires, Buenos Aires, C1084AAD, Argentina |
| CORDIS S.A., España 1067, Salta, Salta, A4400ANW, Argentina | Administración Nacional de Medicamentos, Alimentos y Tecnologia Médica (Argentina), Avenida de Mayo 869, Ciudad Autónoma de Buenos Aires, Buenos Aires, C1084AAD, Argentina |
| Instituto Medico de alta Complejidad San Isidro S.A (IMAC), Avenida Del Libertador 16958, San Isidro, Buenos Aires, 1643, Argentina | Comite de Etica San Isidro, Avenida Libertador 16958, San Isidro, Buenos Aires, B1643CSQ, Argentina |
| Aprillus Asistencia e Investigación de Arcis Salud SRL, Avenue Corrientes 2554 2do piso, Ciudad Autonoma de Buenos Aires, Buenos Aires, C1046AAQ, Argentina | Comité Independiente de Ética para Ensayos en Farmacología Clínica (FEFyM), Pte. J. E. Uriburu 774 1er Piso, C.A.B.A.,Buenos Aires, C1027AAP, Argentina |
| Fundacion Respirar, Av. Cabildo 1548 1° A, Ciudad Autonoma de Buenos Aires, Buenos Aires, 1426, Argentina | Administración Nacional de Medicamentos, Alimentos y Tecnologia Médica (Argentina),Avenida de Mayo 869, Buenos Aires, C1084AAD, Argentina |
| CER San Juan, Laprida 532, San Juan, San Juan, J5402DIL, Argentina | Comite de Docencia e Investigacion Clinica de CER San Juan, Laprida 568 (E), San Juan, San Juan, J5402DIL, Argentina |
| Sanatorio Parque S.A., Boulevard Orono 860, Rosario, Santa Fe, S2000DSV, Argentina | Comite Provincial de Bioetica - Ministerio de Salud Provincia de Santa Fe, Maipu 835, 2° piso, Rosario, Santa Fe, Santa Fe, 2000, Argentina |
| CCBR - Buenos Aires - AR, Ruiz Huidobro 4693, Ciudad Autonoma Buenos Aires, Buenos Aires, C1430CKE, Argentina | Comite Independiente De Etica Luis Maria Zieher, J .E Uriburu 774, Ciudada Autonoma de Buenos Aires, Buenos Aires, 1111, Argentina |

| | |
|---|---|
| Instituto de Investigaciones Clinicas San Nicolas, Pellegrini 346, San Nicolas, Buenos Aires, B2900DMH, Argentina | Administración Nacional de Medicamentos, Alimentos y Tecnologia Médica (Argentina), Avenida de Mayo 869, Ciudad Autónoma de Buenos Aires, Buenos Aires, C1084AAD, Argentina |
| Sanatorio Alberdi SRL, Absalón Rojas 926/936, Santiago Del Estero, Santiago Del Estero, G4200DYB, Argentina | Administración Nacional de Medicamentos, Alimentos y Tecnologia Médica (Argentina), Avenida de Mayo 869, Ciudad Autónoma de Buenos Aires, Buenos Aires, C1084AAD, Argentina |
| Instituto de Investigaciones Clinicas San Nicolas, Pellegrini 346, San Nicolas, Buenos Aires, B2900DMH, Argentina | Administración Nacional de Medicamentos, Alimentos y Tecnologia Médica (Argentina), Avenida de Mayo 869, Ciudad Autónoma de Buenos Aires, Buenos Aires, C1084AAD, Argentina |
| Sanatorio Alberdi SRL, Absalón Rojas 926/936, Santiago Del Estero, Santiago Del Estero, G4200DYB, Argentina | Administración Nacional de Medicamentos, Alimentos y Tecnologia Médica (Argentina), Avenida de Mayo 869, Ciudad Autónoma de Buenos Aires, Buenos Aires, C1084AAD, Argentina |
| **Canada** | |
| Aggarwal and Associates Limited, Room 201, 490 Bramalea Road, Brampton, Ontario, L6T 0G1, Canada | Western Institutional Review Board, 1019 39th Avenue Southeast, Suite 120, Puyallup, Washington, 98374, Canada |
| Centre de Recherche Musculo-Squelettique, 1119 Suite. Marguerite Street, Trois-Rivieres, Québec, G8Z 1Y2, Canada | Western Institutional Review Board, 1019 39th Avenue Southeast, Suite 120, Puyallup, Washington, 98374, Canada |
| LMC Clinical Research dba Manna Research Inc. Burlington South, 2119 Lakeshore Road, Burlington, Ontario, L7R 1A4, Canada | Western Institutional Review Board, 1019 39th Avenue Southeast, Suite 120, Puyallup, Washington, 98374, Canada |
| **China** | |
| China-Japan Union Hospital of Jilin University, Number 148 Ziyou Road, Changchun, 130033, China | Ethics Committee of China-Japan Union Hospital of Jilin University, Cardiology Department, Number 148 Ziyou Road, Changchun, Jilin, 130033, China |
| Jilin Province People's Hospital, Number 1183 Gongnong Street, Changchun, Jilin, 130021, China | Ethics Committee of Jilin Province People's Hospital, Number 1183 Gongnong Street, Changchun, Jilin, 130021, China |
| The First Affiliated Hospital of Bengbu Medical College, No.287 Changhuai Road, Bengbu, Anhui, 233004, China | Ethics Committee of The First Affiliated Hospital of Bengbu Medical College, No.287 Changhuai Road, Bengbu, Anhui, 233004, China |
| Jiangxi Pingxiang People's Hospital, Number 8 Wugongshanzhong Dadao, Pingxiang, Jiangxi, 337055, China | Ethics Committee of Jiangxi Pingxiang People's Hospital, Number 8 Wugongshanzhong Dadao, Pingxiang, Jiangxi, 337055, China |
| The Affiliated Hospital of Inner Mongolia Medical University, No.1 North Tongdao Road, Huhehaote, Hohhot, 10050, China | Ethics Committee of The Affiliated Hospital of Inner Mongolia Medical University, No.1 North Tongdao Road, Huhehaote, Hohhot, 10050, China |
| ZhuZhou Central Hospital, No.116 South Changjiang Road, ZhuZhou, Hunan, 412007, China | Ethics Committee of ZhuZhou Central Hospital, No.116 South Changjiang Road, ZhuZhou, Hunan, 412007, China |
| Jiangxi Jiujiang 1st People's Hospital, No48 South Taling Rd, Jiujiang, Jiangxi, 332000, China | Ethics Committee of Jiangxi Jiujiang 1st People's Hospital, No48 South Taling Rd, Jiujiang, Jiangxi, 332000, China |
| Xuzhou Central Hospital, No.199 South Jiefang Road, Xuzhou, Jiangsu, 221009, China | Ethics Committee of Xuzhou Central Hospital, No.199 South Jiefang Road, Xuzhou, Jiangsu, 221009, China |

| | |
|---|---|
| West China Hospital, Sichuan University, No.37 Guoxue Lane, Wuhou District, Chengdu, Sichuan, 610041, China | Clinical Trial Ethics Committee of West China Hospital, Sichuan University, No.37 Guoxue Alley Chengdu, Chengdu, Sichuan, 610041, China |
| Yancheng First People's Hospital, No. 66 South Renmin Road, Yancheng, Jiangsu, 224001, China | Medical Ethics Committee of Yancheng First People's Hospital, Number 166 Yulong West Road, Tinghu District, Yancheng, Jiangsu, 224000, China |
| The Affiliated Hospital of Guilin Medical University, No.15 Lequn Road, Guilin, Guangxi, 541001, China | Ethics Committee of The Affiliated Hospital of Guilin Medical University, No.15 Lequn Road, Guilin, Guangxi, 541001, China |
| Subei People Hospital, No. 98 West Nantong Road, Yangzhou, 225000, China | Ethics Committee of Northern Jiangsu People's Hospital, No. 98 West Nantong Road, Yangzhou, Jiangsu, 225001, China |
| Shanghai Huashan Hospital, 12 Wulumuqi Middle Road, Shanghai, 200040, China | Ethics Committee of Huashan Hospital, Fudan University, No. 12, Urumqi Middle Road, Jing'an District, Shanghai, Shanghai, 200040, China |
| The First Affiliated Hospital of Sun Yat-sen University, No. 58 Zhongshan Second Road, Guangzhou, 510080, China | Ethics Committee of The First Affiliated Hospital, Sun Yat-sen University, Number 58 Zhongshan Second Road, Guangzhou, Guangzhou, 510080, China |
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| **India** | |

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| Sri Nidan Hospital and Hope Fertility Centre, 27, Vidut Nagar A, Jaipur, 302006, India | Swastic Independent Ethics Committee, B-130, Modi Nagar, Ajmer Road, Jaipur, Rajasthan, 302019, India |
| Shree Giriraj Multispeciality Hospital, 27 Navjyot Park Corner, 150 Feet Ring Road, Rajkot, 360005, India | Shree Giriraj Hospital Research Ethics Committee, 150 Feet Ring Rd, 27 Navjyot Park Main Road, Amin marg Cross Road, Rajkot, Gujarat, 360005, India |
| 7-Orange Hospital, Pawana Nagar Housing Society, Pimpri-Chinchwad, 411033, India | Intitutional Ethics Committee of Sai Sneh Hospital and Diagnostic Center, 7 Orange Hospital, Pawana Nagar Housing Society, Pimpri Chinchwad, Pune, Maharashtra, 411033, India |
| Government Medical College & Shri Sayajirao General Hospital (SSGH), Jail Road, Raopura, Vadodara, Gujarat, 390001, India | Institutional Ethics Committee For Human Research Medical College Baroda,Government Medical College, Jail Road, Vadodara, Gujarat, 390001, India |
| Nirmal Hospital Pvt. Ltd., Ring Road, Surat, 395002, India | Nirmal Hospital Private Limited Ethics Committee, Nirmal Hospital Private Limited Ethics Committee, Ring Road, Surat, Gujarat, 395002, India |
| Institute of Post Graduate Medical Education And Research, 244 A.J.C. Bose Road, Kolkata, 700020, India | IPGME&R Research Oversight Committee, 244, Acharya Jagdish Chandra Bose Road, Kolkata, West Bengal, 700020, India |
| Sushruta Multispecialty Hospital and Research Centre Pvt. Ltd., Vidyanagar, P. B. Road, Hubli, Karnataka,580021, India | Sushruta Multispeciality Hospital & Res Cen Pvt. Ltd., P. B. Road, Vidyanagar, Hubli, Karnataka 580021, India |
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| Suretech Hospital & Research Centre Ltd, 13 A , Banerjee Marg, Dhantoli, Nagpur, 440012, India | Suretech Hospital & Research Centre Ltd., 13-A, Banerjee Marg,Dhantoli, Nagpur, Maharashtra, 440012,India |
| Sir Ganga Ram Hospital, Department of Internal Medicine, Rajinder Nagar, Delhi, 110060, India | Sir Ganga Ram Hospital Ethics Committee, Room No 1496. IV Floor ,Old Building, Sir Ganga Ram Hospital , Old Rajender Nagar, New Delhi, Delhi, 110060, India |
| Maharaja Agrasen Hospital, West Punjabi Bagh, New Delhi, 110026, India | Institutional Ethics Committee, Maharaja Agrasen Hospital, New Delhi, Delhi, 110026, India |
| S.R.Kalla Memorial Gastro and General Hospital, 78, Dhuleshwar Garden,Behind HSBC Bank,Sardar Patel Marg,, C Scheme, Jaipur, 302001, India | S. R. Kalla Memorial Ethical Committee for Human Research, 78, Dhuleshwar Garden, Behind HDFC Bank,Sardar Patel Marg, C Scheme, Jaipur, Rajasthan, 302001, India |
| Deenanath Mangeshkar Hospital and Research Centre, Erandawane, Pune, 411004, India | Institutional Ethics Committee, Deenanath Mangeshkar Hospital & Research Center, Erandawane, Pune, Maharashtra, 411004, India |
| Chopda Medicare & Research Centre, Magnum Heart Institute, 3/5 Patil Lane No.1, Laxmi Nagar, Nashik, 422005, India | Magna-Care Ethics Committee, Chopda Medicare and Research Centre Pvt.ltd, Magnum Heart Inst, Patil Lane No 1, Near KBH Vidyalaya, Canada Corner, Nashik, Maharashtra, 422005,India |
| Ruby Hall Clinic, Pune, 40 Sasoon Road, Pune,, 411001, India | Institutional Ethics Committee, Poona Medical Research Foundation Pune, E4-C to E4-F, 4th Floor, Fifth Avenue, Pune, Maharashtra, 411001, India |
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| Rheumatic Disease Clinic, 4th Floor, Vedanta Institute of Med Sciences, Ahmedabad, 380009, India | Avron Multi Speciality Hospitals Ethics Committee, 4, Shantiniketan Park, Nr. Sardar Patel Colony, Ahmedabad, Gujarat, 380013, India |
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| Shree Hospital & Critical Care Centre, 799, Omnagar, Sakkardara Square, Umred Road, Nagpur, 440009, India | Shree Hospital Ethics Committee, Nagpur, Maharashtra, 440009, India |
| St. Theresas Hospital, Sanathnagar, Hyderabad, 500018, India | Ethics Committee St. Theresa's Hospital, Erragadda, Sanath Nagar, Hyderabad, Andhra Pradesh, 500018, India |
| Sterling Hospital, Opp. Inox Multiplex, Race course Circle (West), Vadodara, 390007, India | Sterling Ethics Committee, 4th Floor, Phase-1, Sterling Hospital, Opp. Inox, Race Course Circle (West), Vadodara, Gujarat, 390007, India |
| Swastik Rheumatology Clinic, B101 (office) Shilp Aaron, Ahmedabad, 380054, India | Sangini Hospital Ethics Committee, 206-8, Sangini Complex, Near Parimal Garden, Ambawadi, Ellisbridge, Ahmedabad, Gujarat, 380006, India |
| Avron Hospitals, Near Sardar Patel Colony, 4, Shantiniketan Park, Ahmedabad, 380013, India | Avron Multi Speciality Hospitals Ethics Committee, 4, Shantiniketan Park, Nr. Sardar Patel Colony, Ahmedabad, Gujarat, 380013, India |
| Panchsheel Hospital, Near Sabarmati Police Station, High-Way, Ramnagar, Ahmedabad, 380005, India | Panchshil Institutional Ethics Committee, Ahmedabad, Gujarat, 380007, India |
| JSS Medical College, Mahathma Gandhi Road, Jagadguru Sri Shivaratheeshwara Hospital, Mysore, 570004, India | Institutional Ethics Committee, JSS Medical College & Hospital, B. M. Road, Sri Shivarathreeshwara Nagara, New Banimantap Extn, Mysore, Karnataka, 570015, India |
| KLES Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi, 590010, India | Ethics Committee of the KLE University, Nehru Nagar, JNMC Campus, Belgaum, Karnataka, 590010, India |
| **Italy** | |
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| Latvia | |
| Riga Eastern Clinical University Hospital, Hipokrata street .2, Riga, LV 1038, Latvia | Ethics Committee for Clinical Trials of Medicinal Products, Aizkraukles street 21 – 113, Riga, LV1006, Latvia |
| M & M Centre, Gaujas Street 11, Adazi, LV2164, Latvia | Ethics Committee for Clinical Trials of Medicinal Products, Aizkraukles street 21 – 113, Riga, LV1006, Latvia |
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| Hospital Sibu, Bt. 5 1/2, Sibu, 96000, Malaysia | Medical Research Ethics Committee-UMMC, Lembah Pantai, Kuala Lumpur, 59100, Malaysia |
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| Tuanku Ja'afar Hospital, Jalan Rasah, Seremban, Negeri Sembilan, 70300, Malaysia | Medical Research Ethics Committee-UMMC, Lembah Pantai, Kuala Lumpur, 59100, Malaysia |
| University Malaya Medical Centre, Clinical Investigation Centre, 5th Floor, Menara Timur, Kuala Lumpur, 59100, Malaysia | Medical Research Ethics Committee-UMMC, Lembah Pantai, Kuala Lumpur, 59100, Malaysia |
| Hospital Selayang, Lebuhraya Selayang-Kepong, Batu Caves, 68100, Malaysia | Medical Research Ethics Committee-UMMC, Lembah Pantai, Kuala Lumpur, 59100, Malaysia |
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| 1 Wojskowy Szpital Kliniczny w Lublinie, al. Racławickie 23, Lublin, 20-049, Poland | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, Nowowiejskiego, Poznań, 61-734, Poland |
| Silmedic sp. z o.o., ul. Sikorskiego 30 lok 70, Katowice, 40-282, Poland | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, Nowowiejskiego, Poznań, 61-734, Poland |
| NBR Polska Tomasz Kłodawski, ul. 29 Listopada 18A lok. 4, Warszawa, 00-465, Poland | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, Nowowiejskiego, Poznań, 61-734, Poland |
| Synexus Polska Sp. z o.o. Oddzial w Czestochowie, Waly Generala Jozefa Dwernickiego 43/45, Czestochowa, 42202, Poland | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, Nowowiejskiego, Poznań, 61-734, Poland |
| Synexus Polska SCM Sp. z o.o. Gdansku, Beniowskiego 23, Gdansk, 80-382, Poland | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, Nowowiejskiego, Poznań, 61-734, Poland |
| Centrum Medyczne Plejady, ul. Szafrana 5D/U2, U4, U5, Kraków, 30-363, Poland | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, Nowowiejskiego, Poznań, 61-734, Poland |
| Synexus Polska Sp. z o.o., ul. Leszno 12, Warszawa, 01-192, Poland | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, Nowowiejskiego, Poznań, 61-734, Poland |
| RCMed, ul. Zeromskiego 41A, Sochaczew, 96-500, Poland | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, Nowowiejskiego, Poznań, 61-734, Poland |
| KO-MED Centra Kliniczne Lublin II, ul. Przerwy - Tetmajera 21, Lublin, 20-362, Poland | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, Nowowiejskiego, Poznań, 61-734, Poland |
| **Russian Federation** | |
| Pavlov First Saint Petersburg State Medical University, 6-8, L'va Tolstogo street, Saint Petersburg, 197022, Russian Federation | Pavlov First Saint Petersburg State Medical University, 6-8, L'va Tolstogo street, Saint Petersburg, 197022, Russian Federation |
| Siberian State Medical University, 2, Moscovsky trakt, Tomsk, 634050, Russian Federation | Siberian State Medical University, 2, Moscovsky trakt, Tomsk, 634050, Russian Federation |
| Soloviev Hospital, 11 Zagorodny Sad, Yaroslavl, 150003, Russian Federation | Clinical Hospital for Emergency Care n.a. N.V. Solovyov, 11, Zagorodny sad, Yaroslavl, 150003, Russian Federation |
| Kemerovo Regional Clinical Hospital, 22, Oktyabrsky pr., Kemerovo, 650066, Russian Federation | Kemerovo Regional Clinical Hospital, 22, Oktyabrsky pr., Kemerovo, 650066, Russian Federation |
| City Rheumatology Center, Hospital #25, 30, Bolshaya Podyacheskaya, Saint-Petersburg, 190068, Russian Federation | Clinical Rheumatological Hospital # 25, 30, Bolshaya Pod'yacheskay street, Saint-Petersburg, 190068, Russian Federation |
| City Clinical Hospital #15 n.a. O.M. Filatov, 23, Veshnyakovskaya ul., Moscow, 111539, Russian Federation | City Clinical Hospital #15 n.a. O.M. Filatov, 23, Veshnyakovskaya ul. Moscow, 111539, Russian Federation |
| State Institute of Public Health, 45-49, Lunacharskogo pr., Saint-Petersburg, 194291, Russian Federation | State Healthcare Institution "Leningrad Regional Clinical Hospital", 45-49 Lunacharskogo street, Saint Petersburg, 194291, Russian Federation |
| Departmental Hospital on Station Smolensk of OJSC Russian Railways, 15, 1st Krasnoflotsky lane, Smolensk, 214025, Russian Federation | Departmental Hospital on Station Smolensk of OJSC Russian Railways, 15, 1st Krasnoflotsky lane, Smolensk, 214025, Russian Federation |
| TSBIH Krasnoyarsk Interdistrict Clin Hospital of Emergency Medical Care, NSKarpovich, 17, Kurchatova street, Krasnoyarsk, 660062, Russian Federation | Clinical Hospital of Emergency Medical Care n.a. N.S. Karpovich 17, Kurchatova street, Krasnoyarsk, 660062, Russian Federation |

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| Family polyclinic Number 4, Stanzionnaya street, 33, Korolev, 141060, Russian Federation | Family polyclinic Number 4, Stanzionnaya street, 33, Korolev, 141060, Russian Federation |
| State Autonomous Healthcare Institution of Yaroslavl region Hospital # 3, 61,Mayakovskogo street, Yaroslavl, 150007, Russian Federation | Local Ethics Committee at State Autonomous Healthcare Institution of Yaroslavl region Hospital # 3, 61,Mayakovskogo street, Yaroslavl, 150007, Russian Federation |
| Yaroslavl Medical Academy, Rheumatology department of Regional Clinical Hospital, Yakovlevskaya street, 7, Yaroslavl, 150062, Russian Federation | Yaroslavl Regional Clinical Hospital, Cardiovascular department, 7, Yakovlevskaya street, Yaroslavl, 150062, Russian Federation |
| Tver Regional clinical hospital, 105, Peterburgskoe shosse, Tver, 170036, Russian Federation | Tver Regional clinical hospital, 105, Peterburgskoe shosse, Tver, 170036, Russian Federation |
| Centre of Common Medical Practice LLC, 7/1, Krylova street, Novosibirsk, 630091, Russian Federation | Centre of Common Medical Practice LLC, 7/1, Krylova street, Novosibirsk, 630091, Russian Federation |
| Joint-Stock Company "Family Medicine Center", 1, Nachdiva Vasilyeva, Ekaterinburg, 620043, Russian Federation | Joint-Stock Company "Family Medicine Center", 1, Nachdiva Vasilveya, Ekaterinburg, 620043, Russian Federation |
| LLC Practical Medicine, room XII, Birulevskaya street, 1/3, Moscow, 115404, Russian Federation | LLC Practical Medicine, Room XII, Birulevskaya street 1/3, Moscow, 115404, Russian Federation |
| LLC ULTRAMED, 19/12, Krasnykh Zor corner Chkalova street, Omsk, 644024, Russian Federation | LLC ULTRAMED, 19/12, Krasnykh Zor corner Chkalova street, Omsk, 644024, Russian Federation |
| State Budget Healthcare Institution of Yaroslavl Region 'Clinical hospital n.a. N.A. Semashko, 12, Gagarina street, Yaroslavl, 150023, Russian Federation | Clinical Hospital n.a. Semashko N.A. 7, Semashko, Yaroslavl, 150002, Russian Federation |
| SIH Saratov City Clinical Hospital # 2 n.a. V.I. Razumovskiy, 141, Chernyshevskogo street, Saratov, 410028, Russian Federation | SIH Saratov City Clinical Hospital # 2 n.a. V.I. Razumovskiy, 141, Chernyshevskogo street, Saratov, 410028, Russian Federation |
| Ulyanovsk Regional Clinical Hospital, 7, ul. III-go Internatsionala, Ulyanovsk, 432063, Russian Federation | Ulyanovsk Regional Clinical Hospital, 7, ul. III-go Internatsionala, Ulyanovsk, 432063, Russian Federation |
| FSBI "Scientific Research Institute of Rheumatology" of MS, Kashirskoye shosse, 34 A, Moscow, 115522, Russian Federation | Rheumatology Research Institute, Kashirskoye shosse, 34 A, Moscow, Russian Federation, 115522 |
| **Serbia** | |
| Institute of Treatment and Rehabilitation "Niska Banja", Srpskih Junaka 2., Niska Banja, 18205, Serbia | Ethics Committee of Serbia, Vojvode Stepe 458, Belgrade, 11221, Serbia |
| Institute of Rheumatology, Resavska 69, Belgrade, 11000, Serbia | Ethics Committee of Serbia, Vojvode Stepe 458, Belgrade, 11221, Serbia |
| Institute of Rheumatology, Resavska 69, Belgrade, 11000, Serbia | Ethics Committee of Serbia, Vojvode Stepe 458, Belgrade, 11221, Serbia |
| Institute of Rheumatology, Resavska 69, Belgrade, 11000, Serbia | Ethics Committee of Serbia, Vojvode Stepe 458, Belgrade, 11221, Serbia |
| Institute of Rheumatology, ., Resavaska 69, Belgrade, 11000, Serbia | Ethics Committee of Serbia, Vojvode Stepe 458, Belgrade, 11221, Serbia |
| Special Hospital for Rheumatic Diseases, Futoska 68, Novi Sad, 21112, Serbia | Ethics Committee of Serbia, Vojvode Stepe 458, Belgrade, 11221, Serbia |
| Clinical Centre Kragujevac, Clinic for Neurology, Zmaj Jovina 30, Kragujevac, 34000, Serbia | Ethics Committee of Serbia, Vojvode Stepe 458, Belgrade, 11221, Serbia |
| **South Africa** | |
| University of Pretoria Clinical Research Unit, Room 2-54 Pathology Building, Dr Savage Road, Pretoria, 1, South Africa | University of Pretoria, Level 4, Room 4-59, Tswelopele Building opposite BMW building, Pretoria, 0002, South Africa |

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| Iatros International, 20 Captain Proctor Street, Bloemfontein, 9301, South Africa, | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| Synexus SA Stanza Clinical Research Centre, 2 Shilovane Street Mamelodi East, Pretoria, Gauteng, 122, South Africa | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| Dr Halland & Louw Practice, Hennie Winterbach Avenue, Cape Town, 7500, South Africa | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| Dr Halland & Louw Practice, Hennie Winterbach Avenue, Cape Town, 7500, South Africa | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| Newtown Clinical Research Centre, Suite 3, Newgate Centre, 104 Jeppe Street, Johannesburg, 2113, South Africa | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| Tiervlei Trial Centre, Mike Pienaar Boulevard, Cape Town, 7530, South Africa | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| Naidoo, A, Suite 509, Umhlanga Netcare Medical Centre,, Durban, KwaZulu- Natal, 4319, South Africa | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| Synexus SA Watermeyer Clinical Research Centre, Ground Floor Synexus Building, Pretoria, Gauteng, 184, South Africa | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| Clinresco Centres (Pty) Ltd, Central Professional Suites, 20 Central Avenue Kempton Park, Gauteng, 1619, South Africa | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| Synexus Helderberg Clinical Research Centre, Suite 7G and H Arun Place, Sir Lowrys Pass Road, Cape Town, 7130, South Africa | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| Charlotte Maxeke Johannesburg Academic Hospital, Jubilee Road, Johannesburg, 2193, South Africa | Wits Health Consortium, 31 Princess of Wales Terrace, Parktown, Johannesburg, 2193, South Africa |
| Dr Spargo Private Practice, Room 201, 2nd Floor, The Park, Park Road, Pinelands, Cape Town, 7405, South Africa | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| Winelands Medical Research Centre, 14A Oewer Park, Stellenbosch, 7600, South Africa | Pharma Ethics, 123 Amcor Road, 123 Amcor Road,0157, South Africa |
| **Spain** | |
| Hospital Gregorio Marañón, C/ Dr. Esquerdo, 46, Madrid, 28007, Spain | Hospital General Universitario, Pabellón de Gobierno, Primera Planta, C/ Dr. Esquerdo 46, Madrid,28007,spain |
| Hospital Clínico de Santiago, Travesía de Choupana, s/n, Santiago de Compostela. La Coruña., 15706, Spain | Hospital Gregorio Marañón, Comité Ético de Investigación Clínica, Fundación Investigación Biomédica, Pabellón de Gobierno, C/ Dr. Esquerdo, 46, Madrid,28007,spain |
| Complejo Hospitalario Universitario A Coruña, Xubias de Arriba, 84, La Coruña, 15006, Spain | Hospital Gregorio Marañón, Comité Ético de Investigación Clínica, Fundación Investigación Biomédica, Pabellón de Gobierno, C/ Dr. Esquerdo, 46, Madrid,28007,spain |
| Hospital Universitario Reina Sofia, Avda Menendez Pidal S/N, Cordoba, 14004, Spain | Hospital Gregorio Marañón, Comité Ético de Investigación Clínica, Fundación Investigación Biomédica, Pabellón de Gobierno, C/ Dr. Esquerdo, 46, Madrid,28007,spain |
| Institut Universitari Dexeus (Instituto Oncológico Dr. Rosell), C/Sabino Arana, 5-19, Barcelona, 8028, Spain | Hospital Gregorio Marañón, Comité Ético de Investigación Clínica, Fundación Investigación Biomédica, Pabellón de Gobierno, C/ Dr. Esquerdo, 46, Madrid,28007,spain |
| Hospital General Universitario de Elche, Cami, de la Almazara, 11, Elche, 03203, Spain | Hospital Gregorio Marañón, Comité Ético de Investigación Clínica, Fundación Investigación Biomédica, Pabellón de Gobierno, C/ Dr. Esquerdo, 46, Madrid,28007,spain |

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| Hospital Cruces, Plaza de Cruces S/N, Baracaldo/Vizcaya, 48903, Spain | Hospital Gregorio Marañón, Comité Ético de Investigación Clínica, Fundación Investigación Biomédica, Pabellón de Gobierno, C/ Dr. Esquerdo, 46, Madrid,28007,spain |
| Hospital Clinico Universitario de Santiago, Servicio de Reumatologia, Avenida Choupana, s/n, Santiago de Compostela, 15706, Spain | Hospital Gregorio Marañón, Comité Ético de Investigación Clínica, Fundación Investigación Biomédica, Pabellón de Gobierno, C/ Dr. Esquerdo, 46, Madrid,28007,spain |
| Hospital Clínico Universitario de Valencia, Avda. Blasco Ibañez, 17, Valencia, 46010, Spain | Hospital Gregorio Marañón, Comité Ético de Investigación Clínica, Fundación Investigación Biomédica, Pabellón de Gobierno, C/ Dr. Esquerdo, 46,Madrid,28007,spain |
| Hospital Puerta de Hierro, C/ Manuel de Falla, 1, Majadahonda (Madrid), 28222, Spain | Hospital Gregorio Marañón, Comité Ético de Investigación Clínica, Fundación Investigación Biomédica, Pabellón de Gobierno, C/ Dr. Esquerdo, 46, Madrid,28007,spain |
| **Ukraine** | |
| Lviv National Medical University, 4 Nekrasova street., Lviv, 79010, Ukraine | LEC CNE of LRC Lviv Reg Clin Hospital, 7, Chernihivska St., Lviv, 79010, Ukraine |
| Medical Center of Edelweiss Medics LLC, 8-B, Raisy Okipnoyi St., Kyiv, 2002, Ukraine | LEC LLC Treatment and Diagnostic Center ADONIS Plus, 8-B, Raisy Okipnoyi Street, Kyiv , 02002, Ukraine |
| Limited Liability Company Medical Center "Salutem", 46A, Soborna Street., Vinnytsia, 21050, Ukraine | LEC Med Center Saliutem LLC, 46A, Soborna Street, Vinnytsia, 21050, Ukraine |
| Medical Center of Limited Liability Company Medical Clinic Blagomed, 20, Esplanadna street, office 417, Kyiv, 1023, Ukraine | LEC Mun.Inst.Kyiv Reg.Oncolog. Dispensary, 20, Esplanadna street., office 417, Kyiv, 01023, Ukraine |
| Clinical Treatment & Diagnostic Center of LLC SIMEDGROUP, 91-A, Fedkovycha Street., Ivano-Frankivsk, 76008, Ukraine | |
| M.D.Strazhesko Institute of Cardiology AMS Ukraine, 5 Narodnogo Opolchenija Street., Kyiv, 3680, Ukraine | Central Ethics Commission of the Ministry of Health of Ukraine, 5, Narodnoho Opolchennia St., Kyiv, 03680, Ukraine |
| GI L.T.Malaya Therapy Institute of NAMSU, 2A, Prosp. Postysheva Avenue, Kharkiv, 61039, Ukraine | LEC State Institution L.T. Mala Institute of Therapy of Academy of Medical Sciences of Ukraine, 2A, Prosp.Liubovi Maloyi Avenue, Kharkiv, 61039, Ukraine |
| Medical Clinical Investigational Center MC LLC Health Clinic, Department of Gastroenterology, Hepatology and Endocrinology, Rm 166, 1 Striletska Street, Vinnytsia, 21009, Ukraine | The Ethics Commission at Medical Center of LLC Health Clinic, prym.166, 1, Striletska Street., Vinnytsia, 21009, Ukraine |
| National Medical Univ,O.O.Bogomolets, Kyiv Clinical Hospital #3, 26 P. Zaporozhtca street, Kyiv, 2125, Ukraine | The Ethics Commission at CNE Kyiv City Clinical Hospital #3 of Executive Body of Kyiv City Council (Kyiv City State Administration), 26, P.Zaporozhtsia Street, Kyiv, 02125, Ukraine |
| City Clinical Hospital #3, 100, Holovna Street, Chernivtsi, 58000, Ukraine | The Ethics Commission at CNE City Clinical Hospital #3 of Chernivtsi City Council, 100, Holovna Street, Chernivtsi, 58000, Ukraine |
| GI L.T.Malaya Therapy National Institute of the NAMS of Ukraine, 2-a, Prosp. Liubov Malaya Avenue, Kharkiv, 61039, Ukraine | The Ethics Commission and Deontology at Government Institution L.T.Malaya Therapy National Institute of NAMS of Ukraine, 2a, prosp. Luibovi Maloi Avenue, Kharkiv, 61039, Ukraine |
| Medical Center 'Ok!Clinic+' of International Institute of Clinical Trials LLC, 121, Kharkivske shosse street, Kyiv, 2091, Ukraine | LEC Medical Center LLC Ok!Clinic+, 121, Kharkivske shose Street, Kyiv, 02091, Ukraine |

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| Ctr of Reconstructive & Restorative Medicine-Odessa National Medical Uni, Valikhovskyi Lane, 2, Odesa, 65000, Ukraine | LEC Center for Reconstructive and Restorative Medicine (University Hospital) Odessa National MUH U, 8, Tenysta Street, Odesa, 65009, Ukraine |
| MC of Sub Prod Unit Med Scient Pract Union Medbud of PJSc HC Kyivmiskbud, 17, Prosp. Lobanovscogo Avenue Kyiv, 3037, Ukraine | LEC Medical-Practical Association Medbud of PJSC Kyivmiskbud, 17, Prospekt Lobanovskoho Avenue, Kyiv, 03037, Ukraine |
| Zaporizhzhia City Multidisciplinary Clinical Hospital #9, 1 Shchaslyva St, Zaporizhzia, 69065, Ukraine | LEC CNE City Hospital #9 of Zaporizhzhia City Council, Building.1, Shchaslyva Street, Zaporizhzhia, 69065, Ukraine |
| LLC Treatment-Diagnostic Center ADONIS plus, 8b, Raisy Okipnoi, Kyiv, 2002, Ukraine | LEC LLC Treatment and Diagnostic Center ADONIS Plus 8-B, Raisy Okipnoyi St. Kyiv ,02002, Ukraine |
| CI Cherkasy RH of Cherkasy Regional Council, 3, Mendelieieva Street , Cherkasy, 18009, Ukraine | LEC LLC Treatment and Diagnostic Center ADONIS Plus, 8-B, Raisy Okipnoyi Street, LLC Treatment-Diagnostic Center ADONIS plus, Kyiv, 02002, Ukraine |
| LLC Medical Center Concilium Medical, 17,Hlybochytska St., Kyiv, 4054, Ukraine | LEC LLC Medical Centre CONSILIUM MEDICAL, 17, Glybochytska Street, Kyiv, 04050, Ukraine |
| Odessa Regional Clinical Hospital, 26, Zabolotnogo Street., Odessa, 65025, Ukraine | LEC Communal Institution Odesa Regional Clinical Hospital, 26, Acad. Zabolotnyi Street, Odesa, 65025, Ukraine |
| CHI Kharkiv City Clinical Hospital #13, 137, Prosp. Haharina Avenue, Kharkiv, 61124, Ukraine | LEC CNE City Clinical Hospital #13 of Kharkiv City Council, 137, Prosp. Gagarina Avenue Kharkiv, 61124, Ukraine |
| Military&Medical Clinical Ctr of Lvivof State Border Guard Service-Ukraine, 107, Lychakivska St., Lviv, 79049, Ukraine | LEC CNE Vinnytsia City Clinical Hospital #1, 96, Khmelnytske shose Street, Vinnytsia, 21029, Ukraine |
| CNE Vinnytsya City Clinical Hospital #1, 96,Khmelnytske shose St., Vinnytsia, 21029, Ukraine | LEC CNE Vinnytsia City Clinical Hospital #1, 96, Khmelnytske shose Street, Vinnytsia, 21029, Ukraine |
| Kyiv regional clinical hospital, 1, Baggoutivska street, Kyiv, 4107, Ukraine | LEC CNE of Kyiv Regional Council Kyiv Regional Clinical Hospital, 1, Bahhovutivska Street, Kyiv, 04107, Ukraine |
| CI City Hospital #1, 21A, Chumachenka St., Zaporizhzhia, 69014, Ukraine | LEC CI City Hospital #1, 21-A Chumachenko Street, Zaporizhzhia, 69104, Ukraine |
| Medical Center Clinic of Modern Rheumatology, 20, Central blvd, Zaporizhzhia, 69005, Ukraine | The Ethics Commission at LLC “Suchasna klinika”, prym. 210, 20 Tsentralnyi Blvd., Zaporizhzhia,69600, Ukraine |
| Regional Clinical Hosp n a O F Herbachevskyi of Zhytomyr Regional Council, 3 Chervonoho Khresta street, Zhytomyr, 10002, Ukraine | LEC O.F.Herbachevskyi Reg.Clin.Hospital of Zhytomyr RC, 3, Chervonoho Khresta Street, Zhytomyr, 10002, Ukraine |
| Kyiv City Clinical Hospital #3, 26, P.Zaporozhtsia St., Kyiv, 2125, Ukraine | LEC Kyiv City Maternity House #6, 26, Petra .Zaporozhtsia Street, Kyiv, 02125, Ukraine |
| SRI of Invalid Rehabilitation -EST Complex, Vinnytsia M.I.Pyrogov NMU MOHU, 104 Khmelnyske Shosse, Vinnytsya, 21029, Ukraine | LEC Scient.&Research Instit.of Invalid Rehabiltation of Vinnytsia M.I.Pyrogov Nat.Med.Univer. 104, Khmelnytske Shose St., Vinnytsia, 21029, Ukraine |
| CI of TRC Ternopil UH, 1, Klinichna St., Ternopil, 46002, Ukraine | The Ethics Commission at CNE Ternopil University Hospital of Ternopil Regional Council, 1, Klinichna Street, Ternopil, 46002, Ukraine |
| M.I. Pyrogov Vinnytsia RCH, Pyrogova St., 46, Vinnytsia, 21018, Ukraine | LEC Vinnytsia M.I.Pyrogov Regional Clinical Hospital, 46, Pyrogova Street, Vinnytsia, 21018, Ukraine |
| CE Volyn Regional Clinical Hospital, 21,prosp.Presidenta Hrushevskoho, Lutsk, 43005, Ukraine | The Ethics Commission at Communal Enterprise Volyn Regional Clinical Hospital of Volyn Regional Council, 21, prosp.Presidenta Hrushevskoho, Lutsk, 43005, Ukraine |

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| CNE Consultative - Diagnostic Center of Pecherskyi District of Kyiv, 13, Pidvysotskogo Str, Kyiv, 1103, Ukraine | The Ethics Commission at CNE Consultative and Diagnostic Center of Pecherskyi District of Kyiv, 13, Pidvysotskoho Street, Kyiv, 01103, Ukraine |
| Multidisciplinary Medical Center of Odesa National Medical University, 9,Pastera St, Odesa, 65026, Ukraine | LEC Multifield Med.Center of Odesa NMU (University Clinic #1), 9, Pastera Street, Odesa, 65026, Ukraine |
| CI Lutsk CCH Volyn Regional Center, 13, Prosp.Vidrodzhennia Avenue Lutsk, 43024, Ukraine | The Ethics Commission at CE Medical Association of Lutsk City Territorial Community, Volyn Regional Center of Cardiovascular Pathology, 13, Prosp.Vidrodzhennia Avenue 43024, Lutsk, Ukraine |
| CNE City Clinical Hospital #8 of KCC, 266-g, Saltivske Shose St., Kharkiv, 61176, Ukraine | The Ethics Commission at Communal Noncommercial Enterprise City Clinical Hospital #8 of Kharkiv City Council, 266 h, Saltivske shose Street, Kharkiv, 61176, Ukraine |
| Regional Clinical Hospital, 91 Fedkovycha street, Ivano-Frankivsk, 76008, Ukraine | LEC CNE Reg Clinical Hospital Ivano-Frank RC, 91, Fedkovycha Street, Ivano-Frankivsk, 76008, Ukraine |
| Railway Transport Kyiv CH#2-Healthcare Ctr Branch of PJSC Ukrainian Railway, 9, Povitroflotsky prosp, Kyiv, 3049, Ukraine | LEC Kyiv CI Hosp on Railway Transport #2 of Healthcare Center branch of JSC "Ukrainian Railway", 9, Povitroflotsky prosp, Kyiv, 03049, Ukraine |
| Poltava Regional Clinical Hospital, 23 Shevchenko Street., Poltava, 36011, Ukraine | LEC Poltava Reg.Clin.Hosp.n.a.M.V.Sklifosovskogo, 23, Shevchenka Street, Poltava, 36011, Ukraine |
| Private Small Enterprise Medical Center Pulse, 34,Timiriazieva St., Vinnytsia, 21001, Ukraine | LEC Private Small Enterprise Med. Center Pulse, 34, Timirazieva Street, Vinnytsia, 21001, Ukraine |
| **United Kingdom** | |
| MeDiNova East London Clinical Studies Centre, Blackburn House, 22 - 26 Eastern Road, Romford, Essex, RM1 3PJ, United Kingdom | South Central-Berkshire B Research Ethics Committee, Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT. |
| MeDiNova Ltd, North London Clinical Studies Centre, Mount Vernon Hospital, Rickmansworth Road, Northwood, Middlesex, HA6 2RN, United Kingdom | South Central-Berkshire B Research Ethics Committee, Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT. |
| Medinova Warwickshire Quality Research Site, 42 Station Rd, Kenilworth, Warwickshire, CV8 1JD, United Kingdom | South Central-Berkshire B Research Ethics Committee, Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT. |
| **United States of America** | |
| Well Pharma Medical Research Corporation, Suite 100, 7000 Southwest 62 Avenue, South Miami, Florida, 33143, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, 27513, North Carolina, United States. |
| Arizona Arthritis and Rheumatology Research, 9520 W. Palm Ln. Suite 220, Phoenix, Arizona, 85037, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Oklahoma Medical Research Foundation, 630 24th Avenue, SW, Norman, Oklahoma, 73069, United States | Oklahoma Medical Research Foundation, MS22, 825 N.E. 13th St, Oklahoma City, 73104, Oklahoma, United States |
| Omega Research MetroWest, LLC, Suite 400, 1743 Park Center Drive, Orlando, Florida, 32835, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Precision Comprehensive Clinical Research Solutions, 5009 Heritage Avenue, Colleyville, Texas, 76034, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Arizona Arthritis and Rheumatology Research, 4550 E Bell Rd, Phoenix, Arizona, 85032, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |

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| Advanced Rheumatology of Houston, Suite 120, 10857 Kuykendahl Road, The Woodlands, Texas, 77382, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| University of South Florida - Parent, MDC-81, 13330 USF Laurel Drive, Tampa, Florida, 33612, United States | Western Institutional Review Board-Copernicus Group incorporated, Suite 120, 1019 39th Avenue. S.E, Puyallup, 98374-2115, Washington, United States |
| Northside Hospital, 1000 Johnson Ferry Rd NE, Atlanta, Georgia, 30342-1606, United States | Western Institutional Review Board-Copernicus Group incorporated, Suite 120, 1019 39th Avenue. S.E, Puyallup, 98374-2115, Washington, United States |
| Pinnacle Research Group LLC, Suite 200, 409 East 10th Street, Anniston, Alabama, 36207, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, 27513, North Carolina, United States |
| Physicians Research Institute, Suite 120, 3901 Pine Lake Rd, Lincoln, Nebraska, 68516, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Pioneer Research Solutions, 21212 Northwest Fwy #375, Cypress, Texas, 77429, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, 27513, North Carolina, United States |
| Trinity Medical Group Health Center - Medical Arts, 400 East Burdick Expressway, Minot, North Dakota, 58701, United States | Trinity Hospitals IRB, One Burdick Expressway West, Minot, 58701, North Dakota, United States |
| Accurate Clinical Management - Partner, Suite 200, 11920 Astoria Boulevard, Houston, Texas, 77089, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Assuta Medical Group, Suite 1407, 12922 Victory Boulevard, North Hollywood, California, 91606, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Lakes Research LLC, 5801 NW 151 St., Miami Lakes, Florida, 33014, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, 27513, North Carolina, United States |
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| Cincinnati Rheumatic Disease Study Group, Inc. (CRDSG), Suite 26, 10495 Montgomery Road, Cincinnati, Ohio, 45242, United States | Copernicus Group IRB, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513 United States |
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| Kagawa University Hospital, 1750-1, Ikenobe, Miki-cho, Kita-gun, Kagawa, 761-0793, Japan | Kagawa University Hospital Institutional Review Board,<br>1750-1, Ikenobe, Miki-cho, Kita-gun, Kagawa, 761-0793, Japan |
| Chubu Rosai Hospital, 1-10-6, Komei, Minato-ku, Nagoya-city, Aichi, 455-8530, Japan | Review Board of Human Rights and Ethics for Clinical Studies 13-2, Ichibancho Chiyoda-ku, Tokyo, 104-0031, Japan |
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| Showa University Hospital, 1-5-8, Hatanodai, Shinagawa-ku, Tokyo, 142-8666, Japan | Showa University Hospital Institutional Review Board, 1-5-8, Hatanodai, Shinagawa-ku, Tokyo, 142-8666, Japan |
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| Bay Side Misato Medical Center, 1617-5, Niida, Kochi-shi, Kochi, 781-0112, Japan | IHL Shinagawa East One Medical Clinic IRB, 2-16-1, Konan, Minato-ku, Tokyo, 108-0075, Japan |
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| Kita-Harima Medical Center, 926-250, Ichiba-cho, Ono-shi, Hyogo, 675-1392, Japan | Sanyakai Maebashi, Hirosegawa Clinic IRB, Chiyoda-machi 2-10-9, Maebashi-shi, Gunma-Ken, 371-0022, Japan |
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| Hitachi Limited. Hitachinaka General Hospital, 20-1, Ishikawa-cho, Hitachinaka-city, Ibaraki, 312-0057, Japan | Review Board of Human Rights and Ethics for Clinical Studies, 13-2 Ichibancho, Chiyoda-ku, Tokoyo, 102-0082, Japan |
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| Saint Luke's International Hospital, 9-1, Akashi-cho, Chuo-ku, Tokyo, 104-8560, Japan | Saint Luke's International Hospital Institution Review, Board, Akashi-cho 9-1 Chuo-ku Tokyo, 104-8560, Japan |
| Shimonoseki City Hospital, 1-13-1, Koyo-cho, Shimonoseki-shi, Yamaguchi, 750-8520, Japan | Shimonoseki City Hospital IRB, Koyo-cho 1-13-1, Shimonoseki-shi, Yamaguchi-ken, 750-8520, Japan |
| Nagaoka Red Cross Hospital, 2-297-1, Senshu, Nagaoka-shi, Niigata, 940-2085, Japan | Nagaoka Red Cross Hospital, 2-297-1, Senshu, Nagaoka-shi, Niigata, 940-2085, Japan |
| Kumamoto Orthopaedic Hospital, 1-15-7, Kuhonji, Chuo-ku, Kumamoto-shi, Kumamoto, 862-0976, Japan | Kumamoto Orthopaedic Hospital, 1-15-7, Kuhonji, Chuo-ku, Kumamoto-shi, Kumamoto, 862-0976, Japan |
| National Hospital Organization Shimoshizu National Hospital, 934-5, Shikawatashi, Yotsukaido-city, Chiba, 284-0003, Japan | NHO Institutional Review Board, Higashigaoka 2-5-21<br>Meguro-ku, Tokyo, 152-8621, Japan |
| Seijinkai Hokkaido Medical Center for Rheumatic Diseases, 3-1-45, Kotoni1jo, Nishi-ku, Sapporo-shi, Hokkaido, 063-0811, Japan | Seijinkai Hokkaido Medical Center for Rheumatic Diseases IRB, Nishi-ku Kotoni 1jo 3-1-45, Sapporo-shi, Hokkaido, 063-0811, Japan |
| National Hospital Organization Tokyo Hospital, 3-1-1, Takeoka, Kiyose-city, Tokyo, 204-8585, Japan | NHO Institutional Review Board, 2-5-21, Higashigaoka,<br>Meguro-ku Tokyo, 152-8621<br>Japan |
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| Hallym University Sacred Heart Hospital, 22 Gwanpyeong-ro 170beon-gil, Dongan-gu, Anyang-si, 431-070, Republic of Korea | Hallym University Sacred Heart Hospital, 22 Gwanpyeong-ro 170beon-gil, Dongan-gu, Anyang-si, 431-070, Republic of Korea |
| Keimyung University Dongsan Hospital, 1035, Dalgubeol-daero, Dalseo-gu, Daegu-si, 42601, Republic of Korea | Keimyung University Dongsan Hospital, 1035, Dalgubeol-daero, Dalseo-gu, Daegu-si, 42601, Republic of Korea |
| Asan Medical Center-Seoul-Korea-C, 88, Olympic-ro, 43-gil, Songpa-gu, Seoul, 5505, Republic of Korea | Asan Medical Center-Seoul-Korea-C, 88, Olympic-ro, 43-gil, Songpa-gu, Seoul, 5505, Republic of Korea |
| Seoul National University Hospital, 101 Daehak-ro Jongno-gu, Seoul, 3080, Republic of Korea | Seoul National University Hospital, 101 Daehak-ro Jongno-gu, Seoul, 3080, Republic of Korea |
| Chonnam National University Hospital, 42 Jebong-ro, Dong-gu, Gwangju, 61469, Republic of Korea | Chonnam National University Hospital, 42 Jebong-ro, Dong-gu, Gwangju, 61469, Republic of Korea |
| Seoul National University Bundang Hospital, 82 Gumi-ro 173 beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, 13620, Republic of Korea | Seoul National University Bundang Hospital, 82 Gumi-ro 173 beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, 13620, Republic of Korea |
| Inha University Hospital, 27,Inhang-ro, Jung-gu,, Incheon, 22332, Republic of Korea | Inha University Hospital, 27,Inhang-ro, Jung-gu,, Incheon, 22332, Republic of Korea |
| Severance Hospital, Yonsei University Health System, 50-1 Yonsei-ro Seodaemun-gu, Seoul, 3722, Republic of Korea | Severance Hospital, Yonsei University Health System, 50-1 Yonsei-ro Seodaemun-gu, Seoul, 3722, Republic of Korea |
| Chungnam National University Hospital, 282 Munhwa-ro, Jung-gu, Daejeon, 301-721, Republic of Korea | Chungnam National University Hospital, 282 Munhwa-ro, Jung-gu, Daejeon, 301-721, Republic of Korea |
| Ajou University Hospital, 164, World Cup-ro, Yeongtong-gu, Suwon, 16499, Republic of Korea | Ajou University Hospital, 164, World Cup-ro, Yeongtong-gu, Suwon, 16499, Republic of Korea |
| Kyung Hee University Hospital at Gangdong, 149 Sangil-dong, Seoul, 134-727, Republic of Korea | Kyung Hee University Hospital at Gangdong, 149 Sangil-dong, Seoul, 134-727, Republic of Korea |
| Hanyang University Seoul Hospital, 222-1 Wangsimni-ro Seongdong-gu, Seoul, 4763, Republic of Korea | Hanyang University Seoul Hospital, 222-1 Wangsimni-ro Seongdong-gu, Seoul, 4763, Republic of Korea |
| Jeonbuk national university hospital, 20, Geonjiro, Deokjin-gu, Jeonju-si, Jeollabuk-do, 54907, Republic of Korea | Jeonbuk national university hospital, 20, Geonjiro, Deokjin-gu, Jeonju-si, Jeollabuk-do, 54907, Republic of Korea |
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| Synexus Polska sp. z o.o. Oddział we Wrocławiu, Ul. Marii. Curie-Skłodowskiej 12, Wrocław, 50-381, Poland. | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, ul. Nowowiejskiego 51, Poznań, 61-734, Poland. |
| ai centrum medyczne sp. z o.o. sp.k., ul. Swietojanska 1, Poznan, 61-113, Poland. | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, ul. Nowowiejskiego 51, Poznań, 61-734, Poland. |
| Silmedic sp. z o.o., ul. Sikorskiego 30 lok 70, Katowice, 40-282, Poland. | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, ul. Nowowiejskiego 51, Poznań, 61-734, Poland. |
| Synexus Polska Sp. z o.o. Oddzial w Czestochowie, Waly Generala Jozefa Dwernickiego 43/45, Czestochowa, 42202, Poland. | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, ul. Nowowiejskiego 51, Poznań, 61-734, Poland. |
| Synexus Polska SCM Sp. z o.o. Gdansku, Beniowskiego 23, Gdansk, 80-382, Poland. | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, ul. Nowowiejskiego 51, Poznań, 61-734, Poland. |
| Synexus Polska Sp. z o.o., ul. Leszno 12, Warszawa, 01-192, Poland. | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, ul. Nowowiejskiego 51, Poznań, 61-734, Poland. |
| RCMed, ul. Zeromskiego 41A, Sochaczew, 96-500, Poland | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, ul. Nowowiejskiego 51, Poznań, 61-734, Poland. |
| Medycyna Kliniczna, ul. Wronia 53 lok. B10 (Green Corner), Warszawa, 00-874, Poland. | Kom Bioet przy Okręgowej Izbie Lekarskiej Wielkopolskiej Izby Lekarskiej, ul. Nowowiejskiego 51, Poznań, 61-734, Poland. |
| **Russian Federation** | |
| City Hospital #8, Suzdalskoe shosse, 39, Yaroslavl, 150030, Russian Federation. | Clinical Hospital #2, 39 Suzdalskoe shosse, Yaroslavl, 150030, Russian Federation. |
| Siberian State Medical University, 2, Moscovskiy trakt, Tomsk, 634050, Russian Federation. | LEC under Siberian State Medical University of Roszdrav, 2, Moskovsky trakt, Tomsk, 634050, Russian Federation. |
| Sverdlovsk Regional Clinical Hospital # 1, 185, Volgogradskaya Street, Ekaterinburg, 620102, Russian Federation. | Sverdlovsk Regional Clinical Hospital # 1, 185, Volgogradskaya Street, Ekaterinburg, 620102, Russian Federation. |
| Kemerovo Regional Clinical Hospital, 22, Oktyabrsky pr., Kemerovo, 650066, Russian Federation. | Kemerovo Regional Clinical Hospital, 22, Oktyabrsky pr., Kemerovo, 650066, Russian Federation. |
| City Rheumatology Center, Hospital #25, 30, Bolshaya Podyacheskaya, Saint-Petersburg, 190068, Russian Federation. | Clinical Rheumatological Hospital # 25, 30, Bolshaya Pod'yacheskay str, Saint-Petersburg, 190068, Russian Federation. |
| City Clinical Hospital #15 n.a. O.M.Filatov, 23, Veshnyakovskaya ul., Moscow, 111539, Russian Federation. | Moscow City Independent Ethics Committee, 12, bld, 2, Minskaya street, Moscow, 121096, Russian Federation. |
| LLC Consultative and Diagnostic Center of Rheumatology "Healthy Joints", 30, Ordzhonikidze street, Novosibirsk, 630099, Russian Federation. | LLC Consultative and Diagnostic Center of Rheumatology "Healthy Joints", 30, Ordzhonikidze street, Novosibirsk, 630099, Russian Federation. |
| Family polyclinic № 4, Stanzionnaya str., 33, Korolev, 141060, Russian Federation. | LEC of OOO "Family polyclinic", Stanzionnaya str.33, Korolev, Moscow Region, 141060 |
| State Autonomous Healthcare Institution of Yaroslavl region Hospital # 3, 61,Mayakovskogo street, Yaroslavl, 150007, Russian Federation. | |
| Moscow Regional Research Clinical Institute n.a. M.F.Vla, 61/2, Shchepkina ul., Moscow, 129110, Russian Federation. | Moscow Regional Research Clinical Institute n.a. M.F.Vla, 61/2, Shchepkina ul., Moscow, 129110, Russian Federation. |
| Yaroslavl Regional Clinical Hospital, Yakovlevskaya street, 7, Yaroslavl, 150062, Russian Federation. | Yaroslavl Regional Clinical Hospital, Yakovlevskaya street, 7, Yaroslavl, 150062, Russian Federation. |

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| Centre of Common Medical Practice LLC, 7/1, Krylova street, Novosibirsk, 630091, Russian Federation. | Centre of Common Medical Practice LLC, 7/1, Krylova street, Novosibirsk, 630091, Russian Federation. |
| LLC "Medical Center" Revma-Med ", 6-4, Molodezhny prospekt, Kemerovo, 650070, Russian Federation. | LLC "Medical Center" Revma-Med ", 6-4, Molodezhny prospect, Kemerovo, 650070, Russian Federation. |
| LLC Practical Medicine, room XII, Birulevskaya str, 1/3,, Moscow, 115404, Russian Federation. | LLC Practical Medicine, room XII, Birulevskaya str, 1/3, Moscow, 115404, Russian Federation. |
| LLC ULTRAMED, 19/12, Krasnykh Zor corner Chkalova str, Omsk, 644024, Russian Federation. | LLC Ultramed, 19/12, Krasnykh Zor corner Chkalova str, Omsk, 644024, Russian Federation. |
| LLC Medical Centre "Maximum Health", Pritomsky prospekt 35, bldg.1, Kemerovo, 650066, Russian Federation. | LLC Medical Centre "Maximum Health", Pritomsky prospekt 35, bldg.1, Kemerovo, 650066, Russian Federation. |
| Krasnoyarsk State Medical University, 12, Instrumentalnaya, Krasnoyarsk, 660123, Russian Federation. | Krasnoyarsk State Medical University, 12, Instrumentalnaya, Krasnoyarsk, 660123, Russian Federation. |
| Ulyanovsk Regional Clinical Hospital, 7, ul. III-go Internatsionala, Ulyanovsk, 432063, Russian Federation. | LEC of SHI Ulyanovsk Reg Clinical Hospital, 7, Street of III International, Ulyanovsk, 432063 |
| Federal State Budgetary Scientific Inst Research Institute of Rheumatology, V.A. Nasonova, 34A, Kashirskoe shosse, Moscow, 115522, Russian Federation. | Rheumatology Research Institute, Kashirskoye shosse, 34 A, Moscow, 115522, Russian Federation. |
| **Spain** | |
| Hospital Universitario Ramon y Cajal, Carretera de Colmenar Viejo km 9,100, Madrid, 28034, Spain. | Hospital General Universitario Gregorio Marañon, C/ Doctor Esquerdo, 46, Madrid, Madrid, 228007, Spain. |
| Hospital Universitario Marqués de Valdecilla, Avda.de Valdecilla s/n, Santander, 39008, Spain. | Hospital General Universitario Gregorio Maranon, Dr Esquerdo 46, Madrid, 28007, Spain. |
| Hospital de Merida, Poligono Nueva Ciudad S/N, Merida, 6800, Spain. | Hospital General Universitario Gregorio Maranon, Dr Esquerdo 46, Madrid, 28007, Spain. |
| Hospital de la Santa Creu y Sant Pau, Sant Antoni Maria Claret 167, Barcelona, 8025, Spain. | Hospital Gregorio Marañón, C/ Dr. Esquerdo, 46, Madrid, 28007, Spain. |
| Hospital Nuestra Sra. de Valme, Ctra. de Cádiz-Bellavista, km.548,9n, Sevilla, 41014, Spain. | Hospital General Universitario, Pabellón de Gobierno, Primera Planta, C/ Dr. Esquerdo 46, Madrid, 28007, Spain. |
| Hospital Universitari Vall d'Hebron, Passeig Vall d'Hebron 119-129, Barcelona, 8035, Spain. | Hospital Gregorio Marañón, C/ Dr. Esquerdo, 46, Madrid, 28007, Spain. |
| Hospital del Mar, Passeig Maritim 25-29, Badalona, Catalonia, 08003, Spain. | Hospital Gregorio Marañón, C/ Dr. Esquerdo, 46, Madrid, 28007, Spain |
| Hospital Universitario Virgen Macarena, Avd. Dr Fedriani, 3, Sevilla, 41007, Spain. | Hospital Gregorio Marañón, C/ Dr. Esquerdo, 46, Madrid, 28007, Spain. |
| **Thailand** | |
| Rajavithi Hospital, 2 Phayathai Rd., Rachathewee, Bangkok, 10400, Thailand. | Central Research Ethics Committee (CREC), National Research Council of Thailand, 196 Phahonyothin Rd, Lat Yao, Chatuchak, Bangkok, Bangkok, 10900, Thailand. |
| Siriraj Hospital, Division of Rheumatology, 2 Prannok road, Bangkok, 10700, Thailand | Siriraj Institutional Review Board (SiRB), His Majesty the King's 80th Birthday Anniversary, 5th December 2007 Building. 2nd Floor, Room no. 210. 2 Prannok Road, Prannok, Bangkoknoi, Bangkok, 10700, Thailand |
| Srinagarind Hospital, 123 Mittraparb Road., Muang, 40002, Thailand | Central Research Ethics Committee (CREC), National Research Council of Thailand, 196 |

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| | Phahonyothin Rd, Lat Yao, Chatuchak, Bangkok, Bangkok, 10900, Thailand |
| Phramongkutklao Hospital, 315 Rajavithi Road, Rajathevee, 10400, Thailand. | Narongroeknawin, Pongthorn. MD, 315 Rajavithi Road, Rajathevee, 10400, Thailand. |
| Prince of Songkla University, Department of Medicine, 15 Karnjanavanit Road, Songkla, 90110, Thailand. | Central Research Ethics Committee, 5th Fl. bulding 2, The National Research Council of Thailand, Paholyothin Rd.,Bangkhen, Bangkok, 10900, Thailand. |
| **United Kingdom** | |
| Accellacare East London, Blackburn House, 22-26 Eastern Road, Romford, Essex, RM1 3PJ, United Kingdom | NA |
| Medinova Clinical Reasearch Ltd, Rickmansworth Rd, Northwood, HA6 2RN, United Kingdom | NA |
| Mile End Hospital, Bancroft Road, London, London, E1 4DG, United Kingdom | NA |
| Western General Hospital, Crewe Road, Edinburgh, EH4 2XU, United Kingdom | NA |
| Medinova Warwickshire Quality Research Site, 42 Station Road, Kenilworth, Warwickshire, CV8 1JD, United Kingdom | Accellacare – Amendments, ACCELLACARE Head Office, Friars House, Manor House Drive, Coventry, West Midlands, CV1 2TE, United Kingdom |
| **United States of America** | |
| DM Clinical Research, Suite 53, 13406 Medical Complex Drive, Tomball, Texas, 77375, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Denver Arthritis Clinic, Suite 100, 200 Spruce Street, Denver, Colorado, 80230, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States |
| Riverside Medical Clinic, 7117 Brockton Avenue, Riverside, California, 92506, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States |
| Clinical Trials of SW Louisiana LLC, 600 Bayou Pines East Drive, Lake Charles, Louisiana, 70601, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way Cary, North Carolina, 27513, United States |
| Precision Comprehensive Clinical Research Solutions, Suite 200, 1452 Hughes Road, Grapevine, Texas, 76051, United States | Copernicus Group IRB, 5000 CentreGreen Way, Suite 200, Cary, North Carolina, 27513, United States |
| Arizona Arthritis & Rheumatology Research, 2152 S Vineyard Ave Suite 129, Mesa, Arizona, 85210, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Clinical Pharmacology Study Group, 25 Oak Ave, Worcester, Massachusetts, 1605, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Arthritis Center of North Georgia, 961A Smoky Mountain Springs Lane, Gainesville, Georgia, 30501, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Cullman Clinical Trials, 501 Clark Street NE, Cullman, Alabama, 35055, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina , 27513 United States |
| Health Research of Oklahoma, PLLC, Suite 409, 1211 N. Shartel Avenue, Oklahoma City, Oklahoma, 73103, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina , 27513 United States |
| Amarillo Center for Clinical Research, 6842 Plum Creek Dr, Amarillo, Texas, 79124, United States | Copernicus Group IRB, 5000 CentreGreen Way, Suite 200, Cary, North Carolina, 27513, United States |

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| Accurate Clinical Research, Suite 135, 7959 Fredericksburg Road, San Antonio, Texas, 78229, United States | Copernicus Group IRB, 5000 CentreGreen Way, Suite 200, Cary, North Carolina, 27513, United States |
| Triwest Research Associates, 300 S.Pierce Street, Suite 201, El Cajon, California, 92020, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Trinity Medical Group Health Center - Medical Arts, 400 East Burdick Expressway, Minot, North Dakota, 58701, United States | Trinity Hospital Institutional Review Board, One Burdick Expressway West, Minot, North Dakota, 58701, United States |
| Dore, Robin K., 12791 Newport Avenue, Tustin, California, 92780, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| The Alliance of Multispeciality Research, LLC, Suite 426/224A, 1010 Carondelet Drive, Kansas City, Missouri, 64114, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Texas Medical and Surgical Associates, Suite 580, 8440 Walnut Hill Lane, Dallas, Texas, 75231, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Mercy Research, 3231 National Ave, Springfield, Missouri, 65714, United States | Western Institutional Review Board, 1019 39th Avenue SE, Puyallup, Washington, 98374, United States |
| Arthritis and osteoporosis associates, 4247 Route 9 north, Freehold, New Jersey, 7728, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Metroplex Clinical Research Center, 8144 Walnut Hill Lane, Dallas, Texas, 75231, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Columbia Arthritis Center, P.A., 1711 St. Julian Place, Columbia, South Carolina, 29204, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| RASF Clinical Research Center, Suite 212A, 1050 NW 15th Street, Boca Raton, Florida, 33489, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Graves Gilbert Clinic, 201 Park Street, Bowling Green, Kentucky, 42101, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States |
| Clinical Interventions Research Institute, Suite 708, 16300 Sand Canyon Avenue, Irvine, California, 92618, United States | Copernicus Group IRB, 5000 CentreGreen Way, Suite 200, Cary, North Carolina, 27513, United States |
| Arthritis & Rheumatic Disease Specialties, Suite 801, 2801 NE 213th Street, Aventura, Florida, 33180, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Stanford University, Suite 203, 1000 Welch Road, Palo Alto, California, 94304, United States | |
| West Virginia Research Institute PLLC, Suite 402, 4610 Kanawha Avenue SW, South Charleston, West Virginia, 25309, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States |
| NYU Langone Ambulatory Care, 186 Joralemon Street, 8th Floor, Brooklyn, New York, 11201, United States. | Western Institutional Review Board, 1019 39th Avenue SE, Puyallup, Washington, 98374, United States. |
| St. Joseph Hospital Comprehensive Research Institute, Suite 2E, 620 10th Street North, St. Petersburg, Florida, 33705, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States |
| East Bay Rheumatology Medical Group, 13851 East 14th Street, San Leandro, California, 94578, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States |

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| Carolina Arthritis Associates, 1710 S. 17th St., Wilmington, North Carolina, 28401, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Sierra Rheumatology, Suite 295, 151 N. Sunrise Boulevard., Roseville, California, 95661, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way Cary, North Carolina, 27513, United States |
| La Salud Research Clinic, Suite 203, 8415 Southwest 24th Street, Miami, Florida, 33155, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Klein & Associates, M.D., PA, 346 Mill Street, Hagerstown, Maryland, 21740, United States | Copernicus Group IRB, 5000 CentreGreen Way, Suite 200, Cary, North Carolina, 27513, United States |
| Arizona Arthritis & Rheumatology Research, PLLC, Suite 108, 399 S. Malpais Ln, Flagstaff, Arizona, 86001, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Medical Research Center of Miami II, Inc., Suite 209, 3971 SW 8TH Street, Miami, Florida, 33134, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Clinical and Translational Research Center of Alabama, PC, Suite 112, 4280 Watermelon Road, Northport, Alabama, 35473, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| June DO. PC, Suite-200, 4052 Legacy Parkway, Lansing, Michigan, 48910, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Kadlec Clinic Rheumatology, 6710 W. Okanogan Place, Kennewick, Washington, 99336, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way Cary, North Carolina, 27513, United States |
| Harbor-UCLA Medical Center, Bld J4, 1124 West Carson Street, Torrance, California, 90502, United States | Western Institutional Review Board-Copernicus Group incorporated, Suite 120, 1019 39th Avenue. S.E, Puyallup, Washington, 98374-2115, United States |
| AA MRC LLC, Suite D, 8200 South Saginaw Street, Grand Blanc, Michigan, 48439, United States | Copernicus Group IRB, 5000 CentreGreen Way, Suite 200, Cary, North Carolina, 27513, United States |
| Accurate Clinical Management, LLC., 2222 Greenhouse Road, Houston, Texas, 77084, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Altoona Center for Clinical Research, 175 Meadowbrook Lane, Duncansville, Pennsylvania, 16635, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| University of Arizona, 1501 North Campbell Avenue, Tucson, Arizona, 85724, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States |
| Carolina Health Specialists, Ste. 4, 945 82nd Parkway, Myrtle Beach, South Carolina, 29572, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Clinical Research of West Florida, 2147 NE Coachman Road, Clearwater, Florida, 33765, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Ochsner Health Center - Baton Rouge, 9001 Summa Ave., Baton Rouge, Louisiana, 70809, United States | Ochsner Clinic Foundation Institutional Review Board, 1514 Jefferson Highway, BH 334, New Orleans, Louisiana, 70121, United States |
| SIMEDHealth, LLC, Suite 17., 4343 West Newberry Road, Gainesville, Florida, 32607, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |

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| Clinical Research of West Florida, Inc., 605 N. Howard Avenue, Tampa, Florida, 33606, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Piedmont Healthcare, Inc, Suite 500, 1800 Howell Mill Road, Atlanta, Georgia, 30318, United States | Western Institutional Review Board-Copernicus Group incorporated, Suite 120, 1019 39th Avenue. S.E, Puyallup, Washington, 98374-2115, United States |
| The Arthritis & Diabetes Clinic, Incorporated., 3402 Magnolia Cove, Monroe, Louisiana, 71203, United States | Copernicus Group IRB, 5000 CentreGreen Way, Suite 200, Cary, North Carolina, 27513, United States |
| The Center for Rheumatology and Bone Research, Suite 306, 2730 University Boulevard West, Wheaton, Maryland, 20902, United States | WIRB Copernicus Group, Suite 301, 212 Carnegie Center, Princeton, New Jersey, 08540, United States |
| Henry Ford Medical Center, New Center One, Department of Dermatology, Suite 800, 3031 West Grand Blvd, Detroit, Michigan, 48202, United States. | Western Institutional Review Board, 1019 39th Avenue SE, Puyallup, Washington, 98374, United States. |
| St. Paul Rheumatology, P.A., 2854 Highway 55, Eagan, Minnesota, 55121, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Articularis Healthcare Group Inc. d/b/a Low Country Rheumatology, Suite 201, 2001 2nd Avenue, Summerville, South Carolina, 29486, United States | Copernicus Group IRB, 5000 CentreGreen Way, Suite 200, Cary, North Carolina, 27513, United States |
| Rheumatic Disease Center, 7080 N. Port Washington Rd, Glendale, Wisconsin, 53217, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Albuquerque Center For Rheumatology, 1617 University Boulevard NE, Albuquerque, New Mexico, 87102, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States |
| Four Rivers Clinical Research, Inc., Suite 305, 225 Medical Center Drive, Paducah, Kentucky, 42003, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Tekton Research Inc, 4534 West Gate Blvd, Suite 110, Austin, Texas, 78745, United States | Copernicus Group IRB, 5000 CentreGreen Way, Suite 200, Cary, North Carolina, 27513, United States |
| Adriana Pop Moody Clinic PA, Suite 704, 613 Elizabeth Street, Corpus Christi, Texas, 78404, United States | Copernicus Group IRB, 5000 CentreGreen Way, Suite 200, Cary, North Carolina, 27513, United States |
| Marietta Rheumatology, 670 North Ave # A, Marietta, Georgia, 30060, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| ACRC Studies, Suite 108, 15725 Pomerado Road, Poway, California, 92064, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Rheumatology Clinic of Houston, P.A., Suite 240, 11307 FM 1960 West, Houston, Texas, 77065, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Tekton Research, 3rd Floor, 9600 Broadway, Oklahoma City, Oklahoma, 73114, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| American Research Institute, Inc., Suite B110, 18951 SW 106th Avenue, Cutler Bay, Florida, 33157, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Clinical Research Center of CT/NY, Suite 206, 27 Hospital Drive, Danbury, Connecticut, 6810, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |

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| Innovation Medical Research Center, Inc, 9299 SW 152nd Street, Palmetto Bay, Florida, 33157, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Novi Research, 39500 W 10 Mile Road Ste 101, Novi, Michigan, 48375, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way Cary, North Carolina, 27513, United States |
| Institute of Arthritis Research, 2220 E 25th Steet, Idaho Falls, Idaho, 83404, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Sweet Hope Research Specialty, Inc., 14160 Palmetto Frontage Rd, Miami Lakes, Florida, 33016, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Life Clinical Trials, 5901 Colonial Drive, Suite 303, Margate, Florida, 33063, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Heartland Research Associates an AMR Company, 1709 S Rock Rd, Wichita, Kansas, 67207, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Allegheny Health Network, 4800 Friendship Avenue, Pittsburgh, Pennsylvania, 15224, United States. | Western Institution Review Board, 1019 39th Avenue SE, Puyallup, Washington, 98374, United States. |
| Qualmedica Research, LLC, 4933 Plaza East Boulevard, Evansville, Indiana, 47715, United States | Copernicus Group Independent Review Board (CGIRB), 1019 39th Avenue SE, Suite 120, Puyallup, Washington, 98374, United States |
| Arizona Arthritis & Rheumatology Research, PLLC, B100, 10615 West Thunderbird Blvd, SunCity, Arizona, 85351, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| West Broward Rheumatology Associates, Inc., Suite 300, 7431 North University Drive, Tamarac, Florida, 33321, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States |
| Medication Management LLC, Suite 106, 802 Green Valley Road, Greensboro, North Carolina, 27408, United States | Copernicus Group Independent Review Board (CGIRB), 1019 39th Avenue SE, Suite 120, Puyallup, Washington, 98374, United States |
| Arizona Arthritis & Rheumatology Research, PLLC, B100, 10615 West Thunderbird Blvd, SunCity, Arizona, 85351, United States | Copernicus Group IRB, 5000 CentreGreen Way, Suite 200, Cary, North Carolina, 27513, United States |
| Tekton Research Inc., Suite 361, 2121 East Harmony Road, Fort Collins, Colorado, 80528, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way Cary, North Carolina, 27513, United States |
| The Center for Rheumatology, LLP, 8th Floor, 4 Tower Place, Albany, New York, 12203, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| DMI Research, 6699 90th Avenue N, Pinellas Park, Florida, 33782, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Better Health Clinical Research, Suite 100, 1665 Highway 34 East, Newnan, Georgia, 30265, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way Cary, North Carolina, 27513, United States |
| West Texas Clinical Research, Suite 2C, 3809 22nd Street, Lubbock, Texas, 79410, United States | Copernicus Group Independent Review Board (CGIRB), 1019 39th Avenue SE, Suite 120, Puyallup, Washington, 98374, United States |
| Clinical Research Center of Reading LLP, 2760 Century Boulevard, Wyomissing, Pennsylvania, 19610, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |

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| Accurate Clinical Research, Inc., Suite 102, 11003 Resource Parkway, Houston, Texas, 77089, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Rheumatology Consultants PLLC, Suite 200, Colony Park, 4707 Papermill Drive, Knoxville, Tennessee, 37909-1907, United States | Copernicus Group Independent Review Board (CGIRB), 1019 39th Avenue SE, Suite 120, Puyallup, Washington, 98374, United States |
| Medvin Clinical Research, Suite 306, 15243 Vanowen Street, Van Nuys, California, 91405, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Suncoast Clinical Research, Inc., 5604 Gulf Drive, New Port Richey, Florida, 34652, United States | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |
| Oklahoma Center for Arthritis Therapy & Research, Inc., 1430 Terrace Drive, Tulsa, Oklahoma, 74104, United States | Copernicus Group Institutional Review Board, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States |
| DMI Research, 6699 90th Avenue N, Pinellas Park, Florida, 33782, United States. | Copernicus Group, Suite 200, 5000 Centregreen Way, Cary, North Carolina, 27513, United States. |

All centres participated in the study under the US IND

IEC, Independent Ethics Committee; IND, Investigational New Drug; IRB, Institutional Review Board.

**Supplementary Table 2.** Permitted medications in contRAst 1 and contRAst 2

| **Medications/Treatments** | **Restriction** | | |
|---|---|---|---|
| | **Prior to study treatment period** | **During study treatment period** (Day 1 to Week 52) | **During 8-week follow-up** |
| **Conventional synthetic DMARDs** ***ContRAst 1*** | | | |
| Methotrexate* 15-25mg/week oral or injected.<br>A lower dose of ≥7.5 mg/week is acceptable if reduced for reasons of intolerance to MTX. e.g. hepatic or hematologic toxicity, or per local requirement (this must be clearly documented in medical records).<br>Exception: A lower dose of 6 mg/week is only allowed if the minimum locally approved or recommended dose is lower than 7.5 mg/week. | Required (must have received at least 12 weeks treatment prior to Day 1, with stable and tolerated dose for at least 8 weeks prior to Day 1) | Required (dose must remain stable except adjustment for safety reasons) | Permitted |
| **Conventional synthetic DMARDs** ***ContRAst 2*** *Patients must currently be taking at least one and at most two of the following concomitant csDMARDs* | | | |

| | | | |
|---|---|---|---|
| Methotrexate* 15-25mg/week oral or injected.<br>A lower dose of ≥7.5 mg/week is acceptable if reduced for reasons of intolerance to MTX. e.g. hepatic or hematologic toxicity, or per local requirement (this must be clearly documented in medical records).<br>Exception: A lower dose of 6 mg/week is only allowed if the minimum locally approved or recommended dose is lower than 7.5 mg/week. | At least one and at most two required (must have received at least 12 weeks treatment prior to Day 1, with stable and tolerated dose for at least 8 weeks prior to Day 1) | At least one and at most two required (dose must remain stable except adjustment for safety reasons) | Permitted |
| Hydroxychloroquine up to 400 mg/day | | | |
| Chloroquine up to 250 mg/day | | | |
| Sulfasalazine up to 3000 mg/day | | | |
| Leflunomide up to 20 mg/day | | | |
| Bucillamine up to 100 mg/day (or up to 300 mg/day if permitted per local requirements) | | | |
| Iguratimod up to 50 mg/day | | | |
| **Corticosteroids*** | | | |
| Stable dosing regimen of oral corticosteroids ≤10 mg/day prednisolone or equivalent. | Permitted<br>(dose must be stable 4 weeks prior to Day 1 and during screening if longer, with no changes except for safety reasons) | Permitted<br>(dose must remain stable except for safety reasons) | Permitted |
| Intra-articular corticosteroids | Prohibited within 4 weeks prior to Day 1 and during screening, if longer. | Permitted after Week 12<br>(Post week 12, the number of IA steroid injections should be | Permitted |

| | | | |
|---|---|---|---|
| | | limited to 2 injections through Week 52, administration should not occur during the 4 weeks prior to Week 24 or Week 52. The site(s) of injection must be recorded) | |
| Inhaled steroids, topical steroids or topical immunosuppressive agents (e.g., eye drops, creams) | Permitted | Permitted | Permitted |
| **Analgesics** | | | |
| Acetaminophen (paracetamol) **taken as rescue for RA pain:** up to a maximum of 4g/day or locally approved maximum (if lower). | Permitted as needed (but not within 24 hours of Day 1 baseline visit) | Permitted as needed (but not within 24 hours of assessment visits) | Permitted |
| NSAIDs including aspirin and selective cyclooxygenase inhibitors.<br><br>*In this study, aspirin is considered a NSAID, except for low-doses (e.g. 75-150 mg/day) prescribed for cardiovascular or cerebrovascular disease.* | Permitted<br><br>**Patients on regular doses:** Dosing regimen must be stable 7 days prior to Day 1, no changes except for safety reasons. Do not discontinue in advance of visits.<br><br>**Patients on PRN prescription:** Record each dose during screening, or frequency with start/end dates, in CRF. Should not be taken within 24h of Day 1 baseline visit. | Permitted<br><br>**Patients on stable, regular doses:** From Day 1 to Week 12, dose regimen must not change except for safety reasons. Do not discontinue in advance of visits. After Week 12, any new analgesic or change in regimen should not occur within 24h of assessment visits.<br><br>**Patients on PRN prescription:** Record each dose, or frequency with start/end dates, in CRF. Should not be taken within 24h of assessment visits. | Permitted |

| | | | |
|---|---|---|---|
| Weak opioid analgesics (e.g. tramadol up to 400 mg/day, codeine) | Permitted<br><br>**Patients on regular doses:** Dosing regimen must be stable 7 days prior to Day 1, no changes except for safety reasons.<br>Do not discontinue in advance of visits.<br><br>**Patients on PRN prescription:**<br>Record each dose during screening, or frequency with start/end dates, in CRF. Should not be taken within 24h of Day 1 baseline visit. | Permitted<br><br>**Patients on stable, regular doses:** From Day 1 to Week 12, dose regimen must not change except for safety reasons.<br>Do not discontinue in advance of visits.<br>After Week 12, any new analgesic or change in regimen should not occur within 24h of assessment visits.<br><br>**Patients on PRN prescription:** Record each dose, or frequency with start/end dates, in CRF. Should not be taken within 24h of assessment visits. | Permitted |
| Strong opioid analgesics (e.g. morphine, hydromorphone, oxycodone, hydrocodone, fentanyl, meperidine, methadone) | Prohibited within 4 weeks prior to Day 1 and during screening, if longer. | Permitted after Week 12<br>After week 12, PRN or regular doses may be considered, but any new analgesic or change in regimen should not occur within 24h of assessment visits.<br><br>**Patients on PRN prescription:** Record each dose, or frequency with start/end dates, in CRF. Should not be taken within 24h of assessment visits. | Permitted |
| **Other Medications** | | | |

| | | | |
|---|---|---|---|
| Intra-articular Hyaluronic acid and any other intra-articular compounds used as lubricant in the joints. | Prohibited within 2 weeks prior to Day 1 and during screening, if longer. | Prohibited within 2 weeks prior to Week 12, Week 24 and Week 52 assessments. | Permitted |

Restrictions apply to both contRAst 1 and contRAst 2 unless otherwise stated.

*Prior to any dose changes in MTX or oral corticosteroids, it was recommended that the Investigator contact the medical monitor to discuss and agree on the dose change.

CRF, case report form; csDMARD, conventional synthetic disease-modifying anti-rheumatic drug; MTX, methotrexate; NSAID, non-steroidal anti-inflammatory drug; PRN, pro re nata (as needed); RA, rheumatoid arthritis.

**Supplementary Table 3.** Prohibited medications/treatments in contRAst 1 and contRAst 2

| Medications/Treatments | Restriction | | |
|---|---|---|---|
| | **Prior to study treatment period** | **During study treatment period** (Day 1 to Week 52) | **During 8-week follow-up** |
| **Treatments affecting GM-CSF pathway** | | | |
| Any treatment antagonising GM-CSF or its receptor | Prohibited (Exclusion criterion) | Prohibited (Except study intervention) | Prohibited |
| **Conventional synthetic DMARDs** | | | |
| *ContRAst 1* Hydroxychloroquine, chloroquine, sulfasalazine, minocycline, cyclosporin, bucillamine, iguratimod | Discontinue at least 4 weeks prior to Day 1 | Prohibited | No restriction |
| *ContRAst 2* Hydroxychloroquine, chloroquine, sulfasalazine, minocycline, cyclosporin, bucillamine, iguratimod | Discontinue at least 4 weeks prior to Day 1 if not being continued as background medication | Prohibited | No restriction |
| *ContRAst 1* Tacrolimus | Discontinue at least 4 weeks prior to Day 1 | Prohibited | No restriction |
| *ContRAst 2* Tacrolimus Not permitted as background medication | Discontinue at least 4 weeks prior to Day 1 | Prohibited | No restriction |
| Azathioprine | Discontinue at least 4 weeks prior to Day 1 | Prohibited | No restriction |
| Leflunomide without washout treatment | Discontinue at least 12 weeks prior to Day 1 | Prohibited | No restriction |
| Leflunomide with washout treatment for 11 days with oral cholestyramine (8 g three times daily) or charcoal (50 g four times daily) | Washout treatment must complete at least 2 weeks prior to Day 1 | Prohibited | No restriction |
| *ContRAst 1* Other csDMARDs | Discontinue at least 4 weeks prior to Day 1 | Prohibited | No restriction |



Fleischmann RM, *et al. Ann Rheum Dis* 2023; 82:1516–1526. doi: 10.1136/ard-2023-224482

| | | | |
|---|---|---|---|
| *ContRAst 2*<br>Other csDMARDs<br>If not being continued as background medication | Discontinue at least 4 weeks prior to Day 1 | Prohibited | No restriction |
| **Biologic DMARDs**<br>In contRAst 1: the number of patients with prior bDMARD exposure will be limited to approximately 20% of overall sample size. | | | |
| Etanercept (including its biosimilars).<br>(*ContRAst 1*: Only if discontinued for reasons *other than* inadequate response*) | Discontinue at least 4 weeks prior to Day 1 | Prohibited | Prohibited |
| Any cell-depleting therapies, e.g., anti-CD20.<br>*(ContRAst 1*: Only if discontinued for reasons *other than* inadequate response*) | Discontinue at least 52 weeks prior to Day 1 | Prohibited | Prohibited |
| *ContRAst 1*<br>Any other bDMARDs (experimental or approved) discontinued for reasons *other than* inadequate response* | Discontinue at least 8 weeks prior to Day 1 | Prohibited | Prohibited |
| *ContRAst 1*<br>Any bDMARD (experimental or approved) that was discontinued *due to* inadequate response* | Prohibited<br>(Exclusion criterion) | Prohibited | Prohibited |
| *ContRAst 2*<br>Any other bDMARDs (experimental or approved) | Discontinue at least 8 weeks prior to Day 1 | Prohibited | Prohibited |
| **Targeted synthetic DMARDs** | | | |
| JAK inhibitors (experimental or approved; e.g., tofacitinib, baricitinib, upadacitinib, filgotinib and peficitinib) | Prohibited<br>(Exclusion criterion) | Prohibited<br>(Except study intervention) | Prohibited |
| Other (non-JAK inhibitor) tsDMARD (experimental or approved) | Discontinue at least 4 weeks or 5 half-lives (whichever is longer) prior to Day 1 | Prohibited | Prohibited |
| **Other RA therapies** | | | |

| | | | |
|---|---|---|---|
| Plasmapheresis or intravenous immunoglobulin (IVIG) or use of plasma filtering devices (e.g., Staph protein A column – Prosorba) | Discontinue at least 26 weeks prior to Day 1 | Prohibited | Prohibited |
| **Corticosteroids** | | | |
| Dose changes in oral corticosteroids ≤10 mg/day prednisolone or equivalent | Prohibited 4 weeks prior to Day 1, and during screening if longer, except for safety reasons | Prohibited (except for safety reasons) | No restriction |
| Oral corticosteroids >10 mg/day prednisolone or equivalent | Discontinue or reduce to ≤10 mg/day, at least 4 weeks prior to Day 1 | Prohibited (except for safety reasons) | No restriction |
| Intra-muscular or intravenous corticosteroids | Discontinue at least 4 weeks prior to Day 1, and during screening if longer | Prohibited (except for safety reasons) | No restriction |
| **Other medications** | | | |
| Potent inhibitors of cytochrome P450 3A4 (CYP3A4; e.g., ketoconazole).<br>One or more concomitant medications that result in both moderate inhibition of CYP3A4 and potent inhibition of CYP2C19 (e.g., fluconazole).<br>Potent CYP3A4 inducers (e.g., rifampin) | Refer to SRM for additional guidance | Prohibited | No restriction |
| **Vaccine immunisations**<br>Investigators should review and update the vaccination status of potential patients as per local guidelines for adult vaccination prior to entering them into the study; refer to EULAR recommendations[1] where no local guidelines are available, with particular attention to the vaccination status of patients over 65 years of age. All patients who have not received the herpes zoster vaccine at study entry will be recommended to complete vaccination >30 days prior to randomisation. All patients may receive inactivated flu vaccines during the study at the discretion of the investigator. | | | |
| Live-attenuated vaccinations | Discontinue at least 30 days prior to Day 1 | Prohibited | Prohibited |

| | | | |
|---|---|---|---|
| BCG vaccination | Discontinue at least 365 days prior to Day 1 | Prohibited | Prohibited |

Restrictions apply to both contRAst 1 and contRAst 2 unless otherwise stated.
*Inadequate response to treatment is defined as: In the opinion of the investigator, after at least 3 months of treatment, the participant experienced insufficient efficacy or loss of response (e.g., no EULAR response; failure to achieve ACR20; any other clinical criteria recommended per local guidelines that would trigger a change of treatment) or the participant discontinued treatment due to intolerability or toxicity irrespective of treatment duration.

b/cs/tsDMARD, biologic/conventional synthetic/targeted synthetic disease-modifying anti-rheumatic drug; GM-CSF, granulocyte-macrophage colony-stimulating factor; JAK, Janus kinase.

1. Furer V, Rondaan C, Heijstek MW, Agmon-Levin N, van Assen S, Bijl M,et al. 2019 update of EULAR recommendations for vaccination in adult patients with autoimmune inflammatory rheumatic diseases. Ann Rheum Dis. 2020;79(1):39-52.

**Supplementary Table 4.** Secondary endpoints at Week 24 in contRAst 1 and contRAst 2

| | ContRAst 1 | | | ContRAst 2 | | |
|---|---|---|---|---|---|---|
| | **Otilimab 90 mg QW (N=513)** | **Otilimab 150 mg QW (N=510)** | **Tofacitinib 5 mg BID (N=258)** | **Otilimab 90 mg QW (N=545)** | **Otilimab 150 mg QW (N=539)** | **Tofacitinib 5 mg BID (N=271)** |
| **ACR20** | | | | | | |
| Responders, % | 63.9 | 61.3 | 74.4 | 65.0 | 62.5 | 79.8 |
| Difference vs tofacitinib, % (95% CI) | –10.4 (–17.6, –3.3) | –13.0 (–20.2, –5.8) | | –14.7 (–21.3, –8.1) | –17.2 (–23.9, –10.6) | |
| OR vs tofacitinib (95% CI) | 0.61 (0.43, 0.87) | 0.55 (0.38, 0.78) | | 0.46 (0.32, 0.66) | 0.42 (0.29, 0.60) | |
| **CDAI LDA** | | | | | | |
| Responders, % | 29.9 | 29.8 | 45.9 | 32.8 | 34.3 | 49.6 |
| Difference vs tofacitinib, % (95% CI) | –16.0 (–23.6, –8.4) | –16.1 (–23.7, –8.5) | | –16.8 (–24.2, –9.4) | –15.3 (–22.7, –7.8) | |
| OR vs tofacitinib (95% CI) | 0.50 (0.35, 0.70) | 0.50 (0.36, 0.70) | | 0.42 (0.30, 0.59) | 0.47 (0.34, 0.65) | |
| **HAQ–DI** | | | | | | |
| LS mean change (SE) | –0.51 (0.027) | –0.41 (0.026) | –0.56 (0.037) | –0.38 (0.033) | –0.37 (0.033) | –0.53 (0.041) |
| LS mean difference from tofacitinib (95% CI) | 0.05 (–0.04, 0.14) | 0.15 (0.06, 0.24) | | 0.14 (0.06, 0.23) | 0.16 (0.08, 0.25) | |
| **Pain VAS** | | | | | | |
| LS mean change (SE) | –25.43 (1.096) | –22.56 (1.069) | –31.02 (1.530) | –23.32 | –22.32 | –31.27 |

| | | | | | | |
|---|---|---|---|---|---|---|
| LS mean difference from tofacitinib (95% CI) | 5.58 (1.98, 9.19) | 8.46 (4.85, 12.07) | | 7.95 (4.40, 11.50) | 8.95 (5.39, 12.51) | |
| **CDAI** | | | | | | |
| LS mean change (SE) | –20.63 (0.561) | –19.88 (0.551) | –24.50 (0.781) | –20.14 (0.669) | –20.68 (0.677) | –24.93 (0.848) |
| LS mean difference from tofacitinib (95% CI) | 3.87 (2.02, 5.72) | 4.62 (2.77, 6.47) | | 4.80 (3.03, 6.56) | 4.26 (2.48, 6.03) | |
| **FACIT-Fatigue** | | | | | | |
| LS mean change (SE) | 8.52 (0.418) | 7.59 (0.406) | 8.56 (0.585) | 6.10 (0.523) | 6.12 (0.528) | 8.37 (0.654) |
| LS mean difference from tofacitinib (95% CI) | –0.04 (–1.42, 1.34) | –0.97 (–2.35, 0.40) | | –2.28 (–3.65, –0.90) | –2.25 (–3.63, –0.88) | |
| **CDAI remission** | | | | | | |
| Responders, % | 6.1 | 5.2 | 12.1 | 6.9 | 7.2 | 17.9 |
| Difference vs tofacitinib, % (95% CI) | –6.0 (–10.8, –1.2) | –6.9 (–11.6, –2.1) | | –11.0 (–16.3, –5.7) | –10.8 (–16.1, –5.4) | |
| OR vs tofacitinib (95% CI) | 0.48 (0.27, 0.84) | 0.41 (0.23, 0.74) | | 0.31 (0.19, 0.50) | 0.32 (0.20, 0.53) | |
| **DAS28-CRP** | | | | | | |
| LS mean change (SE) | –1.74 (0.056) | –1.67 (0.055) | –2.31 (0.078) | –1.65 (0.070) | –1.71 (0.071) | –2.45 (0.089) |
| LS mean difference from tofacitinib (95% CI) | 0.57 (0.38, 0.75) | 0.63 (0.45, 0.82) | | 0.80 (0.61, 0.98) | 0.74 (0.56, 0.93) | |
| **DAS28-CRP ≤3.2** | | | | | | |
| Responders, % | 26.8 | 29.0 | 47.4 | 31.3 | 33.0 | 55.3 |
| Difference vs tofacitinib, % (95% CI) | –20.6 (–28.3, 13.0) | –18.4 (–26.1, –10.7) | | –24.0 (–31.3, –16.7) | –22.3 (–29.6, –14.9) | |

| | | | | | | |
|---|---|---|---|---|---|---|
| OR vs tofacitinib (95% CI) | 0.40 (0.28, 0.57) | 0.44 (0.31, 0.62) | | 0.30 (0.22, 0.42) | 0.33 (0.23, 0.46) | |
| **DAS28-CRP <2.6** | | | | | | |
| Responders, % | 14.5 | 14.1 | 26.3 | 16.7 | 19.6 | 38.0 |
| Difference vs tofacitinib, % (95% CI) | –11.8 (–18.3, –5.3) | –12.2 (–18.7, –5.7) | | –21.4 (–28.2, –14.5) | –18.4 (25.4, –11.5) | |
| OR vs tofacitinib (95% CI) | 0.48 (0.32, 0.73) | 0.46 (0.31, 0.69) | | 0.27 (0.19, 0.39) | 0.33 (0.23, 0.48) | |
| **ACR50** | | | | | | |
| Responders, % | 31.4 | 29.1 | 46.7 | 31.6 | 32.8 | 53.6 |
| Difference vs tofacitinib, % (95% CI) | –15.3 (–22.9, –7.8) | –17.6 (–25.1, –10.1) | | –22.0 (–29.4, –14.6) | –20.8 (–28.2, –13.4) | |
| OR vs tofacitinib (95% CI) | 0.52 (0.38, 0.72) | 0.47 (0.34, 0.65) | | 0.38 (0.28, 0.52) | 0.41 (0.30, 0.56) | |
| **ACR70** | | | | | | |
| Responders, % | 12.5 | 10.1 | 25.1 | 14.0 | 13.0 | 28.7 |
| Difference vs tofacitinib, % (95% CI) | –12.5 (–18.7, –6.3) | –15.0 (–21.1, –8.9) | | –14.6 (–20.9, –8.4) | –15.6 (–21.9, –9.4) | |
| OR vs tofacitinib (95% CI) | 0.43 (0.29, 0.64) | 0.34 (0.22, 0.51) | | 0.38 (0.27, 0.56) | 0.36 (0.24, 0.52) | |
| **Additional ACR core data set measures** | | | | | | |
| **TJC68** | | | | | | |
| LS mean change (SE) | –13.24 (0.452) | –12.11 (0.445) | –15.00 (0.631) | –12.23 (0.561) | –12.86 (0.571) | –14.80 (0.706) |
| LS mean difference from tofacitinib (95% CI) | 1.75 (0.26, 3.25) | 2.88 (1.39, 4.37) | | 2.57 (1.10, 4.05) | 1.94 (0.45, 3.42) | |
| **SJC66** | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| LS mean change (SE) | –8.96 (0.316) | –8.50 (0.311) | –10.70 (0.442) | –8.92 (0.359) | –9.24 (0.365) | –10.69 (0.451) |
| LS mean difference from tofacitinib (95% CI) | 1.75 (0.70, 2.79) | 2.21 (1.16, 3.25) | | 1.77 (0.82, 2.71) | 1.45 (0.50, 2.40) | |
| **PtGA** | | | | | | |
| LS mean change (SE) | –24.87 (1.037) | –22.43 (1.010) | –30.24 (1.445) | –22.36 (1.305) | –21.55 (1.320) | –30.24 (1.645) |
| LS mean difference from tofacitinib (95% CI) | 5.37 (1.96, 8.77) | 7.80 (4.40, 11.21) | | 7.88 (4.44, 11.32) | 8.68 (5.24, 12.13) | |
| **PhGA** | | | | | | |
| LS mean change (SE) | –37.50 (0.964) | –35.72 (0.945) | –41.45 (1.342) | –34.62 (1.214) | –35.62 (1.228) | –40.65 (1.527) |
| LS mean difference from tofacitinib (95% CI) | 3.95 (0.77, 7.12) | 5.73 (2.56, 8.90) | | 6.04 (2.85, 9.22) | 5.03 (1.84, 8.21) | |
| **CRP (mg/L)** | | | | | | |
| LS mean change (SE) | –4.67 (0.857) | –5.39 (0.836) | –9.97 (1.194) | –3.74 (0.980) | –3.54 (0.998) | –11.33 (1.225) |
| LS mean difference from tofacitinib (95% CI) | 5.30 (2.49, 8.11) | 4.59 (1.78, 7.40) | | 7.58 (5.03, 10.14) | 7.79 (5.22, 10.36) | |
| **Van der Heijde mTSS** | | | | | | |
| LS mean change (SE) | 0.25 (0.080) | 0.38 (0.078) | 0.20 (0.112) | 0.42 (0.092) | 0.32 (0.094) | 0.15 (0.115) |
| LS mean difference from tofacitinib (95% CI) | 0.05 (–0.21, 0.31) | 0.18 (–0.08, 0.44) | | 0.26 (0.03, 0.50) | 0.17 (–0.07, 0.41) | |
| **HRQoL** | | | | | | |
| **SF-36 PCS** | | | | | | |
| LS mean change (SE) | 6.26 (0.319) | 5.82 (0.313) | 8.07 (0.448) | 5.42 (0.416) | 5.24 (0.421) | 7.33 (0.520) |
| LS mean difference from tofacitinib (95% CI) | –1.80 (–2.86, –0.75) | –2.25 (–3.31, –1.19) | | –1.91 (–3.00, –0.82) | –2.09 (–3.18, –1.00) | |
| **SF-36 MCS** | | | | | | |
| LS mean change (SE) | 3.69 (0.401) | 3.87 (0.393) | 2.92 (0.563) | 2.69 (0.522) | 3.16 (0.528) | 4.80 (0.652) |

| | | | | | | |
|---|---|---|---|---|---|---|
| LS mean difference from tofacitinib (95% CI) | 0.77 (–0.55, 2.10) | 0.96 (–0.37, 2.29) | | –2.11 (–3.48, –0.74) | –1.64 (–3.02, –0.27) | |

ACR, American College of Rheumatology; BID, twice daily; CDAI, clinical disease activity index; CI, confidence interval; CRP, C-reactive protein; DAS28, disease activity score-28 joints; FACIT, Functional Assessment of Chronic Illness Therapy; HAQ-DI, Health Assessment Questionnaire-Disability Index; LDA, low disease activity; LS, least squares; MCS, mental component summary; mTSS, modified total Sharp scale; OR, odds ratio; PCS, physical component summary; PhGA, physician's global assessment; PtGA, patient's global assessment; HRQoL, health-related quality of life; SE, standard error; SF-36, Short Form–36; SJC, swollen joint count; TJC, tender joint count; QW, once weekly; VAS, visual analogue scale.

**Supplementary Table 5.** Additional secondary endpoints at Week 12 in contRAst 1 and 2

| | ContRAst 1 | | | | ContRAst 2 | | | |
|---|---|---|---|---|---|---|---|---|
| | **Pooled placebo (N=256)** | **Otilimab 90 mg QW (N=513)** | **Otilimab 150 mg QW (N=510)** | **Tofacitinib 5 mg BID (N=258)** | **Pooled placebo (N=270)** | **Otilimab 90 mg QW (N=545)** | **Otilimab 150 mg QW (N=539)** | **Tofacitinib 5 mg BID (N=271)** |
| **CDAI remission** | | | | | | | | |
| Responders, % | 1.0 | 3.8 | 2.4 | 5.8 | 3.8 | 4.7 | 4.5 | 9.7 |
| Difference vs placebo, % (95% CI) | | 2.8 (0.5, 5.2) | 1.4 (–0.5, 3.3) | 4.8 (1.3, 8.3) | | 0.9 (–2.2, 4.1) | 0.6 (–2.5, 3.8) | 5.8 (1.3, 10.3) |
| OR vs placebo (95% CI) | | 4.18 (0.97, 18.10) | 2.67 (0.58, 12.24) | 6.28 (1.40, 28.18) | | 1.26 (0.56, 2.86) | 1.20 (0.52, 2.75) | 2.93 (1.28, 6.72) |
| **DAS28-CRP** | | | | | | | | |
| LS Mean change (SE) | –1.01 (0.075) | –1.49 (0.054) | –1.44 (0.053) | –1.96 (0.076) | –0.71 (0.085) | –1.28 (0.064) | –1.35 (0.064) | –2.02 (0.082) |
| LS mean difference from placebo (95% CI) | | –0.48 (–0.66, –0.30) | –0.43 (–0.61, –0.25) | –0.95 (–1.16, –0.74) | | –0.57 (–0.75, –0.40) | –0.64 (–0.82, –0.47) | –1.31 (–1.52, –1.11) |
| **DAS28-CRP ≤3.2** | | | | | | | | |
| Responders, % | 11.3 | 20.2 | 19.4 | 33.5 | 10.4 | 23.2 | 23.6 | 40.7 |
| Difference vs placebo, % (95% CI) | | 9.0 (3.6, 14.3) | 8.2 (2.8, 13.5) | 22.2 (15.0, 29.4) | | 12.8 (7.6, 18.1) | 13.2 (7.9, 18.5) | (23.2, 37.4) |
| OR vs placebo (95% CI) | | 2.04 (1.28, 3.26) | 1.89 (1.18, 3.04) | 4.00 (2.44, 6.58) | | 2.89 (1.80, 4.64) | 2.93 (1.82, 4.70) | 7.84 (4.73, 13.00) |
| **DAS28-CRP <2.6** | | | | | | | | |
| Responders, % | 5.2 | 10.3 | 8.4 | 17.1 | 5.5 | 11.5 | 12.0 | 23.2 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Difference vs placebo, % (95% CI) | | 5.2 (1.2, 9.1) | 3.3 (–0.5, 7.0) | 11.9 (6.4, 17.5) | | 6.0 (2.0, 10.0) | 6.5 (2.4, 10.6) | 17.6 (11.7, 23.6) |
| OR vs placebo (95% CI) | | 2.13 (1.11, 4.09) | 1.66 (0.84, 3.26) | 3.68 (1.86, 7.27) | | 2.42 (1.27, 4.59) | 2.50 (1.32, 4.75) | 6.34 (3.27, 12.28) |
| **ACR50** | | | | | | | | |
| Responders, % | 12.2 | 23.3 | 20.0 | 34.1 | 9.5 | 21.6 | 25.1 | 39.4 |
| Difference vs placebo, % (95% CI) | | 11.0 (5.5, 16.6) | 7.8 (2.3, 13.2) | 21.9 (14.6, 29.1) | | 12.2 (7.1, 17.2) | 15.6 (10.4, 20.8) | 30.0 (23.0, 36.9) |
| OR vs placebo (95% CI) | | 2.18 (1.41, 3.37) | 1.79 (1.15, 2.78) | 3.69 (2.31, 5.87) | | 2.65 (1.65, 4.26) | 3.28 (2.05, 5.25) | 6.57 (4.01, 10.78) |
| **ACR70** | | | | | | | | |
| Responders, % | 3.5 | 8.5 | 6.1 | 13.9 | 4.2 | 6.9 | 9.6 | 18.9 |
| Difference vs placebo, % (95% CI) | | 5.0 (1.4, 8.5) | 2.6 (–0.6, 5.8) | 10.3 (5.3, 15.3) | | 2.7 (–0.7, 6.1) | 5.4 (1.7, 9.0) | 14.7 (9.2, 20.1) |
| OR vs placebo (95% CI) | | 2.54 (1.17, 5.49) | 1.79 (0.80, 4.02) | 4.37 (1.96, 9.73) | | 1.70 (0.82, 3.50) | 2.43 (1.20, 4.92) | 5.44 (2.67, 11.10) |
| **Additional ACR core data set measures** | | | | | | | | |
| **TJC68** | | | | | | | | |
| LS mean change (SE) | –7.43 (0.638) | –11.38 (0.458) | –10.39 (0.449) | –12.72 (0.638) | –5.41 (0.715) | –8.86 (0.547) | –9.70 (0.543) | –12.29 (0.698) |
| LS mean difference from placebo (95% CI) | | –3.95 (–5.47, –2.43) | –2.96 (–4.48, –1.44) | –5.29 (–7.05, –3.53) | | –3.45 (–4.95, –1.95) | –4.29 (–5.79, –2.79) | –6.88 (–8.61, –5.15) |
| **SJC66** | | | | | | | | |
| LS mean change (SE) | –6.14 (0.426) | –8.31 (0.306) | –7.68 (0.300) | –9.71 (0.426) | –4.70 (0.485) | –7.20 (0.371) | –7.81 (0.368) | –9.51 (0.473) |
| LS mean difference from placebo (95% CI) | | –2.17 (–3.19, –1.16) | –1.54 (–2.56, –0.53) | –3.57 (–4.74, –2.40) | | –2.49 (–3.51, –1.48) | –3.10 (–4.12, –2.09) | –4.81 (–5.98, –3.63) |
| **PtGA** | | | | | | | | |
| LS mean change (SE) | –15.58 (1.410) | –22.06 (1.014) | –19.12 (0.991) | –26.93 (1.414) | –10.49 (1.559) | –18.46 (1.191) | –17.33 (1.180) | –26.72 (1.518) |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| LS mean difference from placebo (95% CI) | | –6.48 (–9.83, –3.12) | –3.53 (–6.89, –0.18) | –11.34 (–15.22, –7.46) | | –7.97 (–11.24, –4.71) | –6.84 (–10.11, –3.57) | –16.23 (–20.00, –12.46) |
| **PhGA** | | | | | | | | |
| LS mean change (SE) | –23.88 (1.387) | –30.34 (0.996) | –30.03 (0.974) | –36.08 (1.390) | –18.69 (1.563) | –27.26 (1.185) | –27.87 (1.180) | –34.47 (1.520) |
| LS mean difference from placebo (95% CI) | | –6.46 (–9.77, –3.16) | –6.16 (–9.46, –2.85) | –12.20 (–16.02, –8.38) | | –8.57 (–11.84, –5.29) | –9.18 (–12.45, –5.91) | –15.78 (–19.55, –12.01) |
| **CRP (mg/L)** | | | | | | | | |
| LS mean change (SE) | 0.31 (1.294) | –3.27 (0.929) | –5.50 (0.908) | –9.34 (1.315) | 0.35 (1.213) | –4.16 (0.913) | –4.24 (0.909) | –11.49 (1.163) |
| LS mean difference from placebo (95% CI) | | –3.58 (–6.65, –0.50) | –5.81 (–8.88, –2.74) | –9.65 (–13.23, –6.06) | | –4.51 (–7.03, –1.99) | –4.58 (–7.11, –2.05) | –11.84 (–14.74, –8.94) |
| **Van der Heijde mTSS** | | | | | | | | |
| LS Mean change (SE) | 0.55 (0.103) | 0.15 (0.075) | 0.19 (0.073) | 0.13 (0.104) | 0.13 (0.095) | 0.31 (0.072) | 0.15 (0.073) | 0.09 (0.092) |
| LS mean difference from placebo (95% CI) | | –0.40 (–0.64, –0.15) | –0.36 (–0.61, –0.12) | –0.42 (–0.71, –0.14) | | 0.19 (–0.01, 0.38) | 0.02 (–0.18, 0.22) | –0.04 (–0.27, 0.19) |
| **HRQoL** | | | | | | | | |
| **SF-36 PCS** | | | | | | | | |
| LS mean change (SE) | 3.19 (0.423) | 5.38 (0.305) | 4.96 (0.297) | 6.93 (0.427) | 2.05 (0.478) | 4.29 (0.363) | 4.48 (0.361) | 6.58 (0.464) |
| LS mean difference from placebo (95% CI) | | 2.19 (1.19, 3.20) | 1.77 (0.76, 2.77) | 3.74 (2.57, 4.90) | | 2.24 (1.24, 3.24) | 2.43 (1.43, 3.43) | 4.53 (3.38, 5.68) |
| **SF-36 MCS** | | | | | | | | |
| LS mean change (SE) | 2.46 (0.569) | 2.88 (0.410) | 2.54 (0.399) | 4.04 (0.574) | 2.21 (0.624) | 2.24 (0.474) | 2.68 (0.471) | 3.56 (0.604) |
| LS mean difference from placebo (95% CI) | | 0.42 (–0.93, 1.77) | 0.08 (–1.27, 1.43) | 1.58 (0.02, 3.15) | | 0.02 (–1.28, 1.33) | 0.47 (–0.83, 1.78) | 1.35 (–0.15, 2.86) |

ACR, American College of Rheumatology; BID, twice daily; CDAI, clinical disease activity index; CI, confidence interval; CRP, C-reactive protein; DAS28, disease activity score-28 joints; FACIT, Functional Assessment of Chronic Illness Therapy; HAQ-DI, Health Assessment Questionnaire-Disability Index; LDA, low disease activity; LS, least squares; MCS, mental component summary; mTSS, van der Heijde modified total Sharp score; OR, odds ratio; PCS, physical component summary; PhGA, physician's global assessment; PtGA, patient's global assessment; HRQoL, health-related quality of life; SE, standard error; SF-36, Short Form–36; SJC, swollen joint count; TJC, tender joint count; QW, once weekly; VAS, visual analogue scale.



Fleischmann RM, *et al. Ann Rheum Dis* 2023; 82:1516–1526. doi: 10.1136/ard-2023-224482

**Supplementary Table 6.** Safety summary following switch from placebo to active treatment

| | ContRAst 1 | | | ContRAst 2 | | |
|---|---|---|---|---|---|---|
| **Adverse event, number of patients (%)** | **Placebo to otilimab 90 mg QW (N=80)** | **Placebo to otilimab 150 mg QW (N=82)** | **Placebo to tofacitinib 5 mg BID (N=68)** | **Placebo to otilimab 90 mg QW (N=85)** | **Placebo to otilimab 150 mg QW (N=80)** | **Placebo to tofacitinib 5 mg BID (N=67)** |
| **Week 12 to 52** | | | | | | |
| Any AE | 49 (61) | 52 (63) | 44 (65) | 54 (64) | 52 (65) | 45 (67) |
| Any SAE | 8 (10) | 9 (11) | 5 (7) | 5 (6) | 3 (4) | 2 (3) |
| Any AESI | 9 (11) | 9 (11) | 3 (4) | 6 (7) | 12 (15) | 3 (4) |
| Serious infection* | 0 (0) | 2 (2) | 0 (0) | 1 (1) | 1 (1) | 1 (1) |
| Serious infection, excluding COVID-19* | 0 (0) | 2 (2) | 0 (0) | 1 (1) | 1 (1) | 1 (1) |
| Active TB* | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Latent TB* | 5 (6) | 3 (4) | 1 (1) | 0 (0) | 0 (0) | 2 (3) |
| TB reactivation* | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| PAP* | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| COVID-19 diagnosis† | 6 (8) | 9 (11) | 2 (3) | 4 (5) | 7 (9) | 9 (13) |
| Any adjudicated CV event | 0 (0) | 3 (4) | 1 (1) | 0 (0) | 1 (1) | 0 (0) |
| Adjudicated MACE | 0 (0) | 3 (4) | 1 (1) | 0 (0) | 1 (1) | 0 (0) |
| VTE (DVT and/or PE) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |

| | | | | | | |
|---|---|---|---|---|---|---|
| PE | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| DVT | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Any malignancy | 0 (0) | 2 (2) | 1 (1) | 2 (2) | 1 (1) | 0 (0) |
| Any malignancy, excluding NMSC | 0 (0) | 2 (2) | 1 (1) | 0 (0) | 1 (1) | 0 (0) |
| Any Fatal SAE | 0 (0) | 1 (1) | 0 (0) | 1 (1) | 1 (1) | 0 (0) |
| Haemorrhagic stroke | 0 (0) | 1 (1) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Cardiac arrest | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (1) | 0 (0) |
| Circulatory collapse | 0 (0) | 0 (0) | 0 (0) | 1 (1) | 0 (0) | 0 (0) |

*Only select AESIs with relevance to the MoA of otilimab or tofacitinib are reported; †Total cases (either AEs or SAEs).

AE, adverse event; AESI, adverse event of special interest; BID, twice daily; COVID-19, coronavirus disease 2019; CV, cardiovascular; DVT, deep vein thrombosis; MACE, major adverse cardiovascular event; NMSC, non-melanoma skin cancer; PAP, pulmonary alveolar proteinosis; PE, pulmonary embolism; QW, once weekly; SAE, serious adverse event; TB, tuberculosis; VTE, venous thromboembolism.

**Supplementary Table 7.** Most common (>5%) AEs in contRAst 1 up to Week 12 and Week 52

| | ContRAst 1 | | | |
|---|---|---|---|---|
| **Adverse event, number of patients (%)** | **Pooled placebo (N=241)** | **Otilimab 90 mg QW (N=513)** | **Otilimab 150 mg QW (N=510)** | **Tofacitinib 5 mg BID (N=273)** |
| **Week 0 to 12** | | | | |
| Any event | 95 (39) | 222 (43) | 234 (46) | 122 (45) |
| **Week 0 to 52*** | | | | |
| Any event | | 367 (72) | 383 (75) | 207 (76) |
| COVID-19 | | 43 (8) | 49 (10) | 31 (11) |
| Lymphopaenia | | 30 (6) | 35 (7) | 16 (6) |
| ALT increase | | 23 (4) | 31 (6) | 13 (5) |
| Urinary tract infection | | 23 (4) | 23 (5) | 19 (7) |
| Upper respiratory tract infection | | 22 (4) | 20 (4) | 18 (7) |
| Anaemia | | 22 (4) | 27 (5) | 8 (3) |

Events listed according to the MedDRA Preferred Terms used for the coding of events reported by investigators. *Data reported for patients who were randomised to active treatments from baseline.

AE, adverse event; ALT, alanine aminotransferase; COVID-19, coronavirus disease 2019.

**Supplementary Table 8.** Most common (>5%) AEs in contRAst 2 up to Week 12 and Week 52

| | ContRAst 2 | | | |
|---|---|---|---|---|
| **Adverse event, number of patients (%)** | **Pooled placebo (N=255)** | **Otilimab 90 mg QW (N=545)** | **Otilimab 150 mg QW (N=539)** | **Tofacitinib 5 mg BID (N=286)** |
| **Week 0 to 12** | | | | |
| Any event | 127 (50) | 267 (49) | 268 (50) | 143 (50) |
| Injection site reaction | 3 (1) | 23 (4) | 36 (7) | 2 (<1) |
| **Week 0 to 52*** | | | | |
| Any event | | 420 (77) | 408 (76) | 224 (78) |
| COVID-19 | | 50 (9) | 34 (6) | 27 (9) |
| RA | | 42 (8) | 42 (8) | 21 (7) |
| Lymphopaenia | | 33 (6) | 38 (7) | 24 (8) |
| Injection site reaction | | 42 (8) | 47 (9) | 5 (2) |
| Urinary tract infection | | 34 (6) | 39 (7) | 19 (7) |
| Hypertension | | 30 (6) | 31 (6) | 19 (7) |
| Nasopharyngitis | | 28 (5) | 33 (6) | 15 (5) |
| Headache | | 33 (6) | 19 (4) | 13 (5) |
| Anaemia | | 35 (6) | 20 (4) | 9 (3) |

Events listed according to the MedDRA Preferred Terms used for the coding of events reported by investigators. *Data reported for patients who were randomised to active treatments from baseline.

AE, adverse event; COVID-19, coronavirus disease 2019; RA, rheumatoid arthritis.

**Supplementary Table 9.** All SAEs in contRAst 1 up to Week 12 and Week 52

| | ContRAst 1 | | | |
|---|---|---|---|---|
| **Adverse event, number of patients (%)** | **Pooled placebo (N=241)** | **Otilimab 90 mg QW (N=513)** | **Otilimab 150 mg QW (N=510)** | **Tofacitinib 5 mg BID (N=273)** |
| **Week 0 to 12** | | | | |
| Any event | 8 (3) | 8 (2) | 6 (1) | 9 (3) |
| Any infection or infestation | 3 (1) | 3 (1) | 2 (1) | 4 (1) |
| COVID-19 | 1 (<1) | 0 | 0 | 0 |
| COVID-19 pneumonia | 1 (<1) | 1 (<1) | 1 (<1) | 2 (<1) |
| Sepsis | 1 (<1) | 0 | 1 (<1) | 1 (<1) |
| Cellulitis | 0 | 0 | 0 | 2 (<1) |
| Pneumonia | 0 | 0 | 1 (<1) | 1 (<1) |
| Cellulitis staphylococcal | 0 | 1 (<1) | 0 | 0 |
| Gastroenteritis | 0 | 1 (<1) | 0 | 0 |
| Septic shock | 0 | 0 | 1 (<1) | 0 |
| Any neoplasms benign, malignant and unspecified (including cysts and polyps) | 2 (<1) | 1 (<1) | 0 | 1 (<1) |
| Adenocarcinoma of colon | 1 (<1) | 0 | 0 | 0 |
| Laryngeal squamous cell carcinoma | 0 | 0 | 0 | 1 (<1) |
| Ovarian fibroma | 0 | 0 | 0 | 1 (<1) |
| Pancoast's tumour | 1 (<1) | 0 | 0 | 0 |
| Any blood and lymphatic system disorders | 0 | 0 | 2 (<1) | 0 |
| Anaemia | 0 | 0 | 1 (<1) | 0 |
| Neutropenia | 0 | 0 | 1 (<1) | 0 |
| Any musculoskeletal and connective tissue disorders | 0 | 1 (<1) | 0 | 1 (<1) |
| Osteoarthritis | 0 | 0 | 0 | 1 (<1) |
| Rheumatoid arthritis | 0 | 1 (<1) | 0 | 0 |
| Any nervous system disorders | 0 | 1 (<1) | 1 (<1) | 0 |
| Cerebrovascular accident | 0 | 1 (<1) | 1 (<1) | 0 |

| | | | | |
|---|---|---|---|---|
| Any renal and urinary disorders | 0 | 0 | 1 (<1) | 1 (<1) |
| Acute kidney injury | 0 | 0 | 0 | 1 (<1) |
| Renal failure | 0 | 0 | 1 (<1) | 0 |
| Any respiratory, thoracic and mediastinal disorders | 0 | 0 | 0 | 2 (<1) |
| Chronic obstructive pulmonary disease | 0 | 0 | 0 | 1 (<1) |
| Haemothorax | 0 | 0 | 0 | 1 (<1) |
| Any cardiac disorder | 1 (<1) | 0 | 0 | 0 |
| Atrial fibrillation | 1 (<1) | 0 | 0 | 0 |
| Any ear and labyrinth disorders | 0 | 1 (<1) | 0 | 0 |
| Meniere's disease | 0 | 1 (<1) | 0 | 0 |
| Any gastrointestinal disorder | 0 | 0 | 0 | 1 (<1) |
| Gastric ulcer perforation | 0 | 0 | 0 | 1 (<1) |
| Any general disorders and administration site conditions | 0 | 0 | 1 (<1) | 0 |
| Death | 0 | 0 | 1 (<1) | 0 |
| Any hepatobiliary disorders | 0 | 1 (<1) | 0 | 0 |
| Chronic hepatitis | 0 | 1 (<1) | 0 | 0 |
| Hepatic cirrhosis | 0 | 1 (<1) | 0 | 0 |
| Hepatorenal failure | 0 | 1 (<1) | 0 | 0 |
| Any injury, poisoning and procedural complications | 1 (<1) | 0 | 0 | 0 |
| Tendon rupture | 1 (<1) | 0 | 0 | 0 |
| Any metabolism and nutrition disorders | 0 | 0 | 0 | 1 (<1) |
| Hyperglycaemic hyperosmolar non-ketotic syndrome | 0 | 0 | 0 | 1 (<1) |
| Any psychiatric disorders | 1 (<1) | 0 | 0 | 0 |
| Conversion disorder | 1 (<1) | 0 | 0 | 0 |
| Any reproductive system and breast disorders | 0 | 0 | 1 (<1) | 0 |
| Intermenstrual bleeding | 0 | 0 | 1 (<1) | 0 |
| Any vascular disorders | 0 | 0 | 0 | 1 (<1) |

| | | | | |
|---|---|---|---|---|
| Hypertension | 0 | 0 | 0 | 1 (<1) |
| | | **Otilimab 90 mg QW (N=513)** | **Otilimab 150 mg QW (N=510)** | **Tofacitinib 5 mg BID (N=273)** |
| **Week 0 to 52*** | | | | |
| Any event | | 33 (6) | 39 (8) | 23 (8) |
| Any infection or infestation | | 16 (3) | 18 (4) | 8 (3) |
| COVID-19 | | 0 | 1 (<1) | 2 (<1) |
| COVID-19 pneumonia | | 7 (1) | 10 (2) | 4 (1) |
| Pneumonia | | 2 (<1) | 3 (<1) | 1 (<1) |
| Cellulitis | | 1 (<1) | 0 | 2 (<1) |
| Abscess limb | | 0 | 2 (<1) | 0 |
| Sepsis | | 0 | 1 (<1) | 1 (<1) |
| Septic shock | | 0 | 2 (<1) | 0 |
| Acinetobacter sepsis | | 0 | 1 (<1) | 0 |
| Arthritis bacterial | | 0 | 1 (<1) | 0 |
| Bursitis infective | | 0 | 1 (<1) | 0 |
| Cellulitis staphylococcal | | 1 (<1) | 0 | 0 |
| Chronic tonsillitis | | 1 (<1) | 0 | 0 |
| Diverticulitis | | 1 (<1) | 0 | 0 |
| Diverticulitis intestinal perforated | | 0 | 1 (<1) | 0 |
| Gastroenteritis | | 1 (<1) | 0 | 0 |
| Hepatitis E | | 0 | 1 (<1) | 0 |
| Joint abscess | | 1 (<1) | 0 | 0 |
| Post procedural cellulitis | | 0 | 1 (<1) | 0 |
| Postoperative wound infection | | 1 (<1) | 0 | 0 |
| Urinary tract infection | | 0 | 1 (<1) | 0 |
| Wound infection pseudomonas | | 1 (<1) | 0 | 0 |
| Wound infection staphylococcal | | 1 (<1) | 0 | 0 |
| Any musculoskeletal and connective tissue disorders | | 4 (<1) | 6 (1) | 4 (1) |
| Rheumatoid arthritis | | 2 (<1) | 5 (<1) | 0 |
| Osteoarthritis | | 2 (<1) | 0 | 2 (<1) |
| Arthritis | | 0 | 1 (<1) | 0 |
| Costochondritis | | 0 | 0 | 1 (<1) |
| Foot deformity | | 0 | 0 | 1 (<1) |
| Fracture non-union | | 0 | 1 (<1) | 0 |

| | | | | |
|---|---|---|---|---|
| Musculoskeletal chest pain | | 0 | 0 | 1 (<1) |
| Any injury, poisoning and procedural complications | | 4 (<1) | 5 (<1) | 1 (<1) |
| Ankle fracture | | 0 | 1 (<1) | 0 |
| Cervical vertebral fracture | | 1 (<1) | 0 | 0 |
| Femoral neck fracture | | 0 | 1 (<1) | 0 |
| Femur fracture | | 1 (<1) | 0 | 0 |
| Humerus fracture | | 0 | 1 (<1) | 0 |
| Lower limb fracture | | 0 | 1 (<1) | 0 |
| Multiple injuries | | 1 (<1) | 0 | 0 |
| Post procedural complication | | 1 (<1) | 0 | 0 |
| Radius fracture | | 0 | 0 | 1 (<1) |
| Rib fracture | | 1 (<1) | 0 | 0 |
| Tibia fracture | | 0 | 0 | 1 (<1) |
| Ulna fracture | | 0 | 1 (<1) | 0 |
| Any nervous system disorders | | 2 (<1) | 5 (<1) | 1 (<1) |
| Cerebrovascular accident | | 1 (<1) | 1 (<1) | 0 |
| Neuropathy peripheral | | 1 (<1) | 1 (<1) | 0 |
| Cerebral infarction | | 0 | 1 (<1) | 0 |
| Dizziness | | 0 | 1 (<1) | 0 |
| Headache | | 0 | 1 (<1) | 0 |
| Hypertensive encephalopathy | | 0 | 1 (<1) | 0 |
| Ischaemic stroke | | 0 | 1 (<1) | 0 |
| Lumbar radiculopathy | | 0 | 0 | 1 (<1) |
| Metabolic encephalopathy | | 0 | 1 (<1) | 0 |
| Syncope | | 0 | 1 (<1) | 0 |
| Vascular encephalopathy | | 0 | 1 (<1) | 0 |
| Vertebrobasilar insufficiency | | 0 | 1 (<1) | 0 |
| Any neoplasms, benign, malignant and unspecified (including cysts and polyps) | | 2 (<1) | 1 (<1) | 3 (1) |
| Lung adenocarcinoma | | 0 | 0 | 2 (<1) |
| Breast cancer | | 0 | 1 (<1) | 0 |
| Laryngeal squamous cell carcinoma | | 1 (<1) | 0 | 0 |
| Ovarian adenoma | | 1 (<1) | 0 | 0 |
| Ovarian fibroma | | 0 | 0 | 1 (<1) |
| Any blood and lymphatic system disorders | | 0 | 4 (<1) | 0 |
| Anaemia | | 0 | 2 (<1) | 0 |

| | | | | |
|---|---|---|---|---|
| Neutropenia | | 0 | 1 (<1) | 0 |
| Pancytopenia | | 0 | 1 (<1) | 0 |
| Any cardiac disorders | | 4 (<1) | 0 | 0 |
| Acute myocardial infarction | | 2 (<1) | 0 | 0 |
| Cardiac arrest | | 1 (<1) | 0 | 0 |
| Coronary artery disease | | 1 (<1) | 0 | 0 |
| Myocardial infarction | | 1 (<1) | 0 | 0 |
| Any gastrointestinal disorders | | 1 (<1) | 1 (<1) | 2 (<1) |
| Colitis ischaemic | | 0 | 1 (<1) | 0 |
| Diverticulum intestinal | | 0 | 0 | 1 (<1) |
| Gastric ulcer perforation | | 0 | 0 | 1 (<1) |
| Gastritis erosive | | 1 (<1) | 0 | 0 |
| Intussusception | | 1 (<1) | 0 | 0 |
| Any renal and urinary disorders | | 1 (<1) | 2 (<1) | 1 (<1) |
| Acute kidney injury | | 0 | 0 | 1 (<1) |
| Nephrolithiasis | | 1 (<1) | 0 | 0 |
| Neurogenic bladder | | 0 | 1 (<1) | 0 |
| Renal failure | | 0 | 1 (<1) | 0 |
| Any vascular disorders | | 2 (<1) | 1 (<1) | 1 (<1) |
| Hypertension | | 1 (<1) | 0 | 1 (<1) |
| Circulatory collapse | | 0 | 1 (<1) | 0 |
| Deep vein thrombosis | | 1 (<1) | 0 | 0 |
| Any general disorders and administration site conditions | | 0 | 2 (<1) | 1 (<1) |
| Death | | 0 | 2 (<1) | 0 |
| Chest pain | | 0 | 0 | 1 (<1) |
| Any endocrine disorders | | 0 | 1 (<1) | 1 (<1) |
| Cushing's syndrome | | 0 | 1 (<1) | 0 |
| Goitre | | 0 | 0 | 1 (<1) |
| Any hepatobiliary disorders | | 1 (<1) | 1 (<1) | 0 |
| Chronic hepatitis | | 1 (<1) | 0 | 0 |
| Drug-induced liver injury | | 0 | 1 (<1) | 0 |
| Hepatic cirrhosis | | 1 (<1) | 0 | 0 |
| Hepatorenal failure | | 1 (<1) | 0 | 0 |
| Any respiratory, thoracic and mediastinal disorders | | 0 | 0 | 2 (<1) |
| Chronic obstructive pulmonary disease | | 0 | 0 | 1 (<1) |
| Haemothorax | | 0 | 0 | 1 (<1) |

| | | | | |
|---|---|---|---|---|
| Any ear and labyrinth disorders | | 1 (<1) | 0 | 0 |
| Meniere's disease | | 1 (<1) | 0 | 0 |
| Any investigations | | 0 | 0 | 1 (<1) |
| ALT increased | | 0 | 0 | 1 (<1) |
| Any metabolism and nutrition disorders | | 0 | 0 | 1 (<1) |
| Hyperglycaemic hyperosmolar nonketotic syndrome | | 0 | 0 | 1 (<1) |
| Any product issues | | 0 | 1 (<1) | 0 |
| Device malfunction | | 0 | 1 (<1) | 0 |
| Any reproductive system and breast disorders | | 0 | 1 (<1) | 0 |
| Intermenstrual bleeding | | 0 | 1 (<1) | 0 |

Events listed according to the MedDRA Preferred Terms used for the coding of events reported by investigators. *Data reported for patients who were randomised to active treatments from baseline.

ALT, alanine aminotransferase; BID, twice daily; COVID-19, coronavirus disease 2019; MedDRA, Medical Dictionary for Regulatory Activities; QW, once weekly; SAE, serious adverse event.

**Supplementary Table 10**. All SAEs in contRAst 2 up to Week 12 and Week 52

| | ContRAst 2 | | | |
|---|---|---|---|---|
| **Adverse event, number of patients (%)** | **Pooled placebo (N=255)** | **Otilimab 90 mg QW (N=545)** | **Otilimab 150 mg QW (N=539)** | **Tofacitinib 5 mg BID (N=286)** |
| **Week 0 to 12** | | | | |
| Any event | 6 (2) | 12 (2) | 19 (4) | 6 (2) |
| Any infection or infestation | 1 (<1) | 2 (<1) | 7 (1) | 1 (<1) |
| COVID-19 | 0 | 0 | 1 (<1) | 0 |
| COVID-19 pneumonia | 0 | 0 | 3 (<1) | 0 |
| Pneumonia | 0 | 1 (<1) | 1 (<1) | 0 |
| Appendicitis | 0 | 0 | 1 (<1) | 0 |
| Herpes zoster | 0 | 0 | 1 (<1) | 0 |
| Pneumocystis jirovecii pneumonia | 0 | 0 | 0 | 1 (<1) |
| Pyelonephritis | 0 | 1 (<1) | 0 | 0 |
| Urinary tract infection | 1 (<1) | 0 | 0 | 0 |
| Any musculoskeletal and connective tissue disorders | 2 (<1) | 2 (<1) | 2 (<1) | 1 (<1) |
| Osteoarthritis | 1 (<1) | 2 (<1) | 1 (<1) | 0 |
| Back pain | 0 | 0 | 1 (<1) | 0 |
| Intervertebral disc degeneration | 0 | 0 | 0 | 1 (<1) |
| Synovitis | 1 (<1) | 0 | 0 | 0 |
| Any cardiac disorder | 0 | 3 (<1) | 3 (<1) | 0 |
| Acute myocardial infarction | 0 | 1 (<1) | 0 | 0 |
| Angina unstable | 0 | 0 | 1 (<1) | 0 |
| Atrial fibrillation | 0 | 0 | 1 (<1) | 0 |
| Myocardial infarction | 0 | 1 (<1) | 0 | 0 |
| Pericardial effusion | 0 | 0 | 1 (<1) | 0 |
| Sinus node dysfunction | 0 | 1 (<1) | 0 | 0 |
| Any neoplasms benign, malignant and unspecified (including cysts and polyps) | 1 (<1) | 1 (<1) | 3 (<1) | 0 |

| | | | | |
|---|---|---|---|---|
| Colorectal adenoma | 1 (<1) | 1 (<1) | 0 | 0 |
| Cardiac myxoma | 0 | 0 | 1 (<1) | 0 |
| Invasive ductal breast carcinoma | 0 | 0 | 1 (<1) | 0 |
| Invasive lobular breast carcinoma | 0 | 0 | 1 (<1) | 0 |
| Metastases to liver | 0 | 0 | 1 (<1) | 0 |
| Any hepatobiliary disorders | 0 | 2 (<1) | 1 (<1) | 0 |
| Acute hepatic failure | 0 | 0 | 1 (<1) | 0 |
| Bile duct stone | 0 | 1 (<1) | 0 | 0 |
| Cholecystitis acute | 0 | 1 (<1) | 0 | 0 |
| Any injury, poisoning and procedural complications | 0 | 0 | 2 (<1) | 1 (<1) |
| Joint injury | 0 | 0 | 1 (<1) | 0 |
| Overdose | 0 | 0 | 1 (<1) | 0 |
| Tendon rupture | 0 | 0 | 0 | 1 (<1) |
| Any investigations | 2 (<1) | 0 | 0 | 0 |
| ALT increased | 1 (<1) | 0 | 0 | 0 |
| Transaminases increased | 1 (<1) | 0 | 0 | 0 |
| Any nervous system disorders | 0 | 0 | 1 (<1) | 1 (<1) |
| Seizure | 0 | 0 | 0 | 1 (<1) |
| Subarachnoid haemorrhage | 0 | 0 | 1 (<1) | 0 |
| Syncope | 0 | 0 | 0 | 1 (<1) |
| Any reproductive system and breast disorders | 0 | 1 (<1) | 1 (<1) | 0 |
| Menopausal symptoms | 0 | 0 | 1 (<1) | 0 |
| Uterine polyp | 0 | 1 (<1) | 0 | 0 |
| Any respiratory, thoracic and mediastinal disorders | 0 | 0 | 2 (<1) | 0 |
| Pleural effusion | 0 | 0 | 1 (<1) | 0 |
| Pulmonary embolism | 0 | 0 | 1 (<1) | 0 |
| Any blood and lymphatic system disorders | 0 | 0 | 1 (<1) | 0 |
| Anaemia | 0 | 0 | 1 (<1) | 0 |

| | | | | |
|---|---|---|---|---|
| Any gastrointestinal disorder | 0 | 0 | 1 (<1) | 0 |
| Mesenteric cyst | 0 | 0 | 1 (<1) | 0 |
| Any general disorders and administration site conditions | 0 | 0 | 0 | 1 (<1) |
| Pyrexia | 0 | 0 | 0 | 1 (<1) |
| Any immune system disorders | 0 | 0 | 0 | 1 (<1) |
| Secondary amyloidosis | 0 | 0 | 0 | 1 (<1) |
| Any metabolism and nutrition disorders | 0 | 1 (<1) | 0 | 0 |
| Dehydration | 0 | 1 (<1) | 0 | 0 |
| Any renal and urinary disorders | 0 | 0 | 1 (<1) | 0 |
| Calculus urinary | 0 | 0 | 1 (<1) | 0 |
| | | **Otilimab 90 mg QW (N=545)** | **Otilimab 150 mg QW (N=539)** | **Tofacitinib 5 mg BID (N=286)** |
| **Week 0 to 52*** | | | | |
| Any event | | 44 (8) | 43 (8) | 31 (11) |
| Any infection or infestation | | 12 (2) | 13 (2) | 12 (4) |
| COVID-19 | | 1 (<1) | 2 (<1) | 0 |
| COVID-19 pneumonia | | 5 (<1) | 5 (<1) | 7 (2) |
| Pneumonia | | 2 (<1) | 1 (<1) | 2 (<1) |
| Appendicitis | | 0 | 2 (<1) | 0 |
| Pneumocystis jirovecii pneumonia | | 1 (<1) | 0 | 1 (<1) |
| Diverticulitis | | 0 | 1 (<1) | 0 |
| Escherichia sepsis | | 0 | 0 | 1 (<1) |
| Herpes simplex | | 0 | 1 (<1) | 0 |
| Herpes zoster | | 0 | 1 (<1) | 0 |
| Pneumonia bacterial | | 1 (<1) | 0 | 0 |
| Post-procedural infection | | 0 | 1 (<1) | 0 |
| Pyelonephritis | | 1 (<1) | 0 | 0 |
| Pyelonephritis acute | | 0 | 0 | 1 (<1) |
| Sepsis | | 1 (<1) | 0 | 0 |
| Septic shock | | 0 | 0 | 1 (<1) |
| Any musculoskeletal and connective tissue disorders | | 8 (1) | 9 (2) | 4 (1) |
| Osteoarthritis | | 4 (<1) | 4 (<1) | 0 |
| Rheumatoid arthritis | | 1 (<1) | 2 (<1) | 1 (<1) |

| | | | | |
|---|---|---|---|---|
| Back pain | | 0 | 1 (<1) | 0 |
| Intervertebral disc degeneration | | 0 | 0 | 1 (<1) |
| Joint destruction | | 1 (<1) | 0 | 0 |
| Lumbar spinal stenosis | | 1 (<1) | 0 | 0 |
| Osteonecrosis | | 0 | 0 | 1 (<1) |
| Osteoporotic fracture | | 0 | 0 | 1 (<1) |
| Spinal osteoarthritis | | 0 | 1 (<1) | 0 |
| Synovial cyst | | 0 | 1 (<1) | 0 |
| Tenosynovitis | | 1 (<1) | 0 | 0 |
| Any neoplasms benign, malignant and unspecified (including cysts and polyps) | | 2 (<1) | 5 (<1) | 5 (2) |
| Invasive lobular breast carcinoma | | 0 | 2 (<1) | 0 |
| Adenocarcinoma of colon | | 0 | 0 | 1 (<1) |
| Breast cancer | | 0 | 0 | 1 (<1) |
| Cardiac myxoma | | 0 | 1 (<1) | 0 |
| Chronic lymphocytic leukaemia | | 0 | 0 | 1 (<1) |
| Colorectal adenoma | | 1 (<1) | 0 | 0 |
| Gastric cancer | | 0 | 1 (<1) | 0 |
| Invasive ductal breast carcinoma | | 0 | 1 (<1) | 0 |
| Lung neoplasm | | 1 (<1) | 0 | 0 |
| Metastases to liver | | 0 | 1 (<1) | 0 |
| Pancreatic carcinoma metastatic | | 0 | 0 | 1 (<1) |
| Rectal adenocarcinoma | | 0 | 0 | 1 (<1) |
| Any injury, poisoning and procedural complications | | 2 (<1) | 6 (1) | 3 (1) |
| Ankle fracture | | 1 (<1) | 0 | 1 (<1) |
| Spinal compression fracture | | 0 | 1 (<1) | 1 (<1) |
| Incisional hernia | | 0 | 1 (<1) | 0 |
| Joint injury | | 0 | 1 (<1) | 0 |
| Overdose | | 0 | 1 (<1) | 0 |
| Skin laceration | | 1 (<1) | 0 | 0 |
| Tendon rupture | | 0 | 0 | 1 (<1) |
| Tibia fracture | | 0 | 1 (<1) | 0 |
| Wound dehiscence | | 0 | 1 (<1) | 0 |
| Any cardiac disorder | | 5 (<1) | 3 (<1) | 0 |
| Acute myocardial infarction | | 2 (<1) | 0 | 0 |

| | | | | |
|---|---|---|---|---|
| Atrial fibrillation | | 1 (<1) | 1 (<1) | 0 |
| Angina unstable | | 0 | 1 (<1) | 0 |
| Myocardial infarction | | 1 (<1) | 0 | 0 |
| Pericardial effusion | | 0 | 1 (<1) | 0 |
| Sinus node dysfunction | | 1 (<1) | 0 | 0 |
| Any nervous system disorders | | 3 (<1) | 2 (<1) | 3 (1) |
| Subarachnoid haemorrhage | | 1 (<1) | 1 (<1) | 0 |
| Cerebral infarction | | 0 | 1 (<1) | 0 |
| Cerebrovascular accident | | 1 (<1) | 0 | 0 |
| Facial paralysis | | 1 (<1) | 0 | 0 |
| Ischaemic stroke | | 0 | 0 | 1 (<1) |
| Paraparesis | | 0 | 0 | 1 (<1) |
| Seizure | | 0 | 0 | 1 (<1) |
| Syncope | | 0 | 0 | 1 (<1) |
| Any gastrointestinal disorders | | 3 (<1) | 2 (<1) | 2 (<1) |
| Acute abdomen | | 1 (<1) | 0 | 0 |
| Duodenal ulcer perforation | | 1 (<1) | 0 | 0 |
| Enteritis | | 0 | 1 (<1) | 0 |
| Gastric ulcer | | 0 | 0 | 1 (<1) |
| Inguinal hernia | | 0 | 0 | 1 (<1) |
| Mesenteric cyst | | 0 | 1 (<1) | 0 |
| Peritoneal adhesions | | 1 (<1) | 0 | 0 |
| Any hepatobiliary disorders | | 3 (<1) | 1 (<1) | 2 (<1) |
| Cholecystitis acute | | 2 (<1) | 0 | 0 |
| Acute hepatic failure | | 0 | 1 (<1) | 0 |
| Bile duct stone | | 1 (<1) | 0 | 0 |
| Cholelithiasis | | 0 | 0 | 1 (<1) |
| Hepatic steatosis | | 0 | 0 | 1 (<1) |
| Any blood and lymphatic system disorders | | 1 (<1) | 1 (<1) | 2 (<1) |
| Anaemia | | 0 | 1 (<1) | 1 (<1) |
| Iron deficiency anaemia | | 1 (<1) | 0 | 1 (<1) |
| Any general disorders and administration site conditions | | 2 (<1) | 1 (<1) | 1 (<1) |
| Death | | 1 (<1) | 0 | 0 |
| Fatigue | | 1 (<1) | 0 | 0 |
| Pyrexia | | 0 | 0 | 1 (<1) |

| | | | | |
|---|---|---|---|---|
| Sudden death | | 0 | 1 (<1) | 0 |
| Any reproductive system and breast disorders | | 3 (<1) | 1 (<1) | 0 |
| Endometrial hyperplasia | | 1 (<1) | 0 | 0 |
| Hydrosalpinx | | 1 (<1) | 0 | 0 |
| Menopausal symptoms | | 0 | 1 (<1) | 0 |
| Ovarian cyst | | 1 (<1) | 0 | 0 |
| Uterine polyp | | 1 (<1) | 0 | 0 |
| Any respiratory, thoracic and mediastinal disorders | | 0 | 4 (<1) | 0 |
| Pulmonary embolism | | 0 | 2 (<1) | 0 |
| Pleural effusion | | 0 | 1 (<1) | 0 |
| Pulmonary fibrosis | | 0 | 1 (<1) | 0 |
| Any eye disorders | | 1 (<1) | 0 | 1 (<1) |
| Glaucoma | | 0 | 0 | 1 (<1) |
| Ulcerative keratitis | | 1 (<1) | 0 | 0 |
| Any renal and urinary disorders | | 0 | 2 (<1) | 0 |
| Calculus urinary | | 0 | 1 (<1) | 0 |
| IgA nephropathy | | 0 | 1 (<1) | 0 |
| Any immune system disorders | | 0 | 0 | 1 (<1) |
| Secondary amyloidosis | | 0 | 0 | 1 (<1) |
| Any investigations | | 0 | 0 | 1 (<1) |
| International normalised ratio increased | | 0 | 0 | 1 (<1) |
| Any metabolism and nutrition disorders | | 1 (<1) | 0 | 0 |
| Dehydration | | 1 (<1) | 0 | 0 |
| Any product issues | | 1 (<1) | 0 | 0 |
| Device dislocation | | 1 (<1) | 0 | 0 |
| Any vascular disorders | | 0 | 1 (<1) | 0 |
| Deep vein thrombosis | | 0 | 1 (<1) | 0 |

Events listed according to the MedDRA Preferred Terms used for the coding of events reported by investigators. *Data reported for patients who were randomised to active treatments from baseline.

ALT, alanine aminotransferase; BID, twice daily; COVID-19, coronavirus disease 2019; MedDRA, Medical Dictionary for Regulatory Activities; QW, once weekly; SAE, serious adverse event.

**Supplementary Table 11.** AESIs up to Week 12 and Week 52 in contRAst 1 and contRAst 2

| | ContRAst 1 | | | | ContRAst 2 | | | |
|---|---|---|---|---|---|---|---|---|
| **Adverse event, number of patients (%)** | **Pooled placebo (N=241)** | **Otilimab 90 mg QW (N=513)** | **Otilimab 150 mg QW (N=510)** | **Tofacitinib 5 mg BID (N=273)** | **Pooled placebo (N=255)** | **Otilimab 90 mg QW (N=545)** | **Otilimab 150 mg QW (N=539)** | **Tofacitinib 5 mg BID (N=286)** |
| **Week 0 to 12** | | | | | | | | |
| Any AESI | 4 (2) | 25 (5) | 26 (5) | 5 (2) | 5 (2) | 27 (5) | 44 (8) | 5 (2) |
| Serious infections | 3 (1) | 3 (<1) | 2 (<1) | 4 (1) | 1 (<1) | 2 (<1) | 7 (1) | 1 (<1) |
| Serious infections, excluding COVID-19 infections | 1 (<1) | 2 (<1) | 1 (<1) | 3 (1) | 1 (<1) | 2 (<1) | 3 (<1) | 1 (<1) |
| Opportunistic infections | 0 | 0 | 1 (<1) | 0 | 0 | 0 | 1 (<1) | 2 (<1) |
| Active TB | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Latent TB | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TB reactivation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Neutropenia | 1 (<1) | 4 (<1) | 5 (<1) | 0 | 1 (<1) | 1 (<1) | 1 (<1) | 0 |
| Persistent cough (for ≥21 days) | 0 | 0 | 0 | 0 | 0 | 2 (<1) | 1 (<1) | 0 |
| Persistent dyspnoea (≥21 days) | 0 | 1 (<1) | 0 | 0 | 0 | 1 (<1) | 1 (<1) | 0 |
| PAP | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Serious hypersensitivity reactions | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Injection site reactions | 0 | 18 (4) | 19 (4) | 1 (<1) | 3 (1) | 23 (4) | 36 (7) | 3 (1) |
| **Week 0 to 52*** | | | | | | | | |
| Any AESI, n (%) | | 65 (13) | 58 (11) | 22 (8) | | 72 (13) | 75 (14) | 32 (11) |
| Serious infections | | 16 (3) | 18 (4) | 8 (3) | | 12 (2) | 13 (2) | 12 (4) |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Serious infections, excluding COVID-19 infections | | 9 (2) | 8 (2) | 3 (1) | | 6 (1) | 7 (1) | 6 (2) |
| Opportunistic infections | | 0 | 2 (<1) | 0 | | 3 (<1) | 1 (<1) | 5 (2) |
| Active TB | | 0 | 0 | 0 | | 0 | 0 | 0 |
| Latent TB | | 22 (4) | 9 (2) | 11 (4) | | 15 (3) | 10 (2) | 8 (3) |
| TB reactivation | | 0 | 0 | 0 | | 0 | 0 | 0 |
| Neutropenia | | 6 (1) | 8 (2) | 1 (<1) | | 2 (<1) | 3 (<1) | 1 (<1) |
| Persistent cough | | 0 | 0 | 1 (<1) | | 2 (<1) | 1 (<1) | 0 |
| Persistent dyspnoea | | 1 (<1) | 0 | 1 (<1) | | 1 (<1) | 3 (<1) | 0 |
| PAP | | 0 | 0 | 0 | | 0 | 0 | 0 |
| Serious hypersensitivity reactions | | 0 | 0 | 0 | | 0 | 0 | 0 |
| Injection site reactions | | 21 (4) | 24 (5) | 2 (<1) | | 42 (8) | 47 (9) | 7 (2) |

*Data reported for patients who were randomised to active treatments from baseline.

AESI, adverse event of special interest; BID, twice daily; COVID-19, coronavirus disease 2019; MedDRA, Medical Dictionary for Regulatory Activities; QW, once weekly; TB, tuberculosis.

**Supplementary Table 12.** Fatal SAEs up to Week 12 and Week 52 in contRAst 1 and contRAst 2

| | ContRAst 1 | | | | ContRAst 2 | | | |
|---|---|---|---|---|---|---|---|---|
| **Adverse event, number of patients** | **Pooled placebo (N=241)** | **Otilimab 90 mg QW (N=513)** | **Otilimab 150 mg QW (N=510)** | **Tofacitinib 5 mg BID (N=273)** | **Pooled placebo (N=256)** | **Otilimab 90 mg QW (N=545)** | **Otilimab 150 mg QW (N=539)** | **Tofacitinib 5 mg BID (N=286)** |
| **Week 0 to 12** | | | | | | | | |
| Any fatal SAE | 1 | 1 | 1 | 2 | 0 | 0 | 4 | 0 |
| COVID-19 pneumonia | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 |
| Adenocarcinoma of colon | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatorenal failure | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hemothorax | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |
| Overdose | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| Subarachnoid haemorrhage | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| Acute hepatic failure | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| **Week 0 to 52*** | | | | | | | | |
| Any fatal SAE | | 2 | 7 | 3 | | 5 | 6 | 2 |
| COVID-19 | | 0 | 1 | 1 | | 0 | 0 | 0 |
| COVID-19 pneumonia | | 0 | 1 | 1 | | 1 | 2 | 1 |
| Pneumonia | | 0 | 1 | 0 | | 0 | 0 | 0 |
| Cardiac arrest | | 1 | 0 | 0 | | 0 | 0 | 0 |
| Colitis ischaemic | | 0 | 1 | 0 | | 0 | 0 | 0 |
| Circulatory collapse | | 0 | 1 | 0 | | 0 | 0 | 0 |
| Death | | 0 | 2 | 0 | | 1 | 0 | 0 |
| Hepatorenal failure | | 1 | 0 | 0 | | 0 | 0 | 0 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Haemothorax | | 0 | 0 | 1 | | 0 | 0 | 0 |
| Septic shock | | 0 | 0 | 0 | | 0 | 0 | 1 |
| Lung neoplasm | | 0 | 0 | 0 | | 1 | 0 | 0 |
| Subarachnoid haemorrhage | | 0 | 0 | 0 | | 1 | 1 | 0 |
| Acute abdomen | | 0 | 0 | 0 | | 1 | 0 | 0 |
| Acute hepatic failure | | 0 | 0 | 0 | | 0 | 1 | 0 |
| Sudden death | | 0 | 0 | 0 | | 0 | 1 | 0 |
| Overdose† | | 0 | 0 | 0 | | 0 | 1 | 0 |

Events listed according to the MedDRA Preferred Terms used for the coding of events reported by investigators. *Data reported for patients who were randomised to active treatments from baseline; †Accidental overdose to a concomitant medication.

BID, twice daily; COVID-19, coronavirus disease 2019; MedDRA, Medical Dictionary for Regulatory Activities; QW, once weekly; SAE, serious adverse event.



Fleischmann RM, *et al. Ann Rheum Dis* 2023; 82:1516–1526. doi: 10.1136/ard-2023-224482

**Supplementary Table 13.** Summary of laboratory parameters worst grade shift from baseline grade up to Week 52 in contRAst 1

| Number of patients (%) | Maximum grade during time period | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Otilimab 90mg QW N=513 | | | | | Otilimab 150mg QW N=510 | | | | | Tofacitinib 5mg BID N=273 | | | | |
| **Baseline grade** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** |
| **ALT increased** | **n=509** | | | | | **n=508** | | | | | **n=273** | | | | |
| Grade 0 | 353 (69%) | 145 (28%) | 6 (1%) | 5 (<1%) | 0 | 348 (69%) | 143 (28%) | 10 (2%) | 6 (1%) | 1 (<1%) | 184 (67%) | 83 (30%) | 5 (2%) | 1 (<1%) | 0 |
| Grade 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **ALP increased** | **n=509** | | | | | **n=508** | | | | | **n=273** | | | | |
| Grade 0 | 411 (81%) | 96 (19%) | 2 (<1%) | 0 | 0 | 406 (80%) | 101 (20%) | 1 (<1%) | 0 | 0 | 228 (84%) | 44 (16%) | 1 (<1%) | 0 | 0 |
| Grade 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **AST increased** | **n=509** | | | | | **n=508** | | | | | **n=273** | | | | |
| Grade 0 | 383 (75%) | 119 (23%) | 7 (1%) | 0 | 0 | 357 (70%) | 140 (28%) | 6 (1%) | 5 (<1%) | 0 | 186 (68%) | 83 (30%) | 2 (<1%) | 1 (<1%) | 1 (<1%) |
| Grade 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Blood bilirubin increased** | **n=509** | | | | | **n=508** | | | | | **n=273** | | | | |
| Grade 0 | 499 (98%) | 7 (1%) | 2 (<1%) | 0 | 0 | 496 (98%) | 9 (2%) | 1 (<1%) | 1 (<1%) | 0 | 255 (93%) | 15 (5%) | 0 | 0 | 0 |
| Grade 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

| Number of patients (%) | Maximum grade during time period | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Otilimab 90mg QW N=513 | | | | | Otilimab 150mg QW N=510 | | | | | Tofacitinib 5mg BID N=273 | | | | |
| **Baseline grade** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total Cholesterol (High)** | **n=503** | | | | | **n=504** | | | | | **n=266** | | | | |
| Grade 0 | 167 (33%) | 105 (21%) | 1 (<1%) | 0 | 0 | 171 (34%) | 126 (25%) | 1 (<1%) | 0 | 0 | 64 (24%) | 82 (31%) | 1 (<1%) | 0 | 0 |
| Grade 1 | 18 (4%) | 198 (39%) | 9 (2%) | 0 | 0 | 19 (4%) | 177 (35%) | 6 (1%) | 1 (<1%) | 0 | 1 (<1%) | 107 (40%) | 10 (4%) | 0 | 0 |
| Grade 2 | 0 | 1 (<1%) | 4 (<1%) | 0 | 0 | 0 | 3 (<1%) | 0 | 0 | 0 | 0 | 0 | 1 (<1%) | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Haemoglobin decreased** | **n=509** | | | | | **n=508** | | | | | **n=273** | | | | |
| Grade 0 | 241 (47%) | 110 (22%) | 7 (1%) | 0 | 0 | 242 (48%) | 112 (22%) | 2 (<1%) | 0 | 0 | 144 (53%) | 46 (17%) | 0 | 0 | 0 |
| Grade 1 | 4 (<1%) | 88 (17%) | 31 (6%) | 1 (<1%) | 0 | 4 (<1%) | 88 (17%) | 19 (4%) | 1 (<1%) | 0 | 2 (<1%) | 57 (21%) | 10 (4%) | 0 | 0 |
| Grade 2 | 0 | 0 | 14 (3%) | 1 (<1%) | 0 | 0 | 4 (<1%) | 14 (3%) | 3 (<1%) | 0 | 0 | 2 (<1%) | 7 (3%) | 1 ((<1%)) | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (<1%) | 1 (<1%) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Haemoglobin increased** | **n=509** | | | | | **n=508** | | | | | **n=273** | | | | |
| Grade 0 | 241 (47%) | 10 (2%) | 0 | 0 | 0 | 242 (48%) | 10 (2%) | 0 | 0 | 0 | 144 (53%) | 3 (1%) | 0 | 0 | 0 |
| Grade 1 | 1 (<1%) | 1 (<1%) | 0 | 0 | 0 | 2 (<1%) | 5 (<1%) | 0 | 0 | 0 | 0 | 1 (<1%) | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Leukocytes decreased** | **n=509** | | | | | **n=508** | | | | | **n=273** | | | | |
| Grade 0 | 460 (90%) | 32 (6%) | 9 (2%) | 1 (<1%) | 0 | 443 (87%) | 36 (7%) | 19 (4%) | 1 (<1%) | 0 | 246 (90%) | 17 (6%) | 6 (2%) | 0 | 0 |

| Number of patients (%) | Maximum grade during time period | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Otilimab 90mg QW N=513 | | | | | Otilimab 150mg QW N=510 | | | | | Tofacitinib 5mg BID N=273 | | | | |
| **Baseline grade** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** |
| Grade 1 | 2 (<1%) | 0 | 4 (<1%) | 0 | 0 | 2 (<1%) | 3 (<1%) | 3 (<1%) | 0 | 0 | 1 (<1%) | 1 (<1%) | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 1 (<1%) | 0 | 0 | 0 | 1 (<1%) | 0 | 0 | 0 | 0 | 0 | 2 (<1%) | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Neutrophil count decreased** | **n=509** | | | | | **n=508** | | | | | **n=273** | | | | |
| Grade 0 | 466 (92%) | 25 (5%) | 10 (2%) | 2 (<1%) | 1 (<1%) | 446 (88%) | 22 (4%) | 24 (5%) | 5 (<1%) | 2 (<1%) | 242 (89%) | 13 (5%) | 12 (4%) | 0 | 1 (<1%) |
| Grade 1 | 1 (<1%) | 0 | 0 | 2 (<1%) | 0 | 0 | 0 | 2 (<1%) | 1 (<1%) | 1 (<1%) | 1 (<1%) | 1 (<1%) | 1 (<1%) | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 1 (<1%) | 1 (<1%) | 0 | 2 (<1%) | 0 | 0 | 0 | 1 (<1%) | 1 (<1%) | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (<1%) | 1 (<1%) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 1 (<1%) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Platelet count decreased** | **n=509** | | | | | **n=508** | | | | | **n=273** | | | | |
| Grade 0 | 497 (98%) | 7 (1%) | 0 | 0 | 0 | 500 (98%) | 7 (1%) | 0 | 0 | 0 | 268 (98%) | 4 (1%) | 0 | 0 | 1 (<1%) |
| Grade 1 | 1 (<1%) | 1 (<1%) | 2 (<1%) | 1 (<1%) | 0 | 0 | 1 (<1%) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

**Supplementary Table 14.** Summary of laboratory parameters worst grade shift from baseline grade up to Week 52 in contRAst 2

| Number of patients (%) | Maximum grade during time period | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Otilimab 90mg QW N=545 | | | | | Otilimab 150mg QW N=539 | | | | | Tofacitinib 5mg BID N=286 | | | | |
| **Baseline grade** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** |
| **ALT increased** | **n=541** | | | | | **n=536** | | | | | **n=282** | | | | |
| Grade 0 | 425 (79%) | 101 (19%) | 11 (2%) | 4 (<1%) | 0 | 410 (76%) | 108 (20%) | 11 (2%) | 5 (<1%) | 2 (<1%) | 189 (67%) | 84 (30%) | 5 (2%) | 4 (1%) | 0 |
| Grade 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **ALP increased** | **n=541** | | | | | **n=536** | | | | | **n=282** | | | | |
| Grade 0 | 532 (98%) | 8 (1%) | 1 (<1%) | 0 | 0 | 526 (98%) | 9 (2%) | 1 (<1%) | 0 | 0 | 279 (99%) | 2 (<1%) | 1 (<1%) | 0 | 0 |
| Grade 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **AST increased** | **n=541** | | | | | **n=536** | | | | | **n=282** | | | | |
| Grade 0 | 443 (82%) | 90 (17%) | 6 (1%) | 2 (<1%) | 0 | 422 (79%) | 104 (19%) | 5 (<1%) | 3 (<1%) | 2 (<1%) | 205 (73%) | 72 (26%) | 4 (1%) | 1 (<1%) | 0 |
| Grade 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Blood bilirubin increased** | **n=541** | | | | | **n=536** | | | | | **n=282** | | | | |
| Grade 0 | 531 (98%) | 6 (1%) | 1 (<1%) | 0 | 0 | 527 (98%) | 6 (1%) | 1 (<1%) | 0 | 0 | 278 (99%) | 2 (<1%) | 1 (<1%) | 0 | 0 |
| Grade 1 | 0 | 1 (<1%) | 1 (<1%) | 0 | 0 | 1 (<1%) | 1 (<1%) | 0 | 0 | 0 | 0 | 1 (<1%) | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

| Number of patients (%) | Maximum grade during time period | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Otilimab 90mg QW N=545 | | | | | Otilimab 150mg QW N=539 | | | | | Tofacitinib 5mg BID N=286 | | | | |
| **Baseline grade** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total cholesterol (high)** | **n=537** | | | | | **n=533** | | | | | **n=281** | | | | |
| Grade 0 | 231 (43%) | 108 (20%) | 1 (<1%) | 0 | 0 | 225 (42%) | 109 (20%) | 0 | 0 | 0 | 85 (30%) | 87 (31%) | 0 | 0 | 0 |
| Grade 1 | 21 (4%) | 163 (30%) | 9 (2%) | 0 | 0 | 21 (4%) | 159 (30%) | 17 (3%) | 0 | 0 | 4 (1%) | 89 (32%) | 14 (5%) | 0 | 0 |
| Grade 2 | 0 | 1 (<1%) | 3 (<1%) | 0 | 0 | 0 | 0 | 2 (<1%) | 0 | 0 | 0 | 2 (<1%) | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Haemoglobin decreased** | **n=540** | | | | | **n=536** | | | | | **n=282** | | | | |
| Grade 0 | 243 (45%) | 99 (18%) | 6 (1%) | 0 | 0 | 264 (49%) | 102 (19%) | 7 (1%) | 1 (<1%) | 0 | 144 (51%) | 45 (16%) | 5 (2%) | 1 (<1%) | 0 |
| Grade 1 | 6 (1%) | 128 (24%) | 28 (5%) | 0 | 0 | 7 (1%) | 107 (20%) | 13 (2%) | 0 | 0 | 4 (1%) | 58 (21%) | 5 (2%) | 1 (<1%) | 0 |
| Grade 2 | 0 | 0 | 12 (2%) | 3 (<1%) | 0 | 0 | 2 (<1%) | 10 (2%) | 4 (<1%) | 0 | 0 | 2 (<1%) | 4 (1%) | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Haemoglobin increased** | **n=540** | | | | | **n=536** | | | | | **n=282** | | | | |
| Grade 0 | 243 (45%) | 8 (1%) | 0 | 1 (<1%) | 0 | 264 (49%) | 15 (3%) | 1 (<1%) | 0 | 0 | 144 (51%) | 9 (3%) | 0 | 0 | 0 |
| Grade 1 | 0 | 7 (1%) | 0 | 0 | 0 | 1 (<1%) | 2 (<1%) | 0 | 0 | 0 | 1 (<1%) | 3 (1%) | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Leukocytes decreased** | **n=540** | | | | | **n=536** | | | | | **n=282** | | | | |
| Grade 0 | 469 (87%) | 53 (10%) | 9 (2%) | 1 (<1%) | 0 | 487 (91%) | 38 (7%) | 8 (1%) | 0 | 0 | 245 (87%) | 26 (9%) | 5 (2%) | 0 | 0 |

| Number of patients (%) | Maximum grade during time period | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Otilimab 90mg QW N=545 | | | | | Otilimab 150mg QW N=539 | | | | | Tofacitinib 5mg BID N=286 | | | | |
| **Baseline grade** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** |
| Grade 1 | 1 (<1%) | 3 (<1%) | 3 (<1%) | 1 (<1%) | 0 | 0 | 2 (<1%) | 1 (<1%) | 0 | 0 | 1 (<1%) | 2 (<1%) | 2 (<1%) | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (<1%) | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Neutrophil count decreased** | **n=540** | | | | | **n=536** | | | | | **n=282** | | | | |
| Grade 0 | 498 (92%) | 16 (3%) | 17 (3%) | 3 (<1%) | 1 (<1%) | 501 (93%) | 19 (4%) | 12 (2%) | 3 (<1%) | 1 (<1%) | 248 (88%) | 20 (7%) | 10 (4%) | 2 (<1%) | 0 |
| Grade 1 | 0 | 2 (<1%) | 1 (<1%) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (<1%) | 0 | 0 | 0 | 0 |
| Grade 2 | 0 | 1 (<1%) | 0 | 0 | 1 (<1%) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (<1%) | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Platelet count decreased** | **n=540** | | | | | **n=536** | | | | | **n=282** | | | | |
| Grade 0 | 528 (98%) | 9 (2%) | 0 | 0 | 0 | 520 (97%) | 14 (3%) | 1 (<1%) | 0 | 0 | 275 (98%) | 6 (2%) | 0 | 0 | 0 |
| Grade 1 | 0 | 3 (<1%) | 0 | 0 | 0 | 0 | 1 (<1%) | 0 | 0 | 0 | 0 | 1 (<1%) | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |