Appendix A. List of Peer Reviewers

Appendix A. List of Peer Reviewers

To be completed after Peer Review.

Appendix B. Search Strings

Appendix B. Search Strings

2007 Search

#2	Search ("Arthritis, Psoriatic"[MeSH] OR "Arthritis, Rheumatoid"[MeSH])	82356
#3	Search ("Arthritis, Psoriatic"[MeSH] OR "Arthritis, Rheumatoid"[MeSH]) Limits: All Adult: 19+ years, English, Publication Date from 1990, Humans	16462
#5	Search "Adrenal Cortex Hormones"[MeSH] OR corticosteroid*	190820
#6	Search #3 AND #5	686
#7	Search #3 AND #5 Limits: Editorial, Letter, Practice Guideline	18
#8	Search #6 NOT #7	668
#18	Search "Methotrexate"[MeSH] OR "leflunomide"[Substance Name] OR "Sulfasalazine"[MeSH] OR "Hydroxychloroquine"[MeSH]	28712
#28	Search "TNFR-Fc fusion protein"[Substance Name] OR etanercept OR "infliximab"[Substance Name] OR "adalimumab"[Substance Name] OR "cytotoxic T lymphocyte-associated antigen 4-immunoglobulin"[Substance Name] OR abatacept OR remicade OR enbrel OR humira OR "rituximab"[Substance Name] OR "interleukin 1 receptor antagonist protein"[Substance Name] OR anakinra	8701
#29	Search #3 AND #18	1365
#30	Search #3 AND #28	777
#31	Search #3 AND #18 Limits: Editorial, Letter, Practice Guideline	237
#32	Search #29 NOT #31	1128
#33	Search #3 AND #28 Limits: Editorial, Letter, Practice Guideline	178
#34	Search #30 NOT #33	599
#35	Search #8 OR #30 OR #34	1405

July 2009 Search

#1	Search "Arthritis, Psoriatic"[MeSH] OR "Arthritis, Rheumatoid"[MeSH]	85528
#2	Search "Adrenal Cortex Hormones"[MeSH] OR corticosteroid*	239378
#3	Search "Methotrexate"[MeSH] OR "leflunomide"[Substance Name] OR "Sulfasalazine"[MeSH] OR "Hydroxychloroquine"[MeSH]	31900
#4	Search "TNFR-Fc fusion protein"[Substance Name] OR etanercept OR "infliximab"[Substance Name] OR "adalimumab"[Substance Name] OR "cytotoxic T lymphocyte-associated antigen 4-immunoglobulin"[Substance Name] OR abatacept OR remicade OR enbrel OR humira OR "rituximab"[Substance Name] OR "interleukin 1 receptor antagonist protein"[Substance Name] OR anakinra	15567
#5	Search ((("CDP870 "[Substance Name] OR certolizumab OR cimzia) OR "efalizumab "[Substance Name] OR raptiva) OR "alefacept "[Substance Name] OR amevive) OR "natalizumab "[Substance Name] OR tysabri	1127
#6	Search "golimumab "[Substance Name]	12
#7	Search #2 OR #3 OR #4 OR #5 OR #6	283303
#8	Search #7 AND #1	11283
#9	Search #7 AND #1 Limits: Editorial, Letter, Practice Guideline	1368
#10	Search #8 NOT #9	9915
#11	Search #8 NOT #9 Limits: Humans, English, All Adult: 19+ years	4079
#12	Search Limits: Entrez Date from 2006/06/01, Humans, English, All Adult: 19+ years	498212
#13	Search #11 AND #12	1027

August 2009 Search (for Tocilizumab)

Search	Most Recent Queries	Result
#1	Search "Arthritis, Psoriatic"[MeSH] OR "Arthritis, Rheumatoid"[MeSH]	85692
#2	Search actemra	4
#4	Search "tocilizumab "[Substance Name]	103
#5	Search #2 OR #4	104
#6	Search #5 AND #1	75
#7	Search #5 AND #1 Limits: Editorial, Letter, Practice Guideline	8
#8	Search #6 NOT #7	67
#9	Search #6 NOT #7 Limits: Humans, English, All Adult: 19+ years	14
#10	Search #9 Limits: Entrez Date from 2006/06/01	14

Appendix C. Review and Abstraction Forms

Previewing Only: You cannot submit data from this form

Previewing at Level 1

Reviewer Comments (Add a Comment)

Refid: 2161, P. Efthimiou, A. Kontzias, C. M. Ward and N. S. Ogden, Adult-onset Still's disease: can recent advances in our understanding of its pathogenesis lead to targeted therapy?, *Nat Clin Pract Rheumatol*, 3(6), 2007, p. 328-35
State: Excluded, Level: 1

Keywords:
Adrenal Cortex Hormones/therapeutic use

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Abstract:
Adult-onset Still's disease is a rare systemic inflammatory disease of unknown etiology, characterized by daily high, spiking fevers, evanescent rash, and arthritis. There is no single diagnostic test for adult-onset Still's disease; rather, the diagnosis is based on clinical criteria and necessitates the exclusion of infectious, neoplastic, and other 'autoimmune' diseases. Proinflammatory cytokines such as interleukin (IL)-1, IL-6, and IL-18, interferon-gamma, tumor necrosis factor, and macrophage colony-stimulating factor are elevated in patients with adult-onset Still's disease and are thought to have a major role in the pathogenesis of the disease. Treatment consists of nonsteroidal anti-inflammatory drugs, corticosteroids, immunosuppressants (methotrexate, gold, azathioprine, leflunomide, cyclosporin, and cyclophosphamide), intravenous immunoglobulin, and cytokine (tumor necrosis factor, IL-1 and IL-6) inhibitors. Recent advances in basic immunology have enhanced our ability to hinder the pathogenic mechanisms associated with adult-onset Still's disease and have led to a paradigm shift where targeted treatments have an increasingly important role.

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1. Original research (no review articles, editorials, letters to the editor) published in English after 1990 in adult patients with rheumatoid or psoriatic arthritis AND is not a case report or case series?

- ○ Yes
- ○ No
- ○ Cannot determine
- ○ No, but article will be used for background

Clear Selection

2. Study includes one or more of the following pharmaceutical interventions (check all that apply):

- ☐ Corticosteroids
- ☐ Oral DMARDs including methotrexate, leflunomide, sulfasalazine, cyclosporine, hydroxychloroquine
- ☐ Biologic DMARDs including anakinra, etanercept, infliximab, adalimumab, abatacept, certolizumab, golimumab, tocilizumab, rituximab
- ☐ Cannot determine
- ☐ Comparison is not of interest

3. Study compares-

- ○ Two of the included drugs
- ○ Biological DMARD (TIM) versus placebo
- ○ One of the included drugs versus placebo but is of interest because of specific outcome such as adverse events
- ○ Nothing of interest and article should not be included
- ○ Cannot determine

Clear Selection

4. Addresses one or more of the following key questions (check all that apply):

- ☐ KQ1 For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to reduce patient-reported symptoms, to slow or limit progression of radiographic joint damage, or to maintain remission (reduce the incidence flare-ups)?
- ☐ KQ2- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to improve functional capacity or quality of life?
- ☐ KQ3 For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in harms, tolerability, adherence, or adverse effects?
- ☐ KQ4 What are the comparative benefits and harms of drug therapies for rheumatoid arthritis and psoriatic arthritis in subgroups of patients based on stage of disease, history of prior therapy, demographics, concomitant therapies, or comorbidities?
- ☐ Cannot determine by the title or abstract
- ☐ None of the above

5. Study design is one of the following:

- ☐ RCT 3 months or longer

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Previewing at Level 2

Reviewer Comments (Add a Comment)

Refid: 2161, P. Efthimiou, A. Kontzias, C. M. Ward and N. S. Ogden, Adult-onset Still's disease: can recent advances in our understanding of its pathogenesis lead to targeted therapy?, *Nat Clin Pract Rheumatol*, 3(6), 2007, p. 328-35
State: Excluded, Level: 1

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1. **Should the article be *excluded* for any of the following reasons?**

- [ ] Study reported only in abstract
- [ ] Wrong outcome (i.e. pharmakinetic or intermediate outcomes)
- [ ] Wrong drug (not one of the following: corticosteroids, methotrexate, leflunomide, sulfasalazine, cyclosporine, hydroxychloroquine, anakinra, etanercept, infliximab, adalimumab, abatacept, certolizumab, golimumab, tocilizumab, rituximab)
- [ ] Wrong population (For example pediatric studies)
- [ ] Wrong publication type (e.g. letter or editorial)
- [ ] Wrong design (i.e. non--systematic meta-analysis or no comparision arm)
- [ ] RCT (n<100)
- [ ] Other? (Please explain!)
- [ ] Background article
- [ ] None of the above- should be included!

If the article has been excluded in the above question, the next two questions do not need to be answered.

2. **Which of the following key questions are addressed by the article**

- [ ] KQ1- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to reduce patient-reported symptoms, to slow or limit progression of radiographic joint damage, or to maintain remission (reduce the incidence flare-ups)?
- [ ] KQ2- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to improve functional capacity or quality of life?
- [ ] KQ3- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in harms, tolerability, adherence, or adverse effects?
- [ ] KQ4- What are the comparative benefits and harms of drug therapies for rheumatoid arthritis and psoriatic arthritis in subgroups of patients based on stage of disease, history of prior therapy, demographics, concomitant therapies, or comorbidities?
- [ ] None of the above

3. **What is the study design?**

- ( ) RCT > or equal to 100
- ( ) Observational > or equal to 100
- ( ) Meta-analysis or systematic review (i.e. Cochrane Review)

- ○ None of the above, but it should be abstracted- please note why in the box!
- ○ None of the above, so exclude.

Clear Selection

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Previewing at Level 3

Reviewer Comments (Add a Comment)

Refid: 2161, P. Efthimiou, A. Kontzias, C. M. Ward and N. S. Ogden, Adult-onset Still's disease: can recent advances in our understa
State: Excluded, Level: 1

Save to finish later | Submit Data

1. Author, Year, Study name if applicable (i.e. BeST):

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2. Country and setting:

If more than a couple of countries are included just call it multinational. Settings include primary care, hospitals, uni

3. Source of funding

- ☐ Pharmaceutical company or other commercial source- please list name.
- ☐ Government or non-profit organization- please list name.
- ☐ Not reported

4. Condition being treated:

- ☐ Rheumatoid arthritis
- ☐ Psoriatic arthritis
- ☐ Other? Please explain

5. **STUDY DESIGN**

- ○ Controlled Trials
- ○ Observational

Clear Selection

6.
What is being compared?

- ☐ 1 Oral DMARD vs 1 Oral DMARD
- ☐ 1 Oral DMARD vs 1 BIOLOGIC
- ☐ 1 Oral DMARD vs 1 Corticosteroid
- ☐ 1 BIOLOGIC vs 1 BIOLOGIC
- ☐ 1 BIOLOGIC vs 1 Corticosteroid

- [ ] 1 BIOLOGIC vs Placebo
- [ ] Combination therapy vs Combination therapy
- [ ] SINGLE DRUG vs Combination therapy
- [ ] Strategy (Describe the strategy in detail for each arm in the 'Other' text box for numbers 8-12)

7. How many comparison arms does this study have?

- ○ 2 ARMS
- ○ 3 ARMS
- ○ 4 ARMS
- ○ 5 ARMS

Clear Selection

8. Check off the drug(s) studied for **ARM 1** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

9. Check off the drug(s) studied for **ARM 2** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone

- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

10. Check off the drug(s) studied for **ARM 3** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab

- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

11. Check off the drug(s) studied for **ARM 4** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

12. Check off the drug(s) studied for **ARM 5** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine

- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

13. Research objective (*Please be brief and concise*):

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14. Overall study n =

Enlarge Shrink

15. Duration of study:

Enlarge Shrink

16. Inclusion criteria (check all that apply and list additional criteria in the text box)

- [ ] MTX Naive
- [ ] Early RA
- [ ] Treatment resistant

Additional inclusion criteria

17.

Exclusion criteria

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POPULATION CHARACTERISTICS

	ARM 1	ARM 2
18. **Intervention/Treatment**		
19. # in group (n):		
20. Age (mean):		
21. Sex, female (%):		
22. Race, white (%):		
23. Race, black (%):		
24. Ethnicity, Latino (%):		
25. Disease duration (mean & SD):		
26. DMARD use (%):		
27. Corticosteroid use (%):		
28. MTX naive (%):		
29. Treatment resistant (%):		
30. Patients with early RA, three years or less, (%):		
31. Baseline DAS score:		
32. Tender joint count:		
33. Swollen joint count:		
34. Required treatment for latent TB:		
35. Other population characteristics?		

RESULTS: Outcome Measures and Health Outcomes
(Enter results for all time points and please specify units for all results)

	ARM 1	ARM 2
36. ACR 20, %, (CI/SD/P value):		
37. ACR 50, %, (CI/SD/P value):		
38. ACR 70, %, (CI/SD/P value):		
39. PASI 20, %, (CI/SD/P value):		

40. PASI 50, %, (CI/SD/P value):

41. PASI 70, %, (CI/SD/P value):

42. HAQ, mean difference/absolute difference (CI/SD/P Value):

43. DAS, mean difference/absolute difference (CI/SD/P Value):

44. SF-36, mean difference/absolute difference (CI/SD/P Value):

45. PsARC, mean difference/absolute difference (CI/SD/P Value):

46. Radiographic measures, mean difference/absolute difference (CI/SD/P Value):

47. Quality of life scales (please name), mean difference/absolute difference (CI/SD/P Value):

48. Others, (please name); mean difference/absolute difference (CI/SD/P Value):

ATTRITION AND ADHERENCE

	ARM 1	ARM 2
49. Overall attrition/withdrawal (n):		
50. Withdrawals due to adverse events (n):		
51. Withdrawals due to lack of efficacy (n):		
52. Adherent/compliant (n):		

53. Other attrition related comments?

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RESULTS: Adverse Events, n

	ARM 1	ARM 2
54. Overall adverse events reported (n):		
55. Death (n):		
56. Lymphoma or leukemia (n):		
57. Skin cancer (basal cell or squamous cell) (n):		
58. Other cancer (specify) (n):		
59. Cardiovascular events (specify) (n):		
60. Hepatotoxicity/elevated liver enzymes (n):		
61. Tuberculosis (n):		
62. Pneumonia (n):		
63. Upper respiratory infection (n):		
64. Urinary tract infection (n):		
65. Other infections (specify) (n):		
66. Fractures (n):		
67. Infusion/injection site reactions (n):		
68. Skin rash (n):		
69. Demyelenation or multiple sclerosis (n):		
70. Progressive multifocal leukoencephalopathy (n):		
71. Headache (n):		
72. Dizziness (n):		
73. Nausea or vomiting (n):		
74. Abdominal pain (n):		
75. GI bleed or ulcer (n):		
76. Bowel obstruction (n):		
77. Other GI symptoms (specify) (n):		
78. Other AEs 1 (n):		
79. Other AEs 2 (n):		
80. Other AEs 3 (n):		

81. Other AEs 4 (n):

82. Any other AEs:

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83. Which Key Question(s) does this study address (check all that apply)?

- [ ] KQ1- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to reduce disease activity, t
- [ ] KQ2- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to improve functional capac
- [ ] KQ3- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in harms, tolerability, adherence, or adver
- [ ] KQ4- What are the comparative benefits and harms of drug therapies for rheumatoid arthritis and psoriatic arthritis in subgroups

Quality Review for Controlled Trials

84. Randomization adequate?

- ○ Yes
- ○ No
- ○ Not randomized
- ○ Method not reported

Clear Selection

85. Allocation concealment adequate?

- ○ Yes
- ○ No
- ○ Not randomized
- ○ Method not reported

Clear Selection

86. Groups similar at baseline?

- ○ Yes
- ○ No (what are the differences)
- ○ Not reported
- ○ Not applicable

Clear Selection

87. Outcome assessors blinded?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

88. Care provider blinded?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

89. Patient blinded?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

90. Overall attrition high (≥ 20%)?

- ○ Yes (please state how high) [ ]
- ○ No

Clear Selection

91. Differential attrition high (≥ 15%)?

- ○ Yes (please state difference) [ ]
- ○ No

Clear Selection

92. Were the outcome measures valid and reliable?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

93. Were the outcome measures equally applied?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

94. Was the statistical analysis based on intention-to-treat (ITT)?

- ○ Yes
- ○ No
- ○ Cannot tell
- ○ Not applicable

Clear Selection

95. Were there any post-randomization exclusions?

- ○ Yes (how many?) [ ]
- ○ No
- ○ Cannot tell

Clear Selection

96. Quality rating for efficacy/effectiveness

- ☐ Good
- ☐ Fair
- ☐ Poor

If poor, why? [ ]

Quality Review for Observational Studies

97. Were both groups selected from the same source population?

- Yes
- No
- Yes, but method not described
- Not reported

Clear Selection

98. Did both groups have the same risk of having the outcome of interest at baseline?

- Yes
- No
- Not reported

Clear Selection

99. Were subjects in both groups recruited over the same time period?

- Yes
- No
- Yes, but method not described
- Not reported

Clear Selection

100. Were measurement methods adequate and equally applied to both groups?

- Yes
- No
- Not reported

Clear Selection

101. Was an attempt made to blind the outcome assessors?

- Yes
- No
- Yes, but method not described
- Not reported

Clear Selection

102. Was the time of follow-up equal in both groups?

- Yes
- No
- Not reported

Clear Selection

103. Overall attrition high (≥ 20%)?

- Yes (please state how high)
- No

Clear Selection

104. Differential attrition high (≥ 15%)?

- Yes (please state difference)
- No

Clear Selection

105. Was confounding accounted for either through study design or statistical analysis?

- Yes
- No
- Yes, but method not described
- Not reported

Clear Selection

106. Did the statistical analysis adjust for different lengths of follow-up?

- Yes
- No
- Yes, but method not described
- Not reported

Clear Selection

107. Was the length of follow-up adequate to assess the outcome of interest?

- Yes
- No
- Not reported

Clear Selection

108. Quality rating for observational studies

- Good
- Fair
- Poor

Why?

109. Any other quality related comments?

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Quality Review for Adverse Events

110. Methods of adverse effects assessment

- Patient reported
- Physical exam at study visits
- Lab evaluations
- Standardized scale (e.g. WHO, UKU-SES)
- other (please specify)

111. Adverse events pre-specified and defined?

- Yes
- No

Clear Selection

112. Measurement techniques non-biased and adequately described?

- Yes
- No

Clear Selection

113. Quality rating adverse events assessment:

- Good
- Fair
- Poor

Clear Selection

114. First abstraction done by:

- Karen Crotty
- Katrina Donahue
- Rick Hansen
- Dan Jonas
- Linda Lux
- Robert Roubey
- Rachael Scheinman
- Other (please write your name in the adjacent box):

Clear Selection

115. Second abstraction done by:

- Karen Crotty
- Katrina Donahue
- Rick Hansen
- Dan Jonas
- Linda Lux
- Robert Roubey
- Rachael Scheinman
- Other (please write your name in the adjacent box):

Clear Selection

116. Study is already included in systematic review/meta-analysis and does not need to be put in an evidence table

- Yes
- No

Clear Selection

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Appendix D. Bibliography by Database Source

Articles by Database Searched

Cochrane Database = 19 (duplicates excluded)

1. Blumenauer B, Judd M, Cranney A, Burls A, Coyle D, Hochberg M, et al. Etanercept for the Treatment of Rheumatoid Arthritis. The Cochrane Database of Systematic Reviews. 2003;2003(3).
2. Blumenauer B, Judd M, Wells G, Burls A, Cranney A, Hochberg M, et al. Infliximab for the Treatment of Rheumatoid Arthritis. The Cochrane Database of Systematic Reviews. 2002;2002(3).
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9. Kirwan J, Shea B, Boers M. Glucocorticoids for Slowing Radiological Progression in Rheumatoid Arthritis. The Cochrane Database of Systematic Reviews. 2005;2005(1).
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11. Navarro Sarabia F, Ariza Ariza R, Hernandez Cruz B, Villanueva I. Adalimumab for Treating Rheumatoid Arthritis. The Cochrane Database of Systematic Reviews. 2005;2005(3).
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13. Ruiz Garcia V, Burls A, Cabello López Juan CL, Fry- Smith Anne FS, Gálvez Muñoz José G, Jobanputra P, et al. Certolizumab pegol (CDP870) for rheumatoid arthritis in adults. Cochrane Database of Systematic Reviews. 2009(1).
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15. Suarez Almazor M, Belseck E, Shea BJ, Homik J, Wells G, Tugwell P. Antimalarials for Treating Rheumatoid Arthritis. The Cochrane Database of Systematic Reviews. 2000;2000(4).
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19. Wallen Margaret M, Gillies D. Intra-articular steroids and splints/rest for children with juvenile idiopathic arthritis and adults with rheumatoid arthritis. Cochrane Database of Systematic Reviews. 2006(1).

EMBASE = 141 (excluding duplicates)

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Appendix E.
Excluded Studies

Excluded Studies

Not Published in English

1. Garcia JJ, Lobato JP, Garrido SL, Fernandez ME, Eyaralar JR. Biological therapies in rheumatoid arthritis. Atencion Farmaceutica: European Journal of Clinical Pharmacy. 2008;10(98):100-11.
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Wrong Outcome

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Wrong Publication Type

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Appendix F. Studies included in Systematic Evidence Reviews and Meta-Analyses

Studies in an Included Meta-Analysis

1. Clegg DO, Reda DJ, Weisman MH, Cush JJ, Vasey FB, Schumacher HRJ, et al. Comparison of Sulfasalazine and Placebo in the Treatment of Psoriatic Arthritis. A Department of Veterans Affairs Cooperative Study. Arthritis and rheumatism. 1996;39(12):2021-7.
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Appendix G. Evidence Tables

Abbreviations

Evidence Table 1. Key Question 1

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Antoni et al., 2005; Kavanaugh et al., 2006 IMPACT Study **Country, Setting:** Multinational, 9 clinical sites **Funding:** NIH; Centocor, Inc.; Schering-Plough Research Institute; Competence Network **Research Objective:** Efficacy and tolerability of INF for the articular and dermatologic manifestations of active PsA **Study Design:** RCT **Overall N:** 104 **Study Duration:** 50 wks (1-16 wks RCT 16-50 open, all treated with INF)	**Inclusion Criteria:** • Age ≥ 18 • Failure of 1 or more DMARD • Active peripheral polyarticular arthritis • MTX ≥ 15 mg/wk w/ folic acid supplementation • LEF, SSZ, HCQ, intramuscular gold, penicillamine, or azathioprine stable for 4 wks • oral corticosteroids (dosage of 10 mg PRE equivalent/d or less) • NSAIDs stable for at least 2 wks **Exclusion Criteria:** • Monoclonal antibody or fusion protein • History of TB: positive tests for RF or latent TB investigational drug within 3 mos	**Interventions:** **D1:** Placebo **D2:** INF (5mg/kg at wks 0,2,6,14, then every 8 wks) **N:** **D1:** 52 **D2:** 52 **Mean age, yrs:** **D1:** 45.2 **D2:** 45.7 **Sex, % female:** **D1:** 42.3 **D2:** 42.3 **Race, % white:** NR	**Mean disease duration, yrs:** **D1:** 11 **D2:** 11.7 **TJC, mean:** **D1:** 20.4 **D2:** 23.7 **SJC, mean:** **D1:** 14.7 **D2:** 14.6 **DMARD use, %:** NR **Corticosteroid use, %:** NR **MTX naive, %:** NR **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** **D1:** 5.4 **D2:** 5.5 **Concomitant MTX, %:** **56**	• ACR50 Placebo 0/52 (0.0%) vs. INF 24/52 (46.2%) • ACR70 Placebo 0/52 (0.0%) vs. INF 15/52 (28.8%) • # of tender joints Placebo -23.6 vs. INF 55.2 • # of swollen joints Placebo -1.8 vs. INF 59.9 • DAS Placebo 2.8 vs. INF 45.5 $P < 0.001$ • HAQ Placebo -1.6 vs. INF 49.8 $P < 0.001$ • PsARC Placebo -12% vs. INF +86% $P < 0.001$ • ACR20 wk 16 Placebo 5/52 (9.6%) vs. INF 34/52 (65.4%) $P < 0.001$ • At 50 wks • Total modified vdH-S score, 85% and 84% in Placebo/INF and INF/INF groups had no worsening. • Change in erosion scores INF/INF 0.921, placebo/INF 0.536 ($P = 0.780$) • Change in JSN INF/INF -0.51, placebo/INF -0.47 ($P = 0.211$) • 16 wks-PsARC INF 75% vs. Placebo 21% ($P < 0.001$) • PASI75 INF 68% vs, placebo 0% ($P < 0.001$)	**Overall:** **D1:** 65 **D2:** 73 **D3:** 84 **Headache:** **D1:** 3 **D2:** 4 **URTI:** **D1:** 5 **D2:** 1	**Overall Attrition Rate (%):** 5 **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Antoni, 2005; Kavanaugh et al., 2006 IMPACT2 study **Country, Setting:** Multinational 36 sites in clinics **Funding:** Centocor Inc and Schering-Plough **Research Objective:** Efficacy, health related quality of life and physical function in pts with PsA **Study Design:** RCT **Overall N:** 200 **Study Duration:** 14 to 24 wks (pts with inadequate response entered early escape at wk 16)	**Inclusion Criteria:** • Diagnosed with PsA • Diagnosed at least 6 mos before first infusion of study drug • Inadequate response to current or previous DMARDs or NSAIDs • Pts had to have active plaque psoriasis with at least 1 qualifying target lesion at least 2 cm in diameter • Negative test for RF in their serum • Stable doses of MTX, oral corticosteroids, NSAIDs **Exclusion Criteria:** • TNF α inhibitors; active or latent TB • Chronic or clinically significant infection, malignancy, or CHF	**Interventions:** **D1:** Placebo **D2:** INF (5 mg/kg at wks 0, 2, 6, 14, 22) **N:** **D1:** 100 **D2:** 100 **Mean age, yrs:** **D1:** 46.5 **D2:** 47.1 **Sex, % female:** **D1:** 49 **D2:** 29 **Race, % white:** NR	**Mean disease duration, yrs:** **D1:** 7.5 **D2:** 8.4 **TJC, mean:** **D1:** 25.1 **D2:** 24.6 **SJC, mean:** **D1:** 14.4 **D2:** 13.9 **DMARD use, %:** NR **Corticosteroid use, %:** **D1:** 10 **D2:** 15 **MTX naive, %:** NR **Txt resistant, %:Overall 100** **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX, %:** **D1:** 45 **D2:** 47 **PASI:** **D1:** 10.2 **D2:** 11.4	• Placebo vs. INF (%): • ACR 50 at wk 14 3 vs. 36 (P < 0.001) and wk 24 4 vs. 41 (P < 0.001) • ACR70 at wk 14 1 vs. 15 (P < 0.001) and wk 24 2 vs. 27 (P < 0.001) • PsARC at wk 14 27 vs. 77 (P < 0.001) and wk 24 32 vs. 70 (P < 0.001) • •HAQ improvement at wk 14 - 18.4 vs. 48.6 (P < 0.001) and wk 24 -19.4 vs. 46 (P < 0.001) • •SF-36 (change from baseline) • Physical wk 14 1.1 vs. 9.1 (P < 0.001) and wk 24 1.3 vs. 7.7 (P < 0.001) • Mental wk 14-1.2 vs. 3.8 (P = 0.001) and wk 24 0.4 vs. 3.9 (P = 0.047) • ACR20 at Wk 14 11 vs. 58 (P < 0.001) and Wk 24 16 vs. 54 (P < 0.001) • PASI 50: wk 14: 9 vs. 82 (P <0.01), wk 24: 8 vs. 75 (P <75 (P<0.01); PASI 75 wk 14: 2 vs. 64 (P < 0.01), wk 24: 1 vs. 50 (P < 0.01); • improvement wk 14: 0 vs. 41 (P < 0.01), wk 24: 0 vs. 39 (P < 0.01) • median productivity at 14 wks 9.2% vs. 67.5% (P < 0.0001) • missed workdays at 14 wks 13% vs. 3.7% (P = 0.138)	**Overall:** **D1:** 67 **D2:** 67 **SAEs:** **D1:** 6 **D2:** 9 **Infusion or injection reaction:** **D1:** 6 **D2:** 7 **Dizziness:** **D1:** 5 **D2:** 4 **Headache:** **D1:** 5 **D2:** 6 **URTI:** **D1:** 14 **D2:** 10	**Overall:** **Attrition Rate (%):** Wk 14: NR Wk 24: 7.5 **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Genovese et al., 2007[2] **Country and setting** 16 sites in Canada and United States **Source of funding** Abott Laboratories **Research objective** Determine safety and efficacy of ADA in pts with inadequate response to DMARDs **Study design** Controlled Trials **Overall N** 102 **Duration of study** 12 weeks double-blind **Quality rating** Fair	**Inclusion Criteria** • Treatment resistant, previous inadequate response to DMARD therapy • ≥ 18 yrs old • General good health determined by medical history, physical exam, laboratory profile, chest radiograph, and 12-lead electrocardio-gram • Pts required to have ≥ 3 swollen joints and ≥ 3 tender or painful joints • Active cutaneous lesion of chronic plague psoriasis or a documented history of chronic plaque psoriasis • Either currently receiving concomitant DMARD therapy or had a history	**Interventions, Dose** D1: Placebo D2: ADA: 40 mg every other week **Number in group** D1: 49 D2: 51 **Mean age, yrs (SD)** D1: 47.7 (11.3) D2: 50.4 (11.0) **Sex, % female** D1: 49.0 D2: 43.1 **Race, % white** D1: 93.9 D2: 98.0 **Race, % black** NR **Ethnicity, Latino** NR	**Mean disease duration, years (SD)** D1: 7.2 yrs (7.0) D2: 7.5 yrs (7.0) **Patients with early RA, three years or less, %:** NR **Treatment resistant, %:** 100% inadequate response to previous DMARD treatment **Tender Joint Count, mean (SD)** D1: 29.3 (18.1) D2: 25.3 (18.3) **Swollen Joint Count, mean (SD)** D1: 18.4 (12.1) D2: 18.2 (10.9) **Corticosteroid use, %** At baseline" D1: 18.4 D2: 7.8 Previous Use D1: 30.6 D2: 9.6 **DMARD use, %:** At baseline D1: 67.3 D2: 64.7 Previous Use: 100% **MTX naïve, %:** D1: 20.4 D2: 19.6	**ACR mean difference/ absolute difference (95% CI):** ACR 20: D1: 16 D2: 39 (5%-4%) *P* = 0.012 ACR 50: D1: 2 D2: 25 *P* = 0.001 ACR 70: D1: 0 D2: 14 *P* = 0.013 **HAQ, mean difference/ absolute difference (CI/SD/*P* Value):** D1: -0.1 ± 0.3 D2: -0.3 ± 0.5 *P* = 0.010 **DAS, mean difference/absolute difference: NR** **SF-36, mean difference/absolute difference (CI/SD/P Value):** PCS D1: 2.8 ± 7.1 (n = 45); D2: 5.7 ± 8.5 (n = 49); *P* = 0.082; MCS D1: -0.6 ± 7.8 (n = 45) D2: 1.1 ± 7.4 (n = 49)	**Attrition/withdrawal, n:** Overall D1: 5 D2: 1 Withdrawals due to adverse events , n: D1: 1 D2: 1 Withdrawals due to lack of efficacy, n: D1: 1 D2: 0 Adherent/compliant , n: D1: 46 D2: 50 **Overall adverse events reported, n:** D1: 39 D2: 27 *P* ≤ 0.01 **Serious adverse events:** Death, n: D1: 0 D2: 0 Congestive heart failure ,n: D1: 0 D2: 0 **Malignancies:** Lymphoma or leukemia, n: D1: 0 D2: 0 Skin cancer (basal cell or squamous cell) , n: D1: 0

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
	of DMARD therapy with inadequate response • Evidence of previous TB infection were required to have documented history of treatment for latent TB or TB treatment initiated before first dose of study drug. **Exclusion Criteria** • History of previous anti-TNF therapy • Intravenous infusions or intraarticular injections of corticosteroids within 4 weeks of baseline • Topical psoriasis therapies within 2 weeks of baseline • Ultraviolent A (UVA) phototherapy within 2 weeks of baseline visit • Oral retinoids		**Baseline DAS score** NR **Required treatment for latent TB** D1: 100% D2: 100%	*P* = 0.242 **Radiographic measures, mean difference/absolute difference: NR** **Quality of life scales, mean difference/absolute difference (CI/SD/*P* Value):** Facit-F score (0-52) D1:: 2.3 ± 6.7 (n = 46) D2: 2.6 ± 7.1 *P* = 0.783 **Others, (please name); mean difference/absolute difference (SD):** Swollen Joint Count D1:-1.9 ± 11.5 D2:-5.7 ± 13.7 *P* = 0.140 Tender Joint Count D1:-6.2 ± 10.3 D2:-9.7 ± 17.3 *P* = 0.231	D2: 0 Other cancer, n: D1: 0 D2: 0 **Respiratory events:** Tuberculosis, n: D1: 0 D2: 0 Upper respiratory infection , n: D1: 4 D2: 7 Other infections (any), n: D1: 16 D2: 9 **GI:** Diarrhea: D1: 3 D2: 1 **Other:** Infusion/injection site reactions, n: D1: 6 D2: 6 Demyelenation or multiple sclerosis , n: D1: 0 D2: 0 HeD2che, n: D1: 3 D2: 0 Back pain, n: D1: 3 D2: 1

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
	within 4 weeks • Alefacept or siplizumab within 12 weeks • Any biologic or investigational therapy within 6 weeks • Current use of or likely to need antiretroviral therapy • Persistent or severe infections or history of active TB, or active nonpsoriatic skin disease which may interfere with assessment of target lesions • Significant history of cardiac, renal, neurologic, psychiatric, endocrinologic, metabolic or hepatic disease • Neurologic symptoms suggestive of CNS demyelinating disease • History of malignancy other than				Psoriasis aggravated D1: 8 D2: 2 Aggravated Psoriatic Arthropathy At week 12 D1: 7 D2: 1 $P \leq 0.05$ Diverticulitis, n: D1: 0 D2: 1

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
	carcinoma in situ of cervix or adequately treated nonmetastatic squamous or basal cell skin carcinoma • Oral corticosteroids > equivalent of PRED 10mg/d, use of cyclosporine, tacrolimus • Long term (> 3 mths) treatment with MTX or other DMARDs • Unstable dose of MTX or other DMARDs during 4 wks preceding baseline visit • MTX dose > 30 mg/wk				

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Characteristics of Included Stidies	Results	Adverse Events	Assessments, Study Appraisals, and Qulaity Rating
Author, year, country, funding: Jones, Crotty and Brooks, 2000 Multinational Cochrane **Study Design:** Systematic review. **Aims of the Review:** How do various treatments compare in terms of both efficacy and toxicity in the treatment of PsA?; To assess the effects of SSZ, auranofin, etretinate, fumaric acid, IMI gold, azathioprine, efamol marine and MTX, in PsA. **Number of Patients:** Twenty randomized trials were identified of which thirteen were included in the quantitative analysis with data from 1022 subjects.	**Studies included:** Published data only Carette et al. 1989; Clegg et al. 1996; Gupta et al. 1995; Hopkins et al. 1985; Levy et al. 1972; Peeters et al. 1992 Published/unpublished data Combe et al. 1996; Dougados et al. 1995; Farr et al. 1990; Fraser et al. 1993; McKendry et al. 1993; Palit et al. 1990; Willkens et al. 1984 **Characteristics of included studies:** At least two treatment groups, and the allocation to these must have been by formal randomization; in for quality assessment.; **Characteristics of included populations:** patients aged 20 years and over, with a clinical diagnosis of PsA. **Characteristics of interventions:** All conservative therapeutic agents were eligible for inclusion in this review. Comparative trials without a placebo arm were not included.	Parenteral high dose MTX (data not available), SSZ, azathioprine and etretinate were the agents that achieved statistical significance in a global index of disease activity; SSZ (improvement in disease index 0.38 units (95% CI 0.21-0.54) and azathioprine (improvement in disease index 2.20 units (95% CI 1.06-3.33) and etretinate (improvement in disease index 0.84 units (95% CI 0.08-1.59) were statistically better than placebo.; In all trials the placebo group improved over baseline (pooled improvement 0.39 DI units, 95% CI 0.26-0.54).; One outstanding difference is the placebo group with PsA improves three times as much as the placebo RA group ($p<0.05$) Therefore, the results of uncontrolled trials are likely to be misleading in PsA	There was insufficient data to examine toxicity.	**Publication Bias Assessed**: Yes **Heterogeneity Assessed:** Yes **Standard Method of Study Appraisals:** Yes **Comprehensive Search Strategy:** Yes **Quality Rating:** Good

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Kaltwasser et al., 2004 and Nash et al., 2006 **Country, Setting:** Multinational, multicenter (31) **Funding:** Aventis **Research Objective:** Efficacy and safety of LEF versus placebo in pts with PsA and psoriasis **Study Design:** RCT **Overall: N:** 190 (ITT = 186) **Study Duration:** 24 wks	**Inclusion Criteria:** • Age 18 to 70 • Diagnosed with PsA • NSAIDs or Css (prednisone dose of 10 mg/day or steroid equivalent administered orally) • Discontinue DMARDs, biologics and systemic antipsoriatic txt 28 days **Exclusion Criteria:** • Pregnant or lactating; leflunomide • Impaired renal or hepatic system • Nonpsoriatic inflammatory joint disease or arthritis onset < 16 yrs • RH factor +, rheumatoid nodules, serious infections, malignancy, or CVD, HIV, hepatitis B or C antigen positivity, guttate, pustular, or erythrodermic forms of psoriasis, body weight <45 kg • Impaired bone marrow function; history of drug or alcohol abuse	**Interventions:** **D1:** Placebo **D2:** LEF **N:** **D1:** 91 **D2:** 95 **Mean age, yrs:** Drug 1: 46.9 Drug 2: 48.6 Overall **Sex, % female:** **D1:** 37.4 **D2:** 42.1 **Race, % white:** **D1:** 95.6 **D2:** 97.9	**Mean disease duration, yrs:** **D1:** 10 **D2:** 11 **TJC, mean:** NR **SJC, mean:** NR **DMARD use, %:** **D1:** 49.5 **D2:** 61.1 **Corticosteroid use, %:** **D1:** 9.9 **D2:** 15.8 **DMARD naive, %:** **D1:** e 50.5 **D2:** 38.9 **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX, %:** 0	• 56 of 95 leflunomide-treated pts (58.9%; 95% CI, 48.4-68.9) and 27 of 91 placebo-treated pts (29.7% (95% CI, 20.6-40.2)) were classified as responders by PsARC ($P < 0.0001$) Change in HAQ total score • Placebo (N:90) -0.05 ± 0.46 ($P = 0.0267$) • Leflunomide (N:94) -0.19 ± 0.51 Change in PASI score • Placebo (N:90) -0.6 ± 6.1 $P = 0.0030$ • Leflunomide (N:92) -2.1 ± 5.9 Change in DLQI total score • Placebo (N:89) -0.2 ± 5.1 $P = 0.0173$ • Leflunomide (N:90) -1.9 ± 5.1	**Overall:** **D1:** 76.1 **D2:** 85.4 **SAEs:** **D1:** 5.4 **D2:** 13.5 **Serious Infections:** **D1:** 0 **D2:** 0 **Diarrhea:** **D1:** 13.0 **D2:** 24.0 **Headache:** **D1:** 7.6 **D2:** 11.5 **Nausea:** **D1:** 8.7 **D2:** 9.4	**Overall Attrition Rate (%):** 47.9% **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Kavanaugh et al., 2006;[6] van der Heijde et al., 2007;[7] Antoni et al., 2005[8] IMPACT 2 **Country and setting** United States; multicenter **Source of funding** Centocor, Inc. **Research objective** Examine effect of IFX on employment status, time lost from work **Study design** Controlled Trials **Overall N** 200 **Duration of study** Up to 54 weeks, results at 24 weeks at time of crossover of placebo to IFX **Quality rating** Fair	**Inclusion Criteria** • Treatment resistant (failed with DMARD or NSAID) • At least 1 qualifying target lesion greater than or equal to 2cm in diameter **Exclusion Criteria** NR	**Interventions, Dose** D1: • IFX: patients who entered early escape received IFX 5 mg/kg at weeks 16, 18 and 22, but outcomes were assessed at week 14, prior to early escape • Placebo: 5 mg/kg at weeks 0, 2, 6, 14, and 22 D2: • IFX: 5 mg/kg at weeks 0, 2, 6, and maintenance dose at weeks 14 and 22. • Placebo: early escape received 5 mg/kg of placebo at weeks 16 and 18 and IFX at week 22 **Number in group** D1: 100 D2: 100 **Mean age, yrs** D1: 46.5 (11.2) D2: 47.1 (12.8) **Sex, % female** D1: 49.0 D2: 29.0 **Race, % white** NR **Race, % black**	**Mean disease duration, years (SD)** D1: 7.5 (7.8) D2: 8.4(7.2) Median D1: 4.9 D2: 5.9 **Patients with early RA, three years or less, %:** NR **Treatment resistant, %:** D1: 100 D2: 100 **Tender Joint Count, mean (SD)** D1: 25.1 D2: 24.6 Median D1: 24.0 D2: 20.5 **Swollen Joint Count, mean (SD)** D1: 14.4 D2: 13.9 Median D1: 12.0 D2: 11.5 **Corticosteroid use, %** D1: 10.0 D2: 15.0 **DMARD use, %:** MTX D1: 45.0 D2: 47.0	**ACR mean difference/ absolute difference (CI/SD/*P* Value):** NR **HAQ, mean difference/ absolute difference (CI/SD/*P* Value):** NR **DAS, mean difference/absolute difference (CI/SD/*P* Value):** NR **SF-36, mean difference/absolute difference (CI/SD/*P* Value):** NR **Radiographic measures, mean difference/absolute difference (CI/SD/*P* Value):** Sharp/van der Heijde Total Score, change from baseline D1: 0.82 D2: -0.70 $P < 0.001$ Experienced additional Radiographic progression from baseline as measured by Total Score, % of patients At week 24: D1: 12 D2: 3 $P = 0.017$ **Quality of life scales, mean difference/absolute**	**Attrition/withdrawal Rate (%):** At week 14: NR At week 24: 7.5 **Adherent/compliant** NR **Adverse events:** NR

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
		NR **Ethnicity, Latino** NR	**MTX naïve, %:** NR **Baseline DAS score** NR **Required treatment for latent TB** NR **Other population characteristics, %, (CI/SD/P value):** NSAID (%) D1: 73.0 D2: 71.0 Baseline PASI (SD) D1: 10.2 (9.0) D2: 11.4 **Duration of** morning stiffness, 0-1440 min (SD): D1: 183.4 (303.8) D2: 216.0; (376.0)	**difference (CI/SD/*P* Value):** Productivity VAS change from baseline, increase At week 14 D1: 0.3 D2: 2.6 *P* < 0.001 Median % change D1: 9.2 D2: 7.5 *P* < 0.0001 **Emotional impact on work or daily activities, %:** To Week 14: D1: 88.0 to 84.4 D2: 85.0 to 52.5 *P* < 0.001 **Emotional effect on work or daily activities, %:** To Week 14: D1: 47.0 to 55.2 D2: 57.0 to 41.4 *P* < 0.01 **Employment increase among those not employed, n (%):** D1: 3/26 (11.5) D2: 0/32 (0) *P* = 0.084 **Became employable** D1: 6/20 (30 D2: 3/25 (12) *P* = 0.157	

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Kavanaugh et al., 2009, GO-REVEAL[5] **Country and setting** 58 investigational sites, multinational **Source of funding** Centocor Research and Development, Inc. and Schering-Plough Corporation **Research objective** Assess efficacy and safety of GOL in patients with active PsA **Study design** Controlled Trials **Overall N** 405 **Duration of study** 24 wks **Quality rating** Good	**Inclusion Criteria** • Treatment resistant active PsA despite therapy with DMARDs or NSAIDs • active PsA: ≥ 3 swollen and 3 tender joints, negative rheumatoid factor, at least 1 subset of PsA, presence of plaque psoriasis with lesion ≥ 2 cm in diameter; • MTX, NSAIDs, corticosteroids allowed in stable doses • Latent TB allowed if treated prior or concurrent to study **Exclusion Criteria** • Previous use of anti-TNF agents, RIT, natalizumab, or cytotoxic agents	**Interventions, Dose** D1: Placebo • At week 16, pts with < 10% improvement from baseline in both swollen and tender joint counts entered early escape = dose escalation from placebo to 50 mg GOL every four weeks D2: • GOL: 50 mg every 4 wks • At week 16, pts with < 10% improvement from baseline in both swollen and tender joint counts entered early escape = dose escalation from 50 mg GOL to 100 mg GOL every four wks. D3: GOL: 100 mg every 4 wks D4: Randomized to placebo, crossed over to GOL 50 mg D5: Randomized to GOL 50, crossed over to 100 mg **Number in group** D1: 113 D2: 146 D3: 146 **Mean age, years (SD)** D1: 47.0 (10.6)	**Mean disease duration, years (SD)** D1: 7.6 (7.9) D2: 7.2 (6.8) D3: 7.7 (7.8) **Patients with early RA, three years or less, %:** D1: 33 D2: 34 D3: 27 **Treatment resistant, %:** D1: 100 D2: 100 D3: 100 **Tender Joint Count, mean (SD)** D1: 21.9 (14.7) D2: 24.0 (17.1) D3: 22.5 (15.7) **Swollen Joint Count, mean (SD)** D1: 13.4 (9.8) D2: 14.1 (11.4) D3: 12.0 (8.4) **Corticosteroid use, %** D1: 17 D2: 13 D3: 18 **DMARD use, %:** MTX D1: 48 D2: 49 D3: 47 **MTX naïve, %:**	**ACR mean difference/ absolute difference (CI/SD/P Value):** At week 14: ACR 20: D1: 9 D2: 51 D3: 45 *P* < 0.001 (D1 vs. D2 and D3) At week 24: ACR 20: D1: 12 D2: 52 D3: 61 *P* < 0.001 (D1 vs. D2 and D3) ACR 50 and ACR70 at weeks 14 and 24: Shown in figure only **HAQ, mean difference/ absolute difference (CI/SD/P Value):** D1: -0.01 (0.49) D2: 0.33 (0.55) D3: 0.39 (0.50) *P* < 0.001 (D1 vs. D2 and D3) **DAS, mean difference/absolute difference (SD):** At week 14: D1: -0.18 (0.78) D2: -1.38 (1.16) D3: -1.29 (1.16) *P* < 0.001 (D1 vs. D2 and	**Overall attrition/withdrawal, n:** D1: 12 D2: 9 D3: 4 **Withdrawals due to adverse event, n:** D1: 5 D2: 2 D3: 4 **Withdrawals due to lack of efficacy, n:** D1: 2 D2: 1 D3: 0 **Adherent/compliant, n**: NR **Overall adverse events reported , n:** Through Week 24 D1: 67 D2: 99 D3: 95 **Serious adverse events:** SAEs: D1: 7 D2: 3 D3: 4 Prostate cancer, n: D1: NR D2: NR D3: 1 **Respiratory events:** Tuberculosis, n:

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
		D2: 45.7 (10.7) D3: 48.2 (10.9) **Sex, % female** D1: 39 D2: 39 D3: 41 **Race, % white** D1: 97 D2: 97 D3: 97 **Race, % black** NR **Ethnicity, Latino** NR	D1: 33 D2: 34 D3: 27 **Baseline DAS28-CRP score, mean (SD)** D1: 4.3 (1.0) D2: 4.4 (1.1) D3: 4.3 (1.0) **Required treatment for latent TB** D1: 11 D2 & D3: 33	D3) At week 24: D1: -0.12 (0.97) D2: -1.43 (1.34) D3: -1.56 (1.10) *P* < 0.001 (D1 vs. D2 and D3) DAS28-CRP No. EULAR response: At week 14: D1: 27 D2: 96 (*P* < 0.001) D3: 98 (*P* < 0.001) At week 24: D1: 27 D2: 94 (*P* < 0.001) D3: 114 (*P* < 0.001) **SF-36, mean difference/absolute difference (CI/SD/P Value):** D1: 0.63 (7.68) D2: 6.53 (8.88) D3: 7.85 (9.55) *P* < 0.001 (D1 vs. D2 and D3) **Radiographic measures, mean difference/absolute difference:** NR **Quality of life scales, mean difference/absolute difference:** NR **Morning stiffness, mean change (SD):** At week 14: D1: 23.4 (299.9)	Overall: 0 Pneumonia, n: D1: 2 D2: NR D3: NR Upper respiratory infection (n): D1: 7 D2: 17 D3: 13 **Other infections, n:** D1: Cellulits: 1, Urosepsis: 1 D2: Abscess: 1 D3: Sepsis/Cholecystitis: 1 Infusion/injection site reactions , n: D1: 3 D2: 4 D3: 6 **GI:** Nausea or vomiting, n: D1: 5 D2: 4 D3: 6 Headache, n: D1: 8 D2: 7 D3: 8 Dizziness : NR Nasopharyngitis, n: D1: 5 D2: 10 D3: 19

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
				D2: -72.4 (201.3) (*P* < 0.001) D3: -86.3 (238.3), (*P* < 0.001) At week 24: D1: -20.4 (257.7) D2: -67.2(231.1) (*P* < 0.001) D3: -90.1 (234.5), (*P* < 0.001) PASI90, n: At week 14: D1: 0 D2: 22 (*P* < 0.001) D3: 26, (*P* < 0.001) At week 24: D1: 0 D2: 33 (*P* < 0.001) D3: 34, (*P* < 0.001)	Back pain, n: D1: 5 D2: 6 D3: 7 Diarrhea, n: D1: 4 D2: 5 D3: 7 Cough, n: D1: 5 D2: 7 D3: 4 Elevated ALT levels, n: D1: 4 D2: 4 D3: 5 Injection-site erythema D1: 2 D2: 4 D3: 6 Markedly abnormal ALT levels: D1: 4 D2: 43 D3: 0 Markedly abnormal AST levels: D1: 3 D2: 2 D3: 0 Markedly abnormal total bilirubin levels: D1: 2 D2: 4 D3: 2

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
					Antibodies to GOL: D1: NR D2: 5/114 D3: 7/143

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Kristensen et al., 2008[9] **Country and setting** Sweden **Source of funding** NR **Research objective** Present efficacy and tolerability data and study impact of concomitant MTX, patterns of joint distribution, and other predictors for drug survival with TNF blocking agents **Study design** Observational **Overall N** 261 **Duration of study** 12 months **Quality rating** Fair	**Inclusion Criteria** • Diagnosis of PsA • Pts selected for anti-TNF therapy based on high disease activity and/or unacceptable steroid use • Only pts receiving first treatment course of biological therapy **Exclusion Criteria** NR	**Interventions, Dose** D1: concomitant MTX and anti-TNF • MTX: median dose = 15.0 mg/week, interquartile range (IQR) = 10.0-20.0 • ETN: 25 mg twice a wk • IFX: 3mg/kg wks 0,2, 6, and every eighth week, could be increased in steps of 100 mg to a maximum dose of 500 mg at 4-8 wk intervals,avg dose after 6 mos = 5 mg/kg every eighth wk ADA: 40 mg every other wkD2: • ETN: 25 mg twice a wk • IFX: 3 mg/kg wks 0, 2, 6, and every eighth week, could be increased in steps of 100 mg to a maximum dose of 500 mg at 4-8 wk intervals, avg dose after 6 mos = 5 mg/kg every eigth wk • ADA: 40 mg every other wk **Number in group** D1: 161	**Median disease duration, years (IQR)** D1: 7.9 (3.7-15.0) D2: 9.4 (4.2-17.8) *P* = 0.29 **Patients with early RA, three years or less, %:** NR **Treatment resistant, %:** NR **Tender Joint Count, mean (SD)** NR **Swollen Joint Count, mean (SD)** NR **Corticosteroid use, %** NR **DMARD use, %:** # of Previous DMARDs (IQR) D1: 2 (1.0-2.0) D2: 2 1.0-2.0) *P* = 0.20 **MTX naïve, %:** NR **Baseline DAS28 score, median (IQR)** D1: 4.93 calculated for subgroup, n = 125 (3.87-5.71) D2: 4.82 calculated for subgroup, n = 76 (3.83-5.46) *P* = 0.57	**ACR mean difference/ absolute difference:** NR **HAQ, mean difference/ absolute difference:** NR **DAS, mean difference/absolute difference:** NR **SF-36, mean difference/absolute difference:** NR **Radiographic measures, mean difference/absolute difference:** NR **Quality of life scales, mean difference/absolute difference:** NR **EULAR overall response rates, (%):** At month 3 D1: 104 (78) D2: 67 (75) At month 6 D1: 82 (76) D2: 54 (81) At month 12 D1: 74 (69) D2: 27 (67)	**Attrition/withdrawal** Withdrawals due to adverse events , HR (95% CI): D1: 0.24 (0.11-0.52) Sub-analyses ETN vs. IFX • Termination due to adverse events (HR 0.30 95% CI 0.11-0.80, *P* = 0.02) • Withdrawal due to failure (HR 0.55, 95% CI 0.25-1.20) Withdrawals due to lack of efficacy , HR (95% CI): D1: 1.39 (0.61-3.18) • In corresponding abstraction - no high attrition or differential attrition, although rates are unknown **Overall adverse events reported, n:** D1: 17 D2: 12 **Serious adverse events:** Death (n): D1: 1 D2: NR Cardiovascular events, n: D1: 3 D2: 2 Overall: Includes transient ischemic attack, two acute coronary syndromes, and two tachyarrhythmias. **Septicaemia with E-coli bacteria:** D1: 0

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
		D2: 100 Overall: 261 **Mean age, years (SD)** D1: 48.2 D2: 46.0 Overall, IQR range: D1: 38.6 - 53.9 IQR D2: 36.4 - 58.5 IQR; *P* = 0.99 **Sex, % female** D1: 47.8 D2: 55 *P* = 0.07 **Race, % white** NR **Race, % black** NR **Ethnicity, Latino** NR	**Required treatment for latent TB** NR **Regular NSAID use % (n):** D1: 60.9 (98) D2: 48.0 (48 *P* = 0.04 **HAQ, median (IQR)** D1:1.0 (0.63-1.38) D2: 1.0 (0.50-1.50) *P* = 0.67	EULAR good response rates, %: At month 3 D1: 104 (51) D2: 67 (55) At month 6 D1: 82 (60) D2: 54 (59) At month 12 D1: 74 (54) D2: 27 (52) Lundex EULAR Overall, %: At month 3 D1: 74 D2: 68 At month 6 D1: 68 D2: 67 At month 12 D1: 55 D2: 45 Lundex EULAR Good, %: At month 3 D1: 48 D2: 50 At month 6 D1: 53 D2: 48 At month 12 D1: 43 D2: 35	D2: 1 **Anaphylactic infusion reactions (occurred with IFX):** D1: 0 D2: 2 **Malignancies:** Lymphoma or leukemia (n): D1: 1 D2: 1 Overall: Fatal non-Hodgkin's lymphoma (diffuse large B-cell lymphoma); Chronic lymphatic leukemia (CLL), with probable subclincial debut prior to anti TNF treatment **Other infections:** D1: 5 D2: 2 Overall: Designated as 'Infections' - mainly respiratory tract infections **Other:** Fractures, n: D1: 2 D2: 1 Overall: Three peripheral fractures and one cervical spinaql stenosis requiring surgery Other Adverse Events, n: D1: 3 D2: 3 Overall: Includes: severe vertigo, irritable bowl disease, benign stenosis of the

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
					esophagus, concrement in the urinary tract, non-infectious pleuritis, severe dysplaisa of cervix uteri.

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2000 **Country, Setting:** US, single center in Seattle **Funding:** Immunex Corp. **Research Objective:** To study the efficacy and safety of etanercept in pts with psoriatic arthritis and psoriasis **Study Design:** RCT **Overall N:** 60 **Study Duration:** 12 wks	**Inclusion Criteria:** • Age 18 to 70 • Diagnosed with PsA according to: > 3 swollen, tender, or painful joints • Inadequate response to NSAIDs • Hepatic transasminase concentrations no greater than 2x upper limit of normal • Hemoglobin 85 g/L or higher • Platelet count 125,000 per mL or more and serum creatinine 152-4 mmol/L or below • MTX < 25 mg/wk and stable for 4 wks • Corticosteriods if the dose < 10 mg/d of PRE, stable for at least 2 wks and maintained at a constant dose throughout study **Exclusion Criteria:** • Evidence of skin conditions other than psoriasis	**Interventions:** **D1:** Placebo **D2:** ETA (25mg 2x wkly) **N:** **D1:** 30 **D2:** 30 **Mean age, yrs:** **D1:** 43.5 **D2:** 46 **Sex, % female:** **D1:** 40 **D2:** 47 **Race, % white:** **D1:** 83 **D2:** 90	**Mean disease duration, yrs:** **D1:** 9.5 **D2:** 9 **TJC, mean:** NR **SJC, mean:** NR **DMARD use, %:** NR **Corticosteroid use, %:** **D1:** 40 **D2:** 20 **MTX naive, %:** NR **Txt resistant, %:** Overall 100 **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX:** **D1:** 47 **D2:** 47	• PsARC ETA 26 (87%) vs. Placebo 7 (23%) *P* < 0.0001 95% CI, 44-83; ACR50 ETA 15 (50%) vs. Placebo 1 (3%) *P* = 0.0001 95% CI, 28-66; • ACR70 ETA 4 (13%) vs. Placebo 0 (0%) *P* = 0.0403 95% CI, 1-26; • HAQ ETA 0.1 (0,1) vs. Placebo 1.3 (0.9,1.6) *P* < 0.001 • •ACR20 was achieved by 73% ETA treated pts compared with 13% placebo treated pts (*P* < 0.0001) • Median % improvements in tender and swollen joint counts at 12 wks ETA 75% and 72% respectively vs. placebo 5% worsening and 19% improvement; disability according to HAQ significantly more improved in ETA than placebo (83% vs. 3%, *P* < 0.0001) • 26% of ETA vs. 0 of placebo pts achieved 75% improvement in PASI at 12 wks (*P* = 0.0154); similar differences between ETA and placebo also seen at 25% and 50% improvements in PASI scores	**SAEs:** **D1:** 0 **D2:** 3.3 **Infusion or injection reaction:** **D1:** 20 **D2:** 3 **Headache:** **D1:** 13 **D2:** 10 **URTI:** **D1:** 57 **D2:** 57	**Overall Attrition Rate (%):** 6.6% **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2004; Mease et al., 2006 (2nd yr outcomes) **Country, Setting:** US, 17 sites **Funding:** Immunex **Research Objective:** Safety, efficacy, and effect on radiographic progression of ETA in pts with PsA **Study Design:** RCT **Overall N:** 205 **Study Duration:** 24 wks (with 48 wk open-label phase)	**Inclusion Criteria:** • Age 18 70 • Diagnosed with PsA ≥ 3 swollen and 3 tender joimts • Inadequate response to NSAID • At least one of PsA subtypes: distal interphalangeal joint involvement, polyarticular arthritis, arthritis mutilans, asymmetric peripheral arthritis, or ankylosing spondylitis-like arthritis • Stable plaque psoriasis with a qualifying lesion • MTX therapy (stable 2 mo ≤ 25 mg/wk) • Css (stable 4 wks ≤ 10 mg/d of prednisone) **Exclusion Criteria:** • Oral retinoids, topical vitamin A or D analog preparations, and anthralin	**Interventions:** **D1:** placebo **D2:** ETA (25 mg 2x wkly) **N:** **D1:** 104 **D2:** 101 **Mean age, yrs:** **D1:** 47.3 **D2:** 47.6 **Sex, % female:** **D1:** 55 **D2:** 43 **Race, % white:** **D1:** 91 **D2:** 90	**Mean disease duration, yrs:** **D1:** 9.2 **D2:** 9 **TJC, mean:** NR **SJC, mean:** NR **DMARD use, %:** NR **Corticosteroid use, %:** **D1:** 15 **D2:** 19 **MTX naive, %:** NR **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX use, %:** **D1:** 41 **D2:** 42 **Sharp:** **D1:** 18.3 **D2:** 25.89	• At 12 wks, 59% of ETA pts met ACR20 criteria compared with 15% placebo pts ($P < 0.0001$) • 23% of ETA pts eligible for psoriasis evaluation achieved at least 75% improvement in psoriasis area and severity index, compared with 3% of placebo pts ($P = 0.001$) • 12 mos; the mean annualized rate of change over one yr of txt in modified Sharp score was –0.03 unit, compared with 1.00 unit in the placebo ($P = 0.0001$) • HAQ- improvement from baseline in ETA group 54% vs. 6% of placebo group ($P < 0.0001$) • 72% & 70% of ETA achieved PsARC at 12 and 24 wks, respectively, compared with 31% and 23% of placebo pts	**SAEs:** **D1:** 3.9 **D2:** 4 **Infusion or injection reaction:** **D1:** 9 **D2:** 36 **Headache:** **D1:** 5 **D2:** 8 **URTI:** **D1:** 23 **D2:** 21 **UTI:** **D1:** 6 **D2:** 6	**Overall Attrition Rate (%):** 19.5 **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2005 ADEPT Study **Country, Setting:** Multinational, multi-clinic (50) **Funding:** Abbott Laboratories **Research Objective:** Safety and efficacy of ADA compared with placebo in txt of active psoriatic arthritis **Study Design:** RCT **Overall N:** 313 **Study Duration:** 24 wks	**Inclusion Criteria:** • Age ≥ 18 • Moderate to severe PsA • Active psoriatic skin lesions or a documented history of psoriasis • Inadequate response or intolerance to NSAIDs • MTX ≥ 3 mos with stable dose 4 wks **Exclusion Criteria:** • CYP, tacrolimus, DMARDs, or oral retinoids (4 wks) • Topical txts for psoriasis within 2 wks, other than medicated shampoos or low-potency topical steroids • Anti-TNF • History of TB • Central nervous system demyelinating disease • Listeriosis, or severe infection within 30 ds or oral antibiotics within 14 ds	**Interventions:** **D1:** placebo **D2:** ADA (40mg every other wk) **N:** **D1:** 162 **D2:** 151 **Mean age, yrs:** **D1:** 49.2 **D2:** 48.6 **Sex, % female:** **D1:** 45.1 **D2:** 43.7 **Race, % white:** **D1:** 93.8 **D2:** 97.4	**Mean disease duration, yrs:** **D1:** 9.2 **D2:** 9.8 **TJC, mean:** **D1:** 25.8 **D2:** 23.9 **SJC, mean:** **D1:** 14.3 **D2:** 14.3 **Mean number previous DMARDS:** **D1:** 1.5 **D2:** 1.5 **Corticosteroid use, %:** NR **MTX naive, %:** NR **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline PASI (mean):** **D1:** 8.3 **D2:** 7.4 **Concomitant MTX use, %:** **D1:** 50 **D2:** 51 **Baseline HAQ:** **D1:** 1.0 **D2:** 1.0	• PsARC ADA 60% wk. vs.placebo 23% • ACR50 ADA, 39% vs. placebo, 6% (*P* < 0.001) • ACR70 ADA, 23% vs. placebo, 1% (*P* < 0.001) • The PASI75 ADA 59% vs. placebo 1% (*P* < 0.001) (N:69 per group). • HAQ DI change placebo -0.1 ± 0.4 vs. ADA -0.4 ± 0.5 (*P* < 0.001) • ACR20 ADA 57% vs. placebo 15% (between-group difference 42%, 95% CI, 31-52%; *P* < 0.001). • Mmean change in modified total Sharp was -0.2 for ADA versus placebo (*P* < 0.001) • Erosion scores (mean change ADA 0.0 vs. placebo 0.6) and JSN scores (mean change ADA -0.2 vs. placebo 0.4) (*P* < 0.001 for both) • SF-36: SF-36 PCS; change in baseline to wk 12 for placebo vs ADA; 1.4 vs 9.3 (*P* < 0.001) • Change in baseline to wk 24; 1.4 vs 9.3 (*P* < 0.001) • SF-36 MCS • Change in baseline to wk 12 ; 1.2 vs 1.6 (*P* NS) • Change in baseline to wk 12; 0.6 vs 1.8 (*P* NS)	**Infusion or injection reaction:** **D1:** 3.1 **D2:** 6.6 **Headache:** **D1:** 8.6 **D2:** 6.0 **URTI:** **D1:** 14.8 **D2:** 12.6 **UTI:** NR	**Overall Attrition Rate (%):** 7.6 **ITT Analysis:** Yes **Quality Rating:** Fair.

Evidence Table 1. Key Question 1 (continued)

Study Characteristics	Characteristics of Included Stidies	Results	Adverse Events	Assessments, Study Appraisals, and Qulaity Rating
Author, year, country, funding: Woolacott et al., 2006 Multi-national Health Technology Assessment **Study Design:** Systematic review **Aims of the Review:** to evaluate the clinical effectiveness, safety, tolerability and cost-effectiveness of etanercept and infliximab for the treatment of active and progressive psoriatic arthritis (PsA) in patients who have inadequate response to standard treatment, including disease-modifying antirheumatic drug (DMARD) therapy. **Number of Patients:** 265 patients were included in the etanercept trials and 104 in the infliximab trial.	**Studies included:** three trials of the efficacy of the interventions of interest (two for etanercept and one for infliximab), 23 studies of the adverse effects of the interventions and 14 trials of the efficacy of the DMARDs **Characteristics of included studies:** RCTs **Characteristics of included populations:** Adults with PsA **Characteristics of interventions:** INF and ETA	ETA 12 weeks, 65% of ACR 20 { RR 4.19 [95% CI 2.74 to 6.42]}, . ACR50 45% RR 10.84 (95% CI 4.47 to 26.28)] ACR 70 12%[RR 16.28 (95% CI 2.20 to 120.54)], (PsARC) 85%[RR 2.60 (95% CI 1.96 to 3.45)], INF- 16 weeks, ACR 20 65% [RR 6.80 (95% CI 2.89 to 16.01)], . Almost half achieved an ACR 50 [RR 49.00 (95% CI 3.06 to 785.06)] and over one-quarter achieved an ACR 70 [RR 31.00 (95% CI 1.90 to 504.86)] compared with none of the placebo group, . PsARC 75% [RR 3.55 (95% CI 2.05 to 6.13)]. The beneficial treatment effect on psoriasis was also statistically significant with a mean difference in percentage change from baseline in PASI of –5 (95% CI –6.8 to –3.3), as was the percentage improvement from baseline in HAQ score with infliximab compared with placebo [mean difference 51.4 (95% CI 48.08 to 54.72)], indicating a beneficial effect of infliximab on functional status.	Injection site reactions appear to be the most common adverse effects of etanercept. Overall, ETA appeared to be well tolerated in short-and long-term use, although much of the long-term data are not from patients with psoriastic arthritis. As identified in earlier reviews, the main areas of concern relate to uncommon but serious adverse events the significance of which is not readily discernible from the published reports of clinical trials. Overall, infusion reactions, the development of antibodies and infections appear to be the most common adverse effects of infliximab,	**Publication Bias Assessed**: Yes **Heterogeneity Assessed:** Yes **Standard Method of Study Appraisals:** Yes **Comprehensive Search Strategy:** Yes **Quality Rating:** Good

Evidence Table 2. Key Question 1: Systematic reviews and meta-analysis

Study Characteristics	Characteristics of Included Stidies	Results	Adverse Events	Assessments, Study Appraisals, and Qulaity Rating
Author, year, country, funding: Jones, Crotty and Brooks, 2000 Multinational Cochrane **Study Design:** Systematic review. **Aims of the Review:** How do various treatments compare in terms of both efficacy and toxicity in the treatment of PsA?; To assess the effects of SSZ, auranofin, etretinate, fumaric acid, IMI gold, azathioprine, efamol marine and MTX, in PsA. **Number of Patients:** Twenty randomized trials were identified of which thirteen were included in the quantitative analysis with data from 1022 subjects.	**Studies included:** Published data only Carette et al. 1989; Clegg et al. 1996; Gupta et al. 1995; Hopkins et al. 1985; Levy et al. 1972; Peeters et al. 1992 Published/unpublished data Combe et al. 1996; Dougados et al. 1995; Farr et al. 1990; Fraser et al. 1993; McKendry et al. 1993; Palit et al. 1990; Willkens et al. 1984 **Characteristics of included studies:** At least two treatment groups, and the allocation to these must have been by formal randomization; in for quality assessment.; **Characteristics of included populations:** patients aged 20 years and over, with a clinical diagnosis of PsA. **Characteristics of interventions:** All conservative therapeutic agents were eligible for inclusion in this review. Comparative trials without a placebo arm were not included.	Parenteral high dose MTX (data not available), SSZ, azathioprine and etretinate were the agents that achieved statistical significance in a global index of disease activity; SSZ (improvement in disease index 0.38 units (95% CI 0.21-0.54) and azathioprine (improvement in disease index 2.20 units (95% CI 1.06-3.33) and etretinate (improvement in disease index 0.84 units (95% CI 0.08-1.59) were statistically better than placebo.; In all trials the placebo group improved over baseline (pooled improvement 0.39 DI units, 95% CI 0.26-0.54).; One outstanding difference is the placebo group with PsA improves three times as much as the placebo RA group ($p<0.05$) Therefore, the results of uncontrolled trials are likely to be misleading in PsA	There was insufficient data to examine toxicity.	**Publication Bias Assessed**: Yes **Heterogeneity Assessed:** Yes **Standard Method of Study Appraisals:** Yes **Comprehensive Search Strategy:** Yes **Quality Rating:** Good

Evidence Table 2. Key Question 1: Systematic reviews and meta-analysis (continued)

Study Characteristics	Characteristics of Included Stidies	Results	Adverse Events	Assessments, Study Appraisals, and Qulaity Rating
Author, year, country, funding: Woolacott et al., 2006 Multi-national Health Technology Assessment **Study Design:** Systematic review **Aims of the Review:** to evaluate the clinical effectiveness, safety, tolerability and cost-effectiveness of etanercept and infliximab for the treatment of active and progressive psoriatic arthritis (PsA) in patients who have inadequate response to standard treatment, including disease-modifying antirheumatic drug (DMARD) therapy. **Number of Patients:** 265 patients were included in the etanercept trials and 104 in the infliximab trial.	**Studies included:** three trials of the efficacy of the interventions of interest (two for etanercept and one for infliximab), 23 studies of the adverse effects of the interventions and 14 trials of the efficacy of the DMARDs **Characteristics of included studies:** RCTs **Characteristics of included populations:** Adults with PsA **Characteristics of interventions:** INF and ETA	ETA 12 weeks, 65% of ACR 20 { RR 4.19 [95% CI 2.74 to 6.42]}, . ACR50 45% RR 10.84 (95% CI 4.47 to 26.28)] ACR 70 12%[RR 16.28 (95% CI 2.20 to 120.54)], (PsARC) 85%[RR 2.60 (95% CI 1.96 to 3.45)], INF- 16 weeks, ACR 20 65% [RR 6.80 (95% CI 2.89 to 16.01)], . Almost half achieved an ACR 50 [RR 49.00 (95% CI 3.06 to 785.06)] and over one-quarter achieved an ACR 70 [RR 31.00 (95% CI 1.90 to 504.86)] compared with none of the placebo group, . PsARC 75% [RR 3.55 (95% CI 2.05 to 6.13)]. The beneficial treatment effect on psoriasis was also statistically significant with a mean difference in percentage change from baseline in PASI of –5 (95% CI –6.8 to –3.3), as was the percentage improvement from baseline in HAQ score with infliximab compared with placebo [mean difference 51.4 (95% CI 48.08 to 54.72)], indicating a beneficial effect of infliximab on functional status.	Injection site reactions appear to be the most common adverse effects of etanercept. Overall, ETA appeared to be well tolerated in short-and long-term use, although much of the long-term data are not from patients with psoriastic arthritis. As identified in earlier reviews, the main areas of concern relate to uncommon but serious adverse events the significance of which is not readily discernible from the published reports of clinical trials. Overall, infusion reactions, the development of antibodies and infections appear to be the most common adverse effects of infliximab,	**Publication Bias Assessed**: Yes **Heterogeneity Assessed:** Yes **Standard Method of Study Appraisals:** Yes **Comprehensive Search Strategy:** Yes **Quality Rating:** Good

Evidence Table 3. Key Question 2

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Antoni et al., 2005; Kavanaugh et al., 2006 IMPACT Study **Country, Setting:** Multinational, 9 clinical sites **Funding:** NIH; Centocor, Inc.; Schering-Plough Research Institute; Competence Network **Research Objective:** Efficacy and tolerability of INF for the articular and dermatologic manifestations of active PsA **Study Design:** RCT **Overall N:** 104 **Study Duration:** 50 wks (1-16 wks RCT 16-50 open, all treated with INF)	**Inclusion Criteria:** • Age ≥ 18 • Failure of 1 or more DMARD • Active peripheral polyarticular arthritis • MTX ≥ 15 mg/wk w/ folic acid supplementation • LEF, SSZ, HCQ, intramuscular gold, penicillamine, or azathioprine stable for 4 wks • oral corticosteroids (dosage of 10 mg PRE equivalent/d or less) • NSAIDs stable for at least 2 wks **Exclusion Criteria:** • Monoclonal antibody or fusion protein • History of TB: positive tests for RF or latent TB investigational drug within 3 mos	**Interventions:** **D1:** Placebo **D2:** INF (5mg/kg at wks 0,2,6,14, then every 8 wks) **N:** **D1:** 52 **D2:** 52 **Mean age, yrs:** **D1:** 45.2 **D2:** 45.7 **Sex, % female:** **D1:** 42.3 **D2:** 42.3 **Race, % white:** NR	**Mean disease duration, yrs:** **D1:** 11 **D2:** 11.7 **TJC, mean:** **D1:** 20.4 **D2:** 23.7 **SJC, mean:** **D1:** 14.7 **D2:** 14.6 **DMARD use, %:** NR **Corticosteroid use, %:** NR **MTX naive, %:** NR **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** **D1:** 5.4 **D2:** 5.5 **Concomitant MTX, %:** **56**	• ACR50 Placebo 0/52 (0.0%) vs. INF 24/52 (46.2%) • ACR70 Placebo 0/52 (0.0%) vs. INF 15/52 (28.8%) • # of tender joints Placebo -23.6 vs. INF 55.2 • # of swollen joints Placebo -1.8 vs. INF 59.9 • DAS Placebo 2.8 vs. INF 45.5 $P < 0.001$ • HAQ Placebo -1.6 vs. INF 49.8 $P < 0.001$ • PsARC Placebo -12% vs. INF +86% $P < 0.001$ • ACR20 wk 16 Placebo 5/52 (9.6%) vs. INF 34/52 (65.4%) $P < 0.001$ • At 50 wks • Total modified vdH-S score, 85% and 84% in Placebo/INF and INF/INF groups had no worsening. • Change in erosion scores INF/INF 0.921, placebo/INF 0.536 ($P = 0.780$) • Change in JSN INF/INF -0.51, placebo/INF -0.47 ($P = 0.211$) • 16 wks-PsARC INF 75% vs. Placebo 21% ($P < 0.001$) • PASI75 INF 68% vs, placebo 0% ($P < 0.001$)	**Overall:** **D1:** 65 **D2:** 73 **D3:** 84 **Headache:** **D1:** 3 **D2:** 4 **URTI:** **D1:** 5 **D2:** 1	**Overall Attrition Rate (%):** 5 **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 3. Key Question 2 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Antoni, 2005; Kavanaugh et al., 2006 IMPACT2 study **Country, Setting:** Multinational 36 sites in clinics **Funding:** Centocor Inc and Schering-Plough **Research Objective:** Efficacy, health related quality of life and physical function in pts with PsA **Study Design:** RCT **Overall N:** 200 **Study Duration:** 14 to 24 wks (pts with inadequate response entered early escape at wk 16)	**Inclusion Criteria:** • Diagnosed with PsA • Diagnosed at least 6 mos before first infusion of study drug • Inadequate response to current or previous DMARDs or NSAIDs • Pts had to have active plaque psoriasis with at least 1 qualifying target lesion at least 2 cm in diameter • Negative test for RF in their serum • Stable doses of MTX, oral corticosteroids, NSAIDs **Exclusion Criteria:** • TNF α inhibitors; active or latent TB • Chronic or clinically significant infection, malignancy, or CHF	**Interventions:** **D1:** Placebo **D2:** INF (5 mg/kg at wks 0, 2, 6, 14, 22) **N:** **D1:** 100 **D2:** 100 **Mean age, yrs:** **D1:** 46.5 **D2:** 47.1 **Sex, % female:** **D1:** 49 **D2:** 29 **Race, % white:** NR	**Mean disease duration, yrs:** **D1:** 7.5 **D2:** 8.4 **TJC, mean:** **D1:** 25.1 **D2:** 24.6 **SJC, mean:** **D1:** 14.4 **D2:** 13.9 **DMARD use, %:** NR **Corticosteroid use, %:** **D1:** 10 **D2:** 15 **MTX naive, %:** NR **Txt resistant, %:Overall 100** **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX, %:** **D1:** 45 **D2:** 47 **PASI:** **D1:** 10.2 **D2:** 11.4	• Placebo vs. INF (%): • ACR 50 at wk 14 3 vs. 36 ($P < 0.001$) and wk 24 4 vs. 41 ($P < 0.001$) • ACR70 at wk 14 1 vs. 15 ($P < 0.001$) and wk 24 2 vs. 27 ($P < 0.001$) • PsARC at wk 14 27 vs. 77 ($P < 0.001$) and wk 24 32 vs. 70 ($P < 0.001$) • •HAQ improvement at wk 14 -18.4 vs. 48.6 ($P < 0.001$) and wk 24 -19.4 vs. 46 ($P < 0.001$) • •SF-36 (change from baseline) • Physical wk 14 1.1 vs. 9.1 ($P < 0.001$) and wk 24 1.3 vs. 7.7 ($P < 0.001$) • Mental wk 14-1.2 vs. 3.8 ($P = 0.001$) and wk 24 0.4 vs. 3.9 ($P = 0.047$) • ACR20 at Wk 14 11 vs. 58 ($P < 0.001$) and Wk 24 16 vs. 54 ($P < 0.001$) • PASI 50: wk 14: 9 vs. 82 ($P <0.01$), wk 24: 8 vs. 75 ($P <75$ ($P<0.01$); PASI 75 wk 14: 2 vs. 64 ($P < 0.01$), wk 24: 1 vs. 50 ($P < 0.01$); • improvement wk 14: 0 vs. 41 ($P < 0.01$), wk 24: 0 vs. 39 ($P < 0.01$) • median productivity at 14 wks 9.2% vs. 67.5% ($P < 0.0001$) • missed workdays at 14 wks 13% vs. 3.7% ($P = 0.138$)	**Overall:** **D1:** 67 **D2:** 67 **SAEs:** **D1:** 6 **D2:** 9 **Infusion or injection reaction:** **D1:** 6 **D2:** 7 **Dizziness:** **D1:** 5 **D2:** 4 **Headache:** **D1:** 5 **D2:** 6 **URTI:** **D1:** 14 **D2:** 10	**Overall:** **Attrition Rate (%):** Wk 14: NR Wk 24: 7.5 **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 3. Key Question 2 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Genovese et al., 2007[2] **Country and setting** 16 sites in Canada and United States **Source of funding** Abott Laboratories **Research objective** Determine safety and efficacy of ADA in pts with inadequate response to DMARDs **Study design** Controlled Trials **Overall N** 102 **Duration of study** 12 weeks double-blind **Quality rating** Fair	**Inclusion Criteria** • Treatment resistant, previous inadequate response to DMARD therapy • ≥ 18 yrs old • General good health determined by medical history, physical exam, laboratory profile, chest radiograph, and 12-lead electrocardio-gram • Pts required to have ≥ 3 swollen joints and ≥ 3 tender or painful joints • Active cutaneous lesion of chronic plague psoriasis or a documented history of chronic plaque psoriasis • Either currently receiving concomitant DMARD therapy or had a history of DMARD	**Interventions, Dose** D1: Placebo D2: ADA: 40 mg every other week **Number in group** D1: 49 D2: 51 **Mean age, yrs (SD)** D1: 47.7 (11.3) D2: 50.4 (11.0) **Sex, % female** D1: 49.0 D2: 43.1 **Race, % white** D1: 93.9 D2: 98.0 **Race, % black** NR **Ethnicity, Latino** NR	**Mean disease duration, years (SD)** D1: 7.2 yrs (7.0) D2: 7.5 yrs (7.0) **Patients with early RA, three years or less, %:** NR **Treatment resistant, %:** 100% inadequate response to previous DMARD treatment **Tender Joint Count, mean (SD)** D1: 29.3 (18.1) D2: 25.3 (18.3) **Swollen Joint Count, mean (SD)** D1: 18.4 (12.1) D2: 18.2 (10.9) **Corticosteroid use, %** At baseline” D1: 18.4 D2: 7.8 Previous Use D1: 30.6 D2: 9.6 **DMARD use, %:** At baseline D1: 67.3 D2: 64.7 Previous Use: 100% **MTX naïve, %:** D1: 20.4 D2: 19.6 **Baseline DAS score**	**ACR mean difference/ absolute difference (95% CI):** ACR 20: D1: 16 D2: 39 (5%-4%) *P* = 0.012 ACR 50: D1: 2 D2: 25 *P* = 0.001 ACR 70: D1: 0 D2: 14 *P* = 0.013 **HAQ, mean difference/ absolute difference (CI/SD/*P* Value):** D1: -0.1 ± 0.3 D2: -0.3 ± 0.5 *P* = 0.010 **DAS, mean difference/absolute difference: NR** **SF-36, mean difference/absolute difference (CI/SD/P Value):** PCS D1: 2.8 ± 7.1 (n = 45); D2: 5.7 ± 8.5 (n = 49); *P* = 0.082; MCS D1: -0.6 ± 7.8 (n = 45) D2: 1.1 ± 7.4 (n = 49) *P* = 0.242	**Attrition/withdrawal, n:** Overall D1: 5 D2: 1 Withdrawals due to adverse events , n: D1: 1 D2: 1 Withdrawals due to lack of efficacy, n: D1: 1 D2: 0 Adherent/compliant , n: D1: 46 D2: 50 **Overall adverse events reported, n:** D1: 39 D2: 27 *P* ≤ 0.01 **Serious adverse events:** Death, n: D1: 0 D2: 0 Congestive heart failure ,n: D1: 0 D2: 0 **Malignancies:** Lymphoma or leukemia, n: D1: 0 D2: 0 Skin cancer (basal cell or squamous cell) , n: D1: 0 D2: 0

Evidence Table 3. Key Question 2 (continued)

	therapy with inadequate response • Evidence of previous TB infection were required to have documented history of treatment for latent TB or TB treatment initiated before first dose of study drug. **Exclusion Criteria** • History of previous anti-TNF therapy • Intravenous infusions or intraarticular injections of corticosteroids within 4 weeks of baseline • Topical psoriasis therapies within 2 weeks of baseline • Ultraviolent A (UVA) phototherapy within 2 weeks of baseline visit • Oral retinoids within 4 weeks • Alefacept or siplizumab within 12 weeks	NR **Required treatment for latent TB** D1: 100% D2: 100%	**Radiographic measures, mean difference/absolute difference: NR** **Quality of life scales, mean difference/absolute difference (CI/SD/*P* Value):** Facit-F score (0-52) D1:: 2.3 ± 6.7 (n = 46) D2: 2.6 ± 7.1 *P* = 0.783 **Others, (please name); mean difference/absolute difference (SD):** Swollen Joint Count D1:-1.9 ± 11.5 D2:-5.7 ± 13.7 *P* = 0.140 Tender Joint Count D1:-6.2 ± 10.3 D2:-9.7 ± 17.3 *P* = 0.231	Other cancer, n: D1: 0 D2: 0 **Respiratory events:** Tuberculosis, n: D1: 0 D2: 0 Upper respiratory infection , n: D1: 4 D2: 7 Other infections (any), n: D1: 16 D2: 9 **GI:** Diarrhea: D1: 3 D2: 1 **Other:** Infusion/injection site reactions, n: D1: 6 D2: 6 Demyelenation or multiple sclerosis , n: D1: 0 D2: 0 HeD2che, n: D1: 3 D2: 0 Back pain, n: D1: 3 D2: 1 Psoriasis aggravated D1: 8 D2: 2 Aggravated Psoriatic

Evidence Table 3. Key Question 2 (continued)

	• Any biologic or investigational therapy within 6 weeks • Current use of or likely to need antiretroviral therapy • Persistent or severe infections or history of active TB, or active nonpsoriatic skin disease which may interfere with assessment of target lesions • Significant history of cardiac, renal, neurologic, psychiatric, endocrinologic, metabolic or hepatic disease • Neurologic symptoms suggestive of CNS demyelinating disease • History of malignancy other than carcinoma in situ of cervix or adequately treated nonmetastatic squamous or basal cell skin		Arthropathy At week 12 D1: 7 D2: 1 $P \leq 0.05$ Diverticulitis, n: D1: 0 D2: 1

Evidence Table 3. Key Question 2 (continued)

	carcinoma • Oral corticosteroids > equivalent of PRED 10mg/d, use of cyclosporine, tacrolimus • Long term (> 3 mths) treatment with MTX or other DMARDs • Unstable dose of MTX or other DMARDs during 4 wks preceding baseline visit • MTX dose > 30 mg/wk	

Evidence Table 3. Key Question 2 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Kaltwasser et al., 2004 and Nash et al., 2006 **Country, Setting:** Multinational, multicenter (31) **Funding:** Aventis **Research Objective:** Efficacy and safety of LEF versus placebo in pts with PsA and psoriasis **Study Design:** RCT **Overall: N:** 190 (ITT = 186) **Study Duration:** 24 wks	**Inclusion Criteria:** • Age 18 to 70 • Diagnosed with PsA • NSAIDs or Css (prednisone dose of 10 mg/day or steroid equivalent administered orally) • Discontinue DMARDs, biologics and systemic antipsoriatic txt 28 days **Exclusion Criteria:** • Pregnant or lactating; leflunomide • Impaired renal or hepatic system • Nonpsoriatic inflammatory joint disease or arthritis onset < 16 yrs • RH factor +, rheumatoid nodules, serious infections, malignancy, or CVD, HIV, hepatitis B or C antigen positivity, guttate, pustular, or erythrodermic forms of psoriasis, body weight <45 kg • Impaired bone marrow function; history of drug or alcohol abuse	**Interventions:** **D1:** Placebo **D2:** LEF **N:** **D1:** 91 **D2:** 95 **Mean age, yrs:** Drug 1: 46.9 Drug 2: 48.6 Overall **Sex, % female:** **D1:** 37.4 **D2:** 42.1 **Race, % white:** **D1:** 95.6 **D2:** 97.9	**Mean disease duration, yrs:** **D1:** 10 **D2:** 11 **TJC, mean:** NR **SJC, mean:** NR **DMARD use, %:** **D1:** 49.5 **D2:** 61.1 **Corticosteroid use, %:** **D1:** 9.9 **D2:** 15.8 **DMARD naive, %:** **D1:** e 50.5 **D2:** 38.9 **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX, %:** 0	• 56 of 95 leflunomide-treated pts (58.9%; 95% CI, 48.4-68.9) and 27 of 91 placebo-treated pts (29.7% (95% CI, 20.6-40.2)) were classified as responders by PsARC (P < 0.0001) Change in HAQ total score • Placebo (N:90) -0.05 ± 0.46 (P = 0.0267) • Leflunomide (N:94) -0.19 ± 0.51 Change in PASI score • Placebo (N:90) -0.6 ± 6.1 P = 0.0030 • Leflunomide (N:92) -2.1 ± 5.9 Change in DLQI total score • Placebo (N:89) -0.2 ± 5.1 P = 0.0173 • Leflunomide (N:90) -1.9 ± 5.1	**Overall:** **D1:** 76.1 **D2:** 85.4 **SAEs:** **D1:** 5.4 **D2:** 13.5 **Serious Infections:** **D1:** 0 **D2:** 0 **Diarrhea:** **D1:** 13.0 **D2:** 24.0 **Headache:** **D1:** 7.6 **D2:** 11.5 **Nausea:** **D1:** 8.7 **D2:** 9.4	**Overall Attrition Rate (%):** 47.9% **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 3. Key Question 2 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Kavanaugh et al., 2009, GO-REVEAL[5] **Country and setting** 58 investigational sites, multinational **Source of funding** Centocor Research and Development, Inc. and Schering-Plough Corporation **Research objective** Assess efficacy and safety of GOL in patients with active PsA **Study design** Controlled Trials **Overall N** 405 **Duration of study** 24 wks **Quality rating** Good	**Inclusion Criteria** • Treatment resistant active PsA despite therapy with DMARDs or NSAIDs • active PsA: ≥ 3 swollen and 3 tender joints, negative rheumatoid factor, at least 1 subset of PsA, presence of plaque psoriasis with lesion ≥ 2 cm in diameter; • MTX, NSAIDs, corticosteroids allowed in stable doses • Latent TB allowed if treated prior or concurrent to study **Exclusion Criteria** • Previous use of anti-TNF agents, RIT, natalizumab, or cytotoxic agents	**Interventions, Dose** D1: Placebo • At week 16, pts with < 10% improvement from baseline in both swollen and tender joint counts entered early escape = dose escalation from placebo to 50 mg GOL every four weeks D2: • GOL: 50 mg every 4 wks • At week 16, pts with < 10% improvement from baseline in both swollen and tender joint counts entered early escape = dose escalation from 50 mg GOL to 100 mg GOL every four wks. D3: GOL: 100 mg every 4 wks D4: Randomized to placebo, crossed over to GOL 50 mg D5: Randomized to GOL 50, crossed over to 100 mg **Number in group** D1: 113 D2: 146 D3: 146 **Mean age, years (SD)** D1: 47.0 (10.6)	**Mean disease duration, years (SD)** D1: 7.6 (7.9) D2: 7.2 (6.8) D3: 7.7 (7.8) **Patients with early RA, three years or less, %:** D1: 33 D2: 34 D3: 27 **Treatment resistant, %:** D1: 100 D2: 100 D3: 100 **Tender Joint Count, mean (SD)** D1: 21.9 (14.7) D2: 24.0 (17.1) D3: 22.5 (15.7) **Swollen Joint Count, mean (SD)** D1: 13.4 (9.8) D2: 14.1 (11.4) D3: 12.0 (8.4) **Corticosteroid use, %** D1: 17 D2: 13 D3: 18 **DMARD use, %:** MTX D1: 48 D2: 49 D3: 47 **MTX naïve, %:**	**ACR mean difference/ absolute difference (CI/SD/P Value):** At week 14: ACR 20: D1: 9 D2: 51 D3: 45 *P* < 0.001 (D1 vs. D2 and D3) At week 24: ACR 20: D1: 12 D2: 52 D3: 61 *P* < 0.001 (D1 vs. D2 and D3) ACR 50 and ACR70 at weeks 14 and 24: Shown in figure only **HAQ, mean difference/ absolute difference (CI/SD/P Value):** D1: -0.01 (0.49) D2: 0.33 (0.55) D3: 0.39 (0.50) *P* < 0.001 (D1 vs. D2 and D3) **DAS, mean difference/absolute difference (SD):** At week 14: D1: -0.18 (0.78) D2: -1.38 (1.16) D3: -1.29 (1.16) *P* < 0.001 (D1 vs. D2 and	**Overall attrition/withdrawal, n:** D1: 12 D2: 9 D3: 4 **Withdrawals due to adverse event, n:** D1: 5 D2: 2 D3: 4 **Withdrawals due to lack of efficacy, n:** D1: 2 D2: 1 D3: 0 **Adherent/compliant, n**: NR **Overall adverse events reported , n:** Through Week 24 D1: 67 D2: 99 D3: 95 **Serious adverse events:** SAEs: D1: 7 D2: 3 D3: 4 Prostate cancer, n: D1: NR D2: NR D3: 1 **Respiratory events:** Tuberculosis, n:

Evidence Table 3. Key Question 2 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
		D2: 45.7 (10.7) D3: 48.2 (10.9) **Sex, % female** D1: 39 D2: 39 D3: 41 **Race, % white** D1: 97 D2: 97 D3: 97 **Race, % black** NR **Ethnicity, Latino** NR	D1: 33 D2: 34 D3: 27 **Baseline DAS28-CRP score, mean (SD)** D1: 4.3 (1.0) D2: 4.4 (1.1) D3: 4.3 (1.0) **Required treatment for latent TB** D1: 11 D2 & D3: 33	D3) At week 24: D1: -0.12 (0.97) D2: -1.43 (1.34) D3: -1.56 (1.10) *P* < 0.001 (D1 vs. D2 and D3) DAS28-CRP No. EULAR response: At week 14: D1: 27 D2: 96 (*P* < 0.001) D3: 98 (*P* < 0.001) At week 24: D1: 27 D2: 94 (*P* < 0.001) D3: 114 (*P* < 0.001) **SF-36, mean difference/absolute difference (CI/SD/P Value):** D1: 0.63 (7.68) D2: 6.53 (8.88) D3: 7.85 (9.55) *P* < 0.001 (D1 vs. D2 and D3) **Radiographic measures, mean difference/absolute difference:** NR **Quality of life scales, mean difference/absolute difference:** NR **Morning stiffness, mean change (SD):** At week 14: D1: 23.4 (299.9)	Overall: 0 Pneumonia, n: D1: 2 D2: NR D3: NR Upper respiratory infection (n): D1: 7 D2: 17 D3: 13 **Other infections, n:** D1: Cellulits: 1, Urosepsis: 1 D2: Abscess: 1 D3: Sepsis/Cholecystitis: 1 Infusion/injection site reactions , n: D1: 3 D2: 4 D3: 6 **GI:** Nausea or vomiting, n: D1: 5 D2: 4 D3: 6 Headache, n: D1: 8 D2: 7 D3: 8 Dizziness : NR Nasopharyngitis, n: D1: 5 D2: 10 D3: 19

Evidence Table 3. Key Question 2 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
				D2: -72.4 (201.3) ($P < 0.001$) D3: -86.3 (238.3), ($P < 0.001$) At week 24: D1: -20.4 (257.7) D2: -67.2(231.1) ($P < 0.001$) D3: -90.1 (234.5), ($P < 0.001$) PASI90, n: At week 14: D1: 0 D2: 22 ($P < 0.001$) D3: 26, ($P < 0.001$) At week 24: D1: 0 D2: 33 ($P < 0.001$) D3: 34, ($P < 0.001$)	Back pain, n: D1: 5 D2: 6 D3: 7 Diarrhea, n: D1: 4 D2: 5 D3: 7 Cough, n: D1: 5 D2: 7 D3: 4 Elevated ALT levels, n: D1: 4 D2: 4 D3: 5 Injection-site erythema D1: 2 D2: 4 D3: 6 Markedly abnormal ALT levels: D1: 4 D2: 43 D3: 0 Markedly abnormal AST levels: D1: 3 D2: 2 D3: 0 Markedly abnormal total bilirubin levels: D1: 2 D2: 4 D3: 2

Evidence Table 3. Key Question 2 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
					Antibodies to GOL: D1: NR D2: 5/114 D3: 7/143

Evidence Table 3. Key Question 2 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2000 **Country, Setting:** US, single center in Seattle **Funding:** Immunex Corp. **Research Objective:** To study the efficacy and safety of etanercept in pts with psoriatic arthritis and psoriasis **Study Design:** RCT **Overall N:** 60 **Study Duration:** 12 wks	**Inclusion Criteria:** • Age 18 to 70 • Diagnosed with PsA according to: > 3 swollen, tender, or painful joints • Inadequate response to NSAIDs • Hepatic transasminase concentrations no greater than 2x upper limit of normal • Hemoglobin 85 g/L or higher • Platelet count 125,000 per mL or more and serum creatinine 152-4 mmol/L or below • MTX < 25 mg/wk and stable for 4 wks • Corticosteriods if the dose < 10 mg/d of PRE, stable for at least 2 wks and maintained at a constant dose throughout study **Exclusion Criteria:** • Evidence of skin conditions other than psoriasis	**Interventions:** **D1:** Placebo **D2:** ETA (25mg 2x wkly) **N:** **D1:** 30 **D2:** 30 **Mean age, yrs:** **D1:** 43.5 **D2:** 46 **Sex, % female:** **D1:** 40 **D2:** 47 **Race, % white:** **D1:** 83 **D2:** 90	**Mean disease duration, yrs:** **D1:** 9.5 **D2:** 9 **TJC, mean:** NR **SJC, mean:** NR **DMARD use, %:** NR **Corticosteroid use, %:** **D1:** 40 **D2:** 20 **MTX naive, %:** NR **Txt resistant, %:** Overall 100 **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX:** **D1:** 47 **D2:** 47	• PsARC ETA 26 (87%) vs. Placebo 7 (23%) *P* < 0.0001 95% CI, 44-83; ACR50 ETA 15 (50%) vs. Placebo 1 (3%) *P* = 0.0001 95% CI, 28-66; • ACR70 ETA 4 (13%) vs. Placebo 0 (0%) *P* = 0.0403 95% CI, 1-26; • HAQ ETA 0.1 (0,1) vs. Placebo 1.3 (0.9,1.6) *P* < 0.001 • •ACR20 was achieved by 73% ETA treated pts compared with 13% placebo treated pts (*P* < 0.0001) • Median % improvements in tender and swollen joint counts at 12 wks ETA 75% and 72% respectively vs. placebo 5% worsening and 19% improvement; disability according to HAQ significantly more improved in ETA than placebo (83% vs. 3%, *P* < 0.0001) • 26% of ETA vs. 0 of placebo pts achieved 75% improvement in PASI at 12 wks (*P* = 0.0154); similar differences between ETA and placebo also seen at 25% and 50% improvements in PASI scores	**SAEs:** **D1:** 0 **D2:** 3.3 **Infusion or injection reaction:** **D1:** 20 **D2:** 3 **Headache:** **D1:** 13 **D2:** 10 **URTI:** **D1:** 57 **D2:** 57	**Overall Attrition Rate (%):** 6.6% **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 3. Key Question 2 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2004; Mease et al., 2006 (2nd yr outcomes) **Country, Setting:** US, 17 sites **Funding:** Immunex **Research Objective:** Safety, efficacy, and effect on radiographic progression of ETA in pts with PsA **Study Design:** RCT **Overall N:** 205 **Study Duration:** 24 wks (with 48 wk open-label phase)	**Inclusion Criteria:** • Age 18 70 • Diagnosed with PsA ≥ 3 swollen and 3 tender joimts • Inadequate response to NSAID • At least one of PsA subtypes: distal interphalangeal joint involvement, polyarticular arthritis, arthritis mutilans, asymmetric peripheral arthritis, or ankylosing spondylitis-like arthritis • Stable plaque psoriasis with a qualifying lesion • MTX therapy (stable 2 mo ≤ 25 mg/wk) • Css (stable 4 wks ≤ 10 mg/d of prednisone) **Exclusion Criteria:** • Oral retinoids, topical vitamin A or D analog preparations, and anthralin	**Interventions:** **D1:** placebo **D2:** ETA (25 mg 2x wkly) **N:** **D1:** 104 **D2:** 101 **Mean age, yrs:** **D1:** 47.3 **D2:** 47.6 **Sex, % female:** **D1:** 55 **D2:** 43 **Race, % white:** **D1:** 91 **D2:** 90	**Mean disease duration, yrs:** **D1:** 9.2 **D2:** 9 **TJC, mean:** NR **SJC, mean:** NR **DMARD use, %:** NR **Corticosteroid use, %:** **D1:** 15 **D2:** 19 **MTX naive, %:** NR **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX use, %:** **D1:** 41 **D2:** 42 **Sharp:** **D1:** 18.3 **D2:** 25.89	• At 12 wks, 59% of ETA pts met ACR20 criteria compared with 15% placebo pts ($P < 0.0001$) • 23% of ETA pts eligible for psoriasis evaluation achieved at least 75% improvement in psoriasis area and severity index, compared with 3% of placebo pts ($P = 0.001$) • 12 mos; the mean annualized rate of change over one yr of txt in modified Sharp score was –0.03 unit, compared with 1.00 unit in the placebo ($P = 0.0001$) • HAQ- improvement from baseline in ETA group 54% vs. 6% of placebo group ($P < 0.0001$) • 72% & 70% of ETA achieved PsARC at 12 and 24 wks, respectively, compared with 31% and 23% of placebo pts	**SAEs:** **D1:** 3.9 **D2:** 4 **Infusion or injection reaction:** **D1:** 9 **D2:** 36 **Headache:** **D1:** 5 **D2:** 8 **URTI:** **D1:** 23 **D2:** 21 **UTI:** **D1:** 6 **D2:** 6	**Overall Attrition Rate (%):** 19.5 **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 3. Key Question 2 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2005 ADEPT Study **Country, Setting:** Multinational, multi-clinic (50) **Funding:** Abbott Laboratories **Research Objective:** Safety and efficacy of ADA compared with placebo in txt of active psoriatic arthritis **Study Design:** RCT **Overall N:** 313 **Study Duration:** 24 wks	**Inclusion Criteria:** • Age ≥ 18 • Moderate to severe PsA • Active psoriatic skin lesions or a documented history of psoriasis • Inadequate response or intolerance to NSAIDs • MTX ≥ 3 mos with stable dose 4 wks **Exclusion Criteria:** • CYP, tacrolimus, DMARDs, or oral retinoids (4 wks) • Topical txts for psoriasis within 2 wks, other than medicated shampoos or low-potency topical steroids • Anti-TNF • History of TB • Central nervous system demyelinating disease • Listeriosis, or severe infection within 30 ds or oral antibiotics within 14 ds	**Interventions:** **D1:** placebo **D2:** ADA (40mg every other wk) **N:** **D1:** 162 **D2:** 151 **Mean age, yrs:** **D1:** 49.2 **D2:** 48.6 **Sex, % female:** **D1:** 45.1 **D2:** 43.7 **Race, % white:** **D1:** 93.8 **D2:** 97.4	**Mean disease duration, yrs:** **D1:** 9.2 **D2:** 9.8 **TJC, mean:** **D1:** 25.8 **D2:** 23.9 **SJC, mean:** **D1:** 14.3 **D2:** 14.3 **Mean number previous DMARDS:** **D1:** 1.5 **D2:** 1.5 **Corticosteroid use, %:** NR **MTX naive, %:** NR **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline PASI (mean):** **D1:** 8.3 **D2:** 7.4 **Concomitant MTX use, %:** **D1:** 50 **D2:** 51 **Baseline HAQ:** **D1:** 1.0 **D2:** 1.0	• PsARC ADA 60% wk. vs.placebo 23% • ACR50 ADA, 39% vs. placebo, 6% ($P < 0.001$) • ACR70 ADA, 23% vs. placebo, 1% ($P < 0.001$) • The PASI75 ADA 59% vs. placebo 1% ($P < 0.001$) (N: 69 per group). • HAQ DI change placebo -0.1 ± 0.4 vs. ADA -0.4 ± 0.5 ($P < 0.001$) • ACR20 ADA 57% vs. placebo 15% (between-group difference 42%, 95% CI, 31-52%; $P < 0.001$). • Mmean change in modified total Sharp was -0.2 for ADA versus placebo ($P < 0.001$) • Erosion scores (mean change ADA 0.0 vs. placebo 0.6) and JSN scores (mean change ADA -0.2 vs. placebo 0.4) ($P < 0.001$ for both) • SF-36: SF-36 PCS; change in baseline to wk 12 for placebo vs ADA; 1.4 vs 9.3 ($P < 0.001$) • Change in baseline to wk 24; 1.4 vs 9.3 ($P < 0.001$) • SF-36 MCS • Change in baseline to wk 12 ; 1.2 vs 1.6 (*P* NS) • Change in baseline to wk 12; 0.6 vs 1.8 (*P* NS)	**Infusion or injection reaction:** **D1:** 3.1 **D2:** 6.6 **Headache:** **D1:** 8.6 **D2:** 6.0 **URTI:** **D1:** 14.8 **D2:** 12.6 **UTI:** NR	**Overall Attrition Rate (%):** 7.6 **ITT Analysis:** Yes **Quality Rating:** Fair.

Evidence Table 4. Key Question 3

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Antoni et al., 2005; Kavanaugh et al., 2006 IMPACT Study **Country, Setting:** Multinational, 9 clinical sites **Funding:** NIH; Centocor, Inc.; Schering-Plough Research Institute; Competence Network **Research Objective:** Efficacy and tolerability of INF for the articular and dermatologic manifestations of active PsA **Study Design:** RCT **Overall N:** 104 **Study Duration:** 50 wks (1-16 wks RCT 16-50 open, all treated with INF)	**Inclusion Criteria:** • Age ≥ 18 • Failure of 1 or more DMARD • Active peripheral polyarticular arthritis • MTX ≥ 15 mg/wk w/ folic acid supplementation • LEF, SSZ, HCQ, intramuscular gold, penicillamine, or azathioprine stable for 4 wks • oral corticosteroids (dosage of 10 mg PRE equivalent/d or less) • NSAIDs stable for at least 2 wks **Exclusion Criteria:** • Monoclonal antibody or fusion protein • History of TB: positive tests for RF or latent TB investigational drug within 3 mos	**Interventions:** **D1:** Placebo **D2:** INF (5mg/kg at wks 0,2,6,14, then every 8 wks) **N:** **D1:** 52 **D2:** 52 **Mean age, yrs:** **D1:** 45.2 **D2:** 45.7 **Sex, % female:** **D1:** 42.3 **D2:** 42.3 **Race, % white:** NR	**Mean disease duration, yrs:** **D1:** 11 **D2:** 11.7 **TJC, mean:** **D1:** 20.4 **D2:** 23.7 **SJC, mean:** **D1:** 14.7 **D2:** 14.6 **DMARD use, %:** NR **Corticosteroid use, %:** NR **MTX naive, %:** NR **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** **D1:** 5.4 **D2:** 5.5 **Concomitant MTX, %:** **56**	• ACR50 Placebo 0/52 (0.0%) vs. INF 24/52 (46.2%) • ACR70 Placebo 0/52 (0.0%) vs. INF 15/52 (28.8%) • # of tender joints Placebo -23.6 vs. INF 55.2 • # of swollen joints Placebo -1.8 vs. INF 59.9 • DAS Placebo 2.8 vs. INF 45.5 $P < 0.001$ • HAQ Placebo -1.6 vs. INF 49.8 $P < 0.001$ • PsARC Placebo -12% vs. INF +86% $P < 0.001$ • ACR20 wk 16 Placebo 5/52 (9.6%) vs. INF 34/52 (65.4%) $P < 0.001$ • At 50 wks • Total modified vdH-S score, 85% and 84% in Placebo/INF and INF/INF groups had no worsening. • Change in erosion scores INF/INF 0.921, placebo/INF 0.536 ($P = 0.780$) • Change in JSN INF/INF -0.51, placebo/INF -0.47 ($P = 0.211$) • 16 wks-PsARC INF 75% vs. Placebo 21% ($P < 0.001$) • PASI75 INF 68% vs, placebo 0% ($P < 0.001$)	**Overall:** **D1:** 65 **D2:** 73 **D3:** 84 **Headache:** **D1:** 3 **D2:** 4 **URTI:** **D1:** 5 **D2:** 1	**Overall Attrition Rate (%):** 5 **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Antoni, 2005; Kavanaugh et al., 2006 IMPACT2 study **Country, Setting:** Multinational 36 sites in clinics **Funding:** Centocor Inc and Schering-Plough **Research Objective:** Efficacy, health related quality of life and physical function in pts with PsA **Study Design:** RCT **Overall N:** 200 **Study Duration:** 14 to 24 wks (pts with inadequate response entered early escape at wk 16)	**Inclusion Criteria:** • Diagnosed with PsA • Diagnosed at least 6 mos before first infusion of study drug • Inadequate response to current or previous DMARDs or NSAIDs • Pts had to have active plaque psoriasis with at least 1 qualifying target lesion at least 2 cm in diameter • Negative test for RF in their serum • Stable doses of MTX, oral corticosteroids, NSAIDs **Exclusion Criteria:** • TNF α inhibitors; active or latent TB • Chronic or clinically significant infection, malignancy, or CHF	**Interventions:** **D1:** Placebo **D2:** INF (5 mg/kg at wks 0, 2, 6, 14, 22) **N:** **D1:** 100 **D2:** 100 **Mean age, yrs:** **D1:** 46.5 **D2:** 47.1 **Sex, % female:** **D1:** 49 **D2:** 29 **Race, % white:** NR	**Mean disease duration, yrs:** **D1:** 7.5 **D2:** 8.4 **TJC, mean:** **D1:** 25.1 **D2:** 24.6 **SJC, mean:** **D1:** 14.4 **D2:** 13.9 **DMARD use, %:** NR **Corticosteroid use, %:** **D1:** 10 **D2:** 15 **MTX naive, %:** NR **Txt resistant, %:Overall 100** **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX, %:** **D1:** 45 **D2:** 47 **PASI:** **D1:** 10.2 **D2:** 11.4	• Placebo vs. INF (%): • ACR 50 at wk 14 3 vs. 36 (P < 0.001) and wk 24 4 vs. 41 (P < 0.001) • ACR70 at wk 14 1 vs. 15 (P < 0.001) and wk 24 2 vs. 27 (P < 0.001) • PsARC at wk 14 27 vs. 77 (P < 0.001) and wk 24 32 vs. 70 (P < 0.001) • •HAQ improvement at wk 14 - 18.4 vs. 48.6 (P < 0.001) and wk 24 -19.4 vs. 46 (P < 0.001) • •SF-36 (change from baseline) • Physical wk 14 1.1 vs. 9.1 (P < 0.001) and wk 24 1.3 vs. 7.7 (P < 0.001) • Mental wk 14-1.2 vs. 3.8 (P = 0.001) and wk 24 0.4 vs. 3.9 (P = 0.047) • ACR20 at Wk 14 11 vs. 58 (P < 0.001) and Wk 24 16 vs. 54 (P < 0.001) • PASI 50: wk 14: 9 vs. 82 (P <0.01), wk 24: 8 vs. 75 (P <75 (P<0.01); PASI 75 wk 14: 2 vs. 64 (P < 0.01), wk 24: 1 vs. 50 (P < 0.01); • improvement wk 14: 0 vs. 41 (P < 0.01), wk 24: 0 vs. 39 (P < 0.01) • median productivity at 14 wks 9.2% vs. 67.5% (P < 0.0001) • missed workdays at 14 wks 13% vs. 3.7% (P = 0.138)	**Overall:** **D1:** 67 **D2:** 67 **SAEs:** **D1:** 6 **D2:** 9 **Infusion or injection reaction:** **D1:** 6 **D2:** 7 **Dizziness:** **D1:** 5 **D2:** 4 **Headache:** **D1:** 5 **D2:** 6 **URTI:** **D1:** 14 **D2:** 10	**Overall: Attrition Rate (%):** Wk 14: NR Wk 24: 7.5 **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Genovese et al., 2007[2] **Country and setting** 16 sites in Canada and United States **Source of funding** Abott Laboratories **Research objective** Determine safety and efficacy of ADA in pts with inadequate response to DMARDs **Study design** Controlled Trials **Overall N** 102 **Duration of study** 12 weeks double-blind **Quality rating** Fair	**Inclusion Criteria** • Treatment resistant, previous inadequate response to DMARD therapy • ≥ 18 yrs old • General good health determined by medical history, physical exam, laboratory profile, chest radiograph, and 12-lead electrocardio-gram • Pts required to have ≥ 3 swollen joints and ≥ 3 tender or painful joints • Active cutaneous lesion of chronic plague psoriasis or a documented history of chronic plaque psoriasis • Either currently receiving concomitant DMARD therapy or had a history	**Interventions, Dose** D1: Placebo D2: ADA: 40 mg every other week **Number in group** D1: 49 D2: 51 **Mean age, yrs (SD)** D1: 47.7 (11.3) D2: 50.4 (11.0) **Sex, % female** D1: 49.0 D2: 43.1 **Race, % white** D1: 93.9 D2: 98.0 **Race, % black** NR **Ethnicity, Latino** NR	**Mean disease duration, years (SD)** D1: 7.2 yrs (7.0) D2: 7.5 yrs (7.0) **Patients with early RA, three years or less, %:** NR **Treatment resistant, %:** 100% inadequate response to previous DMARD treatment **Tender Joint Count, mean (SD)** D1: 29.3 (18.1) D2: 25.3 (18.3) **Swollen Joint Count, mean (SD)** D1: 18.4 (12.1) D2: 18.2 (10.9) **Corticosteroid use, %** At baseline" D1: 18.4 D2: 7.8 Previous Use D1: 30.6 D2: 9.6 **DMARD use, %:** At baseline D1: 67.3 D2: 64.7 Previous Use: 100% **MTX naïve, %:** D1: 20.4 D2: 19.6	**ACR mean difference/ absolute difference (95% CI):** ACR 20: D1: 16 D2: 39 (5%-4%) *P* = 0.012 ACR 50: D1: 2 D2: 25 *P* = 0.001 ACR 70: D1: 0 D2: 14 *P* = 0.013 **HAQ, mean difference/ absolute difference (CI/SD/*P* Value):** D1: -0.1 ± 0.3 D2: -0.3 ± 0.5 *P* = 0.010 **DAS, mean difference/absolute difference: NR** **SF-36, mean difference/absolute difference (CI/SD/P Value):** PCS D1: 2.8 ± 7.1 (n = 45); D2: 5.7 ± 8.5 (n = 49); *P* = 0.082; MCS D1: -0.6 ± 7.8 (n = 45) D2: 1.1 ± 7.4 (n = 49) *P* = 0.242	**Attrition/withdrawal, n:** Overall D1: 5 D2: 1 Withdrawals due to adverse events , n: D1: 1 D2: 1 Withdrawals due to lack of efficacy, n: D1: 1 D2: 0 Adherent/compliant , n: D1: 46 D2: 50 **Overall adverse events reported, n:** D1: 39 D2: 27 *P* ≤ 0.01 **Serious adverse events:** Death, n: D1: 0 D2: 0 Congestive heart failure ,n: D1: 0 D2: 0 **Malignancies:** Lymphoma or leukemia, n: D1: 0 D2: 0 Skin cancer (basal cell or squamous cell) , n: D1: 0

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
	of DMARD therapy with inadequate response • Evidence of previous TB infection were required to have documented history of treatment for latent TB or TB treatment initiated before first dose of study drug. **Exclusion Criteria** • History of previous anti-TNF therapy • Intravenous infusions or intraarticular injections of corticosteroids within 4 weeks of baseline • Topical psoriasis therapies within 2 weeks of baseline • Ultraviolent A (UVA) phototherapy within 2 weeks of baseline visit • Oral retinoids		**Baseline DAS score** NR **Required treatment for latent TB** D1: 100% D2: 100%	**Radiographic measures, mean difference/absolute difference: NR** **Quality of life scales, mean difference/absolute difference (CI/SD/*P* Value):** Facit-F score (0-52) D1:: 2.3 ± 6.7 (n = 46) D2: 2.6 ± 7.1 *P* = 0.783 **Others, (please name); mean difference/absolute difference (SD):** Swollen Joint Count D1:-1.9 ± 11.5 D2:-5.7 ± 13.7 *P* = 0.140 Tender Joint Count D1:-6.2 ± 10.3 D2:-9.7 ± 17.3 *P* = 0.231	D2: 0 Other cancer, n: D1: 0 D2: 0 **Respiratory events:** Tuberculosis, n: D1: 0 D2: 0 Upper respiratory infection , n: D1: 4 D2: 7 Other infections (any), n: D1: 16 D2: 9 **GI:** Diarrhea: D1: 3 D2: 1 **Other:** Infusion/injection site reactions, n: D1: 6 D2: 6 Demyelenation or multiple sclerosis , n: D1: 0 D2: 0 HeD2che, n: D1: 3 D2: 0 Back pain, n: D1: 3 D2: 1

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
	within 4 weeks • Alefacept or siplizumab within 12 weeks • Any biologic or investigational therapy within 6 weeks • Current use of or likely to need antiretroviral therapy • Persistent or severe infections or history of active TB, or active nonpsoriatic skin disease which may interfere with assessment of target lesions • Significant history of cardiac, renal, neurologic, psychiatric, endocrinologic, metabolic or hepatic disease • Neurologic symptoms suggestive of CNS demyelinating disease • History of malignancy other than				Psoriasis aggravated D1: 8 D2: 2 Aggravated Psoriatic Arthropathy At week 12 D1: 7 D2: 1 $P \leq 0.05$ Diverticulitis, n: D1: 0 D2: 1

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
	carcinoma in situ of cervix or adequately treated nonmetastatic squamous or basal cell skin carcinoma • Oral corticosteroids > equivalent of PRED 10mg/d, use of cyclosporine, tacrolimus • Long term (> 3 mths) treatment with MTX or other DMARDs • Unstable dose of MTX or other DMARDs during 4 wks preceding baseline visit • MTX dose > 30 mg/wk				

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Kaltwasser et al., 2004 and Nash et al., 2006 **Country, Setting:** Multinational, multicenter (31) **Funding:** Aventis **Research Objective:** Efficacy and safety of LEF versus placebo in pts with PsA and psoriasis **Study Design:** RCT **Overall: N:** 190 (ITT = 186) **Study Duration:** 24 wks	**Inclusion Criteria:** • Age 18 to 70 • Diagnosed with PsA • NSAIDs or Css (prednisone dose of 10 mg/day or steroid equivalent administered orally) • Discontinue DMARDs, biologics and systemic antipsoriatic txt 28 days **Exclusion Criteria:** • Pregnant or lactating; leflunomide • Impaired renal or hepatic system • Nonpsoriatic inflammatory joint disease or arthritis onset < 16 yrs • RH factor +, rheumatoid nodules, serious infections, malignancy, or CVD, HIV, hepatitis B or C antigen positivity, guttate, pustular, or erythrodermic forms of psoriasis, body weight <45 kg • Impaired bone marrow function; history of drug or alcohol abuse	**Interventions:** **D1:** Placebo **D2:** LEF **N:** **D1:** 91 **D2:** 95 **Mean age, yrs:** Drug 1: 46.9 Drug 2: 48.6 Overall **Sex, % female:** **D1:** 37.4 **D2:** 42.1 **Race, % white:** **D1:** 95.6 **D2:** 97.9	**Mean disease duration, yrs:** **D1:** 10 **D2:** 11 **TJC, mean:** NR **SJC, mean:** NR **DMARD use, %:** **D1:** 49.5 **D2:** 61.1 **Corticosteroid use, %:** **D1:** 9.9 **D2:** 15.8 **DMARD naive, %:** **D1:** e 50.5 **D2:** 38.9 **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX, %:** 0	• 56 of 95 leflunomide-treated pts (58.9%; 95% CI, 48.4-68.9) and 27 of 91 placebo-treated pts (29.7% (95% CI, 20.6-40.2)) were classified as responders by PsARC ($P < 0.0001$) Change in HAQ total score • Placebo (N:90) -0.05 ± 0.46 ($P = 0.0267$) • Leflunomide (N:94) -0.19 ± 0.51 Change in PASI score • Placebo (N:90) -0.6 ± 6.1 $P = 0.0030$ • Leflunomide (N:92) -2.1 ± 5.9 Change in DLQI total score • Placebo (N:89) -0.2 ± 5.1 $P = 0.0173$ • Leflunomide (N:90) -1.9 ± 5.1	**Overall:** **D1:** 76.1 **D2:** 85.4 **SAEs:** **D1:** 5.4 **D2:** 13.5 **Serious Infections:** **D1:** 0 **D2:** 0 **Diarrhea:** **D1:** 13.0 **D2:** 24.0 **Headache:** **D1:** 7.6 **D2:** 11.5 **Nausea:** **D1:** 8.7 **D2:** 9.4	**Overall Attrition Rate (%):** 47.9% **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Kavanaugh et al., 2009, GO-REVEAL[5] **Country and setting** 58 investigational sites, multinational **Source of funding** Centocor Research and Development, Inc. and Schering-Plough Corporation **Research objective** Assess efficacy and safety of GOL in patients with active PsA **Study design** Controlled Trials **Overall N** 405 **Duration of study** 24 wks **Quality rating** Good	**Inclusion Criteria** • Treatment resistant active PsA despite therapy with DMARDs or NSAIDs • active PsA: ≥ 3 swollen and 3 tender joints, negative rheumatoid factor, at least 1 subset of PsA, presence of plaque psoriasis with lesion ≥ 2 cm in diameter; • MTX, NSAIDs, corticosteroids allowed in stable doses • Latent TB allowed if treated prior or concurrent to study **Exclusion Criteria** • Previous use of anti-TNF agents, RIT, natalizumab, or cytotoxic agents	**Interventions, Dose** D1: Placebo • At week 16, pts with < 10% improvement from baseline in both swollen and tender joint counts entered early escape = dose escalation from placebo to 50 mg GOL every four weeks D2: • GOL: 50 mg every 4 wks • At week 16, pts with < 10% improvement from baseline in both swollen and tender joint counts entered early escape = dose escalation from 50 mg GOL to 100 mg GOL every four wks. D3: GOL: 100 mg every 4 wks D4: Randomized to placebo, crossed over to GOL 50 mg D5: Randomized to GOL 50, crossed over to 100 mg **Number in group** D1: 113 D2: 146 D3: 146 **Mean age, years (SD)** D1: 47.0 (10.6)	**Mean disease duration, years (SD)** D1: 7.6 (7.9) D2: 7.2 (6.8) D3: 7.7 (7.8) **Patients with early RA, three years or less, %:** D1: 33 D2: 34 D3: 27 **Treatment resistant, %:** D1: 100 D2: 100 D3: 100 **Tender Joint Count, mean (SD)** D1: 21.9 (14.7) D2: 24.0 (17.1) D3: 22.5 (15.7) **Swollen Joint Count, mean (SD)** D1: 13.4 (9.8) D2: 14.1 (11.4) D3: 12.0 (8.4) **Corticosteroid use, %** D1: 17 D2: 13 D3: 18 **DMARD use, %:** MTX D1: 48 D2: 49 D3: 47 **MTX naïve, %:**	**ACR mean difference/ absolute difference (CI/SD/P Value):** At week 14: ACR 20: D1: 9 D2: 51 D3: 45 *P* < 0.001 (D1 vs. D2 and D3) At week 24: ACR 20: D1: 12 D2: 52 D3: 61 *P* < 0.001 (D1 vs. D2 and D3) ACR 50 and ACR70 at weeks 14 and 24: Shown in figure only **HAQ, mean difference/ absolute difference (CI/SD/P Value):** D1: -0.01 (0.49) D2: 0.33 (0.55) D3: 0.39 (0.50) *P* < 0.001 (D1 vs. D2 and D3) **DAS, mean difference/absolute difference (SD):** At week 14: D1: -0.18 (0.78) D2: -1.38 (1.16) D3: -1.29 (1.16) *P* < 0.001 (D1 vs. D2 and	**Overall attrition/withdrawal, n:** D1: 12 D2: 9 D3: 4 **Withdrawals due to adverse event, n:** D1: 5 D2: 2 D3: 4 **Withdrawals due to lack of efficacy, n:** D1: 2 D2: 1 D3: 0 **Adherent/compliant, n**: NR **Overall adverse events reported , n:** Through Week 24 D1: 67 D2: 99 D3: 95 **Serious adverse events:** SAEs: D1: 7 D2: 3 D3: 4 Prostate cancer, n: D1: NR D2: NR D3: 1 **Respiratory events:** Tuberculosis, n:

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
		D2: 45.7 (10.7) D3: 48.2 (10.9) **Sex, % female** D1: 39 D2: 39 D3: 41 **Race, % white** D1: 97 D2: 97 D3: 97 **Race, % black** NR **Ethnicity, Latino** NR	D1: 33 D2: 34 D3: 27 **Baseline DAS28-CRP score, mean (SD)** D1: 4.3 (1.0) D2: 4.4 (1.1) D3: 4.3 (1.0) **Required treatment for latent TB** D1: 11 D2 & D3: 33	D3) At week 24: D1: -0.12 (0.97) D2: -1.43 (1.34) D3: -1.56 (1.10) *P* < 0.001 (D1 vs. D2 and D3) DAS28-CRP No. EULAR response: At week 14: D1: 27 D2: 96 (*P* < 0.001) D3: 98 (*P* < 0.001) At week 24: D1: 27 D2: 94 (*P* < 0.001) D3: 114 (*P* < 0.001) **SF-36, mean difference/absolute difference (CI/SD/P Value):** D1: 0.63 (7.68) D2: 6.53 (8.88) D3: 7.85 (9.55) *P* < 0.001 (D1 vs. D2 and D3) **Radiographic measures, mean difference/absolute difference:** NR **Quality of life scales, mean difference/absolute difference:** NR **Morning stiffness, mean change (SD):** At week 14: D1: 23.4 (299.9)	Overall: 0 Pneumonia, n: D1: 2 D2: NR D3: NR Upper respiratory infection (n): D1: 7 D2: 17 D3: 13 **Other infections, n:** D1: Cellulits: 1, Urosepsis: 1 D2: Abscess: 1 D3: Sepsis/Cholecystitis: 1 Infusion/injection site reactions , n: D1: 3 D2: 4 D3: 6 **GI:** Nausea or vomiting, n: D1: 5 D2: 4 D3: 6 Headache, n: D1: 8 D2: 7 D3: 8 Dizziness : NR Nasopharyngitis, n: D1: 5 D2: 10 D3: 19

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
				D2: -72.4 (201.3) (*P* < 0.001) D3: -86.3 (238.3), (*P* < 0.001) At week 24: D1: -20.4 (257.7) D2: -67.2(231.1) (*P* < 0.001) D3: -90.1 (234.5), (*P* < 0.001) PASI90, n: At week 14: D1: 0 D2: 22 (*P* < 0.001) D3: 26, (*P* < 0.001) At week 24: D1: 0 D2: 33 (*P* < 0.001) D3: 34, (*P* < 0.001)	Back pain, n: D1: 5 D2: 6 D3: 7 Diarrhea, n: D1: 4 D2: 5 D3: 7 Cough, n: D1: 5 D2: 7 D3: 4 Elevated ALT levels, n: D1: 4 D2: 4 D3: 5 Injection-site erythema D1: 2 D2: 4 D3: 6 Markedly abnormal ALT levels: D1: 4 D2: 43 D3: 0 Markedly abnormal AST levels: D1: 3 D2: 2 D3: 0 Markedly abnormal total bilirubin levels: D1: 2 D2: 4 D3: 2

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
					Antibodies to GOL: D1: NR D2: 5/114 D3: 7/143

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Kristensen et al., 2008[9] **Country and setting** Sweden **Source of funding** NR **Research objective** Present efficacy and tolerability data and study impact of concomitant MTX, patterns of joint distribution, and other predictors for drug survival with TNF blocking agents **Study design** Observational **Overall N** 261 **Duration of study** 12 months **Quality rating** Fair	**Inclusion Criteria** • Diagnosis of PsA • Pts selected for anti-TNF therapy based on high disease activity and/or unacceptable steroid use • Only pts receiving first treatment course of biological therapy **Exclusion Criteria** NR	**Interventions, Dose** D1: concomitant MTX and anti-TNF • MTX: median dose = 15.0 mg/week, interquartile range (IQR) = 10.0-20.0 • ETN: 25 mg twice a wk • IFX: 3mg/kg wks 0,2, 6, and every eighth week, could be increased in steps of 100 mg to a maximum dose of 500 mg at 4-8 wk intervals,avg dose after 6 mos = 5 mg/kg every eighth wk ADA: 40 mg every other wkD2: • ETN: 25 mg twice a wk • IFX: 3 mg/kg wks 0, 2, 6, and every eighth week, could be increased in steps of 100 mg to a maximum dose of 500 mg at 4-8 wk intervals, avg dose after 6 mos = 5 mg/kg every eigth wk • ADA: 40 mg every other wk **Number in group** D1: 161	**Median disease duration, years (IQR)** D1: 7.9 (3.7-15.0) D2: 9.4 (4.2-17.8) *P* = 0.29 **Patients with early RA, three years or less, %:** NR **Treatment resistant, %:** NR **Tender Joint Count, mean (SD)** NR **Swollen Joint Count, mean (SD)** NR **Corticosteroid use, %** NR **DMARD use, %:** # of Previous DMARDs (IQR) D1: 2 (1.0-2.0) D2: 2 1.0-2.0) *P* = 0.20 **MTX naïve, %:** NR **Baseline DAS28 score, median (IQR)** D1: 4.93 calculated for subgroup, n = 125 (3.87-5.71) D2: 4.82 calculated for subgroup, n = 76 (3.83-5.46) *P* = 0.57	**ACR mean difference/ absolute difference:** NR **HAQ, mean difference/ absolute difference:** NR **DAS, mean difference/absolute difference:** NR **SF-36, mean difference/absolute difference:** NR **Radiographic measures, mean difference/absolute difference:** NR **Quality of life scales, mean difference/absolute difference:** NR **EULAR overall response rates, (%):** At month 3 D1: 104 (78) D2: 67 (75) At month 6 D1: 82 (76) D2: 54 (81) At month 12 D1: 74 (69) D2: 27 (67)	**Attrition/withdrawal** Withdrawals due to adverse events , HR (95% CI): D1: 0.24 (0.11-0.52) Sub-analyses ETN vs. IFX • Termination due to adverse events (HR 0.30 95% CI 0.11-0.80, *P* = 0.02) • Withdrawal due to failure (HR 0.55, 95% CI 0.25-1.20) Withdrawals due to lack of efficacy , HR (95% CI): D1: 1.39 (0.61-3.18) • In corresponding abstraction - no high attrition or differential attrition, although rates are unknown **Overall adverse events reported, n:** D1: 17 D2: 12 **Serious adverse events:** Death (n): D1: 1 D2: NR Cardiovascular events, n: D1: 3 D2: 2 Overall: Includes transient ischemic attack, two acute coronary syndromes, and two tachyarrhythmias. **Septicaemia with E-coli bacteria:** D1: 0

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
		D2: 100 Overall: 261 **Mean age, years (SD)** D1: 48.2 D2: 46.0 Overall, IQR range: D1: 38.6 - 53.9 IQR D2: 36.4 - 58.5 IQR; *P* = 0.99 **Sex, % female** D1: 47.8 D2: 55 *P* = 0.07 **Race, % white** NR **Race, % black** NR **Ethnicity, Latino** NR	**Required treatment for latent TB** NR **Regular NSAID use % (n):** D1: 60.9 (98) D2: 48.0 (48 *P* = 0.04 **HAQ, median (IQR)** D1:1.0 (0.63-1.38) D2: 1.0 (0.50-1.50) *P* = 0.67	EULAR good response rates, %: At month 3 D1: 104 (51) D2: 67 (55) At month 6 D1: 82 (60) D2: 54 (59) At month 12 D1: 74 (54) D2: 27 (52) Lundex EULAR Overall, %: At month 3 D1: 74 D2: 68 At month 6 D1: 68 D2: 67 At month 12 D1: 55 D2: 45 Lundex EULAR Good, %: At month 3 D1: 48 D2: 50 At month 6 D1: 53 D2: 48 At month 12 D1: 43 D2: 35	D2: 1 **Anaphylactic infusion reactions (occurred with IFX):** D1: 0 D2: 2 **Malignancies:** Lymphoma or leukemia (n): D1: 1 D2: 1 Overall: Fatal non-Hodgkin's lymphoma (diffuse large B-cell lymphoma); Chronic lymphatic leukemia (CLL), with probable subclincial debut prior to anti TNF treatment **Other infections:** D1: 5 D2: 2 Overall: Designated as 'Infections' - mainly respiratory tract infections **Other:** Fractures, n: D1: 2 D2: 1 Overall: Three peripheral fractures and one cervical spinaql stenosis requiring surgery Other Adverse Events, n: D1: 3 D2: 3 Overall: Includes: severe vertigo, irritable bowel disease, benign stenosis of the

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
					esophagus, concrement in the urinary tract, non-infectious pleuritis, severe dysplaisa of cervix uteri.

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2000 **Country, Setting:** US, single center in Seattle **Funding:** Immunex Corp. **Research Objective:** To study the efficacy and safety of etanercept in pts with psoriatic arthritis and psoriasis **Study Design:** RCT **Overall N:** 60 **Study Duration:** 12 wks	**Inclusion Criteria:** • Age 18 to 70 • Diagnosed with PsA according to: > 3 swollen, tender, or painful joints • Inadequate response to NSAIDs • Hepatic transasminase concentrations no greater than 2x upper limit of normal • Hemoglobin 85 g/L or higher • Platelet count 125,000 per mL or more and serum creatinine 152-4 mmol/L or below • MTX < 25 mg/wk and stable for 4 wks • Corticosteriods if the dose < 10 mg/d of PRE, stable for at least 2 wks and maintained at a constant dose throughout study **Exclusion Criteria:** • Evidence of skin conditions other than psoriasis	**Interventions:** **D1:** Placebo **D2:** ETA (25mg 2x wkly) **N:** **D1:** 30 **D2:** 30 **Mean age, yrs:** **D1:** 43.5 **D2:** 46 **Sex, % female:** **D1:** 40 **D2:** 47 **Race, % white:** **D1:** 83 **D2:** 90	**Mean disease duration, yrs:** **D1:** 9.5 **D2:** 9 **TJC, mean:** NR **SJC, mean:** NR **DMARD use, %:** NR **Corticosteroid use, %:** **D1:** 40 **D2:** 20 **MTX naive, %:** NR **Txt resistant, %:** Overall 100 **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX:** **D1:** 47 **D2:** 47	• PsARC ETA 26 (87%) vs. Placebo 7 (23%) *P* < 0.0001 95% CI, 44-83; ACR50 ETA 15 (50%) vs. Placebo 1 (3%) *P* = 0.0001 95% CI, 28-66; • ACR70 ETA 4 (13%) vs. Placebo 0 (0%) *P* = 0.0403 95% CI, 1-26; • HAQ ETA 0.1 (0,1) vs. Placebo 1.3 (0.9,1.6) *P* < 0.001 • •ACR20 was achieved by 73% ETA treated pts compared with 13% placebo treated pts (*P* < 0.0001) • Median % improvements in tender and swollen joint counts at 12 wks ETA 75% and 72% respectively vs. placebo 5% worsening and 19% improvement; disability according to HAQ significantly more improved in ETA than placebo (83% vs. 3%, *P* < 0.0001) • 26% of ETA vs. 0 of placebo pts achieved 75% improvement in PASI at 12 wks (*P* = 0.0154); similar differences between ETA and placebo also seen at 25% and 50% improvements in PASI scores	**SAEs:** **D1:** 0 **D2:** 3.3 **Infusion or injection reaction:** **D1:** 20 **D2:** 3 **Headache:** **D1:** 13 **D2:** 10 **URTI:** **D1:** 57 **D2:** 57	**Overall Attrition Rate (%):** 6.6% **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2004; Mease et al., 2006 (2nd yr outcomes) **Country, Setting:** US, 17 sites **Funding:** Immunex **Research Objective:** Safety, efficacy, and effect on radiographic progression of ETA in pts with PsA **Study Design:** RCT **Overall N:** 205 **Study Duration:** 24 wks (with 48 wk open-label phase)	**Inclusion Criteria:** • Age 18 70 • Diagnosed with PsA ≥ 3 swollen and 3 tender joimts • Inadequate response to NSAID • At least one of PsA subtypes: distal interphalangeal joint involvement, polyarticular arthritis, arthritis mutilans, asymmetric peripheral arthritis, or ankylosing spondylitis-like arthritis • Stable plaque psoriasis with a qualifying lesion • MTX therapy (stable 2 mo ≤ 25 mg/wk) • Css (stable 4 wks ≤ 10 mg/d of prednisone) **Exclusion Criteria:** • Oral retinoids, topical vitamin A or D analog preparations, and anthralin	**Interventions:** **D1:** placebo **D2:** ETA (25 mg 2x wkly) **N:** **D1:** 104 **D2:** 101 **Mean age, yrs:** **D1:** 47.3 **D2:** 47.6 **Sex, % female:** **D1:** 55 **D2:** 43 **Race, % white:** **D1:** 91 **D2:** 90	**Mean disease duration, yrs:** **D1:** 9.2 **D2:** 9 **TJC, mean:** NR **SJC, mean:** NR **DMARD use, %:** NR **Corticosteroid use, %:** **D1:** 15 **D2:** 19 **MTX naive, %:** NR **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline DAS, mean:** NR **Concomitant MTX use, %:** **D1:** 41 **D2:** 42 **Sharp:** **D1:** 18.3 **D2:** 25.89	• At 12 wks, 59% of ETA pts met ACR20 criteria compared with 15% placebo pts ($P < 0.0001$) • 23% of ETA pts eligible for psoriasis evaluation achieved at least 75% improvement in psoriasis area and severity index, compared with 3% of placebo pts ($P = 0.001$) • 12 mos; the mean annualized rate of change over one yr of txt in modified Sharp score was –0.03 unit, compared with 1.00 unit in the placebo ($P = 0.0001$) • HAQ- improvement from baseline in ETA group 54% vs. 6% of placebo group ($P < 0.0001$) • 72% & 70% of ETA achieved PsARC at 12 and 24 wks, respectively, compared with 31% and 23% of placebo pts	**SAEs:** **D1:** 3.9 **D2:** 4 **Infusion or injection reaction:** **D1:** 9 **D2:** 36 **Headache:** **D1:** 5 **D2:** 8 **URTI:** **D1:** 23 **D2:** 21 **UTI:** **D1:** 6 **D2:** 6	**Overall Attrition Rate (%):** 19.5 **ITT Analysis:** Yes **Quality Rating:** Fair

Evidence Table 4. Key Question 3 (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2005 ADEPT Study **Country, Setting:** Multinational, multi-clinic (50) **Funding:** Abbott Laboratories **Research Objective:** Safety and efficacy of ADA compared with placebo in txt of active psoriatic arthritis **Study Design:** RCT **Overall N:** 313 **Study Duration:** 24 wks	**Inclusion Criteria:** • Age ≥ 18 • Moderate to severe PsA • Active psoriatic skin lesions or a documented history of psoriasis • Inadequate response or intolerance to NSAIDs • MTX ≥ 3 mos with stable dose 4 wks **Exclusion Criteria:** • CYP, tacrolimus, DMARDs, or oral retinoids (4 wks) • Topical txts for psoriasis within 2 wks, other than medicated shampoos or low-potency topical steroids • Anti-TNF • History of TB • Central nervous system demyelinating disease • Listeriosis, or severe infection within 30 ds or oral antibiotics within 14 ds	**Interventions:** **D1:** placebo **D2:** ADA (40mg every other wk) **N:** **D1:** 162 **D2:** 151 **Mean age, yrs:** **D1:** 49.2 **D2:** 48.6 **Sex, % female:** **D1:** 45.1 **D2:** 43.7 **Race, % white:** **D1:** 93.8 **D2:** 97.4	**Mean disease duration, yrs:** **D1:** 9.2 **D2:** 9.8 **TJC, mean:** **D1:** 25.8 **D2:** 23.9 **SJC, mean:** **D1:** 14.3 **D2:** 14.3 **Mean number previous DMARDS:** **D1:** 1.5 **D2:** 1.5 **Corticosteroid use, %:** NR **MTX naive, %:** NR **Txt resistant, %:** NR **Pts with Early RA (≤3 yrs):** NR **Baseline PASI (mean):** **D1:** 8.3 **D2:** 7.4 **Concomitant MTX use, %:** **D1:** 50 **D2:** 51 **Baseline HAQ:** **D1:** 1.0 **D2:** 1.0	• PsARC ADA 60% wk. vs.placebo 23% • ACR50 ADA, 39% vs. placebo, 6% ($P < 0.001$) • ACR70 ADA, 23% vs. placebo, 1% ($P < 0.001$) • The PASI75 ADA 59% vs. placebo 1% ($P < 0.001$) (N:69 per group). • HAQ DI change placebo -0.1 ± 0.4 vs. ADA -0.4 ± 0.5 ($P < 0.001$) • ACR20 ADA 57% vs. placebo 15% (between-group difference 42%, 95% CI, 31-52%; $P < 0.001$). • Mmean change in modified total Sharp was -0.2 for ADA versus placebo ($P < 0.001$) • Erosion scores (mean change ADA 0.0 vs. placebo 0.6) and JSN scores (mean change ADA -0.2 vs. placebo 0.4) ($P < 0.001$ for both) • SF-36: SF-36 PCS; change in baseline to wk 12 for placebo vs ADA; 1.4 vs 9.3 ($P < 0.001$) • Change in baseline to wk 24; 1.4 vs 9.3 ($P < 0.001$) • SF-36 MCS • Change in baseline to wk 12 ; 1.2 vs 1.6 (*P* NS) • Change in baseline to wk 12; 0.6 vs 1.8 (*P* NS)	**Infusion or injection reaction:** **D1:** 3.1 **D2:** 6.6 **Headache:** **D1:** 8.6 **D2:** 6.0 **URTI:** **D1:** 14.8 **D2:** 12.6 **UTI:** NR	**Overall Attrition Rate (%):** 7.6 **ITT Analysis:** Yes **Quality Rating:** Fair.

Appendix H: Quality Criteria

APPENDIX H. Quality Criteria

Assessment of Internal Validity
To assess the internal validity of individual studies, the EPC adopted criteria for assessing the internal validity of individual studies from the U.S. Preventive Services Task Force and the NHS Centre for Reviews and Dissemination. To assess the quality of observational studies, we used criteria outlined by Deeks et al., 2003.[1]

For Controlled Trials:

Assessment of Internal Validity

1. Was the assignment to the treatment groups really random?
    - Adequate approaches to sequence generation:
        - Computer-generated random numbers
        - Random numbers tables
    - Inferior approaches to sequence generation:
        - Use of alteration, case record numbers, birth dates or week days
    - Not reported

2. Was the treatment allocation concealed?
    - Adequate approaches to concealment of randomization:
        - Centralized or pharmacy-controlled randomization
        - Serially-numbered identical containers
        - On-site computer-based system with a randomization sequence that is not readable until allocation
        - Other approaches sequence to clinicians and patients
    - Inferior approaches to concealment of randomization:
        - Use of alteration, case record numbers, birth dates or week days
        - Open random numbers lists
        - Serially numbered envelopes (even sealed opaque envelopes can be subject to manipulation)
    - Not reported

3. Were the groups similar at baseline in terms of prognostic factors?

4. Were the eligibility criteria specified?

5. Were outcome assessors blinded to the treatment allocation?

6. Was the care provider blinded?

7. Was the patient kept unaware of the treatment received?

8. Did the article include an intention-to-treat analysis or provide the data needed to calculate it (i.e., number assigned to each group, number of subjects who finished in each group, and their results)?

9. Did the study maintain comparable groups?

10. Did the article report attrition, crossovers, adherence, and contamination?

11. Is there important differential loss to followup or overall high loss to followup? (Give numbers in each group.)

Assessment of External Validity (Generalizability)

1. How similar is the population to the population to whom the intervention would be applied?
2. How many patients were recruited?
3. What were the exclusion criteria for recruitment? (Give numbers excluded at each step.)
4. What was the funding source and role of funder in the study?
5. Did the control group receive the standard of care?
6. What was the length of followup? (Give numbers at each stage of attrition.)

For Observational Studies:

Assessment of Internal Validity

1. Were both groups selected from the same source population?
2. Did both groups have the same risk of having the outcome of interest at baseline?
3. Were subjects in both groups recruited over the same time period?
4. Was there any obvious selection bias?
5. Were ascertainment methods adequate and equally applied to both groups?
6. Was an attempt made to blind the outcome assessors?
7. Was the time of followup equal in both groups?
8. Was overall attrition high ($\geq$ 20%)?
9. Was differential attrition high ($\geq$ 15%)?
10. Did the statistical analysis consider potential confounders or adjust for different lengths of followup?
11. Was the length of followup adequate to assess the outcome of interest?

1. Deeks JJ, Dinnes J, D'Amico R, Sowden AJ, Sakarovitch C, Song F, et al. Evaluating non-randomised intervention studies. Health Technol Assess. 2003;7(27):iii-x, 1-173.

For Systematic Reviews and Meta-analyses:

1. Is the review based on a focused question of interest?
2. Did the search strategy employ a comprehensive, systematic, literature search?
3. Are eligibility criteria for studies clearly described?
4. Did at least 2 persons independently review studies?
5. Did authors use a standard method of critical appraisal before including studies?
6. Was publication bias assessed?
7. Was heterogeneity assessed and addressed?
8. Did statistical analysis maintain trials as the unit of analysis?

Appendix I. Clinical and Self-Reported Scales and Instruments Commonly Used in Studies of Drug Therapy for Rheumatoid Arthritis and Psoriatic Arthritis

Appendix I.
Clinical and Self-Reported Scales and Instruments Commonly Used in Studies of Drug Therapy for Rheumatoid Arthritis and Psoriatic Arthritis

Introduction

This appendix provides a brief overview of the various scales and self-reported measures that investigators used to assess outcomes in all the studies reviewed in this systematic review. The main outcome categories involve radiologic assessments of joint damage (erosion or narrowing) and various instruments that patients or subjects used to report on functional capacity or quality of life; the latter fall into two groups, one related to general health measures and one related to condition- or disease-specific instruments. General measures used in rheumatoid and psoriatic arthritis studies are described first; then the disease-specific measures used in rheumatoid and psoriatic arthritis studies are described separately.

Radiographic Measures

Radiographic assessment of joint damage in hands (including wrists) or both hands and feet are critical to clinical trials in rheumatoid arthritis. The damage can be both joint space narrowing and erosions, and the underlying construct is sometimes referred to as radiographic progression (i.e., changes, whether positive or negative) as detected by radiography and interpretation. Several approaches exist, but the two commonly used are the Sharp Score (and variants) and the Larsen Score. These and other scoring methods have recently been reviewed by Boini and Guillemin;[1] additional citations or sources are given in the brief descriptions below.

Sharp Score and Sharp/van der Heijde Score

The Sharp Score is a means of evaluating joint damage in joints of the hands, including both erosion and joint space narrowing.[2] Although it has undergone modifications since its introduction, the version proposed in 1985 has become the standard approach. In this method, 17 joint areas in each hand are scored for erosions; 18 joint areas in each hand are scored for joint space narrowing. The score per single joint for erosions ranges from 0 to 5 and for joint space narrowing from 0 to 4. In both cases, a higher score is worse. Erosion scores range from 0 to 170 and joint space narrowing scores range from 0 to 144. Thus, the "total Sharp Score" is the sum of the erosion and joint space narrowing scores, or 0 to 314.

The Sharp/van der Heijde (SHS) method, introduced in 1989, overcame one drawback to the Sharp Score, namely its focus on only hands, given that feet can also be involved early in rheumatoid arthritis. Therefore, the SHS method was developed to take account of erosions and joint space narrowing in both hands and feet.[3-4] As with the Sharp Score, higher scores reflect worse damage. Erosion is assessed in 16 joints in each hand and 6 joints in each foot. Each joint is scored from 0 to 5 with a maximal erosion score of 160 in the hands and 120 in the feet. Joint space narrowing and subluxation are assessed in 15 joints in the hands and 6 joints in the feet. Each joint is scored from 0 to 4 with a maximal score of 120 in the hands and 48 in the feet. The erosion and joint space narrowing scores are combined to give a total SHS score with a maximum of 448 (weighted toward hands because more joints are scored).

Numerous variants on the Sharp or SHS scores have been developed, differing subtly in terms of the numbers of joints measured and other details.[5] Generally, all the Sharp methods are very detailed assessments and the approach, although reliable and sensitive to change, is

considered time-consuming and tedious. For a speedier approach, Larsen and colleagues developed a simpler approach.

Larsen Scale for Grading Radiographs

The Larsen Scale is an overall measure of joint damage, originally devised in the 1970s and updated most recently in the late 1990s.[6-10] It produces both a score for each joint (hands and feet) and an overall score that reflects measurement and extent of joint damage. Scores range from 0 ("normal conditions," i.e., intact bony outlines and normal joint space) to 5 ("mutilating abnormality," i.e., original bony outlines have been destroyed), so higher scores reflect greater damage. Scores can range from 0 to 250.

General Health Measures

Health Assessment Questionnaire

The Health Assessment Questionnaire (HAQ) is a widely used self-report measure of functional capacity; it is a dominant instrument in studies of patients with arthritis (particularly trials of drugs in patients with rheumatoid arthritis), but it is considered a generic (not disease-specific) instrument. Detailed information on its variations, scoring, etc., can be found at www.chcr.brown.edu/pcoc/EHAQDESCRSCORINGHAQ372.PDF (accessed for this purpose 1/18/2007) or www.hqlo.com/content/1/1/20 (accessed for this purpose 1/18/2007) and in the seminal reports by Fries et al.[11] and Ramey et al.[12]

The full, five-dimension HAQ consists of four domains: disability, discomfort and pain, toxicity, and dollar costs, plus death (obtained through other sources). More commonly, "the HAQ" as used in the literature refers to the shorter version encompassing the HAQ Disability

Index (HAQ-DI), the HAQ pain measure, and a global patient outcome measure. The HAQ-DI is sometimes used alone.

The HAQ-DI, with the past week as the time frame, focuses on whether the respondent "is able to…" do the activity and covers eight categories in 20 items: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and common daily activities. The four responses for the HAQ-DI questions are graded as follows: without any difficulty = 0; with some difficulty = 1; with much difficulty = 2; and unable to do = 3. The highest score for any component question in a category determines the category score. The HAQ-DI also asks about the use of aids and devices to help with various usual activities. Two composite scores can be calculated, one with and one without the aids/devices element; both range from 0 to 3.

The HAQ pain domain is measured on a doubly-anchored horizontal visual analog scale (VAS) of 15 cm in length; one end is labeled "no pain" (score of 0) and the other is labeled "very severe pain" (score of 100). Patients mark a spot on the VAS, and scores are calculated as the length from "no pain" in centimeters (cm) multiplied by 0.2 to yield a value that can range between 0 and 3.

With respect to interpretation, HAQ-DI scores of 0 to 1 are generally considered to represent mild to moderate disability, 1 to 2 moderate to severe disability, and 2 to 3 severe to very severe disability.

The HAQ global health status scale measures quality of life (essentially, as how the patient is feeling) with a 15 cm doubly-anchored horizontal VAS scored from 0 (very well) to 100 (very poor).

Medical Outcomes Study Short Form 36 Health Survey

The Medical Outcomes Study Short Form 36 Health Survey (SF-36) is an internationally known generic health survey instrument. Information can be found at www.sf-36.org/tools/sf36.shtml (accessed for this purpose 2/18/2007) and in a large number of articles documenting its psychometric properties.[13-19] It comprises 36 items in eight independent domains tapping functioning and well-being: physical functioning, role-physical, bodily pain, and general health in one grouping (physical health) and vitality, role-emotional, social functioning, and mental health in another grouping (mental health). The SF-36 provides a separate scale score for each domain (yielding a profile of health) and two summary scores, one for physical health and one for mental health. Each scale is scored from 0 to 100 where higher scores indicate better health and well-being.

A "version 2" of the SF-36 was introduced in the late 1990s to correct some drawbacks in formatting, wording, and other issues and to update the norm-based scoring with 1998 data. It can be fielded in two versions varying by recall period: 4-week recall (the usual approach) and 1-week recall (acute). More recently, it has been tested and used for computer adaptive testing according to item response theory principles.

EuroQol EQ-5D Quality of Life Questionnaire

A third generic quality-of-life instrument is the EuroQol EQ-5D Quality of Life Questionnaire, typically known just as the EQ-5D. More information can be found at http://www.euroqol.org/ (accessed for this purpose 1/18/2007) and in key descriptive articles,[20] one of which is about patients with rheumatoid arthritis.[21]

The EQ-5D covers health status in five domains (three questions each): mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. It is intended for self-response but

can be used in other administration modes. Each item can take one of three response levels – no problems, some moderate problems, extreme problems – identified as level 1, 2, or 3, respectively. This yields a profile of one level for each of the five domains; this is essentially a five-digit number, and no arithmetic properties attach to these values. Users can convert health states in the five-dimensional descriptive system into a weighted health state index by applying scores from EQ-5D "value sets" elicited from general population samples to the profile pattern (e.g., 1, 2, 3, 3, 1).

The EQ-5D also has a global health VAS scale (20 cm) scored from 0 to 100.

Rheumatoid Arthritis Measures

American College of Rheumatology 20/50/70

The American College of Rheumatology (ACR) criteria are concerned with *improvement* in counts of tender and swollen joints and several domains of health.[22] A principal aim of these criteria is use in studies (particularly trials) of drugs for rheumatoid arthritis. More information can be found at www.rheumatology.org/publications/response/205070.asp and www.hopkins-arthritis.som.jhmi.edu/edu/acr/acr.html#remis_rheum (both accessed for this purpose 1/18/2007). Originally these latter involved patient assessment, physician assessment, erythrocyte sedimentation rate, pain scale, and functional questionnaire.

Today, based on work done in the mid 1990s,[23] values for clinical trial patients are defined as improvement in both tender and swollen joint counts and in three of the following: patient's assessment of pain; patient's global assessment of disease activity, patient's assessment of physical function (sometimes referred to as physical disability), the physician's global assessment of disease activity, and acute phase reactant (C-reactive protein, or CRP). The 20, 50, or 70 designations (sometimes called the ACR Success Criteria) refer to improvements in

percentage terms to 20 percent, 50 percent, or 70 percent in the relevant dimensions. A physician's global assessment of 70 percent improvement is considered remission.

Thus, patients are said to meet ACR 20 criteria when they have at least 20 percent reductions in tender and swollen joint counts and in at least three of the domains. ACR 50 and ACR 70 criteria are defined in a manner similar to that for ACR 20, but with improvement of at least 50 percent and 70 percent in the individual measures, respectively. The table illustrates, in a study context, how a patient might be said to have an ACR 50 response.

Outcomes Measured	Baseline	Endpoint
Tender joints count *	12	6
Swollen joints count *	8	3
Patient's pain score*	60	20
Patient's physical function (disability) score	80	60
Physician's global activity score*	50	20
C-reactive protein*	3.6	1.4

* At least 50 percent improvement between baseline and endpoint measurements.

Ritchie Articular Index

This is a long-standing approach to doing a graded assessment of the tenderness of 26 joint regions, based on summation of joint responses after applying firm digital pressure.[24] Four grades can be used: 0, patient reported no tenderness; +1, patient complained of pain; +2, patient complained of pain and winced; and +3, patient complained of pain, winced, and withdrew. Thus, the index ranges from 0 to 3 for individual measures and 0 to 78 overall, with higher scores being worse tenderness.

Certain joints are treated as a single unit, such as the metacarpal-phalangeal and proximal interphalangeal joints of each hand and the metatarsal-phalangeal joints of each foot. For example, the maximum score for the five metacarpal-phalangeal joints of the right hand would be 3, not 15. No weights are used for different types of joints (e.g., by size), because the issue is one of measuring changes (improvements) in tenderness; this is especially relevant for rheumatoid arthritis.

Disease Activity Score

The Disease Activity Score (DAS) is an index of disease activity first developed in the mid 1980s. The history of its development and current definitions, scoring systems, and other details can be found at http://www.das-score.nl/www.das-score.nl/ (accessed for this purpose 1/19/2007) and in recent articles.[4,25] The DAS originally included the Ritchie Articular Index (see above), the 44 swollen joint count, the erythrocyte sedimentation rate, and a general health assessment on a VAS. A cut-off level of the DAS of 1.6 is considered to be equivalent with being in remission.

More recently, an index of RA disease activity using only 28 joints – the DAS 28 – has been developed, focusing on joint counts for both tenderness (TJC) and swelling (SJC). It also uses either the patient's or a physician's global assessment (PGA) of disease activity (on a 100 mm VAS) and the erythrocyte sedimentation rate (ESR) or C-reactive protein. The formula for calculating a DAS 28 score is as follows: $= (0.56 \times TJC^{1/2}) + (0.28 \times SJC^{1/2}) + (0.7 \times \ln [ESR]) + (0.014 \times PGA [\text{in mm}])$. Numerous formulas to calculate a variety of DAS and DAS 28 scores exist (see the website above), such as when a global patient assessment of health is unavailable.

The DAS 28 yields a score on a scale ranging from 0 to 10. A DAS 28 of 2.6 is considered to correspond to remission; a DAS 28 of 3.2 is a threshold for low disease activity; and a DAS 28 of more than 5.1 is considered high disease activity

EULAR Response Criteria

The European League Against Rheumatism (EULAR) response criteria classify patients as good, moderate, or nonresponders based on both change in disease activity and current disease activity, using either the DAS or the DAS28 (see description above).[26] For example, to be classified as a good responder a patient must have relevant change in DAS (≥1.2) and low

current disease activity (≤2.4), while a nonresponder must have ≤0.6 change in DAS and high disease activity (>3.7).[27]

The EULAR criteria have been validated in multiple clinical trials, and confirmed in an analysis of nine clinical trials that concluded a high level of agreement and equal validity between ACR and EULAR improvement classifications.[28] Good and moderate responders showed significantly more improvement in functional capacity and significantly less progression of joint damage than patients classified as nonresponders.[28]

Psoriatic Arthritis Measures

Psoriatic Arthritis Response Criteria

The psoriatic arthritis response criteria (PsARC) was initially designed for use in a clinical trial that compared sulphasalazine to placebo in the setting of the Veterans Administration.[29] It has since been used as the primary or secondary outcome in all the studies that examined biologics versus placebo in the treatment of PsA. The PsARC includes improvement in at least two of the following, one of which had to be a joint count, and no worsening of any measure: tender or swollen joint count improvement of at least 30%, patient global improvement by one point on a five-point Likert scale, or physician global improvement on the same scale.[29]

American College of Rheumatology 20

The ACR 20 (American College of Rheumatology 20 percent response) is the other outcome that is used as the primary outcome in clinical trials of biologics. The measurement is similar to that of the ACR 20 used for rheumatoid arthritis with modifications made that increased the number of joints tested from 68 tender and 66 swollen to 76 and 78, respectively, with the addition of distal interphalangeal joints of the feet and carpometacarpal joints of the hands.[29] The

outcomes from the ACR 20 are generally poorer when compared to the PsARC due to the variation in items measured; this is due in part to the need to see an improvement in tender *and* swollen joints in the ACR 20 versus an improvement in tender *or* swollen joint counts.

The Psoriasis Area and Severity Index

The Psoriasis Area and Severity Index (PASI) was developed to measure the effect of treatments in clinical trials of psoriasis and is utilized to capture the psoriasis component found in psoriatic arthritis. The scale was originally published in 1978 in a trial of 27 patients suffering from severe chronic generalized psoriasis that were treated with Ro 10-9359, a retinoic acid derivative.[30] The PASI is a composite index of disease severity incorporating measures of scaling, erythema, and induration, and it is weighted by severity and affected body surface area. A PASI >12 defines severe, PASI 7-12 moderate, and PASI <7 mild psoriasis.

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