

## **Appendix B: Clinical Literature Search Procedure**

The literature search identified infliximab and comparator trials simultaneously, as per the NICE technology appraisal of etanercept and efalizumab. The data from this search informed the infliximab efficacy review and the indirect comparison analysis.

Medline and Embase formed the foundation of the search. These databases were combined and de-duplicated and paper selection was carried out on this combined database. The Cochrane library was also searched, but the retrieved records from this database were not systematically excluded; rather they were manually cross-checked against the results of the Medline and Embase search to ensure that no RCTs had been missed.

The figure on page 17 of the submission was intended to show how papers relating to infliximab trials only were excluded, as required out in the STA procedure manual. However since the main literature search was carried out using combined literature databases for three drugs simultaneously this figure had to be derived by hand calculation. The following should be noted about this figure:

- a) The numbers of papers written against each database include comparator medications
- b) All numbers except those of papers finally selected include duplicates

A detailed breakdown of the paper selection procedure is set out below together with a list of excluded and included papers at each step.

### ***Breakdown of Medline/Embase Search Strategy***

Total Medline Records: 334

Total Embase Records: 936

Total Medline/Embase Duplicates identified electronically: 339

Medline/Embase Combined: 1112

### ***Further Duplicates identified Manually (n=24)***

Anonymous (2006). "Efalizumab. Plaque psoriasis: Too many unknowns." *Prescribe International* 15(81): 8-11.

Bhosle, M. J., S. R. Feldman, et al. (2006). "Medication adherence and health care costs associated with biologics in Medicaid-enrolled patients with psoriasis." *Journal of Dermatological Treatment* 17(5): 294-301.

Carlin, C. S., S. R. Feldman, et al. (2004). "A 50% reduction in the Psoriasis Area and Severity Index (PASI 50) is a clinically significant endpoint in the assessment of psoriasis.[see comment]." *Journal of the American Academy of Dermatology* 50(6): 859-66.

Doggrell, S. A. (2004). "Efalizumab for psoriasis?" *Expert Opinion on Investigational Drugs* 13(5): 551-4.

Dubertret, L., W. Sterry, et al. (2006). "Clinical experience acquired with the efalizumab (Raptiva) (CLEAR) trial in patients with moderate-to-severe plaque psoriasis: results from a phase III international randomized, placebo-controlled trial." *British Journal of Dermatology* 155(1): 170-81.

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Gordon, K. B., A. B. Gottlieb, et al. (2006). "Clinical response in psoriasis patients discontinued from and then reinitiated on etanercept therapy.[erratum appears in J Dermatolog Treat. 2006;17(3):192]." *Journal of Dermatological Treatment* 17(1): 9-17.

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- Leonardi, C. L., J. L. Powers, et al. (2003). "Etanercept as monotherapy in patients with psoriasis.[see comment]." New England Journal of Medicine **349**(21): 2014-22.
- Mease, P. J., B. S. Goffe, et al. (2000). "Etanercept in the treatment of psoriatic arthritis and psoriasis: a randomised trial.[see comment]." Lancet **356**(9227): 385-90.
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## **Excluded Non-English Papers (n=141)**

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- Anonymous (2004). "Rheumatoid arthritis: Prevention of joint disorders with infliximab. [German]." *Deutsche Apotheker Zeitung* **144**(31): 35.
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- Anonymous (2006). "Current side-effects of drugs: Isotretinoin - A drug for acne with risk; hepatosplenic T-cell lymphoma under infliximab therapy. [German]." *Tagliche Praxis* **47**(4): 843-844.
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- Bernhard, J. (2002). "Seronegative spondyloarthropathies. [German]." *Therapeutische Umschau* **59**(10): 529-534.
- Bianchi, L., A. Giunta, et al. (2006). "Efficacy and safety of long-term infliximab therapy in moderate to severe psoriasis and psoriatic arthritis." *Giornale Italiano di Dermatologia e Venereologia* **141**(1): 73-78.
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## Included Journal Articles

### **Infliximab (n=4)**

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### **Etanercept (n=4)**

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## **Efalizumab (n=4)**

Dubertret, L., W. Sterry, et al. (2006). "Clinical experience acquired with the efalizumab (Raptiva) (CLEAR) trial in patients with moderate-to-severe plaque psoriasis: Results from a phase III international randomized, placebo-controlled trial." *British Journal of Dermatology* 155(1): 170-181.

**NOTE TO REVIEWER: The indirect comparison analysis in Schering-Plough submission section 5.6 used data from the above efalizumab RCT.**

**The analysis updated a previous analysis, at which time the Dubertret 2006 RCT was unpublished and referred to by its conference abstract which is as follows:**

Papp KA, Langley RGB, Shear NH, Sterry W, Kwon P, Dubertret L (2005a) Efficacy and safety of efalizumab therapy in high-need psoriasis patients. Presented at 63rd annual meeting of the American Academy of Dermatology, February 18-22, 2005, New Orleans, LA

**At the time of submission, due to an oversight the submission's reference to Papp (2005a) was not corrected to its published equivalent nor was the correct, published reference listed in the Appendix.**

Gordon, K. B., K. A. Papp, et al. (2003). "Efalizumab for Patients with Moderate to Severe Plaque Psoriasis: A Randomized Controlled Trial." *Jama* 290(23): 3073-3080.

Lebwohl, M., S. K. Tyring, et al. (2003). "A novel targeted T-cell modulator, efalizumab, for plaque psoriasis." *New England Journal of Medicine* 349(21): 2004-13.

Leonardi, C. L., K. A. Papp, et al. (2005). "Extended efalizumab therapy improves chronic plaque psoriasis: results from a randomized phase III trial." *Journal of the American Academy of Dermatology* 52(3 Pt 1): 425-33.

## **Excluded Journal Articles**

### **Not Adult Plaque Psoriasis (n=266)**

(2002). "Efalizumab. Anti-CD11a monoclonal antibody--Genentech/Xoma, HU 1124, hu1124, xanelim." *Drugs in R & D* 3(1): 40-3.

(2003). "Etanercept: new preparation. Useful after methotrexate failure in inflammatory rheumatism." *Prescribe International* 12(66): 127-32.

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