

Template	Title	Development Safety Update Reporting for IMP Clinical Trials				
	Scope	Template DSUR form including additional guidance				
	Version	2.0	Date	120209	WI ID	CTT55

STANDARD CARE ARM		
	Relationship 1=not related to study drug 2=related to study drug	Grade 1=mild 2=moderate
Toothache	1	2
Diarrhoea	1	2
Cold and cough	1	1
'cold' sores	1	1
Runny nose	1	1
WITHDRAWAL ARM		
Ankle swelling	1	1
Nausea	1	1
Fatigue	1	1
Sore throat	1	1
Tooth abscess	1	2
Back pain	1	1
Back pain	1	1
Diarrhoea	2	1

3.

2. References

1. Chimenti M, Esposito M, Giunta A, Graceffa D, Babino G, Teoli M, et al. Remission of psoriatic arthritis after etanercept discontinuation: analysis of patients clinical characteristics leading to disease relapse. *Int J Immunopath Pharmacol* 2013;26(3):833-8.
2. Araujo E, Finzel S, Schreiber D, Kleyer A, Englebrecht M, Schett G. High incidence of flare after discontinuation of disease modifying anti-rheumatic drugs in patients with psoriatic arthritis. *AnnRheumDis*. 2013;72(Suppl 3):679.