

Table 1b. References Endorsed Core Domains (For Systemic Rheumatologic Health Conditions)

Note: the clinical conditions included in this table are placed here as a way of separating the conditions into two tables and does not imply a formal definition of “systemic rheumatologic health conditions”

CTD-ILD = connective tissue disease-interstitial lung disease; HCU= Health care utilization; LVV=Large vessel vasculitis; SLE = Systemic Lupus Erythematosus;

- I. Osteoporosis: core set depends on focus of trial, ² core domains for randomized trials where prevention of rapid bone loss is the primary aim, core domains for randomized clinical trials of therapies for treating high risk patients for osteoporotic fractures
- II. Bone Mineral Density measured at 2 sites: hip and spine
- III. If impact of symptoms is specified, these would fall under Impact
- IV. Mandatory in specific circumstances: these domains should be measured in trials targeting either or all these symptoms.
- V. Organ systems named to be mandatory in specific circumstances: mucocutaneous, eye, central nervous system, vascular, musculoskeletal, gastrointestinal.
- VI. Reporting of adverse events (including death) is mandatory in trials

References

1. Wolfe F, Lassere M, van der Heijde D, et al: Preliminary core set of domains and reporting requirements for longitudinal observational studies in rheumatology. *J Rheumatol* 1999; 26:484–489
2. Boers M, Kirwan, JR, Wells G, Beaton D, Gossec L, d’Agostino MA, et al. Developing Core Outcome Measurement Sets for Clinical Trials: OMERACT Filter 2.0. *J Clin Epidemiol* 2014; 67: 745-753
3. Boers M, Beaton D, Shea B, Maxwell LJ, Bartlett S, Bingham III C, et al. OMERACT Filter 2.1: elaboration of the conceptual framework for outcome measurement in health intervention studies. *J Rheumatol* 2019. 46(8):1021–1027
4. Smolen JS, Strand V, Cardiel M, Edworthy S, Furst D, Gladman D, et al. Randomized Clinical Trials and Longitudinal Observational Studies in Systemic Lupus Erythematosus: Consensus on a Preliminary Core Set of Outcome Domains. *J Rheumatol* 1999;26:504–7
5. Merkel 2011
Merkel PA, Aydin SZ, Boers M, Direskeneli H, Herlyn K, Seo P, et al. The OMERACT Core Set of Outcome Measures for Use in Clinical Trials of ANCA-Associated Vasculitis. *J Rheumatol* 2011;38:1480-1486
6. Sreih AG, Alibaz-Oner F, Kermani TA, Aydin SZ, Cronholm PF, Davis T, et al. Development of a Core Set of Outcome Measures for Large-vessel Vasculitis: Report from OMERACT 2016. *The Journal of Rheumatology* Dec 2017, 44 (12) 1933-1937; DOI: 10.3899/jrheum.161467
7. Mease P, Arnold LM, Choy EH, Clauw DJ, Crofford LJ, Glass JM, et al. Fibromyalgia Syndrome Module at OMERACT 9: Domain Construct. *J Rheumatol* 2009;36:2318–29
8. Sambrook PN, Cummings SR, Eisman JA, Genant HK, Eastell R, Reginster JY, et al. Guidelines of Osteoporosis Trials. *J Rheumatol* 1997; 24:1234-1236
9. Khanna D, Mitto S, Aggarwal R, Proudman SM, Dalbeth N, Matteson E, et al. Connective Tissue Disease-associated Interstitial Lung Diseases—Report from OMERACT CTD-ILD Working Group. *J Rheumatol* 2015; 42: 2168–2171
10. Regardt M, Mecoli C, Park JK, de Groot I, Sarver C, Needham M, et al. OMERACT 2018 Modified Patient-Reported Outcome Domain Core Set in the Life Impact Area for Adult Idiopathic Inflammatory Myopathies. *J Rheumatol* 2019;46:1351–4; doi:10.3899/jrheum.181065
11. Hatemi G, Meara A, Özgüler Y, Direskeneli H, Mahr A, Shea B, et al. Outcome Measures in Rheumatology Behçet's Syndrome Working Group. Core Set of Domains for Outcome Measures in Behçet's Syndrome. *Arthritis Care Res (Hoboken)*. 2022 Apr;74(4):691-699. doi: 10.1002/acr.24511.