**Table S1: Supplementary Appendix of Included Publications in:**

***Patient-reported functional health and well-being outcomes with drug therapy:***

***A systematic review of randomized trials using the SF-36 Health Survey***

A key for interpretation of symbols and abbreviations is provided at the bottom of the document before the references. *Individual trial level data are sorted by therapeutic area, beginning with the most studied clinical areas and most studied medical conditions followed by alphabetical order of medication. References (S1-S184) are at the end of the document and are numbered and listed in alphabetical order by the first author’s surname.*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ref # | Author | Year | Condition | Medication | Sample Size | Clinical Endpoint | End point Cat. | Jadad score | Outcome (Clinical/  SF-36) | Tool Used (SF36 or SF12) | SF-36 PCS /MCS Reported | SF-36 Profile Reported |
| RHEUMATOLOGY | | | | | | | | | | | | |
| S80 | **Kremer** | **2003** | **rheumatoid arthritis** | **abatacept** | **339** | **ACR20** | **H** | **4** | **I/I** | **SF-36E** | **■** | **■** |
| S142 | **Russell AS** | **2007** | **rheumatoid arthritis** | **abatacept** | **652** | **ACR20** | **H** | **4** | **I/I** | **SF-36E** | **■** | **■** |
| S176 | **Westhovens R** | **2006** | **rheumatoid arthritis** | **abatacept** | **391** | **ACR20** | **H** | **2** | **I/I** | **SF-36** | **■** | **■** |
| S182 | **Zhao SZ** | **2000** | **rheumatoid arthritis** | **celecoxib** | **1149** | **Health Assessment Questionnaire Disability Index** | **S** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S155 | **Strand V** | **2011** | **rheumatoid arthritis** | **certolizumab** | **619** | **ACR20** | **H** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S156 | **Strand V** | **2009** | **rheumatoid arthritis** | **certolizumab** | **982** | **ACR20** | **H** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S97 | **Mathias SD** | **2000** | **rheumatoid arthritis** | **etanercept** | **234** | **ACR20, ACR50** | **H** | **2** | **I/I** | **SF-36E** | **■** | **NR** |
| S79 | **Kremer** | **2002** | **rheumatoid arthritis** | **leflunomide** | **263** | **ACR20** | **H** | **4** | **I/I** | **SF-36** | **■** | **NR** |
| S157 | **Strand V** | **1999** | **rheumatoid arthritis** | **leflunomide** | **438** | **ACR20, ACR50** | **H** | **3** | **I/I** | **SF-36** | **□** | **■** |
| S105 | **Mease PJ** | **2009** | **rheumatoid arthritis** | **milnacipran** | **888** | **composite endpoint pain: ≥30% improvement, as recorded by daily morning-recall pain score and patient global impression of change score** | **S** | **3** | **I/I** | **SF-36CE** | **NR** | **■** |
| S164 | **Taylor** | **2011** | **rheumatoid arthritis** | **ofatumumab** | **265** | **ACR20** | **H** | **3** | **I/I** | **SF-36** | **■** | **NR** |
| S73 | **Keystone E** | **2008** | **rheumatoid arthritis** | **rituximab** | **520** | **ACR20** | **H** | **2** | **I/I** | **SF-36** | **■** | **■** |
| S104 | **Mease PJ** | **2008** | **rheumatoid arthritis** | **rituximab** | **367** | **ACR20** | **H** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S135 | **Rigby** | **2011** | **rheumatoid arthritis** | **rituximab** | **748** | **change in general-modified sharp score (radiographic measure)** | **O** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S22 | **Coombs** | **2010** | **rheumatoid arthritis** | **tofacitinib** | **264** | **ACR20** | **H** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S7 | **Arnold LM** | **2004** | **fibromyalgia** | **duloxetine** | **207** | **Fibromyalgia Impact Questionnaire total score and FIQ pain score** | **S** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S6 | **Arnold LM** | **2010** | **fibromyalgia** | **duloxetine** | **530** | **patient's global impression of improvement** | **S** | **5** | **I/I** | **SF-36** | **■** | **■** |
| S16 | **Chappell** | **2008** | **fibromyalgia** | **duloxetine** | **330** | **brief pain inventory average pain severity score** | **S** | **3** | **N/I** | **SF-36** | **■** | **■** |
| S4 | **Arnold LM** | **2010** | **fibromyalgia** | **esreboxetine** | **268** | **co-primary endpoints: 11 point likert scale for pain, patient global impression of pain** | **S** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S5 | **Arnold LM** | **2010** | **fibromyalgia** | **milnacipran** | **1025** | **composite > 30% improvement in VAS pain and rating of "very much" or "much" improved on patient global impression of change** | **S** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S11 | **Branco** | **2010** | **fibromyalgia** | **milnacipran** | **884** | **composite > 30% improvement in VAS pain and rating of "very much" or "much" improved on fibromyalgia impact questionnaire patient global impression of change** | **S** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S20 | **Clauw DJ** | **2008** | **fibromyalgia** | **milnacipran** | **1207** | **≥30% improvement, as recorded by daily morning-recall pain score** | **S** | **5** | **I/I** | **SF-36** | **■** | **NR** |
| S8 | **Bennett RM** | **2003** | **fibromyalgia** | **tramadol and acetaminophen combination therapy** | **315** | **≥30% reduction in brief pain inventory score** | **S** | **5** | **I/I** | **SF-36** | **■** | **■** |
| S141 | **Russel** | **2011** | **fibromyalgia** | **sodium oxybate** | **548** | **> 30% reduction in pain VAS** | **S** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S131 | **Pope JE** | **2004** | **osteoarthritis** | **diclofenac** | **51** | **patient global assessment VAS** | **S** | **2** | **N/N** | **SF-36** | **□** | **NR** |
| S151 | **Snijders** | **2011** | **osteoarthritis** | **doxycycline** | **232** | **proportion of patients achieving clinical response OMERACT-OARSI criteria (WOMAC)** | **S** | **5** | **N/N** | **SF-36** | **□** | **NR** |
| S181 | **Zhao SZ** | **1999** | **osteoarthritis** | **oxaprozin** | **463** | **knee pain on weight bearing and motion patient and physician global assessment of OA VAS pain, time to walk 50 feet** | **S** | **2** | **I/I** | **SF-36** | **■** | **■** |
| S76 | **Kivitz** | **2006** | **osteoarthritis** | **oxymorphone extended release** | **370** | **VAS for arthritis pain intensity** | **S** | **5** | **I/I** | **SF-36** | **■** | **NR** |
| S32 | **Ehrich EW** | **2001** | **osteoarthritis** | **rofecoxib** | **672** | **walking on flat surface scored from WOMAC and clinical investigator global assessment** | **S** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S169 | **Vorsanger** | **2007** | **osteoarthritis** | **tramadol** | **317** | **WOMAC** | **S** | **5** | **I/N** | **SF-36** | **□** | **NR** |
| S34 | **Emkey** | **2004** | **osteoarthritis** | **tramadol / acetaminophen** | **307** | **VAS for pain** | **S** | **3** | **I/I** | **SF-36** | **□** | **■** |
| S84 | **Lambert RG** | **2007** | **osteoarthritis** | **triamcinolone hexacetonide** | **52** | **WOMAC: pain score improvement of 20%** | **S** | **5** | **I/I** | **SF-36** | **■** | **■** |
| S102 | **Mease PJ** | **2011** | **psoriatic arthritis** | **abatacept** | **110** | **ACR20** | **H** | **4** | **I/I** | **SF-36** | **■** | **NR** |
| S53 | **Gladman DD** | **2007** | **psoriatic arthritis** | **adalimumab** | **315** | **ACR20** | **H** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S103 | **Mease PJ** | **2010** | **psoriatic arthritis** | **etanercept** | **205** | **ACR20** | **H** | **3** | **I/I** | **SF-36** | **■** | **NR** |
| S72 | **Kavanaugh A** | **2006** | **psoriatic arthritis** | **infliximab** | **200** | **ACR20** | **H** | **5** | **I/I** | **SF-36** | **■** | **■** |
| S114 | **Nash** | **2006** | **psoriasis and psoriatic arthritis** | **leflunomide** | **186** | **Psoriasis Area Severity Index and Psoriasis Arthritis Response Criteria** | **O** | **5** | **I/I** | **SF-36** | **□** | **■** |
| S27 | **Davis JC** | **2007** | **ankylosing spondilitis** | **adalimumab** | **315** | **Assessment of Ankylosing Spondylitis (ASAS) international working group criteria 20% response** | **O** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S66 | **Inman** | **2008** | **ankylosing spondilitis** | **golimumab** | **356** | **ASAS 20% improvement** | **O** | **4** | **I/I** | **SF-36** | **■** | **NR** |
| S168 | **Van der Heijde D** | **2005** | **ankylosing spondilitis** | **infliximab** | **279** | **ASAS 20% improvement** | **O** | **4** | **I/I** | **SF-36** | **■** | **NR** |
| S123 | **Olson LG** | **2003** | **chronic fatigue syndrome** | **dexamphetamine** | **10** | **Fatigue Severity Scale and Epworth Sleepiness Scale** | **S** | **4** | **I/N** | **SF-36** | **□** | **□** |
| S127 | **Peterson PK** | **1998** | **chronic fatigue syndrome** | **fludrocortisone acetate** | **25** | **Symptom Severity Scale** | **S** | **5** | **N/N** | **SF-36C** | **NR** | **□** |
| S9 | **Blockmans** | **2003** | **chronic fatigue syndrome** | **hydrocortisone / fludrocortisone** | **100** | **VAS for fatigue** | **S** | **4** | **N/N** | **SF-36** | **□** | **NR** |
| S112 | **Munteau** | **2011** | **osteoporosis** | **hyaluron** | **151** | **foot pain domain of Foot Health Status Questionnaire** | **S** | **3** | **N/N** | **SF-36 C** | **NR** | **■** |
| S95 | **Mariette** | **2004** | **Sjogren's syndrome** | **infliximab** | **103** | **30% improvement between wk 0-10 on 2 of 3 VAS joint pain, fatigue, mucous membrane dryness** | **S** | **5** | **N/N** | **SF-36** | **□** | **NR** |
| S106 | **Merill** | **2010** | **systemic** lupus erythematosus | **abatacept** | **118** | **proportion of patients with new flare during steroid taper** | **O** | **5** | **N/I** | **SF-36** | **■** | **NR** |
| S154 | **Strand V** | **2003** | **systemic** lupus erythematosus | **abetimus sodium** | **230** | **renal flare (24hr proteinuria or >20% or 0.3mg/dl creatinine increase or new onset hematuria + proteinuria)** | **O** | **3** | **I/I** | **SF-36** | **□** | **■** |
| S172 | **Wallace** | **2009** | **systemic** lupus erythematosus | **belimumab** | **476** | **% change in SLENDA-SLEDAL score at 24 weeks and time to first SLE flair** | **O** | **3** | **N/I** | **SF-36** | **■** | **NR** |
| NEUROLOGY | | | | | | | | | | | | |
| S158 | **Svendsen** | **2004** | **multiple sclerosis and central pain** | **dronabinol** | **24** | **median spontaneous pain intensity (last week of treatment)** | **S** | **4** | **I/I** | **SF-36C** | **NR** | **■** |
| S120 | **Nortvedt** | **1999** | **multiple sclerosis** | **interferon alfa-2A** | **97** | **MRI evidence of disease activity** | **O** | **2** | **I/N** | **SF-36C** | **NR** | **□** |
| S139 | **Rudick** | **2007** | **multiple sclerosis** | **natalizumab** | **942** | **rate of clinical relapse @ 1 year (new symptoms on neurological exam), cumulative probability of disability progression** | **O** | **5** | **I/I** | **SF-36** | **■** | **■** |
| S139 | **Rudick** | **2007** | **multiple sclerosis** | **natalizumab** | **1171** | **rate of clinical relapse @ 1 year (new symptoms on neurological exam), cumulative probability of disability progression** | **O** | **5** | **I/I** | **SF-36** | **■** | **■** |
| S183 | **Ziegler** | **2009** | **diabetic peripheral neuropathy** | **actovegin** | **567** | **total symptom score and vibration perception threshold** | **S** | **4** | **I/I** | **SF-36** | **■** | **NR** |
| S107 | **Merkies** | **2009** | **chronic inflammatory demyelenating polyradiculo-neuropathy** | **intravenous immunoglobulin** | **117** | **% maintaining improvement of >1 in inflammatory neuropathy cause and treatment disability score** | **S** | **2** | **I/I** | **SF-36** | **■** | **■** |
| S175 | **Watson** | **2003** | **neuropathy (diabetic)** | **oxycodone-CR** | **36** | **change in pain intensity score** | **S** | **5** | **I/I** | **SF-36** | **■** | **■** |
| S12 | **Brandes** | **2006** | **migraine** | **topiramate** | **483** | **change in migraine frequency** | **S** | **4** | **I/I** | **SF-36C** | **NR** | **■** |
| S24 | **Dahlof** | **2007** | **migraine** | **topiramate** | **756** | **migraine specific questionnaire (functional impairment measure)** | **S** | **3** | **I/I** | **SF-36** | **□** | **■** |
| S148 | **Silberstein** | **2006** | **migraine** | **topiramate** | **469** | **mean monthly migraine frequency** | **S** | **5** | **I/N** | **SF-36 C** | **NR** | **□** |
| S45 | **Fernandez-Rhodes** | **2011** | **bulbar muscular atrophy** | **dutasteride** | **57** | **quantitative module assessment** | **O** | **4** | **N/I-W** | **SF-36** | **■/~** | **NR** |
| S88 | **Linde** | **2011** | **cervicogenic headache** | **onabotulinum toxin A** | **28** | **days with moderate to severe headache diary** | **S** | **5** | **N/N** | **SF-36C** | **NR** | **□** |
| S28 | **Dodel** | **2010** | **multi-system atrophy parkinson type** | **minocycline** | **63** | **change in unified multiple system atrophy rating scale** | **H** | **4** | **N/N** | **SF-12** | **□** | **NR** |
| S143 | **Sanders** | **2008** | **myasthenia gravis** | **mycophenolate mofetil** | **176** | **minimal manifestations or pharmacologic remission with reduction of corticosteroid dose** | **O** | **5** | **N/N** | **SF-36** | **□** | **NR** |
| S122 | **Olanow** | **2004** | **parkinson's disease** | **entacapone** | **750** | **motor subscale of unified Parkinson's Disease Rating Scale** | **O** | **4** | **N/I** | **SF-36** | **■** | **■** |
| S137 | **Rowbotham** | **1998** | **postherpetic neuralgia** | **gabapentin** | **229** | **change in average daily pain (11-point likert scale)** | **S** | **5** | **I/I** | **SF-36C** | **NR** | **■** |
| S167 | **Trojan** | **1999** | **post-polio syndrome** | **pyridostigmine** | **126** | **isometric muscle strength, fatigue and serum IGF-I level** | **O** | **5** | **N/N** | **SF-36C** | **NR** | **□** |
| S55 | **Gonzalez** | **2006** | **post-polio syndrome** | **intravenous immunoglobulin** | **135** | **muscle strength** | **O** | **4** | **I/I** | **SF-36** | **□** | **■** |
| S173 | **Walsh** | **2007** | **sleep** | **eszopiclone** | **830** | **patent reported sleep measures and insomnia severity index** | **S** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S94 | **Maanum** | **2011** | **spastic cerebral palsy** | **botulinum toxin type A** | **66** | **sagittal kinematics of ankle, knee and hip** | **O** | **5** | **N/N** | **SF-36C** | **NR** | **□** |
| S19 | **Choi-Kwon** | **2008** | **stroke (post stroke emotion changes)** | **fluoxetine** | **152** | **scores of emotional disturbances** | **S** | **3** | **I/I** | **SF-36** | **□** | **■** |
| PAIN | | | | | | | | | | | | |
| S98 | **Mazurek** | **2009** | **tinnitus** | **vardenafil** | **42** | **tinnitus questionnaire score** | **S** | **3** | **N/N** | **SF-36C** | **NR** | **□** |
| S70 | **Katz** | **2003** | **chronic lower back pain** | **rofecoxib** | **690** | **low back pain intensity** | **S** | **5** | **I/I** | **SF-12** | **■** | **NR** |
| S111 | **Muehlbacher** | **2006** | **chronic lower back pain** | **topiramate** | **96** | **McGill Pain Questionnaire, state trait anger expression inventory** | **S** | **3** | **I/I** | **SF-36C** | **NR** | **■** |
| S126 | **Peloso** | **2004** | **chronic lower back pain** | **tramadol / acetaminophen** | **338** | **final VAS pain score** | **S** | **5** | **I/I** | **SF-36** | **■** | **■** |
| S140 | **Ruoff** | **2003** | **chronic lower back pain** | **tramadol / acetaminophen** | **318** | **pain visual analog scale** | **S** | **5** | **I/I** | **SF-36** | **■** | **■** |
| S74 | **Khoromi** | **2007** | **chronic lumbar root pain** | **morphine, nortiptyline** | **61** | **mean daily leg pain score** | **S** | **5** | **N/I** | **SF-36C** | **NR** | **■** |
| S93 | **Ma** | **2008** | **chronic neck pain** | **oxycodone-CR** | **116** | **frequency of pain flairs and visual analog scale pain** | **S** | **2** | **I/I** | **SF-36C** | **NR** | **■** |
| S54 | **Goldstein** | **2005** | **diabetic neuropathy** | **duloxetine** | **457** | **weekly mean score of 24 hr average pain score (likert 11 pt scale)** | **S** | **2** | **I/I** | **SF-36** | **■** | **■** |
| S52 | **Gilron** | **2005** | **neuropathic pain management** | **morphine and gabapentin** | **57** | **mean daily pain intensity** | **S** | **4** | **I/I** | **SF-36C** | **NR** | **■** |
| S171 | **Vranken** | **2008** | **intractable central pain** | **pregabalin** | **40** | **pain intensity score via visual analog scale** | **S** | **5** | **I/I** | **SF-36C** | **NR** | **■** |
| S170 | **Vranken** | **2005** | **intractable central pain** | **S(+)-ketamine** | **33** | **pain visual analog scale** | **S** | **5** | **N/I** | **SF-36C** | **NR** | **■** |
| S68 | **Jirarattanaphochai** | **2007** | **post-surgical pain** | **methylprednisolone and bupivicane** | **103** | **amount of morphine consumption post-surgically** | **O** | **2** | **I/I** | **SF-36C** | **NR** | **■** |
| S150 | **Singh** | **2009** | **refractory shoulder pain** | **botulinum toxin type A** | **36** | **change in pain severity on VAS at 1 month** | **S** | **5** | **I/I** | **SF-36C** | **NR** | **■** |
| S47 | **Finlayson** | **2011** | **thoracic outlet syndrome** | **botulinum toxin type A** | **38** | **VAS for pain** | **S** | **5** | **N/N** | **SF-36** | **□** | **NR** |
| GASTROENTEROLOGY | | | | | | | | | | | | |
| S99 | **Mazzoleni** | **2011** | **functional dyspepsia** | **amoxicillin, clarithromycin and omeprazole combination** | **404** | **50% symptom improvement with disease specific assessment** | **H** | **4** | **I/I** | **SF-36** | **■** | **NR** |
| S78 | **Koskenpato** | **2001** | **dyspepsia and H. pylori eradication** | **amoxicillin, metronidazole and omeprazole** | **151** | **dyspepsia symptom score reduction** | **S** | **4** | **N/N** | **SF-36C** | **NR** | **□** |
| S162 | **Tan** | **2011** | **gastroesophagal reflux/ dyspepsia** | **esomeprazole** | **175** | **reflux index score** | **S** | **4** | **I/N** | **SF-36C** | **NR** | **□** |
| S38 | **Fass** | **2010** | **gastroesophagal reflux** | **esomeprazole** | **41** | **video stroposcopic reflux finding scores and acoustic measures of pitch range** | **O** | **2** | **N/N** | **SF-36C** | **NR** | **□** |
| S69 | **Kato** | **2005** | **functional dyspepsia** | **famotidine** | **21** | **gastrointestinal symptoms rating scale scores** | **S** | **2** | **I/I** | **SF-36C** | **NR** | **■** |
| S86 | **Leplege** | **2005** | **gastroesophagal reflux/ dyspepsia** | **gaiazulene and dimeticone** | **233** | **GERD symptom score improvement of >50%** | **S** | **2** | **I/I** | **SF-36 C** | **NR** | **■** |
| S179 | **Wong** | **2002** | **dyspepsia** | **lansoprazole** | **453** | **dyspepsia symptom score reduction** | **S** | **4** | **N/N** | **SF-36C** | **NR** | **□** |
| S50 | **Froehlich** | **2001** | **dyspepsia and H. pylori eradication** | **lansoprazole, carithromycin and amoxicillin** | **74** | **decrease in epigastric pain, heartburn, bloating, belching, flatulence** | **S** | **3** | **N/N** | **SF-12** | **□** | **NR** |
| S174 | **Watson** | **1997** | **gastroesophagal reflux** | **omeprazole** | **18** | **symptom frequency, severity, and antacid consumption** | **S** | **3** | **I/I** | **SF-36C** | **NR** | **■** |
| S91 | **Loftus** | **2008** | **Crohn’s disease** | **adalimumab** | **374** | **% patients achieving remission via Crohn’s Disease activity index score** | **H** | **2** | **I/I** | **SF-36** | **■** | **NR** |
| S41 | **Feagan** | **2009** | **Crohn’s disease** | **certolizumab** | **425** | **Crohn's Disease activity index** | **H** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S42 | **Feagan** | **2003** | **Crohn’s disease** | **infliximab** | **573** | **% patients in remission and time to loss of response** | **H** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S39 | **Feagan** | **2007** | **Crohn’s disease** | **natalizumab** | **339** | **% of patients maintaining remission or response** | **H** | **2** | **I/I** | **SF-36** | **■** | **■** |
| S43 | **Feagan** | **2007** | **ulcerative colitis** | **infliximab** | **728** | **Mayo score of disease severity** | **O** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S37 | **Farup CE** | **1998** | **diabetic gastroperesis** | **domperidone** | **208** | **likert symptom scale: nauseum, abdominal distention/bloating, satiety, vomiting, abdominal pain** | **S** | **2** | **I/I** | **SF-36** | **■** | **NR** |
| S2 | **Afdhal** | **2004** | **hepatitis C** | **epotin alfa and ribavirin** | **185** | **ability to maintain ribavirin dose** | **O** | **5** | **I/I** | **SF-36CE** | **NR** | **■** |
| S161 | **Talley** | **2008** | **irritable bowel** | **imipramine** | **51** | **adequate relief of IBS symptoms (yes/no)** | **S** | **3** | **N/N** | **SF-36** | **□** | **NR** |
| S124 | **Olsson** | **2005** | **primary sclerosing cholangitis** | **ursodeoxycholic acid** | **219** | **death or liver transplantation** | **O** | **4** | **N/N** | **SF-36** | **□** | **□** |
| PSYCHIATRY | | | | | | | | | | | | |
| S184 | **Zisook** | **2009** | **depression and schizophrenia** | **citalopram** | **198** | **Hamilton rating scale for depression, Calgary depression rating scale** | **S** | **3** | **I/I** | **SF-12** | **■** | **NR** |
| S178 | **Wise TN** | **2007** | **major depressive disorder** | **duloxetine** | **311** | **composite: verbal learning and recall test + symbol digit substitution test + two digit cancellation test + letter-number sequencing test.** | **O** | **2** | **I/I** | **SF-36** | **■** | **□** |
| S129 | **Philipp** | **1999** | **minor depression** | **imipramine** | **263** | **Hamilton depression scale change** | **S** | **3** | **I/N** | **SF-36** | **□** | **NR** |
| S145 | **Shi** | **2004** | **bipolar depression** | **olanzapine plus fluoxetine** | **573** | **Montgomery-Asberg Depression Rating Scale (MADRS) score change of at least 20** | **S** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S56 | **Gottlieb** | **2007** | **depression in chronic heart failure** | **paroxetine** | **28** | **Beck depression inventory score** | **S** | **2** | **I/I** | **SF-36** | **□** | **■** |
| S147 | **Shores** | **2009** | **minor depression** | **testosterone** | **33** | **Hamilton rating scale for depression** | **S** | **4** | **I/N** | **SF-36** | **□** | **NR** |
| S117 | **Nickel C** | **2005** | **major depressive disorder** | **topiramate** | **64** | **Hamilton depression rating scale, state-trait anger expression inventory** | **S** | **2** | **I/I** | **SF-36C** | **NR** | **■** |
| S89 | **Litten** | **2011** | **alcoholism** | **quetiapine** | **224** | **percentage of heavy drinking days** | **S** | **3** | **N/N** | **SF-12** | **□** | **NR** |
| S59 | **Gual** | **2003** | **relapse prevention in alcohol dependence** | **sertraline** | **83** | **rate of relapse to alcohol consumption and Montgomery Asberg depression rating scale** | **H** | **4** | **N/I** | **SF-36** | **□** | **■** |
| S100 | **McElroy** | **2011** | **binge eating** | **acamprosate** | **40** | **binge eating episode frequency** | **S** | **3** | **N/N** | **SF-12** | **□** | **NR** |
| S116 | **Nickel** | **2005** | **bulimia nervosa** | **topiramate** | **60** | **frequency of binging/purging and body weight** | **H** | **3** | **I/I** | **SF-36C** | **NR** | **■** |
| S119 | **Nickel MK** | **2005** | **weight/fat gain and medication treatment** | **topiramate** | **43** | **body weight** | **O** | **3** | **I/I** | **SF-36C** | **NR** | **■** |
| S90 | **Loew TH** | **2006** | **borderline personality disorder** | **topiramate** | **81** | **symptom checklist and inventory of interpersonal problems** | **S** | **3** | **I/I** | **SF-36C** | **NR** | **■** |
| S83 | **Krystal** | **2011** | **post-traumatic stress disorder** | **risperidone** | **296** | **Clinician Administered PTSD Scale (CAPS) based on clinician interview judgement** | **O** | **5** | **N/N** | **SF-36** | **□** | **NR** |
| S48 | **Francois C** | **2008** | **social anxiety disorder** | **escitalopram** | **371** | **relapse defined as: Liebowitz social anxiety scale score >10** | **S** | **4** | **I/I** | **SF-36C** | **NR** | **■** |
| S110 | **Muehlbacher** | **2005** | **social anxiety disorder** | **mirtazapine** | **66** | **social phobia inventory and Liebowitz social anxiety scale** | **S** | **2** | **I/I** | **SF-36C** | **NR** | **■** |
| DERMATOLOGY | | | | | | | | | | | | |
| S134 | **Revicki** | **2007** | **psoriasis** | **adalimumab** | **1205** | **psoriasis area severity index 75** | **O** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S146 | **Shikiar** | **2007** | **psoriasis** | **adalimumab** | **147** | **psoriasis area severity index 75** | **O** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S33 | **Ellis** | **2003** | **psoriasis** | **alefacept** | **205** | **psoriasis area severity index** | **O** | **5** | **I/N** | **SF-36** | **□** | **□** |
| S40 | **Feldman** | **2004** | **psoriasis** | **alefacept** | **553** | **psoriasis area severity index 75** | **O** | **3** | **I/I** | **SF-36** | **□** | **■** |
| S46 | **Finlay** | **2003** | **psoriasis** | **alefacept** | **507** | **psoriasis area severity index** | **O** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S82 | **Krueger** | **2005** | **psoriasis** | **etanercept** | **583** | **psoriasis area severity index 75** | **O** | **5** | **I/I** | **SF-36** | **■** | **■** |
| S44 | **Feldman** | **2008** | **psoriasis** | **infliximab** | **835** | **psoriasis area severity index** | **O** | **3** | **I/I** | **SF-36** | **■** | **■** |
| S133 | **Reich** | **2006** | **psoriasis** | **infliximab** | **378** | **psoriasis area severity index** | **O** | **5** | **I/I** | **SF-36** | **■** | **■** |
| S65 | **Igarashi** | **2011** | **psoriasis** | **ustekinumab** | **158** | **psoriasis area severity index 75** | **O** | **3** | **I/I** | **SF-36** | **■** | **NR** |
| S85 | **Lebwohl** | **2010** | **psoriasis** | **ustekinumab** | **766** | **psoriasis and severity index (pasi 75%) both doses identical on endpoint** | **O** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S115 | **Naumann** | **2002** | **excessive axillary hyperhidrosis** | **botulinum toxin type A** | **320** | **incidence of treatment responders at week 4** | **S** | **4** | **I/I** | **SF-12** | **■** | **NR** |
| ENDOCRINOLOGY | | | | | | | | | | | | |
| S113 | **Nair** | **2006** | **hormone supplementation older men and women** | **dehydroepi-androsterone / testosterone** | **144** | **muscle strength, peak aerobic capacity (v02), body composition, fasting glucose and insulin** | **O** | **4** | **N/N** | **SF-36** | **□** | **NR** |
| S101 | **McMillan** | **2003** | **hormone supplementation** | **growth hormone** | **19** | **growth hormone levels** | **O** | **3** | **I/I** | **SF-36C** | **NR** | **■** |
| S51 | **Giannoulis** | **2006** | **hormone supplementation older men** | **growth hormone and testosterone** | **69** | **body composition (lean body mass and muscle mass)** | **O** | **4** | **I/N** | **SF-36C** | **NR** | **□** |
| S35 | **Emmelot-Vonk** | **2008** | **hormone supplementation older men** | **testosterone** | **237** | **functional mobility (Stanford Health Assessment Questionnaire) timed get up and go test, isometric hard grip, cognitive function** | **H** | **5** | **N/N** | **SF-36C** | **NR** | **□** |
| S71 | **Katznelson** | **2006** | **hormone supplementation older men** | **testosterone** | **70** | **body composition via dual x-ray absorptiometry scan** | **O** | **4** | **I/I** | **SF-36C** | **NR** | **■** |
| S152 | **Snyder** | **1999** | **hormone supplementation older men** | **testosterone** | **108** | **lean and fat body mass** | **O** | **4** | **I/I** | **SF-36C** | **NR** | **■** |
| S92 | **Lovas** | **2003** | **adrenal failure** | **DHEA** | **39** | **subjective health and sexuality scales** | **S** | **5** | **N/N** | **SF-36C** | **NR** | **□** |
| S180 | **Yaffe** | **2006** | **cognition** | **estradiol** | **417** | **seven cognitive tests** | **O** | **3** | **N/N** | **SF-36** | **□** | **NR** |
| S81 | **Kritz-Silverstien** | **2008** | **cognitive function and hormone supplement** | **DHEA** | **225** | **cognitive function (formal assessment)** | **O** | **2** | **N/N** | **SF-36** | **□** | **NR** |
| S128 | **Peyrot** | **2010** | **diabetes** | **insulin (inhaled)** | **119** | **change in HBA1C, mean reduction of > 6%** | **O** | **3** | **I/N** | **SF-36** | **□** | **□** |
| S57 | **Grady** | **2007** | **menopausal hot flushes** | **sertraline** | **99** | **quantitative reduction in vasomotor symptoms (number hot flushes)** | **S** | **4** | **N/W** | **SF-36** | **~** | **NR** |
| S96 | **Marquis** | **2008** | **osteoporosis** | **strontium ranelate** | **1240** | **vertebral fracture** | **O** | **2** | **I/N** | **SF-36** | **□** | **NR** |
| PULMONOLOGY | | | | | | | | | | | | |
| S21 | **Cook** | **2001** | **COPD** | **albuterol** | **73** | **FEV1, slow vital capacity, and peak expiratory flow before and after medication administration at regular intervals** | **O** | **5** | **N/N** | **SF-36** | **□** | **NR** |
| S3 | **Albert RK** | **2011** | **COPD** | **azithromycin** | **1142** | **time to first acute exacerbation of COPD** | **O** | **3** | **I/I** | **SF-36c** | **NR** | **■** |
| S61 | **He** | **2010** | **COPD** | **erythromycin** | **36** | **neutrophil number in sputum and COPD exacerbations** | **O** | **3** | **I/N** | **SF-36C** | **NR** | **□** |
| S60 | **Hawkins** | **2009** | **COPD** | **bisoprostol** | **27** | **FEV1** | **O** | **2** | **W/N** | **SF-36** | **□** | **NR** |
| S153 | **Spencer S** | **2001** | **COPD** | **fluticasone** | **751** | **St. George’s Respiratory Questionnaire** | **S** | **3** | **I/I** | **SF-36** | **□** | **■** |
| S30 | **Eaton** | **2006** | **COPD** | **short-burst oxygen therapy** | **78** | **acute healthcare utilization** | **O** | **4** | **N/N** | **SF-36** | **□** | **□** |
| S15 | **Casaburi** | **2002** | **COPD** | **tiotropium** | **921** | **FEV1 prior to dosing** | **O** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S18 | **Chervinsky** | **2002** | **asthma** | **mometasone furoate** | **395** | **FEV1** | **O** | **3** | **I/I** | **SF-36CE** | **NR** | **■** |
| S165 | **The idiopathic pulmonary fibrosis CRN** | **2010** | **idiopathic pulmonary fibrosis** | **Sildenafil** | **180** | **proportion of patients with an increase in 6 minute walking distance > 20%** | **O** | **4** | **N/I** | **SF-36** | **□** | **■** |
| S163 | **Tashkin DP** | **2006** | **scleroderma** | **cyclophosphamide** | **158** | **FVC@12 mos** | **O** | **4** | **I/I** | **SF-36** | **□** | **■** |
| S75 | **Kingshott** | **2001** | **sleep apnea** | **modafinil** | **32** | **sleepiness via Epworth sleepiness scale** | **S** | **3** | **N/N** | **SF-36** | **□** | **NR** |
| S159 | **Swenson** | **2003** | **acute coronary syndrome and depression** | **sertraline** | **369** | **Left Ventricular Ejection Fraction** | **O** | **5** | **W/I** | **SF-36** | **■** | **■** |
| CARDIOVASCULAR | | | | | | | | | | | | |
| S14 | **Budzynski** | **2011** | **angina** | **omeprazole** | **48** | **% achieving decrease in angina symptoms by > 50%, # chest pain episodes, nitroglycerin doses** | **H** | **5** | **I/I** | **SF-36C** | **■** | **■** |
| S1 | **Adamson DL** | **2001** | **cardiac X syndrome** | **esterified estrogens** | **19** | **treadmill testing** | **O** | **2** | **N/N** | **SF-36C** | **NR** | **□** |
| S10 | **Botoni** | **2007** | **chagas cardiomyopathy** | **carvedilol** | **42** | **Left Ventricular Ejection Fraction** | **O** | **4** | **N/N** | **SF-36C** | **NR** | **□** |
| S149 | **Simons** | **2002** | **coronary artery disease** | **recombinant fibroblast growth factor (RFGF2)** | **337** | **exercise tolerance test** | **O** | **3** | **N/I** | **SF-36** | **■** | **NR** |
| S144 | **Schrier** | **2006** | **hyponatremia in heart failure** | **tolvaptan** | **448** | **change in serum sodium concentration** | **O** | **4** | **I/I** | **SF-12E** | **■** | **NR** |
| S77 | **Knudtson** | **2002** | **ischemic heart disease** | **chelation** | **84** | **treadmill time to 1mm ST-segment depression** | **O** | **5** | **N/N** | **SF-36** | **□** | **NR** |
| S138 | **Rowe** | **2001** | **neural mediated hypotension** | **fludrocortisone acetate** | **100** | **proportion of patients with 15 point improvement in mean daily wellness score** | **S** | **5** | **N/N** | **SF-36** | **□** | **NR** |
| S160 | **Swinburn** | **2005** | **obesity and cardiovascular disease** | **orlistat** | **339** | **10 year risk of developing cardiovascular disease** | **O** | **3** | **N/I** | **SF-36C** | **NR** | **■** |
| S109 | **Mozaffarian** | **2005** | **systemic inflammation in heart failure** | **atorvastatin** | **22** | **inflammatory markers (IL-6, TNF, CRP, endothelin, BNP)** | **O** | **4** | **I/N** | **SF-36** | **□** | **NR** |
| VASCULAR | | | | | | | | | | | | |
| S121 | **O'Donnell** | **2009** | **peripheral arterial disease** | **cilostazol** | **80** | **walking distance (treadmill)** | **O** | **2** | **N/I** | **SF-36** | **■** | **■** |
| S132 | **Regensteiner**  **-composite data from of 6 trials-** | **2002** | **peripheral arterial disease** | **cilostazol** | **1751** | **walking distance (treadmill)** | **O** | **2** | **I/I** | **SF-36** | **■** | **■** |
| S58 | **Gresele** | **2000** | **peripheral arterial disease** | **cloricromene** | **159** | **initial claudication distance** | **O** | **3** | **N/N** | **SF-36C** | **NR** | **□** |
| S13 | **Brass** | **2006** | **peripheral arterial disease/ intermittent claudication** | **parogrelil hydrochloride** | **391** | **peak walking time on treadmill test** | **O** | **2** | **I/I** | **SF-36** | **■** | **■** |
| S63 | **Hiatt** | **2001** | **peripheral arterial disease** | **propionyl-L-carnitine** | **155** | **peak walking time on graded treadmill** | **O** | **3** | **I/I** | **SF-36C** | **NR** | **■** |
| S62 | **Hiatt** | **2011** | **peripheral arterial disease** | **propionyl-L-carnitine** | **69** | **peak walking time on treadmill test** | **O** | **3** | **N/N** | **SF-36** | **□** | **□** |
| S108 | **Mohler** | **2003** | **intermittent claudication** | **beraprost** | **762** | **walking distance (treadmill)** | **O** | **3** | **N/N** | **SF-36** | **□** | **NR** |
| S166 | **The Propranolol Aneurysm Trial Investigators** | **2002** | **abdominal aortic aneurysm** | **propranolol** | **552** | **mean annual growth rate as determined by ultrasound** | **O** | **4** | **N/W** | **SF-36C** | **NR** | **~** |
| S177 | **WGET Research Group** | **2005** | **Wegener’s granulomatosis** | **etanercept** | **174** | **sustained remission (Brigham Vasculitis Activity Score of 0)** | **O** | **3** | **N/N** | **SF-36** | **□** | **NR** |
| OTHER | | | | | | | | | | | | |
| S31 | **Ebbens** | **2006** | **chronic rhinosinusitis** | **amphotericin** | **116** | **visual analog scale for (nasal blockage, rhinorrhea, facial pain, post nasal drip, and anosmia vas score) and nasal endoscopy** | **S** | **4** | **N/N** | **SF-36** | **□** | **NR** |
| S29 | **Dolor** | **2001** | **rhinosinusitis** | **cefuroxime / fluticasone** | **95** | **time to patient report of cure or significant improvement** | **S** | **5** | **I/N** | **SF-12** | **□** | **NR** |
| S136 | **Rimmer** | **2011** | **rhinitis/asthma** | **fluticasone** | **19** | **acoustic rhinometry and peak nasal inspiratory flow** | **O** | **3** | **N/N** | **SF-36C** | **NR** | **□** |
| S125 | **Passalaqua** | **2006** | **allergic rhinitis** | **sublingual carbamylatal allergoid immunotherapy** | **68** | **symptom severity/presence and drug intake** | **H** | **3** | **N/N** | **SF-36C** | **NR** | **□** |
| S36 | Fallowfield | 2002 | cancer related anemia | epotin alfa | 375 | transfusions after the first 28 days | **O** | 4 | I/N | SF-36 | □ | NR |
| S23 | **Cunningham** | **2005** | **chronic kidney disease and cardiovascular health in hyperparathyroidism** | **cinacalcet** | **1184** | **parathyroidectomy, fracture,**  **cardiovascular hospitalization,**  **all-cause hospitalization** | **O** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S118 | **Nickel JC** | **2011** | **chronic prostatitis/ pelvic pain** | **silodosin** | **151** | **National Institutes of Health chronic**  **Prostatitis symptom index score** | **S** | **5** | **I/I** | **SF-12** | **■** | **NR** |
| S17 | **Chatterton ML** | **1999** | **HIV** | **lamivudine or lamivudine plus loviride** | **495** | **AIDS event or death** | **O** | **4** | **I/I** | **SF-36** | **■** | **■** |
| S26 | **Davis EL** | **2008** | **interstitial cystitis** | **pentosan polysulfate sodium** | **41** | **O’Leary-Sant interstitial cystitis symptoms/problem index** | **H** | **5** | **I/I** | **SF-36C** | **NR** | **■** |
| S130 | **Podichetty** | **2004** | **lumbar stenosis** | **salmon calcitonin** | **55** | **pain intensity VAS and walking time and distance to pain** | **H** | **3** | **N/N** | **SF-36** | **□** | **NR** |
| S64 | **Hogan** | **2010** | **polycystic kidney and liver disease** | **octotreide** | **42** | **liver volume** | **O** | **3** | **I/N** | **SF-36** | **□** | **□** |
| S67 | **Jackson S** | **1999** | **post-menopausal urinary stress incontinence** | **oestrogen** | **67** | **Bristol female lower urinary tract**  **Symptom questionnaire, incontinence**  **diary, cystometry, urethral profilometry,perineal pad test** | **H** | **3** | **N/N** | **SF-36C** | **NR** | **□** |
| S49 | **Fransen M** | **2006** | **post-op ibuprofen and hip replacement** | **ibuprofen** | **902** | **self-reported hip pain and physical**  **function from WOMAC** | **S** | **4** | **N/N** | **SF-36** | **□** | **□** |
| S87 | **Lewis** | **2011** | **renal failure** | **darbepotin alfa** | **4038** | **composite: death or cardiovascular event (MI, CHF, stroke, hospitalization for myocardial ischemia) and end stage renal disease** | **O** | **5** | **N/I** | **SF-36C** | **NR** | **■** |
| S25 | **Davis A** | **2000** | **uterine bleeding** | **triphasic norgestimate / ethinyl estradiol** | **201** | **investigator and subject assessments**  **of dysfunctional uterine bleeding**  **resolution and abnormal uterine**  **bleeding patterns** | **H** | **4** | **I/I** | **SF-36C** | **NR** | **■** |

PCS MCS∆ RX Arm = PCS and MCS score changes from baseline to follow-up in the treatment arm

PCS MCS∆ RX Arm Net of PBO = Net of Placebo PCS and MCS score changes from baseline to follow-up

Jadad Score is based on Jadad Scale which rates trials on a 0-5 basis awarding points for randomization, blinding and description of dropouts/withdrawals by each study group.

S= Subjective clinical endpoint that involved patient report of symptoms

O= Objective clinical endpoint that relied on clinical tests, biomarkers or clinician evaluation

H= Hybrid endpoint, i.e. an endpoint that combines both objective components and subjective patient report into one combined measure

I = Improved to statistically significant extent

N = Did not improve to statistically significant extent

W= Worsened to statistically significant extent

SF-36: Short Form-36 survey; SF-12: Short Form-12 survey; PCS: physical component score; MCS: mental component score; PF

□=Non-significant (p>0.05) Results reported

■=Indicates statistically significant improvement over placebo (p<0.05);

**~**=Indicates a statistically significant worsening vs. placebo (p<0.05)

NR= Not Reported

E = Numerical score estimated based on figure presented in publication

C=Calculated SF-36 summary physical or mental component summary score based on the reported 8 domains in the publication

CE=Change scores were reported for the 8 domains without baseline data, therefore to generate a PCS and MCS score we added the change scores to a of a norm of 50 for each of the domains to calculate a PCS and MCS change score net of placebo

ACR= American College of Rheumatology ACR20= American College of Rheumatology 20% improvement criteria ACR50= American College of Rheumatology 50% improvement criteria

ASAS 20% = Assessment of Ankylosing Spondylitis international working group criteria 20% response

FEV= Forced expiratory volume FEV1= Forced expiratory volume over 1 second

FVC=Forced vital capacity

GERD= gastro-esophageal reflux disease

WOMAC= Western Ontario and McMaster Universities Arthritis Index

VAS= Visual analog scale

**References:**

1. Adamson DL, Webb CM, Collins P. Esterified estrogens combined with methyltestosterone improve emotional well-being in postmenopausal women with chest pain and normal coronary angiograms. *Menopause* 2001; 8: 233-238.
2. Afdhal NH, Dieterich DT, Pockros PJ, Schiff ER, Shiffman ML, Sulkowski, MS et al. Epoetin alfa maintains ribavirin dose in HCV-infected patients: A prospective, double-blind, randomized controlled study. *Gastroenterology* 2004; 126:1302-1311.
3. Albert RK, Connett J, Bailey WC, Casaburi R, Cooper JAD, Criner GJ, et al. Azithromycin for Prevention of Exacerbations of COPD. *New England Journal of Medicine* 2011; 365: 689-698. doi: 10.1056/NEJMoa1104623
4. Arnold LM, Chatamra K, Hirsch I, Stoker M. Safety and efficacy of esreboxetine in patients with fibromyalgia: An 8-week, multicenter, randomized, double-blind, placebo-controlled study. *Clinical Therapy* 2010; 32: 1618-1632. doi: 10.1016/j.clinthera.2010.08.003
5. Arnold LM, Gendreau RM, Palmer RH, Gendreau JF, Wang Y. Efficacy and safety of milnacipran 100 mg/day in patients with fibromyalgia: results of a randomized, double-blind, placebo-controlled trial. *Arthritis and Rheumatology* 2010; 62: 2745-2756. doi: 10.1002/art.27559
6. Arnold LM, Clauw D, Wang F, Ahl J, Gaynor PJ, Wohlreich MM. Flexible dosed duloxetine in the treatment of fibromyalgia: a randomized, double-blind, placebo-controlled trial. *Journal of Rheumatology* 2010; 37: 2578-2586. doi: 10.3899/jrheum.100365
7. Arnold LM, Lu YL, Crofford LJ, Wohlreich M, Detke MJ, Iyengar S, et al. A double-blind, multicenter trial comparing Duloxetine with placebo in the treatment of fibromyalgia patients with or without major depressive disorder. *Arthritis and Rheumatism* 2004; 50:2974-2984.
8. Bennett RM, Kamin M, Karim R, Rosenthal N. Tramadol and acetaminophen combination tablets in the treatment of fibromyalgia pain: A double-blind, randomized, placebo-controlled study. *American Journal of Medicine* 2003; 114:537-545.
9. Blockmans D, Persoons P, Van HB, Lejeune M, Bobbaers H. Combination therapy with hydrocortisone and fludrocortisone does not improve symptoms in chronic fatigue syndrome: a randomized, placebo-controlled, double-blind, crossover study. *American Journal of Medicine* 2003; 114: 736-741.
10. Botoni FA, Poole-Wilson PA, Ribeiro AL, Okonko DO, Oliviera BM, Pinto AS, et al. A randomized trial of carvedilol after renin-angiotensin system inhibition in chronic Chagas cardiomyopathy. *American Heart Journal* 2007; 153:544-548.
11. Branco JC, Zachrisson O, Perrot S, Mainguy Y. A European multicenter randomized double-blind placebo-controlled monotherapy clinical trial of milnacipran in treatment of fibromyalgia. *Journal of Rheumatology* 2010; 37: 851-859. doi: 10.3899/jrheum.090884
12. Brandes JL, Kudrow DB, Rothrock JF, Rupnow MFT, Fairclough DL, Greenberg SJ. Assessing the ability of topiramate to improve the daily activities of patients with migraine. *Mayo Clinic Proceedings* 2006; 81:1311-1319.
13. Brass EP, Anthony R, Cobb FR, Koda I, Jiao J, Hiatt WR. The novel phosphodiesterase inhibitor NM-702 improves claudication- limited exercise performance in patients with peripheral arterial disease. *Journal of the American College of Cardiology* 2006; 48:2539-2545.
14. Budzynski J, Pulkowski G, Suppan K, Fabisiak J, Majer M, Klopocka M, et al. Improvement in health-related quality of life after therapy with omeprazole in patients with coronary artery disease and recurrent angina-like chest pain. A double-blind, placebo-controlled trial of the SF-36 survey. *Health and Quality of Life Outcomes* 2011; 9:77 doi: 10.1186/1477-7525-9-77
15. Casaburi R, Mahler DA, Jones PW, Wanner A, San PG, ZuWallack RL, et al. A long-term evaluation of once-daily inhaled tiotropium in chronic obstructive pulmonary disease. *European Respiratory Journal* 2002; 19:217-24.
16. Chappell AS, Bradley LA, Wiltse C, Detke MJ, D'Souza DN, Spaeth M. A six-month double-blind, placebo-controlled, randomized clinical trial of duloxetine for the treatment of fibromyalgia. *International Journal of General Medicine* 2008; 1: 91-102.
17. Chatterton ML, Scott-Lennox J, Wu AW, Scott J. Quality of life and treatment satisfaction after the addition of Lamivudine or Lamivudine plus Loviride to Zidovudine-containing regimens in treatment-experienced patients with HIV infection. *Pharmacoeconomics* 1999; 15: 67-74.
18. Chervinsky P, Nelson HS, Bernstein DI, Berkowitz RA, Siegel SC. Comparison of Mometasone Furoate administered by metered dose inhaler with Beclomethasone Dipropionate. *International Journal of Clinical Practice* 2002; 56:419-425.
19. Choi-Kwon S, Choi J, Kwon SU, Kang DW, Kim JS. Fluoxetine improves the quality of life in patients with poststroke emotional disturbances. *Cerebrovascular Diseases* 2008; 26:266-271. doi: 10.1159/000147454
20. Clauw DJ, Mease P, Palmer RH, Gendreau RM, Wang Y. Milnacipran for the treatment of fibromyalgia in adults: A 15-week, multicenter, randomized, double-blind, placebo-controlled, multiple-dose clinical trial. *Clinical Therapeutics* 2008; 30:1988-2004. doi: 10.1016/j.clinthera.2008.11.009
21. Cook D, Guyatt G, Wong E, Goldstein R, Bedard M, Austin P, et al. Regular versus as-needed short-acting inhaled beta-agonist therapy for chronic obstructive pulmonary disease. *American Journal of Respiratory and Critical Care Medicine* 2001; 163:85-90.
22. Coombs JH, Bloom BJ, Breedveld FC, Fletcher MP, Gruben D, Kremer JM, et al. Improved pain, physical functioning and health status in patients with rheumatoid arthritis treated with CP-690,550, an orally active Janus kinase (JAK) inhibitor: results from a randomised, double-blind, placebo-controlled trial. *Annals of Rheumatic Diseases* 2010; 69:413-416. doi: 10.1136/ard.2009.108159
23. Cunningham J, Danese M, Olson K, Klassen P, Chertow GM. Effects of the calcimimetic cinacalcet HCl on cardiovascular disease, fracture, and health-related quality of life in secondary hyperparathyroidism. *Kidney International* 2005; 68:1793-1800.
24. Dahlof C, Loder E, Diamond M, Rupnow M, Papadopoulos G, Mao L. The impact of migraine prevention on daily activities: A longitudinal and responder analysis from three topiramate placebo-controlled clinical trials - art. no. 56. *Health and Quality of Life Outcomes* 2007; 5: 56.
25. Davis A, Lippman J, Godwin A, Olson W, Kafrissen M. Triphasic Norgestimate/Ethinyl Estradiol oral contraceptive for the treatment of dysfunctional uterine bleeding. *Obstetrics and Gynecology* 2000; 96: 913-920.
26. Davis EL, El Khoudary SR, Talbott EO, Davis J, Regan LJ. Safety and efficacy of the use of intravesical and oral pentosan polysulfate sodium for interstitial cystitis: A randomized double-blind clinical trial. *Journal of Urology* 2008; 179:177-185.
27. Davis JC, Jr., Revicki D, van der Heijde DM, Rentz AM, Wong RL, Kupper H, et al. Health-related quality of life outcomes in patients with active ankylosing spondylitis treated with adalimumab: Results from a randomized controlled study. *Arthritis and Rheumatism* 2007; 57:1050-1057.
28. Dodel R, Spottke A, Gerhard A, Reuss A, Reinecker S, Schimke N, et al. Minocycline 1-year therapy in multiple-system-atrophy: effect on clinical symptoms and [(11)C] (R)-PK11195 PET (MEMSA-trial) *Movement Disorders* 2010; 25:97-107. doi: 10.1002/mds.22732
29. Dolor RJ, Witsell DL, Hellkamp AS, Williams JW, Jr., Califf RM, Simel DL. Comparison of Cefuroxime with or without intranasal Fluticasone for the treatment of rhinosinusitis. The CAFFS Trial: A randomized controlled trial. *Journal of the American Medical Association* 2001; 286: 3097-105.
30. Eaton T, Fergusson W, Kolbe J, Lewis CA, West T. Short-burst oxygen therapy for COPD patients: a 6-month randomised, controlled study. *European Respiratory Journal* 2006; 27: 697-704.
31. Ebbens FA, Scadding GK, Badia L, Hellings PW, Jorissen M, Mullol J, et al. Amphotericin B nasal lavages: not a solution for patients with chronic rhinosinusitis. *Journal of Allergy and Clinical Immunology* 2006; 118: 1149-1156.
32. Ehrich EW, Bolognese JA, Watson DJ, Kong SX. Effect of Rofecoxib therapy on measures of health-related quality of life in patients with osteoarthritis. *American Journal of Managed Care* 2001; 7:609-16.
33. Ellis CN, Mordin MM, Adler EY. Effects of Alefacept on health-related quality of life in patients with psoriasis - Results from a randomized, placebo-controlled phase II trial. *American Journal of Clinical Dermatology* 2003; 4:131-139.
34. Emkey R, Rosenthal N, Wu SC, Jordan D, Kamin M. Efficacy and safety of tramadol/acetaminophen tablets (Ultracet) as add-on therapy for osteoarthritis pain in subjects receiving a COX-2 nonsteroidal antiinflammatory drug: a multicenter, randomized, double-blind, placebo-controlled trial. *Journal of Rheumatology* 2004; 31: 150-156.
35. Emmelot-Vonk MH, Verhaar HJ, Nakhai Pour HR, Aleman A, Lock TM, Bosch JL, et al. Effect of testosterone supplementation on functional mobility, cognition, and other parameters in older men: a randomized controlled trial. *JAMA* 2008; 299: 39-52. doi: 10.1001/jama.2007.51
36. Fallowfield L, Gagnon D, Zagari M Cella D, Bresnahan B, Littlewood TJ, et al. Multivariate regression analyses of data from a randomised, double-blind, placebo-controlled study confirm quality of life benefit of epoetin alfa in patients receiving non-platinum chemotherapy. *British Journal of Cancer* 2002; 87:1341-1353.
37. Farup CE, Leidy NK, Murray M, Williams GR, Helbers L, Quigley EM. Effect of domperidone on the health-related quality of life of patients with symptoms of diabetic gastroparesis. *Diabetes Care* 1998; 21: 1699-1706.
38. Fass R, Noelck N, Willis MR, Navarro-Rodriguez T, Wilson K, Powers J, et al. The effect of esomeprazole 20 mg twice daily on acoustic and perception parameters of the voice in laryngopharyngeal reflux. *Neurogastroenterology and Motility* 2010; 22: 134-41 doi: 10.1111/j.1365-2982.2009.01392.x
39. Feagan BG, Sandborn WJ, Hass S, Niecko T, White J. Health-related quality of life during natalizumab maintenance therapy for Crohn's disease. *American Journal of Gastroenterology* 2007; 102:2737-2746.
40. Feagan BG, Coteur G, Tan S, Keininger DL, Schreiber S. Clinically meaningful improvement in health-related quality of life in a randomized controlled trial of certolizumab pegol maintenance therapy for Crohn's disease. *American Journal of Gastroenterology* 2009; 104:1976-1983. doi: 10.1038/ajg.2009.199
41. Feagan BG, Yan S, Bala M, Bao W, Lichtenstein GR. The effects of Infliximab maintenance therapy on health-related quality of life. *American Journal of Gastroenterology* 2003; 98:2232-2238.
42. Feagan BG, Reinisch W, Rutgeerts P Sandborn WJ, Yan S, Eisenberg D, et al. The effects of infliximab therapy on health-related quality of life in ulcerative colitis patients. *American Journal of Gastroenterology* 2007; 102:794-802.
43. Feldman SR, Menter A, Koo JY. Improved health-related quality of life following a randomized controlled trial of alefacept treatment in patients with chronic plaque psoriasis. *British Journal of Dermatology* 2004; 150:317-326.
44. Feldman SR, Gottlieb AB, Bala M Wu Y, Eisenberg D, Guzzo C, et al. Infliximab improves health-related quality of life in the presence of comorbidities among patients with moderate-to-severe psoriasis. *British Journal of Dermatology* 2008; 159:704-710. doi: 10.1111/j.1365-2133.2008.08727.x
45. Fernandez-Rhodes LE, Kokkinis AD, White MJ, Watts CA, Auh S, Jeffries NO, et al. Efficacy and safety of dutasteride in patients with spinal and bulbar muscular atrophy: a randomised placebo-controlled trial. *Lancet Neurology* 2011; 10: 140-147. doi: 10.1016/S1474-4422(10)70321-5.
46. Finlay AY, Salek MS, Haney J. Intramuscular Alefacept improves health-related quality of life in patients with chronic plaque psoriasis. *Dermatology* 2003; 206:307-315.
47. Finlayson HC, O'Connor RJ, Brasher PM, Travlos A. Botulinum toxin injection for management of thoracic outlet syndrome: a double-blind, randomized, controlled trial. *Pain* 2011; 152: 2023-2028. doi: 10.1016/j.pain.2011.04.027
48. Francois C, Montgomery SA, Despiegel N, Aballea S, Roiz J, Auquier P. Analysis of health-related quality of life and costs based on a randomised clinical trial of escitalopram for relapse prevention in patients with generalised social anxiety disorder. *International Journal of Clinical Practice* 2008; 62:1693-1702. doi: 10.1111/j.1742-1241.2008.01879.x
49. Fransen M, Anderson C, Douglas J MacMahon S, Neal B, Norton R, et al. Safety and efficacy of routine postoperative ibuprofen for pain and disability related to ectopic bone formation after hip replacement surgery (HIPAID): Randomised controlled trial. *British Medical Journal* 2006; 333:519.
50. Froehlich F, Gonvers JJ, Wietlisbach V Burnand B, Hildebrand P, Schneider C, et al. Helicobacter pylori eradication treatment does not benefit patients with nonulcer dyspepsia. *American Journal of Gastroenterology* 2001; 96:2329-36.
51. Giannoulis MG, Sonksen PH, Umpleby M Breen L, Pentecost C, Whyte M, et al. The effects of growth hormone and/or testosterone in healthy elderly men: A randomized controlled trial. *Journal of Clinical Endocrinology and Metabolism* 2006; 91:477-84.
52. Gilron I, Bailey JM, Tu D, Holden RR, Weaver DF, Houlden RL. Morphine, gabapentin, or their combination for neuropathic pain. *New England Journal of Medicine* 2005; 352:1324-1334.
53. Gladman DD, Mease PJ, Cifaldi MA, Perdok RJ, Sasso E, Medich J. Adalimumab improves joint-related and skin-related functional impairment in patients with psoriatic arthritis: patient-reported outcomes of the Adalimumab Effectiveness in Psoriatic Arthritis Trial. *Annals of the Rheumatic Diseases* 2007; 66:163-168.
54. Goldstein DJ, Lu Y, Detke MJ, Lee TC, Iyengar S. Duloxetine vs. placebo in patients with painful diabetic neuropathy. *Pain* 2005; 116: 109-118.
55. Gonzalez H, Sunnerhagen KS, Sjoberg I, Kaponides G, Olsson T, Borg K. Intravenous immunoglobulin for post-polio syndrome: a randomised controlled trial. *Lancet Neurology* 2006; 5:493-500.
56. Gottlieb SS, Kop WJ, Thomas SA, Katzen S, Vesely MR, Greenberg N. A double-blind placebo-controlled pilot study of controlled-release paroxetine on depression and quality of life in chronic heart failure. *American Heart Journal* 2007; 153: 868-873.
57. Grady D, Cohen B, Tice J, Krisof M, Olyaie A, Sawaya GF. Ineffectiveness of sertraline for treatment of menopausal hot flushes - A Randomized controlled trial. *Obstetrics and Gynecology* 2007; 109(4):823-830.
58. Gresele P, Migliacci R, Di Sante G, Nenci GG. Effect of Cloricromene on intermittent claudication. A randomized, double-blind, placebo-controlled trial in patients treated with Aspirin: Effect on claudication distance and quality of life. CRAMPS Investigator Group. Cloricromene Randomized Arteriopathy Multicenter Prospective Study. *Vascular Medicine* 2000; 5:83-9.
59. Gual A, Balcells M, Torres M, Madrigal M, Diez T, Serrano, L. Sertraline for the prevention of relapse in detoxicated alcohol dependent patients with a comorbid depressive disorder: A randomized controlled trial. *Alcohol and Alcoholism* 2003; 38:619-625.
60. Hawkins NM, MacDonald MR, Petrie MC, Chalmers GW, Carter R, Dunn FG. Bisoprolol in patients with heart failure and moderate to severe chronic obstructive pulmonary disease: a randomized controlled trial. *European Journal of Heart Failure* 2009; 11: 684-690. doi: 10.1093/eurjhf/hfp066
61. He ZY, Ou LM, Zhang JQ, Bai J, Liu GN, Li MH, et al. Effect of 6 months of erythromycin treatment on inflammatory cells in induced sputum and exacerbations in chronic obstructive pulmonary disease. *Respiration* 2010; 80:445-52. doi: 10.1159/000321374
62. Hiatt WR, Creager MA, Amato A, Brass EP, Effect of Propionyl-L-Carnitine on a Background of Monitored Exercise in Patients with Claudication Secondary to Peripheral Artery Disease. *Journal of Cardiopulmonary Rehabilitation and Prevention* 2011; 31: 125-132. doi: 10.1097/HCR.0b013e3181f1fd65
63. Hiatt WR, Regensteiner JG, Creager MA, Hirsch AT, Cooke JP, Olin J, et al. Propionyl-L-carnitine improves exercise performance and functional status in patients with claudication. *American Journal of Medicine* 2001; 110:616-22.
64. Hogan, MC, Masyuk TV, Page LJ, Kubly VJ, Bergstralh EJ, Li X, et al. Randomized clinical trial of long-acting somatostatin for autosomal dominant polycystic kidney and liver disease. *Journal of the American Society of Nephrology* 2010; 21: 1052-61. doi: 10.1681/ASN.2009121291
65. Igarishi A, Kato T, Kato M, Song M, Nakagawa H; Japanese Ustekinumab Study Group. Efficacy and safety of ustekinumab in Japanese patients with moderate-to-severe plaque-type psoriasis: long-term results from a phase 2/3 clinical trial. *Journal of Dermatology*. 2012; 39:242-52. doi: 10.1111/j.1346-8138.2011.01347.x
66. Inman RD, Davis JC Jr, Heijde D, Diekman L, Sieper J, Kim SI, et al. Efficacy and safety of golimumab in patients with ankylosing spondylitis: results of a randomized, double-blind, placebo-controlled, phase III trial. *Arthritis and Rheumatology* 2008; 58: 3402-3412. doi: 10.1002/art.23969
67. Jackson S, Shepherd A, Brookes S, Abrams P. The effect of Oestrogen supplementation on post-menopausal urinary stress incontinence: A double-blind placebo-controlled trial. *British Journal of Obstetrics and Gynaecology* 1999; 106:711-8.
68. Jirarattanaphochai K, Jung S, Thienthong S, Krisanaprakornkit W, Sumananont C. Peridural methylprednisolone and wound infiltration with bupivacaine for postoperative pain control after posterior lumbar spine surgery - A randomized double-blinded placebo-controlled trial. *Spine* 2007; 32:609-616.
69. Kato M, Watanabe M, Konishi S, Kudo M, Konno J, Meguro T, et al. Randomized, double-blind, placebo-controlled crossover trial of famotidine in patients with functional dyspepsia. *Alimentary and Pharmacology and Therapy* 2005; 21:27-31.
70. Katz N, Ju WD, Krupa DA, Sperling RS, Rodgers DB, Gertz BJ, et al. Efficacy and safety of Rofecoxib in patients with chronic low back pain - Results from two 4-week, randomized, placebo-controlled, parallel-group, double blind trial. *Spine* 2003; 28:851-858.
71. Katznelson L, Robinson MW, Coyle CL, Lee H, Farrell CE. Effects of modest testosterone supplementation and exercise for 12 weeks on body composition and quality of life in elderly men. *European Journal of Endocrinology* 2006; 155: 867-875.
72. Kavanaugh A, Antoni C, Krueger GG Yan S, Bala M, Dooley LT, et al. Infliximab improves health related quality of life and physical function in patients with psoriatic arthritis. *Annals of the Rheumatic Diseases* 2006; 65:471-477.
73. Keystone E, Burmester GR, Furie R, Loveless JE, Emery P, Kremer J, et al. Improvement in patient-reported outcomes in a rituximab trial in patients with severe rheumatoid arthritis refractory to anti-tumor necrosis factor therapy. *Arthritis and Rheumatology* 2008; 59:785-793. doi: 10.1002/art.23715
74. Khoromi S, Cui L, Nackers L, Max MB. Morphine, nortriptyline and their combination vs. placebo in patients with chronic lumbar root pain. *Pain* 2007; 130:66-75.
75. Kingshott RN, Vennelle M, Coleman EL, Engleman HM, Mackay TW, Douglas NJ. Randomized, double-blind, placebo-controlled crossover trial of Modafinil in the treatment of residual excessive daytime sleepiness in the sleep apnea/hypopnea syndrome. *American Journal of Respiratory and Critical Care Medicine* 2001; 163:918-23.
76. Kivitz A, Ma C, Ahdieh H, Galer BS. A 2-week, multicenter, randomized, double-blind, placebo-controlled, dose-ranging, phase III trial comparing the efficacy of oxymorphone extended release and placebo in adults with pain associated with osteoarthritis of the hip or knee. *Clinical Therapeutics* 2006; 28:352-364.
77. Knudtson ML, Wyse DG, Galbraith PD, Brant R, Hildebrand K, Peterson D, et al. Chelation therapy for ischemic heart disease: A randomized controlled trial. *JAMA* 2002; 287:481-6.
78. Koskenpato J, Farkkila M, Sipponen P. Helicobacter pylori eradication and standardized 3-month Omeprazole therapy in functional dyspepsia. *American Journal of Gastroenterology* 2001; 96:2866-2872.
79. Kremer JM, Genovese MC, Cannon GW, Caldwell JR, Cush JJ, Furst DE, et al. Concomitant Leflunomide therapy in patients with active rheumatoid arthritis despite stable doses of Methotrexate. A randomized, double- blind, placebo-controlled trial. *Annals of Internal Medicine* 2002; 137:726-33.
80. Kremer JM, Westhovens R, Leon M, Di GE, Alten R, Steinfeld S, et al. Treatment of rheumatoid arthritis by selective inhibition of T-cell activation with fusion protein CTLA4IG. *New England Journal of Medicine* 2003; 349:1907-1915.
81. Kritz-Silverstein D, von Muehlen D, Laughlin GA, Bettencourt R. Effects of dehydroepiandrosterone supplementation on cognitive function and quality of life: The DHEA and well-ness (DAWN) trial. *Journal of the American Geriatrics Society* 2008; 56:1292-1298. doi: 10.1111/j.1532-5415.2008.01768.x
82. Krueger GG, Langley RG, Finlay AY, Griffiths CEM, Woolley JM, Lalla D, et al. Patient-reported outcomes of psoriasis improvement with etanercept therapy: Results of a randomized phase III trial. *British Journal of Dermatology* 2005; 153:1192-1199.
83. Krystal JH, Rosenheck RA, Cramer JA, Vessicchio JC, Jones KM, Vertrees JE, et al. Adjunctive risperidone treatment for antidepressant-resistant symptoms of chronic military service-related PTSD: a randomized trial. *JAMA* 2011; 306: 493-502. doi: 10.1001/jama.2011.1080
84. Lambert RG, Hutchings EJ, Grace MG, Jhangri GS, Conner-Spady B, Maksymowych WP. Steroid injection for osteoarthritis of the hip: a randomized, double-blind, placebo-controlled trial. *Arthritis and Rheumatism* 2007; 56:2278-2287.
85. Lebwohl M, Papp K, Han C, Schenkel B, Yeilding N, Wang Y, et al. Ustekinumab improves health-related quality of life in patients with moderate-to-severe psoriasis: results from the PHOENIX 1 trial. *British Journal of Dermatology* 2010; 162:137-146. doi: 10.1111/j.1365-2133.2009.09491.x
86. Leplege A, Mackenzie-Schliacowsky N, Eacute CE, Ruszniewski P. Quality of life scale and impact of a topical treatment on symptoms of gastro-esophageal reflux without severe esophagitis. *Gastroenterology and Clinical Biology* 2005; 29:676-681.
87. Lewis EF, Pfeffer MA, Feng A, Uno H, McMurray JJ, Toto R, et al. Darbepoetin alfa impact on health status in diabetes patients with kidney disease: a randomized trial. *Clinical Journal of the American Society of Nephrology* 2011; 6: 845-855. doi: 10.2215/CJN.06450710
88. Linde M, Hagen K, Salvesen O, Gravdahl GB, Helde G, Stovner LJ, Onabotulinum Toxin A Treatment of Cervicogenic Headache: A Randomised, Double-Blind, Placebo-Controlled Crossover Study. *Cephalalgia* 2011; 31: 797-807. doi: 10.1177/0333102411398402
89. Litten RZ, Fertig JB, Falk DE, Ryan ML, Mattson ME, Collins JF, et al. A double-blind, placebo-controlled trial to assess the efficacy of quetiapine fumarate XR in very heavy-drinking alcohol-dependent patients. *Alcoholism, Clinical Experimental Research* 2012; 36:406-16. doi: 10.1111/j.1530-0277.2011.01649.x
90. Loew TH, Nickel MK, Muehlbacher M Kaplan P, Nickel C, Kettler C, et al. Topiramate treatment for women with borderline personality disorder: a double-blind, placebo-controlled study. *Journal of Clinical Pharmacology* 2006; 26:61-66.
91. Loftus EV, Feagan BG, Colombel JF, Rubin DT, Wu EQ, Yu AP, et al. Effects of Adalimumab maintenance therapy on health-related quality of life of patients with crohn's disease: Patient-reported outcomes of the CHARM Trial. *American Journal of Gastroenterology* 2008; 103:3132-3141. doi: 10.1111/j.1572-0241.2008.02175.x
92. Lovas K, Gebre-Medhin G, Trovik TS, Fougner KJ, Uhlving S, Nedrebo BG, et al. Replacement of dehydroepiandrosterone in adrenal failure: No benefit for subjective health status and sexuality in a 9-month, randomized, parallel group clinical trial. *Journal of Clinical Endocrinology and Metabolism* 2003; 88:1112-8.
93. Ma K, Jiang W, Zhou Q, Du DP. The efficacy of oxycodone for management of acute pain episodes in chronic neck pain patients. *International Journal of Clinical Practice* 2008; 62:241-247.
94. Maanum G, Jahnsen R, Stanghelle JK, Sandvik L, Keller A. Effects of botulinum toxin A in ambulant adults with spastic cerebral palsy: a randomized double-blind placebo controlled-trial. *Journal of Rehabilitation Medicine* 2011; 43: 338-347. doi: 10.2340/16501977-0672
95. Mariette X, Ravaud P, Steinfeld S, Baron G, Goetz J, Hachulla E, et al. Inefficacy of infliximab in primary Sjogren's syndrome: results of the randomized, controlled Trial of Remicade in Primary Sjogren's Syndrome (TRIPSS). *Arthritis and Rheumatism* 2004; 50: 1270-1276.
96. Marquis P, Roux C, De La Loge C, Diaz-Curiel M, Cormier C, Isaia G, et al. Strontium ranelate prevents quality of life impairment in post-menopausal women with established vertebral osteoporosis. *Osteoporosis International* 2008; 19:503-510.
97. Mathias SD, Colwell HH, Miller DP, Moreland LW, Buatti M, Wanke L. Health-related quality of life and functional status of patients with rheumatoid arthritis randomly assigned to receive Etanercept or placebo. *Clinical Therapeutics* 2000; 22:128-39.
98. Mazurek B, Haupt H, Szczepek AJ, Sandmann J, Gross J, Klapp B, et al. Evaluation of vardenafil for the treatment of subjective tinnitus: a controlled pilot study. *Journal of Negative Results in Biomedicine* 2009; 8: 3. doi: 10.1186/1477-5751-8-3
99. Mazzoleni LE, Sander GB, Francesconi CF, Mazzoleni F, Uchoa DM, De Bona LR, et al. Helicobacter pylori eradication in functional dyspepsia: HEROES trial. *Archives of Internal Medicine* 2011; 171: 1929-1936. doi: 10.1001/archinternmed.2011.533
100. McElroy SL, Guerdjikova AI, Winstanley EL, O’Melia AM, Mori N, McCoy J, et al. Acamprosate in the Treatment of Binge Eating Disorder: A Placebo-Controlled Trial. *International Journal of Eating Disorders* 2011; 44: 81-90. doi: 10.1002/eat.20876
101. Mcmillan CV, Bradley C, Gibney J, Healy ML, Russell-Jones DL, Sonksen PH. Psychological effects of withdrawal of growth hormone therapy from adults with growth hormone deficiency. *Clinical Endocrinology* 2003; 59:467-475.
102. Mease P, Genovese MC, Gladstein G, Kivitz AJ, Ritchlin C, Tak PP, et al. Abatacept in the treatment of patients with psoriatic arthritis: results of a six-month, multicenter, randomized, double-blind, placebo-controlled, phase II trial. *Arthritis and Rheumatology* 2011; 63: 939-948. doi: 10.1002/art.30176
103. Mease PJ, Woolley JM, Singh A, Tsuji W, Dunn M, Chiou, CF. Patient-reported outcomes in a randomized trial of etanercept in psoriatic arthritis. *Journal of Rheumatology* 2010; 37: 1221-1227. doi: 10.3899/jrheum.091093
104. Mease PJ, Revicki DA, Szechinski J et al. Improved health-related quality of life for patients with active rheumatoid arthritis receiving rituximab: Results of the Dose-Ranging Assessment: International Clinical Evaluation of Rituximab in Rheumatoid Arthritis (DANCER) Trial. *Journal of Rheumatology* 2008; 35:20-30.
105. Mease PJ, Clauw DJ, Gendreau RM, Rao SG, Kranzler J, Chen W, et al. The efficacy and safety of milnacipran for treatment of fibromyalgiae. A randomized, double-blind, placebo-controlled trial. *Journal of Rheumatology* 2009; 36:398-409. doi: 10.3899/jrheum.080734
106. Merril JT, Burgos-Vargas R, Westhovens R, Chalmers A, D’Cruz D, Wallace DJ, et al. The efficacy and safety of abatacept in patients with non-life-threatening manifestations of systemic lupus erythematosus: results of a twelve-month, multicenter, exploratory, phase IIb, randomized, double-blind, placebo-controlled trial. *Arthritis and Rheumatism* 2010; 62: 3077-3087. doi: 10.1002/art.27601
107. Merkies IS, Bril V, Dalakas MC, Deng C, Donofrio P, Hanna K, et al. Health-related quality-of-life improvements in CIDP with immune globulin IV 10%: the ICE Study. *Neurology* 2009; 72:1337-1344. doi: 10.1212/WNL.0b013e3181a0fd80
108. Mohler ERI, Hiatt WR, Olin JW, Wade M, Jeffs R, Hirsch AT. Treatment of intermittent claudication with beraprost sodium, an orally active prostaglandin I2 analogue: A double-blinded, randomized, controlled trial. *Journal of the American College of Cardiology* 2003; 41:1679-86.
109. Mozaffarian D, Minami E, Letterer RA, Lawler RL, McDonald GB, Levy WC. The effects of Atorvastatin (10 mg) on systemic inflammation in heart failure. *American Journal of Cardiology* 2005; 96:1699-1704.
110. Muehlbacher M, Nickel MK, Nickel C, Kettler C, Lahmann C, Gil FP, et al. Mirtazapine treatment of social phobia in women - A randomized, double-blind, placebo-controlled study. *Journal of Clinical Psychopharmacology* 2005; 25:580-583.
111. Muehlbacher M, Nickel MK, Kettler C, Tritt K, Lahmann C, Leiberich PK, et al. Topiramate in treatment of patients with chronic low back pain - A randomized, double-blind, placebo-controlled study. *Clinical Journal of Pain* 2006; 22:526-531.
112. Munteanu SE, Zammit GV, Menz HB, Landorf KB, Handley CJ, Elzarka A, et al. Effectiveness of intra-articular hyaluronan (Synvisc, hylan G-F 20) for the treatment of first metatarsophalangeal joint osteoarthritis: a randomised placebo-controlled trial. *Annals of Rheumatic Disease* 2011; 70: 1838-1841. doi: 10.1136/ard.2011.153049
113. Nair KS, Rizza RA, O'Brien P, Dhataria K, Short KR, Nehra A, et al. DHEA in elderly women and DHEA or testosterone in elderly men. *New England Journal of Medicine* 2006; 355:1647-1659.
114. Nash P, Thaci D, Behrens F, Falk F, Kaltwasser JP. Leflunomide improves psoriasis in patients with psoriatic arthritis: An in-depth analysis of data from the TOPAS study. *Dermatology* 2006; 212:238-249.
115. Naumann MK, Hamm H, Lowe NJ. Effect of botulinum toxin type A on quality of life measures in patients with excessive axillary sweating: A randomized controlled trial. *British Journal of Dermatology* 2002; 147:1218-26.
116. Nickel C, Tritt K, Muehlbacher M, Gil FP, Mitterlehner FO, Kaplan P, et al. Topiramate treatment in bulimia nervosa patients: A randomized, double-blind, placebo-controlled trial. *International Journal of Eating Disorders* 2005; 38:295-300.
117. Nickel C, Lahmann C, Tritt K, Muehlbacher M, Kaplan P, Kettler C, et al. Topiramate in treatment of depressive and anger symptoms in female depressive patients: a randomized, double-blind, placebo-controlled study. *Journal of Affective Disorders* 2005; 87:243-252.
118. Nickel JC, O’Leary MP, Lepor H, Caramelli KE, Thomas H, Hill LA, et al. Silodosin for Men with Chronic Prostatitis/Chronic Pelvic Pain Syndrome: Results of a Phase II Multicenter, Double-Blind, Placebo Controlled Study. *Journal of Urology* 2011; 186: 125-131. doi: 10.1016/j.juro.2011.03.028
119. Nickel MK, Nickel C, Muehlbacher M Leibrich PK, Kaplan P, Lahmann C, et al. Influence of topiramate on olanzapine-related adiposity in women - A random, double-blind, placebo-controlled study. *Journal of Clinical Psychopharmacology* 2005; 25:211-217.
120. Nortvedt MW, Riise T, Myhr KM, Nyland HI, Hanestad BR. Type I interferons and the quality of life of multiple sclerosis patients. Results from a clinical trial on interferon alfa-2a. *Multiple Sclerosis* 1999; 5:317-322.
121. O'Donnell ME, Badger SA, Sharif MA, Young IS, Lee B, Soong C. The vascular and biochemical effects of cilostazol in patients with peripheral arterial disease. *Journal of Vascular Surgery* 2009; 49: 1226-1234. doi: 10.1016/j.jvs.2008.11.098
122. Olanow CW, Kieburtz K, Stern M, Watts R, Langston JW, Guarnieri M, et al. Double-blind, placebo-controlled study of entacapone in levodopa-treated patients with stable Parkinson disease. *Archives of Neurology* 2004; 61: 1563-1568.
123. Olson LG, Ambrogetti A, Sutherland DC. A pilot randomized controlled trial of Dexamphetamine in patients with chronic fatigue syndrome. *Psychosomatics* 2003; 44:38-43.
124. Olsson R, Boberg KM, De Muckadell OS, Lindgren S, Hultcrantz R, Folvik G, et al. High-dose ursodeoxycholic acid in primary sclerosing cholangitis: A 5-year multicenter, randomized, controlled study. *Gastroenterology* 2005; 129:1464-1472.
125. Passalacqua G, Pasquali M, Ariano R, Lombardi C, Giardini A, Baiardini I, et al. Randomized double-blind controlled study with sublingual carbamylated allergoid immunotherapy in mild rhinitis due to mites. *Allergy* 2006; 61: 849-854.
126. Peloso PM, Fortin L, Beaulieu A, Kamin M, Rosenthal N. Analgesic efficacy and safety of tramadol/ acetaminophen combination tablets (Ultracet) in treatment of chronic low back pain: a multicenter, outpatient, randomized, double blind, placebo controlled trial. *Journal of Rheumatology* 2004; 31: 2454-2463.
127. Peterson PK, Pheley A, Schroeppel J, Schenck C, Marshall P, Kind A, et al. A preliminary placebo-controlled crossover trial of Fludrocortisone for chronic fatigue syndrome. *Archives of Internal Medicine* 1998; 158:908-14.
128. Peyrot M, Rubin RR. Effect of technosphere inhaled insulin on quality of life and treatment satisfaction. *Diabetes Technology and Therapy* 2010; 12: 49-55. doi: 10.1089/dia.2009.0115
129. Philipp M, Kohnen R, Hiller KO. Hypericum extract versus Imipramine or placebo in patients with moderate depression: Randomised multicentre study of treatment for eight weeks. *British Medical Journal* 1999; 319:1534-8.
130. Podichetty VK, Segal AM, Lieber M, Mazanec DJ. Effectiveness of salmon calcitonin nasal spray in the treatment of lumbar canal stenosis - A double-blind, randomized, placebo-controlled, parallel group trial. *Spine* 2004; 29:2343-2349.
131. Pope JE, Prashker M, Anderson J. The efficacy and cost effectiveness of N of 1 studies with diclofenac compared to standard treatment with nonsteroidal antiinflammatory drugs in osteoarthritis. *Journal of Rheumatology* 2004; 31:140-149.
132. Regensteiner JG, Ware JE, Jr, McCarthy WJ, Zhang P, Forbes WP, Heckman J, et al. Effect of cilostazol on treadmill walking distance, community-based walking ability, and health-related quality of life in patients with intermittent claudication due to peripheral arterial disease; meta-analysis of six randomized controlled trials. *Journal of the American Geriatrics Society* 2002; 50:1939-1946.
133. Reich K, Nestle FO, Papp K, Ortonne JP, Wu Y, Bala M, et al. Improvement in quality of life with infliximab induction and maintenance therapy in patients with moderate-to-severe psoriasis: a randomized controlled trial. *British Journal of Dermatology* 2006; 154:1161-1168.
134. Revicki DA, Willian MK, Menter A, Gordon KB, Kimball AB, Leonardi CL, et al. Impact of adalimumab treatment on patient-reported outcomes: Results from a Phase III clinical trial in patients with moderate to severe plaque psoriasis. *Journal of Dermatological Treatment* 2007; 18:341-350.
135. Rigby W, Ferraccioli G, Greenwald M, Zazueta-Montiel B, Fleischmann R, Wassenberg S, et al. Effect of rituximab on physical function and quality of life in patients with rheumatoid arthritis previously untreated with methotrexate. *Arthritis Care Research* 2011; 63: 711-720. doi: 10.1002/acr.20419
136. Rimmer J, Greenwood A, Bartlett D, Hellgren J. Nasal steroids improve regulation of nasal patency in asthma and mild rhinitis: a randomised, cross-over trial. *European Archives of Otorhinolaryngology* 2012; 269: 1133-1138. doi: 10.1007/s00405-011-1803-8
137. Rowbotham M, Harden N, Stacey B, Bernstein P, Magnus-Miller L. Gabapentin for the treatment of postherpetic neuralgia: A randomized controlled trial. *JAMA* 1998; 280:1837-42.
138. Rowe PC, Calkins H, DeBusk K, McKenzie R, Anand R, Sharma G, et al. Fludrocortisone acetate to treat neurally mediated hypotension in chronic fatigue syndrome: A randomized controlled trial. *JAMA* 2001; 285:52-9.
139. Rudick RA, Miller D, Hass S, Hutchinson M, Calabresi PA, Confavreux C, et al. Health-related quality of life in multiple sclerosis: Effects of Natalizumab. *Annals of Neurology* 2007; 62:335-346.
140. Ruoff GE, Rosenthal N, Jordan D, Karim R, Kamin M. Tramadol/Acetaminophen combination tablets for the treatment of chronic lower back pain: A multicenter, randomized, double-blind, placebo-controlled outpatient study. *Clinical Therapeutics* 2003; 25:1123-41.
141. Russel IJ, Holman AJ, Swick TJ, Alvarez-Horine S, Wang YG, Guinta D. Sodium oxybate reduces pain, fatigue, and sleep disturbance and improves functionality in fibromyalgia: results from a 14-week, randomized, double-blind, placebo-controlled study. *Pain* 2011; 152: 1007-1017. doi: 10.1016/j.pain.2010.12.022
142. Russell AS, Wallenstein GV, Li T,Martin MC, Maclean R, Blaisdell B, et al. Abatacept improves both the physical and mental health of patients with rheumatoid arthritis who have inadequate response to methotrexate treatment. *Annals of the Rheumatic Diseases* 2007; 66:189-194.
143. Sanders DB, Hart IK, Mantegazza R, Shokla SS, Siddiqi ZA, De Baets MH, et al. An international, phase III, randomized trial of mycophenolate mofetil in myasthenia gravis. *Neurology* 2008; 71: 400-406. doi: 10.1212/01.wnl.0000312374.95186.cc
144. Schrier RW, Gross P, Gheorghiade M, Berl T, Verbalis JG, Czerwiec FS, et al. Tolvaptan, a selective oral vasopressin V-2-receptor antagonist, for hyponatremia. *New England Journal of Medicine* 2006; 355:2099-2112.
145. Shi LZ, Namjoshi MA, Swindle R, Yu XM, Risser R, Baker RW, et al. Effects of olanzapine alone and olanzapine/fluoxetine combination on health-related quality of life in patients with bipolar depression: Secondary analyses of a double-blind, placebo-controlled, randomized clinical trial. *Clinical Therapeutics* 2004; 26:125-134.
146. Shikiar R, Heffernan M, Langley RG, Willian MK, Okun MM, Revicki DA. Adalimumab treatment is associated with improvement in health-related quality of life in psoriasis: Patient-reported outcomes from a Phase II randomized controlled trial. *Journal of Dermatological Treatment* 2007; 18:25-31.
147. Shores MM, Kivlahan DR, Sadak TI, Li EJ, Matsumoto AM. A randomized, double-blind, placebo-controlled study of testosterone treatment in hypogonadal older men with subthreshold depression (dysthymia or minor depression). *Journal of Clinical Psychiatry* 2009; 70: 1009-1016.
148. Silberstein SD, Loder E, Forde G, Papadopoulos G, Fairclough D, Greenberg S. The impact of migraine on daily activities: Effect of topiramate compared with placebo. *Current Medical Research and Opinion* 2006; 22:1021-1029.
149. Simons M, Annex BH, Laham RJ, Kleiman N, Henry T, Dauerman H, et al. Pharmacological treatment of coronary artery disease with recombinant fibroblast growth factor-2: Double-blind, randomized, controlled clinical trial. *Circulation* 2002; 105:788-93.
150. Singh JA, Mahowald ML, Noorbaloochi S. Intra-articular botulinum toxin A for refractory shoulder pain: a randomized, double-blinded, placebo-controlled trial. *Translational Research* 2009; 153: 205-216. doi: 10.1016/j.trsl.2009.02.004
151. Snidjers GF, van den Ende CHM, van Riel PLCM, van den Hoogen FHJ, den Broeder AA. The Effects of Doxycycline on Reducing Symptoms in Knee Osteoarthritis: Results from a Triple-Blinded Randomised Controlled Trial. *Annals of Rheumatoid Arthritis* 2011; 70: 1191-1196. doi: 10.1136/ard.2010.147967
152. Snyder PJ, Peachey H, Hannoush P, Berlin JA, Loh L, Lenrow DA, et al. Effect of testosterone treatment on body composition and muscle strength in men over 65 years of age. *Journal of Clinical Endocrinology and Metabolism* 1999; 84:2647-53.
153. Spencer S, Calverley PM, Sherwood BP, Jones PW. Health status deterioration in patients with chronic obstructive pulmonary disease. *American Journal of Respiratory and Critical Care Medicine* 2001; 163:122-128.
154. Strand V, Aranow C, Cardiel MH, Alarcon-Segovia D, Furie R, Sherrer Y, et al. Improvement in health-related quality of life in systemic lupus erythematosus patients enrolled in a randomized clinical trial comparing LJP 394 treatment with placebo. *Lupus* 2003; 12:677-686.
155. Strand V, Smolen JS, van Vollenhoven RF, Mease P, Burmester GR, Hiepe F, et al. Certolizumab pegol plus methotrexate provides broad relief from the burden of rheumatoid arthritis: analysis of patient-reported outcomes from the RAPID 2 trial. *Annals of Rheumatic Diseases* 2011; 70: 996-1002. doi: 10.1136/ard.2010.143586
156. Strand V, Mease P, Burmester GR, Nikai E, Coteur G, Van VR, et al. Rapid and sustained improvements in health-related quality of life, fatigue, and other patient-reported outcomes in rheumatoid arthritis patients treated with certolizumab pegol plus methotrexate over 1 year: results from the RAPID 1 randomized controlled trial. *Arthritis Research and Therapy* 2009; 11: R170. doi: 10.1186/ar2859
157. Strand V, Tugwell P, Bombardier C Maetzel A, Crawford B, Dorrier C, et al. Function and health-related quality of life: results from a randomized controlled trial of leflunomide versus methotrexate or placebo in patients with active rheumatoid arthritis. Leflunomide Rheumatoid Arthritis Investigators Group. *Arthritis and Rheumatism* 1999; 42:1870-1878.
158. Svendsen KB, Jensen TS, Bach FW. Does the cannabinoid dronabinol reduce central pain in multiple sclerosis? Randomised double blind placebo controlled crossover trial. *British Medical Journal* 2004; 329:253-257.
159. Swenson JR, O'Connor CM, Barton D, Van Zyl LT, Swedberg K, Forman LM, et al. Influence of depression and effect of treatment with Sertraline on quality of life after hospitalization for acute coronary syndrome. *American Journal of Cardiology* 2003; 92:1271-1276.
160. Swinburn BA, Carey D, Hills AP, Hooper M, Marks S, Proietto J, et al. Effect of orlistat on cardiovascular disease risk in obese adults. *Diabetes Obesity and Metabolism* 2005; 7:254-262.
161. Talley NJ, Kellow JE, Boyce P, Tennant C, Huskic S, Jones M. Antidepressant therapy (imipramine and citalopram) for irritable bowel syndrome: A double-blind, randomized, placebo-controlled trial. *Digestive Diseases and Sciences* 2008; 53:108-115.
162. Tan VP, Wong WM, Cheung TK, Lai KC, Hung IF, Chan P, et al. Treatment of non-erosive reflux disease with a proton pump inhibitor in Chinese patients: a randomized controlled trial. *Journal of Gastroenterology* 2011; 46: 906-912. doi: 10.1007/s00535-011-0402-1
163. Tashkin DP, Elashoff R, Clements PJ, Goldin J, Roth MD, Furst DE, et al. Cyclophosphamide versus placebo in scleroderma lung disease. *New England Journal of Medicine* 2006; 354:2655-2666.
164. Taylor PC, Quattrocchi E, Mallett S, Kurrasch R, Petersen J, Chang DJ. Ofatumumab, a fully human anti-CD20 monoclonal antibody, in biological-naive, rheumatoid arthritis patients with an inadequate response to methotrexate: a randomised, double-blind, placebo-controlled clinical trial. *Annals of Rheumatic Diseases*. 2011; 70: 2119-25. doi: 10.1136/ard.2011.151522
165. The Idiopathic Pulmonary Fibrosis Clinical Research Network. A Controlled Trial of Sildenfanil in Advanced Idiopathic Pulmonary Fibrosis. *New England Journal of Medicine* 2010; 363: 620-628. doi: 10.1056/NEJMoa1002110
166. The Propranolol Aneurysm Trial Investigators. Propranolol for Small Abdominal Aortic Aneurysms: Results of a Randomized Trial. *Journal of Vascular Surgery* 2002; 35: 72-79.
167. Trojan DA, Collet JP, Shapiro S Jubelt B, Miller RG, Agre JC, et al. A multicenter, randomized, double-blinded trial of Pyridostigmine in postpolio syndrome. *Neurology* 1999; 53:1225-33.
168. van der Heijde D, Dijkmans B, Geusens P, Sieper J, DeWoody K, Williamson P, et al. Efficacy and safety of infliximab in patients with ankylosing spondylitis - Results of a randomized, placebo-controlled trial (ASSERT). *Arthritis and Rheumatism* 2005; 52:582-591.
169. Vorsanger G, Xiang J, Jordan D, Farrell J. Post hoc analysis of a randomized, double-blind, placebo-controlled efficacy and tolerability study of tramadol extended release for the treatment of osteoarthritis pain in geriatric patients. *Clinical Therapy* 2007; 29: 2520-35. doi: 10.1016/j.clinthera.2007.12.009
170. Vranken JH, Dijkgraaf MGW, Kruis MR, van Dasselaar NT, van der Vegt MH. Iontophoretic administration of S(+)-ketamine in patients with intractable central pain: A placebo-controlled trial. *Pain* 2005; 118:224-231.
171. Vranken JH, Dijkgraaf MGW, Kruis MR, van der Vegt MH, Hollmann MW, Heesen M. Pregabalin in patients with central neuropathic pain: A randomized, double-blind, placebo-controlled trial of a flexible-dose regimen. *Pain* 2008; 136:150-157.
172. Wallace DJ, Stohl W, Furie RA, Lisse JR, McKay JD, Merrill JT, et al. A phase II, randomized, double-blind, placebo-controlled, dose-ranging study of belimumab in patients with active systemic lupus erythematosus. *Arthritis and Rheumatism* 2009; 61: 1168-1178. doi: 10.1002/art.24699
173. Walsh JK, Krystal AD, Amato DA, Rubens R, Caron J, Wessel TC, et al. Nightly treatment of primary insomnia with eszopiclone for six months: Effect on sleep, quality of life, and work limitations. *Sleep* 2007; 30:959-968.
174. Watson CPN, Moulin D, Watt-Watson J, Gordon A, Eisenhoffer J. Controlled-release Oxycodone relieves neuropathic pain: A randomized controlled trial in painful diabetic neuropathy. *Pain* 2003; 105:71-78.
175. Watson RG, Tham TC, Johnston BT, McDougall NI. Double blind cross-over placebo controlled study of Omeprazole in the treatment of patients with reflux symptoms and physiological levels of acid reflux--the "sensitive oesophagus". *Gut* 1997; 40:587-90.
176. Westhovens R, Cole JC, Li T Martin M, Maclean R, Lin P, et al. Improved health-related quality of life for rheumatoid arthritis patients treated with abatacept who have inadequate response to anti-TNF therapy in a double-blind, placebo-controlled, multicentre randomized clinical trial. *Rheumatology* 2006; 45:1238-1246.
177. WGET Research Group. Etanercept plus standard therapy for Wegener's granulomatosis. *New England Journal of Medicine* 2005; 352:351-361.
178. Wise TN, Wiltse CG, Iosifescu DV, Sheridan M, Xu JY, Raskin J. The safety and tolerability of duloxetine in depressed elderly patients with and without medical comorbidity. *International Journal of Clinical Practice* 2007; 61:1283-1293.
179. Wong WM, Wong BCY, Hung WK, Yee YK, Yip AWC, Szeto ML, et al. Double blind, randomised, placebo controlled study of four weeks of Lansoprazole for the treatment of functional dyspepsia in Chinese patients. *Gut* 2002; 51:502-506.
180. Yaffe K, Vittinghoff E, Ensrud KE, Johnson KC, Diem S, Hanes V, et al. Effects of ultra-low-dose transdermal estradiol on cognition and health-related quality of life. *Archives of Neurology* 2006; 63: 945-950.
181. Zhao SZ, Dedhiya SD, Bocanegra TS, Fort JG, Kuss ME, Rush SM. Health-related quality-of-life effects of oxaprozin and nabumetone in patients with osteoarthritis of the knee. *Clinical Therapy* 1999; 21: 205-217.
182. Zhao SZ, Fiechtner JI, Tindall EA, Dedhiya SD, Zhao WW, Osterhaus JT, et al. Evaluation of health-related quality of life of rheumatoid arthritis patients treated with Celecoxib. *Arthritis Care and Research* 2000; 13:112-121.
183. Ziegler D, Movsesyan L, Mankovsky B, Gurieva I, Abylaiuly Z, Strokov I. Treatment of symptomatic polyneuropathy with actovegin in type 2 diabetic patients. *Diabetes Care* 2009; 32: 1479-1484. doi: 10.2337/dc09-0545
184. Zisook S, Kasckow JW, Golshan S, Fellows I, Solorzano E, Lehman D, et al. Citalopram augmentation for subsyndromal symptoms of depression in middle-aged and older outpatients with schizophrenia and schizoaffective disorder: a randomized controlled trial. *Journal of Clinical Psychiatry* 2009; 70: 562-71.