**Appendix Table E3. Sample selection criteria and allowed co-interventions for included fibromyalgia observational studies**

| **Author, Year, Country, Funder** | **Diagnostic Criteria** | **Additional Inclusion Criteria** | **Exclusion Criteria** | **Disallowed Pharmaceuticals, Nutraceuticals, or**  **Co-interventions** | **Allowed Pharmaceuticals, Nutraceuticals, or Co-interventions** |
| --- | --- | --- | --- | --- | --- |
| **Pharmacologic** |  |  |  |  |  |
| Arnold, 201239  USA, Canada  Industry funded | 1990 ACR criteria | -Male & Female  -18-70y  -Score ≥ 4 on FIQ physical function raw score (range: 0-33) at screening and between 40-90 on VAS pain scale (range: 0-100) during 14-d baseline period | -Other rheumatic or medical disorders with symptoms similar to FM  -Previous exposure to milnacipran  -Treatment with an investigational drug within 30 days of screening  -BDI >25 (moderate-to-severe depressive symptoms) or current MDD as assessed by MINI  -Significant risk of suicide  -History of psychosis, hypomania, or mania  -Substance abuse  -Other severe psychiatric disorder as assessed by investigator  -History of behavior that would prohibit compliance for duration of study as assessed by investigator  -Pregnancy or breastfeeding  -Unacceptable contraception  -Any active or unstable medical condition  -Prostate enlargement or other genitourinary disorder  -Active or pending disability claim, worker’s compensation claim, or litigation | -Digitalis  -Centrally acting medications for FM  -Transcutaneous electrical nerve stimulation, biofeedback, tender and trigger point injections, acupuncture, and anesthetic or narcotic patches | -Acetaminophen, aspirin, and nonsteroidal anti-inflammatory agents  -Short term pain rescue medication included tramadol or hydro-codone between randomization and week 4  -Triptans permitted for acute migrant treatment  -Nonbenzodiazepine hypnotic agents for treatment of insomnia |
| Younger, 200940  USA  Nonprofit/ foundation funded | 1990 ACR criteria | -Held drug dosages steady for at least 2 previous months | -Joint pain/inflammation  -History of autoimmune or rheumatologic condition  -Blood test results: RF >20IU/mL, antinuclear antibody >1:80, and ESR >60 mm/hour | -Current or recent use of opioids | -Medications other than opioids  -Asked not to modify pain treatment regimen without notifying study personnel |
| **Physical** |  |  |  |  |  |
| Drexler, 200241  Austria  Funding not reported | 1990 ACR criteria | Not reported | Not reported | Not reported | Not reported |
| **Mixed** |  |  |  |  |  |
| Joshi, 200942  India  No external funding support | 1990 ACR criteria | -Male & Female  -18-60 years  -Symptoms of chronic muscular pain for at least 12 weeks | -Pregnant or lactating  -History of trauma, fractures, fever, malignancy, chronic renal or hepatic disorders  -Alcohol abuse  -Cerebrovascular or neurological abnormality | Not reported | -Allowed to continue previous medications and exercise regimens, if any |

**Abbreviations:** ACR=American College of Rheumatology; BDI=Beck Depression Inventory; ESR=erythrocyte sedimentation rate; FIQ=Fibromyalgia Impact Questionnaire; FM=Fibromyalgia; MDD=Major Depressive Disorder, MINI=Mini International Neuropsychiatric Interview, RF=rheumatoid factor, VAS=Visual Analog Scale 24-hour recall pain score