

Additional file 3: Main characteristics of included regulatory cohort studies

Study	Cohort types, Speciality	Study design Follow-up	Verification of publication status and results of unpublished studies	Publication rate	Definition of study results and other notes
Lee et al 2008[34]	Trials supporting new drugs approved by FDA between 1998 and 2000. Mixed speciality	Clinical trials Follow-up: >5 years	Searches of PubMed and other databases. Trial results obtained from FDA files.	Statistically significant: 66%(285/432) Not statistically sig.: 36%(52/144)	Statistically significance (primary outcome): $p < 0.05$ or if an equivalency trial $p > 0.05$ or a CI excluding the prespecified difference.
Melander et al 2003[35]	RCTs of five SSRIs submitted to the Swedish drug regulatory authority for marketing approval . Mental: depression	Clinical trials Follow-up: unclear	Literature search for publications. Study results based on submitted material.	Stand alone or pooled publications: Significant 100% (21/21) Non-significant 81% (17/21) Stand alone publications: Significant 90% (19/21) Non-significant 29% (6/21)	Also provided data on duplicate, and selective outcome reporting bias.
Rising et al 2008[36]	Efficacy trials supporting new drug applications approved by FDA from 2001 to 2002. Mixed speciality	Clinical trials Follow-up: >4 years	Search of PubMed and Cochrane Library and contacting sponsors and authors. Trial results obtained from FDA files.	<u>Primary outcomes</u> Favourable: 82% (102/124) Not favourable: 66% (19/29) Unknown: 60% (6/10) <u>Conclusion</u> Favourable: 79% (90/114) Not favourable: 64% (7/11) Unknown: 57% (4/7)	Favourable: statistically significantly in favour of the new drug or equivalence was found. Note: pooled publication not reported separately was considered “not published”.
Turner et al 2008[37]	Trials of 12 antidepressants, submitted to FDA between 1987 and 2004. Mental: depression	Phase 2 and 3 clinical trials. Follow-up: >2 years	Literature search and contacting sponsors for publications. Trial results obtained from FDA files.	Positive results: 97% (37/38) Questionable: 50% (6/12) Negative results: 33% (8/24)	Trial results were classified according to the FDA's regulatory decisions.

Notes: FDA - US Food and Drug Administration. SSRI - Selective Serotonin Reuptake Inhibitor. RCT - Randomized Controlled Trial