**Supplementary File 10 – Assessment of Regulatory Approval Status**

Two authors (NH & HM) independently evaluated all eligible trials for regulatory approval status using Drugs@FDA1 for drug and biological interventions and the 510(k) Premarket Notification website for devices.2 Interventions were classified into one of 3 categories: i) FDA approved prior to trial start (drug, biological or device interventions approved for any use by the time of trial start); ii) FDA approved at least 5 years ago ((drug, biological or device interventions approved for any use prior to October 31, 2016); and, iii) interventions not subject to FDA approval.

Bibliography

1. Drugs@FDA <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>.

2. 510(k) Premarket Notification <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>.