

## Work Stream 3.4

### **Benefits and harms of Mysimba® (naltrexone + bupropion) in the management of overweight and obesity: a systematic review and meta-analysis of unpublished clinical study reports**

#### **Lay summary**

Mysimba is a combination of two different medicines – naltrexone and bupropion. In December 2014, Mysimba® was approved for the European Medicines Agency (EMA) for treatment of overweight and obesity. In 2017, National Institute for Health and Care Excellence (NICE) did not recommend its use because of concerns over the balance of benefits and harms. NICE intends to reassess the drug in 2020. There is evidence that the information in journal publications of pivotal trials of Mysimba® (the trials used by the drug manufacturer to gain marketing license in Europe) provide an incomplete picture of its benefits and harms.

The aim of this review is to examine the benefits and harms of Mysimba®, using information from clinical study reports of pivotal trials, i.e., unpublished trial data from studies that the drug manufacturer used to gain marketing license from the EMA. We will request the data on these studies from the EMA, and then extract information on body weight and other risk measures of heart well-being. We will also extract data on harmful effects and study discontinuation because of harmful effects. We will use statistical software to combine data to get average estimates for each reported outcome. We will use a tool kit to rate the quality of the body of the evidence. We hope that the results of the review will assist the NICE with making robust decisions when they reassess Mysimba®.