

Title: A randomised, 4 way crossover, double blind, placebo controlled pilot study in patients with reflux symptoms, to assess suppression of gastro-oesophageal reflux by 'Gaviscon Double Action Mint ' using the Bravo system

EudraCT number: 2012-004109-28

Sponsor's protocol number: GA1211

The above clinical trial was terminated early; the justification is provided overleaf in Annex I.

Annex I:

D.2.2.1 The justification for early termination of the trial;

In accordance with business requirements the sponsor Reckitt Benckiser Healthcare (UK) Ltd, can confirm that trial GA1211 will not commence. The applicant wishes to confirm that this is purely a commercial decision and that there are no quality or safety reasons involved in this decision. As patient recruitment has not been initiated, there are no patient implications in withdrawing this trial.

D.2.2.2 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;

No patients as the trial did not commence.

D.2.2.3 The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.

No evaluation of results will take place as the trial has not commenced.

Approved