

## WOLFSON INSTITUTE OF PREVENTIVE MEDICINE

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Dr Jenny Flatman  
MHRA  
151 Buckingham Palace Road  
London SW1W 9SZ

9 March 2017

Dear Dr Flatman,

**Reference: 21313/0028/001-0003**  
**Eudract number: 2010-019874-34**  
**Product: Polypill**  
**Protocol number: PPT01**

I was not sure who to send this letter to, and I hope you don't mind me sending it to you since you kindly assisted with approval of our trial in 2010.

I would be grateful for your advice regarding whether we are required to upload the results of this trial onto the Eudract database given that the crossover trial ended in 2011 and was published in the journal PLoS ONE in 2012.

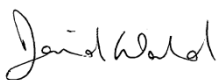
Following completion of the crossover trial, participants continued to take the Polypill for a four year open-label monitoring period and this ended in June 2015, when an end of trial declaration was sent to the MHRA and acknowledged on 21/09/2015.

Given that there were no new results from the end of the crossover trial in 2011 to the end of the monitoring period in 2015, there would be nothing further to disclose on the Eudract results database beyond that which has already been published.

I would be grateful if you would let me know whether we are still required to upload our results to the Eudract database.

Many thanks for your advice.

Yours sincerely,



Prof David Wald  
Consultant Cardiologist  
Professor of Cardiology