

Statistical Engagement Letter

Statistician names:

Professor Victoria Cornelius

Dr Rachel Phillips

Dr Ed Waddingham

Address:

Imperial Clinical Trials Unit, School of Public Health, Imperial College London
Stadium House, 68 Wood Lane, London, W12 7RH

Statistical Engagement Letter

Dear Professor Cornelius, Dr Phillips and Dr Waddingham

All CTIMP studies or blinded RCTs involving drugs sponsored by Imperial College London require appropriate statistical review and oversight. The RGIT as sponsors representative for the College require assurance that the statistician listed on the IRAS form is qualified and has agreed to undertake the appropriate duties in relation to the study.

As identified statistician for the study we therefore request the below:

Please confirm that you have reviewed or agreed to review study (Title Precision medicine Adaptive Network platform Trial in Hypoxaemic acute respiratory failure - PANTHER, IRAS 1008743)

Yes ☒ No ☐

Please confirm that you will be reviewing any blinding and randomisation involved in the trial:

Yes ☒ No ☐

Please list the statistical duties that you will undertake in the study:

<p>We will oversee all statistical aspects of the trial and attend TSC, DMC and TMG meetings.</p> <p>We will work to Imperial Clinical Trials Unit SOPs for statistical analysis</p> <p>We will contribute to the protocol writing the statistical analysis and design sections.</p> <p>We will write the statistical analysis plan.</p> <p>We will undertake all interim and final analyses.</p> <p>We will write statistical reports and contribute to publications.</p> <p>We will check the randomisation system, database and data extractions.</p>
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Please describe your qualifications/expertise to review

We are statisticians with PhDs in medical statistics.
We have extensive experience working as clinical trials statisticians in applied research and methodology research.

Signed: