

Our Ref: MRSA-01_EOT_MHRA_L01

Information Processing Unit
Area 6
MHRA
151 Buckingham Palace Road
Victoria
SW1W 9SZ

13 October 2011

Dear Sir or Madam,

Study Reference: MRSA-01
EudraCT number: 2006-005777-22
Study Title: Control of MRSA skin and wound colonisation

END OF TRIAL NOTIFICATION – EARLY TERMINATION

Please find enclosed a CD containing the declaration of the end of trial for the above study. Regrettably the declaration is an early termination because despite our concerted attempts it is proving impossible to find a satisfactory NHS partner willing to perform the clinical aspects of the study.

The CTA and ethics approvals were granted in April 2009. Since that time, working with the coordinating CRO (Aspect Clinical) and the NIHR, we have been liaising with several PCTs with a view to implementing the research. Thus far 3 PCTs, after initially expressing considerable interest in taking part and progressing a long way towards readiness for implementation, have pulled out at the last minute (in one case after signature of the agreement). In two instances this was due to a change of heart by the nursing staff involved, and in the third case because the PCT changed their minds about the agreed costing that had been set out using the NIHR template, and wanted to in effect treble their charges.

We are extremely dismayed and disappointed by the inordinate amount of time and effort that has been wasted since obtaining permission to undertake this important work more than two years ago. Under the circumstances, we have regrettably decided to abandon the trial in its current design, and have therefore decided to terminate it. No patients have been recruited to the study.

We are hoping to redesign this important trial so it can be performed without any reliance on NHS cooperation. The new design will of course be subject to further CTA and ethics committee approvals.

If you require any further information regarding the information provided, please do not hesitate to contact me.