

28 February 2013

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Dear

I am writing regarding the STAMPEDE (MRC PR08) trial, a trial investigating systemic therapy in advancing or metastatic prostate cancer. In particular, I am writing on behalf of the STAMPEDE Trial Management Group to notify the West Midlands Research Ethics Committee of a recent urgent communication by the manufacturer of abiraterone acetate (Janssen).

The communication emphasised that this study medication may cause harm to the unborn child if it is taken by women who are pregnant or may become pregnant. In particular, **women who are pregnant or may be pregnant should wear gloves if they need to touch or handle abiraterone acetate tablets.**

This information is available in the current Investigator Brochure (page 80 version 9.0) which was circulated to all STAMPEDE centres in November 2012. Furthermore, I would like to highlight that "using an effective contraceptive method" is one of the inclusion criteria for STAMPEDE patients (criteria X protocol section 4.1.4, protocol version 9.0).

As a result, all centres participating in the STAMPEDE trial have been notified via email highlighting drug handling information for all subjects, caregivers and study staff working in clinical trials using this IMP. In addition, all Principal Investigators and Pharmacy staff have been requested to:

:: confirm the receipt of the pregnancy-related warning letter for the handling of Abiraterone Acetate from Janssen.

:: ensure that all staff assisting with the trial and all patients participating in the trial are adequately informed about the information contained within the email circulated on 28-Feb-13

:: ensure that this information is held securely and referred to for the STAMPEDE trial only.

I hope you will deem the actions taken by the Trial Management Team adequate. Please do not hesitate to contact me with any questions or queries.

Kind regards,

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