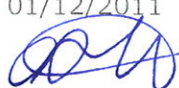


File Note 01/12/2011

PROTOCOL NUMBER: MRC PR08
PROTOCOL TITLE: STAMPEDE: Systemic Therapy in Advancing or Metastatic Prostate cancer: Evaluation of Drug Efficacy

Issue (short description)	Clarification of the guidance given in protocol version 8.0 section 4.3.2 'Hormone therapy prior to randomisation'
Comments/ Description of Issue:	<p>For clarity this section should read as follows:</p> <p>It is preferable that patients are not started on androgen deprivation therapy or given an orchidectomy prior to randomisation. However, if this has happened then patients must be randomised no more than 12 weeks after starting androgen deprivation therapy or having an orchidectomy (although this can be extended for anti-androgens - see below).</p> <p>Anti-androgens can be given for up to 14 weeks prior to randomisation [1] to cover disease flare; [2] with LHRH as maximum androgen blockade (MAB); or [3] as monotherapy.</p> <p>Anti-androgen monotherapy is contraindicated during the STAMPEDE trial. Any patients started on this form of treatment should switch to a permitted form of hormone therapy prior to consent. Anti-androgen use to cover disease flare when switching is permitted if indicated.</p> <p>Note that baseline testosterone measurements will not be required in patients who have already commenced hormone manipulation prior to randomisation.</p>
Action:	A copy of this file note should be signed by the applicable Principal Investigator and kept with protocol v8.0 in the relevant section of the investigator site file at each participating site.

Prepared by:

Name	Charlene Green - Clinical Trial Manager
Date	01/12/2011
Signature	

Principal Investigator:

Name	
Date:	
Signature	

Reviewed by Clinical Project Manager:

Name	Claire Amos - Clinical Project Manager
Date	01/12/2011
Signature	