STAMPEDE TRIAL (MRC PR08)
Telephone Consultation Checklist

This document is to aid you when a STAMPEDE participant's follow-up assessment is to be carried out via telephone consultation.

It is a guidance document which offers key points to be covered during the telephone consultation.

Please note this checklist does not replace the FU CRF, which should be completed as normal.

Please attach this document to the corresponding FU CRF and file with the patient's notes.

Trial ID:	
Hospital Number:	
Research Arm:	
Follow-Up assessment carried out by:	
Role:	
Date of Follow-Up:	
Follow-Up Schedule Week Number: **(refer to patient FU schedule received at randomisation)**	

	Key points for discussion	Tick to confirm discussed	Notes
Consent	Patient confirmed willingness to continue participation in STAMPEDE trial *Please refer to Site Guidance on participants' long term FU (v2.0 Mar 2020)*		
PSA	PSA test done (via GP or outpatient clinic)		
Con-medications	Any new con-medications (not previously reported)		

	Key points for discussion	Tick to confirm discussed	Notes
Progression	Any evidence of biochemical, objective/radiological or symptomatic/clinical progression?		
Non-trial visits	Any hospital admissions since last visit? *Please refer to Protocol v19.0 for guidance on SAE reporting requirements*		
	Any GP visits, outpatients visits (relating to the patient's prostate cancer)		
RTOG toxicities	For patients who have had radiotherapy (either as SOC or for progression) have they experienced any RT late side-effects since last FU?		
Surgical Interventions	Any surgical interventions since last FU? *Please refer to Protocol v19.0 for guidance on SAE reporting requirements*		
Skeletal-related events	Bone pain requiring RT and/or surgery?		
	Any fractures?		
	Metastatic spinal cord compression?		
Metabolic & cardiac events	Has the patient had any metabolic or cardiac events as listed on FU CRF (Form 7, v16.0)		

Metabolic tests	Is the patient due for any scheduled metabolic tests? *(See Randomisation and FU schedule given at randomisation for expected timelines)*		

	Key points for discussion	Tick to confirm discussed	Notes
SOC HT	Have there been any drug change or treatment break to the patient's HT since their last FU? *(Update their HT log as appropriate & attach to FU CRF)*		
Research treatment *(patient's on research arms only)*	For patients on research treatment have there been any changes to the treatment (dose change, treatment suspended, re-started, permanently stopped)? *(Update the relevant treatment log as appropriate & attach to FU CRF)*		
	For patients on Arm G or J, who are on treatment, have they missed any tablets since the last FU? *(Update the relevant treatment log as appropriate & attach to FU CRF)*		
	For patients on Arm G or J, who are on treatment, has blood pressure and safety bloods been performed? *Please refer to Protocol v19.0 for guidance on Schedule of Assessments*		

	For patients on Arm K, who are on treatment, has a treatment break > 3months or 50% doses been missed? *(Update the relevant treatment log as appropriate & attach to FU CRF)*		
	For patients on Arm K, who are on treatment, has safety bloods (eGFR) been performed? *Please refer to Protocol v19.0 for guidance on Schedule of Assessments*		
	For patients on Arm L, who are on treatment, has Testosterone and Oestradiol testing been performed? *Please refer to Protocol v19.0 for guidance on Schedule of Assessments*		
	Any additional or standard blood tests needed (e.g. LFT, FU test for previously reported toxicity)?		
Therapies for progression	For patients who have progressed, have there been any changes to the treatments they are receiving for progression? *(Update their additional treatment log as appropriate and attach to FU CRF)*		

	Key points for discussion	Tick to confirm discussed	Notes
Assessments	Weight and waist circumference? *Please refer to Protocol v19.0 for guidance on Schedule of Assessments*		
	HbA1c and Lipid profile? *(If missed, samples can be obtained +/- 12 weeks of the scheduled visit, maintaining 10-12 weeks in between the tests due at 24 and 48 weeks)* *Please refer to Protocol v19.0 for guidance on Schedule of Assessments*		
Toxicities	Has the patient experienced any toxicity, related to the treatment(s) they are on, since last FU (please refer to Toxicity Form 7E, v3.0) *(Update the toxicity form as appropriate and attach to FU CRF)*		
Quality of Life Questionnaire	Quality of Life questionnaires completed? (if the patient is participating in this aspect)		
Future FU Assessment	Any plans to go on holiday which overlaps with future FU assessments?		
	Next FU visit arranged?		

Name (Print)

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Signature

_____

Date

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