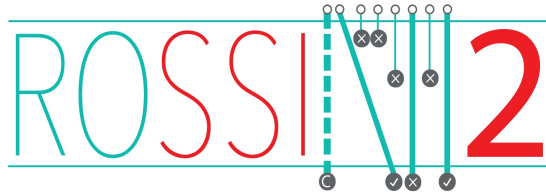


TRIAL ID:

Initials:

Site ID:



PROTOCOL NON-COMPLIANCE FORM

This form is to be used in the event of a protocol non-compliance for ROSSINI 2.

Date of Event: *e.g. 31-JAN-2017*
 D D - M M M - Y Y Y Y

Event Categorisation: *(Please see Event Categories overleaf)*

Event Summary:

Has the PI been informed? *(Please tick one)*
 No
 Yes

Date PI informed: *e.g. 31-JAN-2017*
 D D - M M M - Y Y Y Y

Corrective and preventative action taken (CAPA):

Completed By

Full Name: *(PRINT NAME)*

Signature:

Position:

Date: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Thank you for completing this CRF. You are now required to transcribe this information onto REDCap (<https://bctu-redcap.bham.ac.uk/>). This CRF can be used as Source Documentation and filed in the patient's records.

Reference Number: *(FOR INTERNAL USE ONLY)*

Event Categories

A	CONSENT	F	DATA MANAGEMENT	K	OTHER, (PLEASE SPECIFY)
	<ol style="list-style-type: none"> 1. Consent taken by non-approved trial role 2. Consent taken by non-delegated trial role 3. Consent taken on wrong version of ICF 4. Consent taken post randomisation 5. Consent taken without a valid CV and/or GCP 6. Site unable to provide a copy of the consent form 7. Consent form completed incorrectly 8. A trial activity undertaken but without specific consent. 		<ol style="list-style-type: none"> 1. Patient completed CRFs unobtainable 2. Incorrect version of CRF used 3. CRF completed by inappropriate person 4. Person not on Site Signature and Delegation Log 5. Person has no CV and/or GCP 6. CRF contained no useable data 7. Original CRF not received 		
B	INELIGIBLE PATIENT ENTERED	G	TRIAL PROCEDURES /ACTIVITY NOT DONE BY AUTHORISED PERSON		
C	ELIGIBILITY NOT CONFIRMED BY CLINICALLY QUALIFIED PERSON	H	SAE NOT REPORTED IN CORRECT TIMEFRAME		
D	LACK OF COMPLIANCE WITH INTERVENTION ALLOCATION	I	BLINDING NOT MAINTAINED AT SITE		
	<ol style="list-style-type: none"> 1. Due to error 2. Due to clinical reasons 3. Due to patient's decision 		<ol style="list-style-type: none"> 1. Patient unblinded 2. Staff unblinded 3. Indication of treatment allocation recorded in patient's notes 4. Necessary unblinding required 		
E	TRIAL PROCEDURES / ACTIVITY SCHEDULE NOT ADHERED TO	J	PREGNANCY		
	<ol style="list-style-type: none"> 1. Activity not performed within required window 2. Activity not performed at all 				