National Institute for Health Research

NIHR Clinical Research Network

in conjunction with NHS Research Scotland (NRS), Health and Care Research Wales and Northern Ireland Clinical Research Network (NICRN)

UK wide coordination of expressions of interest for commercial contract studies

Standard Operating Procedure

Version 1 - Agreed 13 June 2017

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Document Control

This document is issued and updated by the National Clinical Research Network Coordinating Centre. Readers should ensure that the latest version is being viewed.

Document Information	
Document Title	NIHR CRN Standard Operating Procedure: UK wide coordination of expressions of interest for commercial studies
Version	Version 1 - Agreed 13 June 2017
Supersedes	Not applicable
Function	Describe the process for coordinating expressions of interest from devolved administrations for commercial contract studies using the CRN site identification service.
Effective Date	31 July 2017
Audience	NIHR Clinical Research Network (CRN), NHS Research Scotland (NRS), Health and Care Research Wales and Northern Ireland Clinical Research Network (NICRN).
Category	For implementation in line with UK wide working Memorandum of Understanding Appendix 2.
Expectation	Required
Purpose	To define the process to be piloted for coordinating expressions of interest from devolved administrations for commercial contract studies as agreed by devolved administration network bodies testing a single approach for UK wide site identification.

Revision History

v1	13June 2017	n/a – first version

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A - INTRODUCTION

This Standard Operating Procedure (SOP) outlines the step-by-step pilot process for coordinating expressions of interest from Devolved Administrations for commercial contract studies using the CRN Site Identification service.

Background

To maximise the opportunities for investigators, sites and patients across the UK to participate in research, the CRN and Devolved Administration networks agreed to pilot a single approach for coordination of expression of interest for commercial contract studies was desirable. This pilot builds on the established CRN process using the Central Portfolio Management System (CPMS) to involve all Devolved Administrations while managing a single point of submission.

Overview

This Standard Operating Procedure describes the pilot process for managing coordination of expression of interest for commercial contract studies and the roles of staff involved in this process. The content has been agreed by each of the Devolved Administration networks involved and the terms of the pilot is governed by a separate Memorandum of Understanding: Management of Cross Border Studies - v1.1.

For the purpose of this process, a commercial contract study is defined as one that is fully sponsored and funded by a commercial company.

Continuous Improvement

The CRN will apply the continuous improvement process of Plan-Do-Study-Act to maintain the effectiveness of this process. Please provide any feedback on this process to the Study Support Helpdesk at supportmystudy@nihr.ac.uk.

B – IDENTIFYING SITE IDENTIFICATION REQUESTS FOR DISTRIBUTION TO DEVOLVED ADMINISTRATION NETWORKS

1.1. From the 31st July 2017, any commercial submissions via the Central Portfolio Management System (CPMS) requesting Site Identification, as either individual service requests or part of multi-service request, will be distributed to Devolved Administrations for expressions of interest only when made by any of the following companies:

- Boehringer Ingelheim
- BMS
- Covance
- Roche

1.2. All commercial submissions are reviewed as per the CRN Feasibility and Commercial Eligibility Process SOP. To confirm the applicant is aware of their company participation in the pilot, the pilot template e-mail for services started will be used and includes:

1.2.1 The one page participant fact sheet for UK wide expression of interest pilot PDF will be provided and highlighted to the applicant as part of the communications notifying them about the progress of their submission. Only when the status of the submission is changed to 'in progress' can Site Identification commence.

1.2.2 Where an applicant has indicated a geographical restriction in the submission preventing UK-wide expressions of interest, contact details for the network of the devolved administration excluded by the restriction should be provided to enable discussion regarding capability.

C – DISTRIBUTION TO DEVOLVED ADMINISTRATION NETWORKS

NOTE: A declaration of 'CRN eligibility for the Portfolio' is not required prior to distribution of information to Devolved Administration networks. Each nation's network will undertake their own eligibility review as per separate defined processes.

2.1 For distribution to Devolved Administration networks, a separate e-mail (Appendix 2) is sent to the relevant Devolved Administrations taking account of any geographical restrictions highlighted in the submission attaching:

1. the PDF of Part B of the CPMS submission
2. the company provided Schedule of Events
3. blank Devolved Administration Site Identification Form (saved in the 'Industry templates' folder on the N Drive).

2.2 E-mail will be sent to:

Health and Care Research Wales	**NHS Research Scotland**	**Northern Ireland Clinical Research Network**
industry-research@wales.nhs.uk	feasibility@nrs.org.uk	NICRNCommercialQuery@nicrn.hscni.net

D – COMPLETION OF THE EXPRESSION OF INTEREST FORM BY THE DEVOLVED ADMINISTRATION NETWORKS

3.1 The process for potential sites in the Devolved Administrations to complete the provided Site Identification Form is defined separately by each Devolved Administration network.

3.2 This process will maintain customer expectations for service timelines, currently 15 working days from validation of the customer submission by the CRN to provision of collated expressions of interest to the customer. Timelines to enable the delivery of completed site identification forms will be provided by the CRN in the request email.

3.3 The commercial company will use the contact details provided in the form to progress feasibility and site selection discussions therefore devolved administration networks are advice to ensure this is completed.

3.4 Each devolved administration is responsible for any quality checking of the each returned Site Identification Form prior to provision to the CRN.

E – RETURN OF COMPLETED EXPRESSION OF INTEREST FORM TO THE CRN

4.1 Completed Devolved Administration Site Identification Forms should be returned to the CRN CC team at: crncc.support@nihr.ac.uk within the timeline defined. The forms should be returned with the filename in the following format: [CPMS ID]_Site ID_[Devolved Administration]_[site name]_[date] to align with the English site forms.

4.2 The form will be uploaded to the 'Attachments' section on the 'Response & Attachments' tab alongside the English site forms.

4.3 The CRN CC team will map the form to the corresponding site in CPMS, which will allow the site to be linked to the study record (displayed as a site in the study record) once the service is closed.

4.4 For studies going on to run in the UK on the CRN Portfolio, the company will confirm their site selections with the CRN CC team by way of returning their Study Milestone Schedule as per the CRN process.

F – COMMUNICATION OF OUTCOME TO DEVOLVED ADMINISTRATION NETWORKS

5.1 The Sponsor is responsible for confirming any subsequent site selections following receipt of the Site Identification form(s) to the relevant Devolved Administration network(s) as per their established operational process.

5.2 Final sites will be defined within the CPMS study record as confirmed through the CRN CC Study Milestone Schedule process.

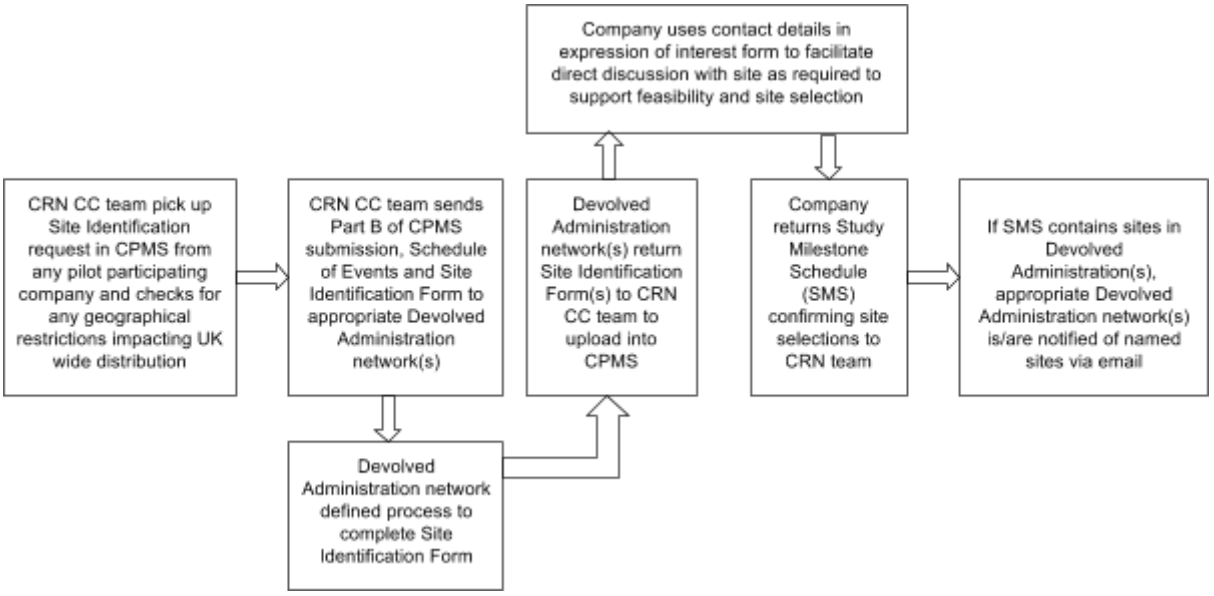
G – ESCALATION

6.1 In the event of any issues, the CRN CC team should be contacted at: crncc.support@nihr.ac.uk, who will aim to respond within 48 hours

6.2 If no response is received after 48 hours, escalate to the Senior Feasibility Coordinator (Davina.Hemmings@nihr.ac.uk).

APPENDICES

APPENDIX 1. Devolved Administration Process Diagram from Distribution to Site Selection



APPENDIX 2. Template E-mails for CRN use only

E-mail 1: Notification to Devolved Administrations Networks of Study Requesting Site Identification

Subject: Notification of Study Requesting Site Identification
Attach Part B of CPMS submission and blank Devolved Administration Site ID Form

Dear Devolved Administration Networks,

RE: CPMS ID xxxxx

We have received a service request for Site Identification for the above study. Attached is Part B of the CPMS submission along with a blank Devolved Administration Site Identification Form. Should you wish to register your expression of interest, please complete the form and return it to: crncc.support@nihr.ac.uk.

Please return the form with the filename in the following format: [CPMS ID]_Site ID_[Devolved Administration]_[site name]_[date] to align with English site form filenames.

Please note that should your site(s) be contacted by the company to undertake in depth feasibility as part of further site selection discussions, they will notify us of final site selection by way of returning their Study Milestone Schedule. We will alert you to this by way of copying you into our standard e-mail to LCRNs requesting they check the Study Milestone Schedule. Please note, you do not need to action the instructions in the e-mail - this is

simply to notify you your site(s) have been selected. If you do not receive this correspondence, please assume your site(s) have not been selected on this occasion.

Best wishes,

APPENDIX 3. Template Devolved Administration Site Identification Form

Request for Devolved Administration Site Identification

This form provides the means for investigators to express their interest in participating in a commercial clinical study. This form should be completed in collaboration with the PI/research team.

Study Title	
NIHR CRN ref	

Note: These responses are based on the information provided from the NIHR CRN online submission.

1	**Investigator name and contact details**	***Enter the full name and contact details (email and telephone)***
2	**Hospital name**	***Please ensure you insert the actual hospital name here and not the Trust name***
3	**Trust name**	***Please ensure you insert the Trust name here and not the Hospital name which should go above***
4	**Site contacts (names and contact details):**	***A contact name and contact details must be completed for each of the site contacts***
	Research team	***Name and contact details***
	R&D department	***Name and contact details***
	Pharmacy	***Name and contact details***
	Other relevant support departments (if applicable)	***Name and contact details***
5	**Study delivery team contact telephone number and email address**	

6	What number and percentage of commercial clinical trials run by this research team within the past 3 years have achieved their recruitment target?	*Must include statistics of previous performance.* *If there is a reason for recruitment target(s) not being met, please provide any relevant supporting information to explain*
7	Does this study compete with any studies (commercial or non-commercial) ongoing or planned at this site during the proposed recruitment period? Please indicate whether these studies will compete for patients or resources, or both.	*This information is useful for local study planning.* *Please refer to study timelines in question B3 of submission form*
8	Are all relevant facilities and staff (eg study coordinators, data managers and research nurses) available to support the set up and delivery of this study? How has this been assessed?	*Describe the resources and organisational support that is in place to optimise the delivery of the study/meet recruitment targets including details of how the assessment has been conducted*
9	What is the anticipated set up time from final protocol availability to R&D Approval? Please indicate what this estimate is based on.	*For studies run in primary care, please indicate anticipated set up time to the relevant approval*
10	Does this site intend to use the following standard NIHR CRN templates:	
	Unmodified model Clinical Trial Agreement?	
	NIHR CRN Industry costing template? (If the site intends to use the standard set up fee, please indicate this here)	
11	Please provide details of the total number of potential recruits to this study by the end of the predicted recruitment window (please refer to study timelines in question B3 of submission form and include details of how these numbers are reached. Please consider how set up time will impact on the recruitment window):	*Please specify actual numbers and how the calculation has been reached*
12	Please provide details of how potential recruits will be identified	
13	Please provide any additional information regarding any anticipated challenges and proposed solutions	

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