National Institute for Health Research

Clinical Research Network

Management of Cross Border Studies on the Central Portfolio Management System

Memorandum of Understanding

Document Control

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Abbreviations and glossary

CRN	Clinical Research Network (England)
Local CRN	Local Clinical Research Network (England)
UK CRN	Clinical Research Network (UK wide) • In England: NIHR CRN • In Scotland: NRS • In Wales: Health and Care Research Wales • In Northern Ireland: NICRN
CRN Support	Research infrastructure support provided by the NIHR clinical research network, this includes research nurses, data managers and NHS Support such as support for radiology, pathology and pharmacy (England).
Cross-Border Study	A study that is eligible for the portfolio of two or more UK Administrations and is being supported to recruit participants in those Administrations. Cross Border studies may require joint support from the NIHR CRNs, therefore Main and Supporting Owning Organisations would be identified as usual.
CSO	Chief Scientist Office (Scotland)
Health and Care Research Wales	Health and Care Research Wales is a national, organisation funded and overseen by the Welsh Government to support and increase capacity in research and development.
IRAS	Integrated Research Application System (UK wide)
Jointly supported study	A study which is receiving support from more than one NIHR CRN. One CRN will be identified as the Main Network. The other(s) will be identified as the Supporting Network(s).
Lead Local CRN [1]	For English led studies, the Lead Local CRN for is the CRN where the Lead R&D office is situated; For Devolved Administration led studies the Lead CRN is assigned by the CRN.
Lead Country[1]	The country in which the UK Chief Investigator for the study is based. *(This is a field in the Central Portfolio Management System and only one of the four UK countries can be a Lead Country).* This is not the same as the Lead Administration. See Table 1.
Lead Administration[1]	The Lead Administration is determined by the location of the lead Research and Development (R&D) office in the UK. (Except for industry studies that are open in England where the Lead Administration is always England) The Main Owning Organisation will be located within the Lead Administration. *(This is <u>not</u> a field in the Central Portfolio Management System)* See Table 1.
Main Owning Organisation	The Main Owning Organisation is the network providing the majority of the support for a study/doing the majority of the work within one Administration. Each Administration in a cross-border study will have a Main Owning Organisation. The Main Owning Organisation has overall responsibility for performance management of the study within their Administration. (*Main Owning Organisation is <u>not</u> a field in the portfolio database, owning organisation is. The Main Owning Organisation in the Lead Administration should be selected at study initialisation and will therefore be responsible for managing the study record. If a study is not eligible for the Portfolio of the country in which the lead R&D office is located, the Main Owning Organisation in a Supporting Administration should be selected instead).* The portfolio database does not currently support the concept of Main Owning Organisation in a Supporting Administration, as only one Main Owning Organisation can be selected. Therefore all other Owning Organisations will appear as supporting. See Table 1.

NICRN	Northern Ireland Clinical Research Network (Northern Ireland)
NICRN CC	NICRN Coordinating centre (Northern Ireland)
NIHR	National Institute for Health Research (England)
NIHR CRN	National Institute for Health Research Clinical Research Network (England)
NRS	NHS Research Scotland (Scotland)
PAT	Portfolio Applications Team, The Portfolio Application Team are part of the CRN Portfolio Team and manage the application process for CRN support. (England)
PCC	Permissions Coordinating Centre (Scotland)
PCU	Permissions Coordinating Unit (PCU) is the Wales central permissions process unit (Wales)
Portfolio Country	Within the Portfolio Database each of the four UK Administrations (England, Scotland, Northern Ireland or Wales) can be selected as having deemed this study eligible for their Portfolio and to receive Network support. *(This is a field in the Central Portfolio Management System)*
Portfolio Manager	Portfolio Manager is a role in the Portfolio Database which allows the initialisation and management of study records. Where more than one owning organisation is participating in a study the Main Owning Organisation in the Lead Administration should undertake this role.
Recruitment Data Contact (RDC)	The Recruitment Data Contact (formerly Accrual Data Contact) is the person who is responsible for supplying and uploading recruitment data into the Portfolio Database. Within the CRN these are part of the study team for non-commercial studies, ie. working within one of the sites which are recruiting into the study, and for commercial studies they are within the Coordinating Centre of the Main Owning Organisation in the Lead Administration[3].
Supporting Administration	A Supporting Administration is any UK Administration, which is involved in recruiting participants into a study led by another UK Administration. See Figure 1
Supporting Owning Organisation	The Supporting Owning Organisation will have an active role in providing additional support for the study (in the case of jointly-supported studies). *'Supporting Owning Organisation'* is <u>not</u> a field in the portfolio database. The Main Owning Organisation is selected at study initialisation and will be 'greyed out' in the Owning Organisation field (ie. cannot be deselected). One or more Supporting Organisations can be added to the Owning Organisation field in the portfolio database after study initialisation. A Supporting Owning Organisation may be in the Lead or a Supporting Administration.

[1.] The fields marked above should not be confused with the 'Lead Network' as referred to in the context of the 'Coordinated Network Support Service'.

1. Introduction

1.1 The UK CRN Portfolio Database comprises the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Portfolio in England, and the corresponding Portfolios of the Northern Ireland Clinical Research Network (NICRN), NHS Research Scotland (NRS) and the Health and Care Research Wales Clinical Research Portfolio in Wales. Each of the four UK Administrations has developed their own eligibility criteria that determine which studies can be included in their respective portfolios. A study must apply to and meet the eligibility criteria of each Administration in order to appear on the Portfolio of that Administration. A study may be eligible for some, but not all UK CRN Portfolios.

1.2 In **England**, the eligibility criteria are outlined in the Department of Health policy '*Eligibility Criteria for 'Clinical Research Network Support (Feb 2011)'*. Studies which meet these criteria are included in the NIHR CRN Portfolio and receive CRN support. Studies on the NIHR CRN Portfolio are required to report recruitment data on a monthly basis. The study and recruitment data within the NIHR CRN Portfolio is used to inform the allocation of NHS research infrastructure funding across the NIHR Clinical Research Network. The reporting of recruitment data is also used to performance-manage studies and each of the Networks. This is particularly important for commercial studies.

1.3 In **Scotland** the Chief Scientist Office (CSO) manages NRS (NHS Research Scotland). NRS comprises NHS Scotland Health Boards and the Scottish Topic Research Networks, which manage studies on the Scottish Portfolio. All Health Boards and Networks have a Management objective to ensure investigators upload recruitment data to the Central Portfolio Management System.

1.4 In **Wales** the Health and Care Research Wales Commercial Research Register holds information on all commercial research studies taking place in the NHS in Wales which are supported via cost recovery.

1.5 In **Northern Ireland** NICRN manages the portfolio studies that are deemed of benefit to Health and Social Care (HSC) Northern Ireland.

1.6 **In order for studies to be effectively managed across the UK Administrations and for this document to be valid, all recruitment for eligible or adopted studies being supported in England, Scotland or Wales must be uploaded into the Central Portfolio Management System (currently Northern Irish only studies do not have to report recruitment data).**

1.7 Intended audience in the UK:

Within England

- NIHR CRN Portfolio Team
- NIHR CRN Industry Team
- NIHR P/T/CCRN Coordinating Centre Portfolio Managers and Industry Liaison Managers
- NIHR CSP Unit
- NIHR CRN Assistant Directors and Clinical Directors (for information)

Within Scotland

- NRS Portfolio Leads
- NRS Portfolio Managers (or equivalent) and Industry Liaison Managers (or equivalent)

Within Wales

- Health and Care Research Wales Specialty Leads
- Health and Care Research Wales Heads of Research Delivery
- Senior Industry Manager
- Welsh Health Board and NHS Trust R&D Managers
- Health and Care Research Wales Support Centre

Within Northern Ireland

- NICRN Coordinating Centre staff

1.8 See appendix for contacts in all Devolved Administrations

2. Purpose

2.1 The purpose of this Memorandum of Understanding is to provide clarity on how the Clinical Research Networks across the UK will work together to enable the entry, site identification and management of studies on the Central Portfolio Management System. It outlines the roles and responsibilities of both the Lead and Supporting Administrations when processing UKCRN Portfolio studies in order to provide clarity on these processes to ensure effective and efficient cross border working.

2.2 Please note this document will not cover the process for gaining study approvals. This document is supplemented by standard operating procedures specific to each Administration.

3. Scope

3.1 The scope of this guidance is from the submission of an application for support to any Research Network in the UK until the study is closed and follow-up is complete.

4. Determining the Lead Country, Lead Administration, Supporting Administrations and Owning Organisation(s) for ***non-commercial*** studies

4.1 The Central Portfolio Management System contains the concepts of Lead Country, Lead Administration and Supporting Administration(s).

4.2 The Main Owning Organisation is the network providing the majority of the support for a study/doing the majority of the work within one Administration. Each Administration in a cross-border study will have a Main Owning Organisation. The Main Owning Organisation has overall responsibility for performance management of the study within their Administration.

4.3 The **Lead Country** is identified by the location of the Chief Investigator; the Lead Country may or may not be the same as the Lead Administration. The Lead Country does not have a role in the management of study but indicates the location of the Chief Investigator on the Central Portfolio Management System.

4.4 The **Lead Administration** for a study is determined by the location of the lead Research and Development (R&D) office in the UK. If the lead R&D office is located within England then the Lead Administration would be England and the Main Owning Organisation in the Lead Administration would be a NIHR Local CRN (ie. the study would be led by an NIHR Local CRN). Similarly if the lead R&D office is located within one of the devolved administrations then the Lead Administration would be Scotland, Wales or Northern Ireland and the Main Owning Organisation would be (ie. the study would be led by) an NHS Scotland Health Board or topic Network within NRS (Scotland), Health and Care Research Wales or NICRN (Northern Ireland).

4.5 A **Supporting Administration** is any administration which is involved in the recruitment of participants into a study that is eligible for the portfolio of that administration. On the Central Portfolio Management System the '*Eligible for the portfolio of*' field should only be completed for those administrations which have deemed the study eligible **as per their own eligibility criteria**, and an Owning Organisation should only be selected for the administrations for which the study is eligible. This must be confirmed as appropriate by that country or organisation.

4.6 Table 1 describes how the Lead and Supporting Administrations are identified as roles in the management of a non-commercial study and on the Portfolio Database.

5. Determining the Lead Administration, Supporting Administration(s) and Owning Organisation(s) for ***commercially funded and sponsored*** studies

5.1 When a commercially funded and sponsored (industry) cross-border study is eligible for support from the NIHR CRN the Main Owning Organisation in the Lead Administration will be an NIHR Network, since the Lead Administration will always be England.

5.2 On the Central Portfolio Management System the field *'Eligible for the portfolio of'* (country) and Owning Organisations within that country should only be selected when this has been confirmed as appropriate by that country or organisation.

5.3 Table 2 describes how the Lead and Supporting Administrations are identified as roles in the management of a commercial study and on the Portfolio Database

Table 1: Determining Lead and Supporting Countries for *non-commercial* studies

Example 1: A non-commercial cancer study is being run by a CI at Edinburgh University, recruiting children at sites across Scotland and England. The study meets the eligibility criteria of Scotland and England.

Example 2: A non-commercial cardiology study is being run by a CI at Leeds General Infirmary, recruiting at general practices across England and in Wales. The study meets the eligibility criteria of England and Wales.

Term	Defined by	Example 1	Example 2
Lead Country	Location of CI	Scotland	England
Lead Administration	Location of Lead R&D office	Scotland	England
Supporting Administration	Location of study sites outside the Lead administration	England	Wales
Portfolio Country	Administrations that have deemed the study eligible for support	Scotland England	England Wales
Lead Local CRN (in England)	If England led: Location of Lead R&D If Devolved Administration led: Assigned by CRN	Trent (assigned by CRN)	Yorkshire and Humber CRN (location of lead R&D office)
Main Owning Organisation in Lead Administration	Lead Administration	NRS Cancer Network	PCRN
Supporting Owning Organisation in Lead Administration	Lead Administration	n/a	CCRN
Main Owning Organisation in Supporting Administration	Supporting Administration	NCRN	Health and Care Research Wales
Supporting Owning Organisation in Supporting Administration	Supporting Administration	n/a	n/a

Table 2: Determining Lead and Supporting Countries for *commercially funded and sponsored* studies

Example 1: A cancer study is funded and sponsored by a company and the CI is in Edinburgh, recruiting children at sites across Scotland and England. The study meets the eligibility criteria of Scotland and England.

Example 2: A cardiology study is funded and sponsored by a company and the CI is in Leeds, recruiting at GP practices across England and in Wales. The study meets the eligibility criteria of England and Wales.

Term	Defined by	Example 1	Example 2
Lead Country	Location of CI	Scotland	England
Lead Administration	Location of Lead R&D office (Except that for commercial studies, with sites in England, this will always be England)	England	England
Supporting Administration	Location of study sites outside the Lead administration	Scotland	Wales
Portfolio Country	Administrations that have deemed the study eligible for support	Scotland England	England Wales
Lead Local CRN	If England: Location of Lead R&D If Devolved Administration: Assigned by CRN	Trent (assigned by CRN)	Yorkshire and Humber CRN (location of lead R&D office)
Main Owning Organisation in Lead Administration	Lead Administration	NCRN	PCRN
Supporting Owning Organisation in Lead Administration	Lead Administration	n/a	CCRN
Main Owning Organisation in Supporting Administration	Supporting Administration	NRS Cancer Network	Health and Care Research Wales
Supporting Owning Organisation in Supporting Administration	Supporting Administration	n/a	n/a

6. Roles and Responsibilities with respect to *non-commercial studies* and *commercially funded and sponsored* studies (summarised in Table 3)

6.1 **Eligibility Assessment -** Each of the four UK administrations has developed its own Eligibility Criteria which determine which studies can be included in their respective Portfolios. Each Administration involved in a study is required to assess the study according to its own eligibility criteria regardless of whether the Administration is leading or supporting the study. For example, a study led by Scotland with English sites must be reviewed by the NIHR CRN before it is added to the NIHR CRN Portfolio (specifically, before England is selected as Portfolio Country in the Ownership tab (at the initialisation stage) on the Central Portfolio Management System).

6.2 **Site Identification for commercial contract studies** – See Appendix 2.

6.3 **Study Record Initialisation -** A study record on the Central Portfolio Management System should be initialised by the Main Owning Organisation in the Lead Administration[3] as soon as it has been made eligible. If a study is not eligible for the Portfolio of the country in which the lead R&D office is located, the Main Owning Organisation in a Supporting Administration should initialise the study.

6.4 **Study Record Management -** The Main Owning Organisation, in the Lead Administration[3] is responsible for the management of the study record, ensuring that all data entered are correct and up to date. (If a study is not eligible for the Portfolio of the country in which the lead R&D office is located, this becomes the responsibility of a Main Owning Organisation in a Supporting Administration in which the study has been deemed eligible.) Any changes to a study record must go through an approvals process before they are released on the live database. The approval and release of the studies is the responsibility of the Main Owning Organisation. If a Supporting Owning Organisation requires a change to be made to the study record a request should be forwarded to the Main Owning Organisation in the Lead Administration.

6.5 **Recruitment data upload -** The Main Owning Organisation in the Lead Administration is responsible for ensuring the accurate and timely collection of recruitment data for a study, via the RDC for non-commercial studies wherever in the UK they are based or via the commercial study representative for Industry studies. (If a study is not eligible for the Portfolio of the country in which the lead R&D office is located, this becomes the responsibility of a Main Owning Organisation in a Supporting Administration in which the study has been deemed eligible.)

6.6 **Performance management** - Each owning organisation is responsible for performance management of the supported sites within their Administration. (If a study is not eligible for the Portfolio of the country in which the lead R&D office is located, this becomes the responsibility of a Main Owning Organisation in a Supporting Administration in which the study has been deemed eligible.)

[3] *Provided the study is eligible for the Portfolio of the Country playing host to the lead R&D office*

Table 3: Roles and Responsibilities of the Lead and Supporting Owning Organisations, in lead and supporting Administrations, for *non-commercial studies* and *commercially funded and sponsored* studies

Action	Lead Administration, Main Owning Organisation[3]	Lead Administration, Supporting Owning Organisation	Supporting Administration, Main Owning Organisation	Supporting Administration, Supporting Owning Organisation
Assess eligibility for own Administration's portfolio	Yes	N/A (participate as required)	Yes	N/A (participate as required)
Inform CI and Lead Administration Lead Owning Organisation of eligibility decision	Yes	N/A	Yes	N/A
Contact the CI for information required to initialise study including RDC details	Yes	No	No	No
Initialise the study on the Central Portfolio Management System (create the study record)	Yes	No	No (unless a Supporting Owning Organisation has deemed the study eligible before the Main has performed an assessment)	No
Maintain the study record with up to date information including recruitment opening and closing	Yes	No	No	No
Inform Lead Administration, Main Owning Organisation of any changes required to study record	N/A	Yes	Yes	Yes
Approve changes to study record	Yes	No	No	No
Responsible for ensuring RDC is supplied with recruitment data	Yes	Yes	Yes	Yes
Responsible for ensuring RDC uploads recruitment in a timely manner	Yes	No	No	No
Responsible for performance management of supported sites	Yes	Yes (at a local level)	Yes	Yes (at a local level)

[3] *Provided the study is eligible for the Portfolio of the Country playing host to the lead R&D office*

Appendix: Devolved administration contacts

KEY CONTACTS

England

Central contacts			
Any query	CRN Helpdesk	0113 343 0245	supportmystudy@nihr.ac.uk
Eligibility queries	Eligibility Coordinators		portfolio.applications@nihr.ac.uk
Site Identification queries Local CRN	Feasibility Coordinators Central Contact Point	As per website	portfolio.helpdesk@nihr.ac.uk http://www.nihr.ac.uk/funding-and-support/study-support-service/study-support-service-contacts/

Scotland

NRS Permissions Coordinating Centre (NRS Permissions CC)
Alison Walker (National Coordinator) Tel: 01224 554051 Email: alisonwalker1@nhs.net

Wales

Central contacts			
Any query	Support Centre	02920 230457	healthandcareresearch@wales.nhs.uk
Eligibility queries	Portfolio Team	02920 230457	portfolio@wales.nhs.uk
Site Identification queries	Commercial studies	02920 230457	industry-research@wales.nhs.uk

Welsh regional contacts

North Wales	Jane Jones	02920 230457	Jayne.jones3@wales.nhs.uk
South East Wales	Sue Figueirido	02920 230457	Susan.figueirido@wales.nhs.uk
South West Wales	Kathy Malinovszky	02920 230457	Kathy.Malinovszky2@wales.nhs.uk
National contact	Lydia Vitolo	02920 230457	Lydia.vitolo@wales.nhs.uk

Northern Ireland

NICRN Coordinating Centre
Email: info.NICRN@belfasttrust.hscni.net

NICRN Senior Manager:	Dr Paul Biagioni	Tel: 028 90 636367 / Mob: 07917 354714	Email: Paul.Biagioni@belfasttrust.hscni.net
NICRN Staff Manager:	Sonia McKenna	Tel: 028 90 636360 / Mob: 07557 919360	Email: Sonia.McKenna@belfasttrust.hscni.net

Scottish Health Board contacts

	Contact	Telephone	Email
North East			
NHS Grampian	Susan Ridge	01224 53 728	s.ridge@nhs.net
	Rituka I. Sharma	01224 551 119	rituka.sharma@nhs.net
NHS Highland	Frances Hines	01463 255 822	frances.hines@nhs.net
East			
NHS Fife	Amanda Wood	01383 565 111	amanda.wood3@nhs.net
NHS Forth Valley	Allyson Bailey	01324 677 564	allyson.bailey@nhs.net
NHS Tayside	Liz Livingstone	01382 383 872	elivingstone@nhs.net
	Charles Weller	01382 383 882	charles.weller@nhs.net
South East			
NHS Lothian	Mr Chris Duncan	0131 242 3341	Chris.Duncan@nhslothian.scot.nhs.uk
	Lynda Campbell	0131 242 3326	Lynda.Campbell@nhslothian.scot.nhs.uk
NHS Borders	Joy Borowska	01896 826 718	Research.Governance@borders.scot.nhs.uk
West			
NHS Greater Glasgow & Clyde	Melissa McBride	0141 211 2888	Melissa.mcbride@ggc.scot.nhs.uk
	Graeme Piper		Graeme.Piper@ggc.scot.nhs.uk
NHS Lanarkshire	Raymond Hamill	01236 712 460	Raymond.hamill@lanarkshire.scot.nhs.uk
NHS Ayrshire & Arran	Karen L Bell	01563 825 850	karen.bell@aaaht.scot.nhs.uk
NHS Dumfries & Galloway	Gwen Baxter	01387 241 165	gwen.baxter@nhs.net
National Waiting Times Centre Board	Catherine Sinclair	0141 951 5440	catherine.sinclair@gjnh.scot.nhs.uk

Scottish Topic Network contacts

	Contact	Telephone	Email
Scottish Cancer Research Network (SCRN)			
Scottish PCRN (SPCRN)	Alison Hinds		A.Hinds@cpse.dundee.ac.uk
Scottish MHRN (SMHRN)	Darren Gibson		dgibson3@staffmail.ed.ac.uk
Scottish Children's Research Network (ScotCRN)	Pamela Dicks		P.Dicks@abdn.ac.uk
Scottish Diabetes Research Network (SDRN)	Shona Brearley		S.M.Brearley@dundee.ac.uk
Scottish Dementia Clinical Research Network (SDCRN)	Emma Law		Emma.Law@nhs.net
Scottish Stroke Research Network (SSRN)			

Northern Ireland Interest Group contacts

NICRN Coordinator for Cardiovascular, Children's, Critical Care, Diabetes, Renal and Stroke
Shane Jackson Tel: 028 9063 6365 / Mob: 07766 294 727 Email: ShaneR.Jackson@belfasttrust.hscni.net

NICRN Coordinator for Dementia, Primary Care, Respiratory Medicine and Vision
Ciara McKenna Tel: 028 9063 6360 Email: Ciara.McKenna@belfasttrust.hscni.net

Appendix 2: UK wide pilot for coordinating expressions of interest for commercial contract studies

The four nations are exploring ways to work together to provide UK wide support for researchers. The devolved administrations have agreed to trial the NIHR CRN Central Portfolio Management System as a process for coordinating UK wide expression of interest with the overall aim of improving patient access and therefore delivery of research.

AIMS

- To assess the potential for a UK-wide feasibility process
- To increase study opportunities to all administrations across the UK
- Challenge industry perceptions around pre-defined study lists
- Design a streamlined, value-add process
- An open and transparent pilot that provides data to assess the effectiveness and allay concerns over a UK-wide process

EXPECTATIONS

- The pilot will test a process for a UK wide approach for commercial studies to identify NHS sites across the UK prior to any national approval process (e.g. HRA Approval/R&D permission) to better inform sites listed in the IRAS Part C.
- The coordination provides high level information regarding a new research opportunity to identify which UK sites within the current timelines promoted to customers (15 working days) who are interested in further discussions about the study.
- The process is a supplementary service to help the Sponsor target their subsequent feasibility activities that inform site selection as required by Good Clinical Practice. This pilot not being considered to replace Sponsor feasibility/site selection activities.
- The process tested during the pilot is defined in the Standard Operating Procedure which has been agreed by all four nations and will be updated as required throughout the pilot.
- The duration of the of the pilot is agreed as commencing on the 31 July 2017 for
    - 25 submissions from the first group of participating companies (confirmed as Boehringer Ingelheim, BMS, Covance, Roche)
    - Another 25 submission including those from an additional second group of organisations (proposed as GSK, MSD, Sanofi)
    - Another 25 submissions including those from an additional third group (proposed as Novartis and Pfizer) to complete thorough testing of the process.
- The confirmed companies participating in the pilot in real-time are defined in the Standard Operating Procedure which should be considered the source of truth.
- The scope of the pilot will be limited to defined companies as described in Standard Operating Procedure for the pilot. Where a non-named sponsor specifically requests UK wide in the current ‘geographical restriction’ questions the Sponsor will be directed to each individual nations contacts.

- Review of the process will be discussed collectively via a teleconference every three months or every 25 submissions, whichever is the earliest. Both customer and network feedback will be discussed.
- Any of the four nations retains the right to withdraw participation from the pilot at any stage.
- Participation in the pilot does not restrict promotion nor continued operation of the individual nation's own feasibility service or system.
- During the pilot the CRN agree to notifying all devolved administrations of each new valid study submission for site identification received through the Central Portfolio Management System where the Sponsor as not provided any geographical restrictions in the submission that would prevent this notification i.e. request English only research sites. Where geographical restriction for any devolved administration(s) the CRN will provide the contact details for that network to enable further discussion regarding that devolved administration research offering. A report will be generated by the CRN to monitor geographical restrictions for all site identification requests in support of the pilot.
- For each new valid study submission, each Devolved administration will receive the same non-confidential information and expression of interest form as potential English site to provide equitable and comparable responses with the notification.
- Each devolved administration network is individually responsible for coordinating completion of responses for their site(s) and the return to the CRN within the provided deadline as required for provision to the Sponsor.
- The Sponsor is responsible for directly contacting any site expressing an interest in the study and the supporting network as per the contact details provided in the 'Site Identification Form' to progress further site feasibility and/or selection activities. The coordination of the expression of interest process will actively promote this direct contact when notifying the Sponsor of the outcomes at the end of the service. This avoids creating additional mechanisms to reach the potential site/investigator.
- The outcomes of the pilot will be used to inform the subsequent business process for UK wide expression of interest coordination, however participation in the pilot does not assume continued participation after the end of the pilot duration.
- The external publishing of any evidence to support the UK wide approach as outlined below will be agreed by the group prior to sharing outside of staff within individual networks.
- Following the conclusion of the pilot and establishment of any subsequent business processes other areas of support (e.g. early feedback) can be considered for streamlining a UK wide approach.

EVIDENCE

To assess the success of the pilot and provide the evidence to challenge perceptions, the following key metrics will be collected and summarized following conclusion of the pilot:

QUANTITATIVE Data Required*	**Variation (1)**	**Variation (2)**	**Data Source**	**Comments**
Number of individual site identification requests received from the companies participating in the pilot per wave	NUMBER INCLUDING those requested alongside pre-defined site lists	NUMBER EXCLUDING those requested alongside pre-defined site lists	CRN	
	NUMBER Of which included devolved administration level geographical restriction in submission questions	NUMBER Of which included devolved administration level geographical restriction in submission questions	CRN	
Response rate per Devolved Administration	NUMBER / % Of which responses provided to express an interest		Each devolved administration (excluding England)	CRN is actively working on systems to enable the capture of the information – currently unavailable
Site contact rate per Devolved Administration	NUMBER / % Of which resulted in direct contact to the site from the Sponsor		Each devolved administration (excluding England)	CRN is actively working on systems to enable the capture of the information – currently unavailable

Site Selection rate per Devolved Administration	NUMBER / % Of which resulted in site selection		Each devolved administration (excluding England)	CRN is actively working on systems to enable the capture of the information – currently unavailable
QUALITATIVE Data Required	**Variation (1)**	**Variation (2)**	**Data Source**	**Comments**
Customer feedback	% repeat use	Benefits and/or Improvements	CRN	Raw data will be shared with all devolved administration networks
Site feedback (optional)	*Where devolved administrations choose to collect*		*Each devolved administration (excluding England) where applicable*	*Data should be shared with all devolved administration networks where available*

*Raw data for the measurements described above will include the following to enable further integration:

- Specialty as defined by the CRN specialties
- Company name as per information provided in the commercial submission in CPMS
- Study type as per information provided in the commercial submission in CPMS
- Study Phase as per information provided in the commercial submission in CPMS