

Standard Operating Procedure for the Lead Network Service

(SOP 09)

Purpose of document:

This document is an appendix to the NIHR CRN Lead Network Service Guidance document. It explains the processes adopted by DeNDRoN for managing the Lead Network Service for NIHR Portfolio multi-centre studies for which DeNDRoN is the Lead Network.

For which NIHR Portfolio Studies is DeNDRoN the Lead Network?

DeNDRoN is the Lead Network for all multi-centre studies on the NIHR Portfolio in dementia, Parkinson's disease, motor neurone disease, Huntington's disease and other neurodegenerative diseases.

Role of Lead Network

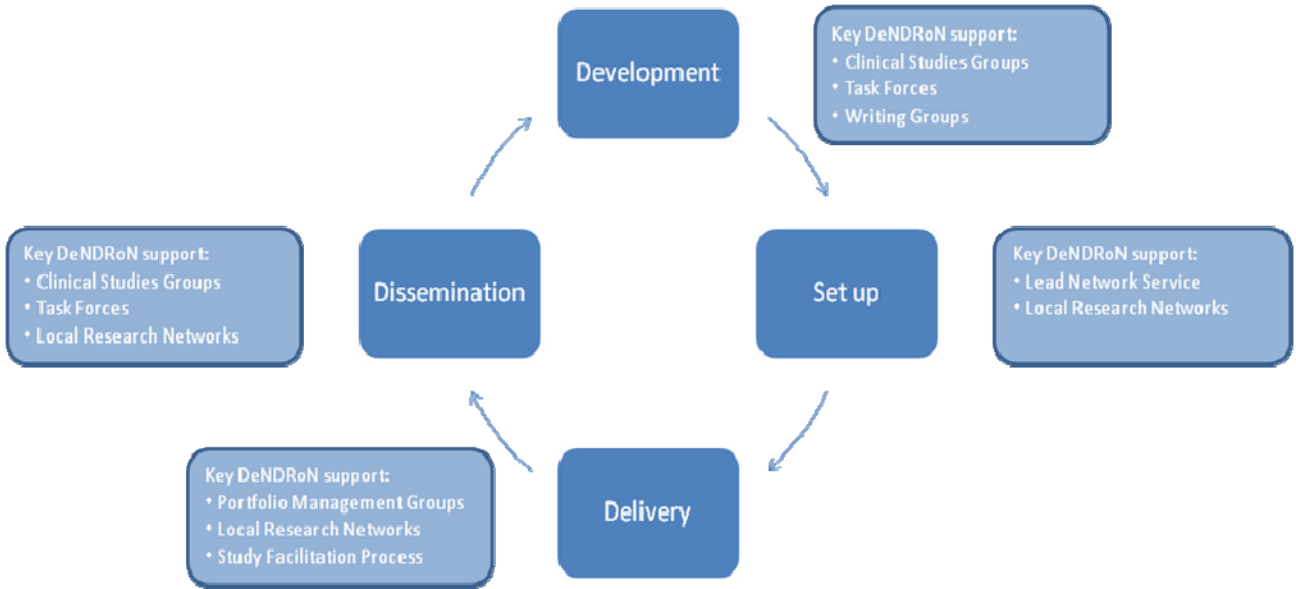
For each multi-centre study, the Lead NIHR Clinical Research Network will be assigned to take responsibility for facilitating the set-up of the study. As the Lead Network DeNDRoN will:

- Identify the elements of support that should be provided by the Networks for the study (i.e. service support)
- Liaise, on behalf of the CI, with other relevant NIHR Clinical Research Networks to confirm that support will be provided at each of the recruiting centres
- Keep the CI informed of progress at the other NIHR Clinical Research Networks and help resolve any problems

For each multi-centre study a Lead CLRN for CSP will also be assigned to coordinate the Research Management & Governance processes for the study through CSP. The Lead CLRN for CSP will usually be the CLRN for the locality where the CI is based.

Note of service context

DeNDRoN can provide support at all stages of the study lifecycle. The Lead Network Service relates to the "Study Set-up" part of the cycle. While this document details the approach to the management of the Lead Network Service in DeNDRoN, it should be noted (a) studies for which DeNDRoN supports the development of the grant application, the Lead Network Service will follow seamlessly from award of funding; and (b) as DeNDRoN supports the delivery of all studies on its portfolio the end of the Lead Network Service will dovetail into the Study Facilitation Process.



Approach to managing the Lead Network Service in DeNDRoN

DeNDRoN treats each study as a unique project and manages the Lead Network Service using project management principles. The service is coordinated from the DeNDRoN Coordinating Centre.

For each study the following roles are assigned:

	Role	Responsibilities	Who?
Project Board members	Project Executive	Represents the NIHR CRN. Ultimately responsible for the timely set up of the study and the key decision maker relating to the Lead Network Service	Relevant DeNDRoN Associate Director
	Senior User	Represents the PIs. Responsible for specifying the needs of the study and ensuring timely provision of necessary study information	Chief Investigator
	Senior Supplier	Represents the (C)LRNs who will provide service support. Responsible for arranging the provision of (C)LRN resources to support the study.	Local Research Director in region where CI is based
Project Team Members	Project Manager (DeNDRoN Coordinating Centre named contact)	The project manager is the single focus for day-to-day management of the Lead Network Service. Key roles: <ul style="list-style-type: none"> • Set up and manage the Project Team for each study • Report progress / escalate issues to the Project Board for each study • On behalf of the CI, liaise with the other relevant NIHR CRNs to confirm that support will be provided at each of the recruiting centres • Keep the CI informed of progress at the other NIHR CRNs and help to resolve any problems 	DeNDRoN Non-Commercial Portfolio Manager (for dementia, Parkinson's disease and other neurodegenerative diseases) MND Coordinator (for MND) HD Coordinator (for HD)
	Project Lead for RM&G (Lead CLRN named contact)	<ul style="list-style-type: none"> • Support the NHS approvals process • Act as a conduit for RM&G queries, keep CI informed of progress at other sites and help to resolve any RM&G issues. 	RM&G Manager at Lead CLRN
	Lead DeNDRoN LRN Manager (or Lead Nurse/CTO)	<ul style="list-style-type: none"> • Supports the Project Manager to identify the elements of support that should be provided by the Networks for the study (i.e. service support) • Supports the Project Manager with effective communications across DeNDRoN LRNs 	DeNDRoN LRN Manager where CI is based, or when another PI is based where CI outside DeNDRoN LRN
	Lead CLRN Senior Manager	<ul style="list-style-type: none"> • Supports the Project Manager to identify the elements of support that should be provided by the Networks for the study (i.e. service support) • Supports the Project Manager with effective communications across CLRNs 	CLRN Senior Manager where CI is based
	Project Administrator	<ul style="list-style-type: none"> • Provides administrative support for the Lead Network Service 	DeNDRoN Portfolio Administrator
	Study Coordinator	<ul style="list-style-type: none"> • Acts as key contact in relation to study specific information 	

For each study the Lead Network Service is directed by a Project Board which:

- Is accountable for the timely set up of the study
- Provides unified direction to the Lead Network Service for the study
- Is responsible for ensuring appropriate resources are available to support study set up
- Ensures effective decision making
- Provides visible and sustained support for the Project Manager in delivering the Lead Network Service for the study
- Provides Project Assurance for the service in relation to the study

The Project Board delegates the management of the service to the Project Manager. The Project Manager reports to the Project Board, which manages by exception.

For each study a project team is created consisting of each of the named individuals above and the managers or senior staff of each of the (C)LRNs in which there are study sites. The project team is responsible for delivering the Lead Network Service and is managed for this purpose by the Project Manager.

Process summary

