Health and Care Research Wales

All Wales Local Portfolio Management System (LPMS) Standard Operating Procedure (SOP)

Title: All Wales LPMS SOP
Version No: V1.2
Implementation date:
Supersedes: NA
Author: Research Systems Advisory Group
Date: 17 January 2020
Approval: Change Management Board
Date:

Version record

Version number: V1.0
Effective date: 14/02/2019
Reason for change: First issue for approval of Change Management Board

Version number: V1.1
Effective date: 18/02/2019
Reason for change: Updated to reflect comments from Change Management Board

Version number: V1.2
Effective date: 17/01/2019
Reason for change: Update to reflect Minimum Data Set Items (as per WalesMinimumDataSet_Final v1.4.2)

Table of contents

1 Introduction

This Standard Operating Procedure defines the procedure, roles and responsibilities for the Health and Care Research Wales infrastructure using the Local Portfolio Management System (LPMS).

In June 2016, and after completing a robust procurement process, Infonetica won the contract to provide Wales LPMS, ReDA 3 (**Re**search **D**atabase **A**pplication). Since that time, Health and Care Research Wales have collaborated with Infonetica to develop and configure ReDA 3 to ensure it meets the needs of research support and delivery teams across Wales.

Overview

ReDA 3 is a web based study management system used to manage studies on the Research Portfolio and Directory, which includes:

- Health and Care Research Wales Portfolio studies
- Biobanks
- Research Data Registries
- Pathway to portfolio and other non-portfolio studies

ReDA3 will be used as the information management system for research and encompasses:

- Recording of all research related data (Wales minimum data set, which includes the UK wide minimum dataset)
- Recording of study recruitment
- Study set up and amendments (from Spring 2019)
- Performance reporting, monitoring and generation of Business Intelligence (BI)
- Expressions of Interest (EoI) (development Spring 2019)

2 System Administration

The Research Systems Advisory Group provides operational input to the Support & Delivery Centre on requirements for providing central LPMS system administration on behalf of Health and Care Research Wales. The role and responsibilities of the group can be found in the Research System Advisory Group Terms of Reference and include:

- Providing a Wales-wide agreed approach for the use of LPMS
- Providing a coordinated approach to the implementation of LPMS to all sites in Wales
- Considering local requests for change and the impact on national implementation

- Providing input into plans for Wales to align with work across the UK around local portfolio management systems and links to the Central Portfolio Management System
- Providing a coordinated approach to the management of LPMS service management and assist the Information Service Team with release management, testing of fixed issues and changes to LPMS system and processes, including changes to this SOP.

Requests for change

All requests for change with the exception of system access requests are processed centrally by the Information Services Team and should be agreed by the local LPMS user group and supported by the Research Systems Advisory Group member for the requesting site before being submitted to Research-Information@Wales.nhs.uk.

High impact or national change requests for LPMS will always be referred to the Research Systems Advisory Group for consideration and approval prior to implementation. However, standard changes with a pre-defined process can be pre-approved by the Research Systems Advisory Group allowing low risk changes to be implemented more efficiently.

On receipt of a LPMS request for change the Information Services Team will assess, categorise and record the request on the LPMS change request log published on the LPMS SharePoint site before processing. If a request for change matches one of the pre-approved changes the Information Services Team will:

- Manage the change using the agreed process for the type of change
- Ensure relevant documentation e.g. the LPMS Data Dictionary is kept up to date
- Advise the Research Systems Advisory Group (RSAG) of any changes for all Wales consideration

Standard change scenarios

Scenario one

Change to an individual's LPMS access

Process:

- Change implemented by local LPMS admin user.
- Information Services Team to provide system access reports every 6 months for RSAG review

RSAG role:

RSAG to review report and ensure users who should not have access are removed.

Scenario two

Request submitted for a local custom field

Process:

- Information Services Team to check the field is not already in the system and if it is inform the requestor.
- If information is not available in LPMS, the Information Services Team will create a custom field or switch on the existing field for the requesting Health Board.
- Local custom fields will be added to the upcoming LPMS RSAG agenda for all Wales consideration.

RSAG role:
LPMS RSAG to review and advise if data field should be switched on for all Wales.

Scenario three

Minor changes e.g.: System field spelling.

Process:

- Information Services Team to log change and assess impact. If change is categorised as a standard change Information Services Team will either implement or request Infonetica to implement change

RSAG role:
LPMS RSAG to review log.

System Issues

Escalation process

On experiencing an issue with LPMS, it is the responsibility of the site where possible, to investigate if the issue is caused by a local issue before contacting the Information Services Team.

System Issues are to be reported to the Information Services Team via Research-Information@wales.nhs.uk or by phoning 02920 230457. All issues will be investigated by the Information Services Team to establish the impact of the issue and recorded on the LPMS Issue Log available on LPMS SharePoint site. All LPMS issues will be categorised as follows:

Impact - Critical

Definition:

- The issue impacts critical functionality or data
- It does not have a workaround

Example:

- Unsuccessful installation, complete failure of a feature
- A significant group of users unable to complete essential work on the system

Resolution:

- Information Services Team to inform Infonetica immediately and work with them to implement a timely resolution.
- Information Services Team to keep LPMS Site key contacts informed of progress and expected resolution times
- LPMS Site key contacts to cascade updates to system users.
- Where appropriate an incident report will be produced and made available to the Research Systems Advisory Group to record and mitigate similar occurrences in the future.

Impact - Major

Definition:

- The issue impacts major functionality of data
- It has a workaround but it is not obvious and is difficult

Example:

- A feature of the system is not available but the task can be completed using another feature of the system
- A significant number of users will be inconvenienced by the issue or there is a difficult workaround.

Resolution:

- Information Services Team to fix issue or inform Infonetica and work with them to implement a resolution.
- Information Services Team to inform LPMS Site key contacts of workaround and expected resolution times
- LPMS Site key contacts to cascade workaround to system users.

Impact – minor

Definition:

- The issue impacts minor functionality or non-critical data
- It has an easy workaround

Example:

- The issue impacts a single or small number of users
- The workaround has little impact on users efficiency

Resolution
Information Services Team fix issue or inform Infonetica and work with them to implement a resolution.

- Information Services Team to inform LPMS user of workaround.

Impact – cosmetic

Definition

- The issue does not impact functionality or data
- It does not require a workaround
- It does not impact productivity or efficiency

Example:

- Layout discrepancies
- Spelling/grammatical errors

Resolution:

- Information Services Team fix issue or inform Infonetica and work with them to implement a resolution.

It is the responsibility of the Research System Advisory Group members to review the LPMS issue log and advise the Information Services Team if categorisation of individual issues should be reviewed or amended.

Local system administration

It is the role of local LPMS system administrators to manage local user system access. Any access issues that cannot be resolved locally should be escalated to the Information Services Team for further analysis and resolution. Responsibilities of Local Administrators include:

- Creating and managing users (see LPMS user settings)
- Disabling and changing user access when staff leave or change roles to prevent unauthorised access
- Organising training when required
- First point of contact for users of LPMS and escalation of issues to the Information Services Team when required
- Implementation and management of locally agreed processes and system changes

LPMS user settings

Access levels are:

- Administrator – write access to studies and management of system users
- Write access – write access to studies

- Health Care Professional (HCP) access – limited write access to studies
- Recruitment Activity (RA) user – access to bulk recruitment upload screen
- Read only access – read only access to studies

Network (Support & Delivery Centre)
Restrictions to individual fields can be set. Example users for each access level are:

- Administrator e.g. Overall system administrator i.e. Information Services Team.
- Write access e.g. Central Portfolio team
- HCP access e.g. not normally applicable
- RA user e.g. not normally applicable
- Read only access e.g. users requiring information only across all Sites

Non-network (NHS Wales sites)
Restrictions to individual screens can be set. Example users for each access level are:

- Administrator e.g. site administrator
- Write access e.g. site research and development team
- HCP access e.g. research nurse
- RA users e.g. study teams
- Read only access e.g. users requiring information across one site only

3 Managing Research Directory Studies

Adding a study to LPMS

As agreed by the Research Systems Advisory Group, all studies will be added to LPMS by the Support and Delivery Centre. If a site is unable to find a study on LPMS, the site is to send the study details via email to Portfolio@wales.nhs.uk to request it is added to the system.

There may be exceptions where NHS organisations are acting as study sponsor and may create the study record prior to the IRAS application being generated. To avoid duplication of studies, it will be the responsibility of the NHS organisation to update the study record with the IRAS ID and other study references as soon as they become available and for the Portfolio & Directory Team to regularly quality assure studies without IRAS ID numbers to ensure they are not duplicated in the system.

Adding your site to a study
LPMS uses site and location data provided by the Organisational Data Service (ODS) to identify NHS Sites and NHS Locations. The aim is to attribute recruitment and other study related data to the correct location and ensure information is linked between LPMS and CPMS (Central Portfolio Management System).

NHS sites are able to add their own locations to a study via the locations screen in LPMS.

To add a research location:
- Click on the plus button above the participating location list
- Tick the location you wish to add to the study in the pop up screen
- Check that the location has been added to list of research sites in the research locations section
- Ensure the correct site type is selected from the Site Type dropdown. In particular, if the site is a Participant Identification Centre.

Once added to the study it is the responsibility of the site to maintain mandatory site, location and status information in the system and record monthly recruitment for those studies.

Removing a study
Study deletion should only be undertaken by the Support & Delivery Centre, as deleting a study means that it will be deleted for all sites.

If a location is no longer involved in a study or has been added in error, the location should be deleted from the study via the locations screen and the reason for deletion recorded in the “reason for deletion” comments box. Sites can delete studies for their use whilst leaving the study record available to other sites by marking all of their locations as deleted using this process.

Archiving a study
The Research Systems Advisory Group have agreed that once a study has been archived for Wales it may be excluded from automatic interface updates in order to ensure that there are no further changes to the Welsh study record.

As this is a study-wide action and may impact other Welsh sites yet to archive the study, a coordinated all Wales process has been agreed which will be administered by the Support and Delivery Centre:
- Local archivist marks the study as archived for their site and emails request to Research-Information@wales.nhs.uk for interface/updates to be switched off

- The Support and Delivery Centre will check to see if other sites involved in the study object to switching off the interfaces
- If appropriate, the Support and Delivery Centre will mark the study as excluded from interface updates.
- If a site objects or wishes to switch the interface back on at a later date, the request to switch updates back on will take precedence.

Some sites have implemented custom fields in LPMS for managing local archiving processes. However, when agreeing local processes the local team is responsible for adhering to the condition of the LPMS Privacy Impact Assessment approved by the Information Governance Management and Advisory Group, for removing all participant identifiable information from the study record before archiving the study on LPMS.

Maintaining the study record on LPMS

In line with the implementation of the Local Portfolio Management System for Wales, there is now requirement that all research studies enter a minimum data set, and keep this maintained in LPMS.

The minimum data set for Wales includes the UK-wide minimum data set. This has been agreed through discussions with the 4 nations working group and as such, aims to be in line with the rest of the UK reporting requirements. The Wales minimum data set also includes other data fields required in order to continue to ensure that Wales' performance data can continue to be monitored on a routine basis and to provide Wales with the ability to generate robust and meaningful analysis for business intelligence related to research in Wales.

The LPMS minimum dataset for Wales can be found in the User Manuals folder of the LPMS SOP Store along with this document and includes the roles, responsibilities and where the data items can be found for maintaining each of these data items in LPMS. Changes or amendments to this document are managed through the LPMS Request for Change process.

A summary of the data items to be captured within LPMS for all studies in Wales is provided below. Text in bold indicates that the responsibility for those data items sit with the Support & Delivery Centre. Those not in bold indicate that the responsibility for entering the data into LPMS sits with the NHS organisation. Those with asterisks*, indicate that the responsibility for entering Location level data, for Primary Care studies, sit with the Support & Delivery Centre:

- **IRAS ID**
- Date site invited
- Date site/locations selected*

- **HRA and Health and Care Research Wales approval date**
- Date site confirmed by sponsor
- Date site/location confirmed*
- Non-confirmation status
- Date site/location ready to start
- First participant recruited date at site/location*
- Reason for delay in recruiting first participant
- Source of delay in recruiting first participant
- Comments/reasons (delay in recruiting first participant)
- Site recruitment target
- No target number of participants available?*
- Minimum agreed recruitment target*
- Maximum agreed recruitment target*
- Target date to recruit participants agreed*
- Date agreed to recruit target number of participants*
- Total number of participants recruited at the agreed target date*
- Monthly recruitment*
- Site/locations actual recruitment close dates*
- Closure reason
- Comments/reasons (recruitment to time and target)
- **Date study initiated**
- **Expression of interest [Not currently used]**
- No confirmation of Capacity & Capability (C&C) required
- **Study actual close date**
- Site/location actual recruitment open date*
- Site/locations planned recruitment open date*
- Site/locations planned recruitment close date*
- Patient Identification Centre (PIC) activity only/location type*
- Investigator name*
- Study supported by research delivery?*
- Recruitment supported by research delivery?*
- **Informed consent required**
- **Study setting**
- Site actual protocol activity complete date
- Site status
- Location status
- Location type

The Support and Delivery Centre will normally maintain study level fields, however sites may take on this responsibility by agreement on a study-by-study basis e.g. site sponsored non-portfolio studies would normally be maintained by sites. Sites can request study-level data changes by emailing details to Portfolio@wales.nhs.uk. When recording information against a study record it is the responsibility of the person recording the information to ensure that the information is recorded at the appropriate level (Study, Site or Location Specific).

Adding recruitment figures

Recruitment is the enrolment of an individual person meeting specific inclusion criteria into a research study. Each study participant who has both provided informed consent to join a study and is taking part in the study (i.e. participants who count towards the sample size of the study as set out in the study protocol) should also be included in recruitment figures recorded in LPMS.

Recruitment activity should be recorded in LPMS as soon as possible after the activity has occurred, ideally within 5 working days of the end of the month of recruitment.

This will enable Wales to have near real-time data, which has not been possible previously, meaning that data required for study teams to monitor progress of studies and recruitment to target proactively in one system.

Recruitment data is a key part of the information used to monitor and improve the work of Health and Care Research Wales Support and Delivery. This data also currently feeds into the process of allocating Research and Development funding to ensure that support and delivery resources are directed to where they are required. Recruitment data for portfolio studies also prompts payments of NHS Support Costs and Excess Treatment costs. Having this information uploaded in a timely way will reduce the work required to process such payments.

Recruitment data may relate to the following (not an exhaustive list):

- Patients recruited to a treatment regime;
- Staff members who have completed a questionnaire(s) or been interviewed in research;
- Individual members of focus groups;
- The collection of tissue or blood samples during research;
- Participants who have answered questions during research.

Each participant recruited into a study should only be counted in one recruitment figure i.e. where the same individual is consented more than once into a study they should only be included in the recruitment figure once.

An interface is being developed to integrate LPMS and CPMS recruitment activity which will mean that recruitment figures maintained in LPMS by local study teams will automatically feed through to CPMS for portfolio studies where the CPMS recruitment upload route is set to LPMS. Central study teams will review and confirm/query the LPMS recruitment activity data in CPMS on a regular basis. Queried monthly recruitment activity figures will then appear in LPMS where they can be corrected and re-submitted to CPMS.

The CPMS recruitment upload route (LPMS, CPMS or N/A) will be determined at the time the study is set-up on CPMS using an agreed UK-wide Standard Operating Procedure and automatically populated in LPMS for portfolio studies.

For studies where the recruitment upload route is CPMS, recruitment information can be populated in LPMS via an CPMS interface and so it will not be necessary to enter recruitment figures into LPMS for these studies. If organisations require historical recruitment data to be populated in ReDA3 this can be requested via Research-Information@wales.nhs.uk.

For portfolio studies where the upload route is LPMS, it will be the responsibility of local study teams to enter timely study recruitment into LPMS and to answer any recruitment activity queries raised by the central study team in CPMS.

The sites are responsible for determining which teams/individuals will be responsible for supporting local study teams in entering and correcting recruitment figures for recruitment at secondary care locations.

The Support and Delivery Centre will support primary care study teams by entering and correcting their recruitment figures in LPMS.

Adding participant information (where recorded)
LPMS has functionality to support HCP users of the system manage study participants. The HCP system user is the only ReDA 3 user type that can access and is responsible for Participant Identifiable Information included in the system.

System users with “write” or “admin” accounts are able to record non identifiable participant and recruitment information either against the participant number or via the bulk upload screen.

Study contact information
Sponsor, Funders and Chief investigator will be prepopulated in LPMS as studies are added to system and are updated via the link from CPMS for portfolio studies. PI

contacts and site or location contact details are kept up to date locally using the Stakeholders screen.

To avoid duplication of contact information in the system, it is the responsibility of the employing site to use the search functionality to ensure the contact does not already exist in the system before creating a new contact. It is also important to ensure any documentation associated with the contact e.g. CVs and Good Clinical Practice Certificates are also maintained within the contact record.

On discovering a duplicate contact within LPMS, it is the responsibility of the employing site to email Research-Information@wales.nhs.uk requesting the two or more contacts be merged. On receipt of the request, the Information Team will seek approval from all sites that have these contacts as stakeholders before merging them.

Expressions of Interest (development scheduled Spring 2019)
A UK-wide EoI process has been in place for commercial contract research studies since 4th June 2018 and has resulted in Wales receiving over two hundred commercial site identification requests. Building on the success of this work and horizon scanning activities, the Support and Delivery Centre is improving and expanding the EoI process, which will now include both commercial and non-commercial research opportunities.

The Support and Delivery Centre is working with Specialty Leads and delivery staff to identify possible sites and investigators for commercial and non-commercial research opportunities and will use LPMS to coordinate and track EoI activities.

Capacity and Capability
Capacity and capability is recorded in LPMS within the Study Governance>events screen. It is the responsibility of individual sites to ensure this section is completed and to tick the “No confirmation of C&C required” field when these checks are unnecessary.

Study set-up (available from Spring 2019)
Progress can be tracked in setting-up studies in LPMS within the Study Governance>set-up screen. Sites can determine which set-up activities to track, additional set-up activities can be requested via the LPMS Change Management process.

Study amendments (available from Spring 2019)
It is the role of the Sponsor to advise study teams of any study amendments. The Support and Delivery Centre will upload amendments documentation to LPMS.

However, it is the responsibility of sites to ensure they are aware of any amendments and have a local process in place to track the local status of amendments in LPMS.

Storing documents in LPMS

It is possible to store and share documentation in LPMS. When uploading documentation to LPMS it is the responsibly of the person uploading the document to ensure the document is saved at the appropriate level (Study, Site or Location Specific), and is made visible to the correct user type.

It is also the role of the owning site to archive or delete any superseded documentation from the system when uploading a new document.

4 Reporting

All data items in LPMS are reportable. When choosing to save a report as visible to all users, the report will be visible to any user of the system with the same organisational access as the report creator.

The following standard naming convention has been agreed by the Research Systems Advisory Group for any report shared in LPMS:

Location/Type of Report/Year Month

To ensure only the optimum number and type of reports are available in LPMS it is the responsibility of the report creator to:

- Make sure one off report templates are not stored in LPMS
- Only share reports thought to be useful to others
- Periodically delete reports no longer required

5 Glossary of terms

Site - The organisation with day-to-day responsibility for the location where a research project is carried out (UK Policy Framework for Health and Social Care Research, paragraph 9.14).

Location - Hospital or GP practice where the study is taking place.