Passionate for Research, Compassion for Patients
since 1998

GCP Compliance in Home Research Nursing

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Home Research Nursing

Also known as Direct to Patient, Off-Site or Homecare service

Procedures carried out at patient’s preferred location:

- Home
- Work
- School

Key words: Safe and Practical

Carried out by a trained and qualified Research Nurse, who is an extension to the Investigator Site.

Aim is to reduce the burden on the patient and their family.
Human regulatory

Overview
Post-authorisation
Research and development
Herbal products
Marketing authorisation

Q&A: Good clinical practice (GCP)
Focus

- Trial Design and Essential Documents
- Contracts and Agreements
- Approvals and Permissions
- Oversight
- Patient Protection
- Data Integrity
Considerations for Trial Design and Essential Documents:

- Does the design, patient condition and drug indication support and justify the Service?
- Design feasibility – can all proposed activities take place off-Site?
- Protocol and Consent must specify what procedures can be done in home setting
- Patient confidentiality information is adequate and complies with local standards
- REC and MHRA submissions specify arrangements for off-site visits
- Identification of risks inherent to being outside of the Site (handling medical emergencies, Infusion Related Reactions etc.)

**Provider will use the Protocol, Lab and Pharmacy Manuals to develop an Operational Manual for the Home Visits.**
Contracts and Agreements

- Sponsor
- Provider
- CRO
- Site
- Service Provider Contract
- Technical/Quality Agreement
- mCTA
Responsibilities for Nurse identification and on-boarding.

Responsibilities for Nurse training.

SOPs and Standards to be followed.

Investigator Responsibilities delegated to the Nurse (or reference to the delegation log).

Lines of Communication between the Institution, Provider and Nurse.

Safety events reporting pathway including expedited SAE notifications.

Issue reporting pathway including escalation of potential Serious Breaches.

IMP Handling expectations – chain of custody and shipment arrangements.

Data protection and Human Tissue Act considerations.
Sponsor/CRO completes vendor selection

Strict pre-engagement checks for each potential research nurse

Investigator/Trust approves the service and each proposed nurse

REC and MHRA approval of the study including the homecare service
Recruitment and On-Boarding

Pre-engagement checks in line with NHS Employment Check Standards:

- criminal record checks
- employment history and reference checks
- identity checks
- professional registration and qualification checks
- right to work checks
- work health assessments

Source:
Research Nurse Training

General training:
ICH GCP
- Foundation in Clinical Research (or equivalent experience)
- Life Support
- Cross Infection
- Handling Dangerous Goods (IATA)
- Manual Handling and other HSE

Project Specific Training:
Attending Site Initiation Visits
Protocol training delivered by the Provider’s Project Manager

*red denotes training documentation provided to Site
Site and Patient Meetings

Site Introductory Meeting
- The site introductory meetings involve the research nurses visiting the site to establish a rapport with the PI, site nurses, pharmacist and any other site personnel that may be involved in the study to ensure that all parties are fully aware of their duties and responsibilities.
- This also gives the nurse the opportunity to sign the delegation log.

Initial Patient Meetings at Site
- Whenever possible the research nurse allocated to a patient should initially meet the patient at the investigative site.
- This initial meeting usually lasts for an hour, and also enables the research nurse to explain to the patient what procedures will be performed at the visits and how many visits will take place.
Oversight and Communication

- Visit scheduling
- Logistical support (courier, supplies)
- QC of worksheets (ALCOA)
- Data queries

Project Manager
- Notification of new patients
- Visit requests
- ISF Documents and queries
- Completed worksheets
- Data queries

Research Nurse
- Pre-visit handover
- Protocol/Visit queries
- Safety reporting
- Delegation log

Home Visit

Investigator Site
Patient Safety

All Nurses are trained in Life Support.

Cross-Infection and ANTT training.

Risk Assessment considering procedures “at home” vs “on Site”.

High risk or important procedures carried out at Site.

Meet the patient visit on Site, before the first home visit.

Handover call (Nurse and Site) before each visit.

Written notes post visit.
Patient Data Privacy

Controlled movement of patient data.

Appropriate controls and restrictions to patient details in Provider’s custody.

Courier services – data minimisation:
- Secure method for data sharing;
- Nurse’s name and telephone no provided instead of patient’s;
- Approximate address can be used;
- Courier should always be met by the Nurse, not the patient.

Sites must only share data for patients who requested the service.
AEs and Safety Management

Procedures for AE and SAE reporting agreed in advance:

Nurses will always collect safety information, regardless of protocol/Sponsor expectations. How these are processed will be protocol dependent.

Other protocol specific aspects, e.g. infusion reaction management to be outlined in the protocol and operational manual.

Medical decisions and AE treatment remains responsibility of the Investigator, Sponsor must not influence Provider’s and/or RN’s actions.

All SAEs are notified to the Site/Investigator in the first instance (via telephone).
Reporting responsibilities remain with the Site, RN may facilitate information gathering.
IMP – considerations in the home

IMP is part of a clinical trial and needs to be handled and stored accordingly. i.e. not stored in a family fridge with no ability to control temperature.

Processes need to be planned to consider the home environment.

Clear chain of custody documentation is available for the full process.
24-48 hours in advance of collection, Provider books drug shipment in consultation with the Site Pharmacy.

Courier picks up drug from the central/Site pharmacy, provides conditioned packaging for the specified temperature range. The IMP is accompanied by the chain of custody form.

Courier delivers the drug to the patient’s home (arrives 15 min before due time) and hands directly to the Nurse, never to the patient.

Courier can wait or return separately for patient’s samples and deliver to appropriate laboratory. IMP packaging/container is returned to Pharmacy to aid accountability.
RNs are trained in ALCOA C, there should be a QC step to ensure integrity of the generated data.

Source Data Agreement between the Site and Monitor must identify source document for any source data collected off-site and identify location during and after the study.

Visits are documented on paper or electronically.

If an electronic system is used, it must comply with expectations of the regulators (Sponsor should verify at the point of Provider qualification).
**Perception**
Using a mobile RN service means sites have less revenue coming in as less visits are performed at site.

**Reality**
- Improving the patient (and family) experience and reducing the stress of participation will reduce the chance of drop outs so, in the long run, everyone wins.
- The site RNs have more time to screen patients and may then enrol more subjects than they had originally committed to - this also increases department revenue. The sites usually perform the high value visits (when specialist equipment such as scans are required).
- Sponsors are more likely to work with sites who have successfully participated in a trial (where the use of the mobile RN has been embraced) and all recruitment promises met as a result.
Perception vs Reality

**Perception**
Using a mobile RN service puts patient safety at risk.

**Reality** - Mobile RNs are NOT medics and will only perform tasks which they are qualified and deemed competent to perform.

**Reality** - The mobile RN is an extension of the site team and always provides visit feedback and source data for the site staff to use to complete the (e)CRF.

**Reality** - Any SAEs and/or AEs are reported immediately. AEs are assessed at every visit, irrespective of the tests being performed within the home.

**Reality** - All hospital trusts/Ethics committees (where needed) approve the individual nurse or nursing service as a whole and the nurse meets both the site and patients prior to commencing the off-site visits.
“Having the blood test done back home provided a much more normal week instead of having to travel. For us, as a family, it was great to have everyone home and not disturb family life more due to one parent and a child being away for days at a time. This also greatly benefitted our two younger daughters, making life as normal as possible. They didn’t notice anything different about the weeks where we got home care nursing. And for us, the parents, no travel meant a normal work week and not needing any days off.”

Thank you

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