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RUMAX LIMITED

INVESTIGATOR SITE

GUIDE TO MOBILE CLINICAL TRIALS SERVICES

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1.0 Introduction

RUMAX LIMITED is a mobile clinical trials service provider based in the UK that offers a range of services for conducting clinical trials activities in a homecare setting. Their services include the provision of GCP (Good Clinical Practice) trained mobile clinical trial nurses who are skilled in performing various activities related to clinical trial procedures

The services provided by RUMAX LIMITED include:

- **Vital Signs Monitoring:** The mobile clinical trial nurses are trained to monitor and record vital signs of the trial participants, such as blood pressure, heart rate, respiratory rate, and temperature. This helps in assessing the overall health status of the participants during the trial.
- **Data Collection:** The mobile clinical trial nurses collect relevant data and information from the trial participants as per the study protocol. This may include demographic details, medical history, and any other data required for the trial.
- **Blood Draws:** Mobile clinical trial nurses are proficient in performing blood draws from the trial participants. They ensure proper collection of blood samples for further analysis and testing as required by the study protocol.
- **Processing and Packaging Samples:** RUMAX Limited's mobile clinical trial nurses handle the processing of collected samples, ensuring they are appropriately prepared for laboratory analysis. They carefully package the samples to maintain their integrity during transportation.
- **Shipment of Samples:** The company arranges the shipment of collected samples from the trial participants to either a central laboratory or investigator sites as specified by the study protocol. They ensure that the samples are appropriately packaged and labelled for secure transportation.
- **Reporting Signs and Symptoms:** The mobile clinical trial nurses are responsible for documenting and reporting any signs

or symptoms observed during the trial. This includes monitoring and reporting any adverse events or changes in the participants' health condition.

- **Reporting Concomitant Medications:** RUMAX Limited's mobile clinical trial nurses keep track of any concomitant medications taken by the trial participants. They document the details of these medications and report them as required by the study protocol.

- **IMP (Investigational Medicinal Product) Administration:** The mobile clinical trial nurses are trained to administer the IMPs to the trial participants in accordance with the study protocol. They follow the prescribed administration procedures and monitor the participants for any immediate adverse reactions.

- **Monitoring for Signs and Symptoms Post-Administration:** After administering the IMP, the mobile clinical trial nurses closely monitor the trial participants for any signs or symptoms of adverse reactions. They document and report these observations as part of the trial data collection.

- **Source Documentation:** RUMAX Limited's mobile clinical trial nurses ensure accurate and complete source documentation for all the activities performed during the trial. This includes maintaining detailed records of the procedures carried out, observations made, and data collected.

- **Study coordination and management.**

- **Centrifugation**

- **ECGs**

- **24/7 Device monitoring for example infusion pumps.**

Overall, RUMAX LIMITED provides comprehensive mobile clinical trials services in the UK, leveraging their GCP trained mobile clinical trial nurses to perform various activities, including vital signs monitoring, data collection, blood draws, sample processing and packaging, sample shipment, reporting signs and symptoms, reporting concomitant medications, IMP administration, monitoring post-administration, and maintaining accurate source documentation.

2.0 Investigator Site - Initiation of the Mobile Clinical Services

The initiation of mobile clinical trials services involves the initial steps taken by RUMAX LIMITED to set up and begin providing their mobile clinical trial services. Here are the key aspects of the initiation process:

- **Project Assessment:** RUMAX LIMITED works closely with the study sponsor or contract research organization (CRO) to assess the specific requirements and goals of the clinical trial. They gather

information about the trial protocol, target population, study objectives, and any specific needs or challenges associated with conducting the trial in a mobile setting.

- **Feasibility Assessment:** RUMAX LIMITED conducts a feasibility assessment to determine the practicality and viability of conducting the clinical trial using their mobile clinical trial services. This assessment considers factors such as the geographical area, patient population, logistics, and regulatory requirements.

- **Service Proposal:** Based on the project assessment and feasibility assessment, RUMAX LIMITED prepares a service proposal outlining the scope of their mobile clinical trial services. The proposal includes details about the services offered, timelines, costs, and any additional resources or support provided by RUMAX LIMITED.

- **Contracting and Agreements:** Once the service proposal is accepted by the study sponsor or CRO, RUMAX LIMITED proceeds with the contracting process. This involves negotiating and finalizing the contractual agreements, which define the terms and conditions of the collaboration, including roles, responsibilities, payment terms, and confidentiality requirements.

- **Study-Specific Training:** RUMAX LIMITED ensures that their staff, including mobile clinical trial nurses and study clinicians, receive study-specific training. This training covers the study protocol, procedures, data collection, safety measures, and any specific requirements or guidelines associated with the trial.

- **Regulatory Compliance:** RUMAX LIMITED ensures compliance with all applicable regulatory requirements and guidelines, including adherence to Good Clinical Practice (GCP) standards. They maintain documentation and procedures that meet regulatory standards and support the integrity and quality of the clinical trial.

- **Logistics and Planning:** RUMAX LIMITED plans and organizes the logistics for the mobile clinical trial services. This includes scheduling visits, coordinating with study sites, managing transportation and sample shipments, ensuring availability of necessary equipment and supplies, and addressing any site-specific requirements.

- **Communication and Collaboration:** RUMAX LIMITED establishes effective communication channels and collaborates closely with the study sponsor, CRO, and study sites. They maintain regular contact to address any questions, concerns, or changes related to the mobile clinical trial services.

- **Initiation Visit:** RUMAX LIMITED may conduct an initiation visit at the study site to further discuss and clarify the trial requirements, processes, and logistics. This visit allows for in-person interaction, building relationships, and ensuring a smooth start to the mobile clinical trial services.

Overall, the initiation of mobile clinical trials services by RUMAX LIMITED involves project assessment, feasibility assessment, service proposal, contracting, study-specific training, regulatory compliance, logistics planning, communication, and an initiation visit if required. These steps set the foundation for the successful implementation of their mobile clinical trial services.

Initiation of the subject's mobile clinical services via Physician Order Form

- Mobile clinical trials services must be requested via completion of the Physician Order Form (POF) and the form must be signed by the Principal Investigator (PI) or any other individual delegated by the PI as indicated on the Delegation log.
- Study subject must give consent to mobile clinical trials services.
- A valid POF must be signed and dated by the individual who completes it.
- Submission of the POF to RUMAX LIMITED initiates mobile clinical trials services.
- A copy of the POF must be filed in the subject's study file.

The POF must be submitted to RUMAX LIMITED as soon as possible once a subject confirms interest in mobile clinical trials services, however a 14-day advanced notice is required for RUMAX LIMITED to:

- Identify a mobile clinical trial trials nurse in the subject's location or nearer the subject's location.
- Train mobile clinical trial trials nurse on the protocol study procedures.
- Ensure mobile clinical trial nurse has the equipment and other study supplies.

RUMAX LIMITED Study Manager will confirm receipt of the POF via email and will notify the investigator site study coordinator once mobile clinical trial nurse has scheduled the visit with the study subject.

Cancellation of the mobile clinical services

Notify RUMAX LIMITED Study Manager as soon as possible if services have been cancelled. Notification can be via contact telephone numbers on the POF and followed by an email to the Study Manager and cc resdoc@rumax.co.uk

The POF must be updated and signed by the PI or any other individual who has been delegated to do that.

If a mobile clinical visit has been cancelled by the study subject, the investigator site will be notified immediately. An administrative worksheet will still be completed by the mobile clinical trial nurse.

3.0 Mobile Clinical Services Documentation

Physician Order Form

It is a document that initiates and authorises subject's mobile clinical services.

Mobile Clinical Source Document

A form that mobile clinical trial nurses complete to record study data at each homecare visit time point.

It is a form that captures data recorded on each mobile clinical visit timepoint by the mobile clinical trial nurses.

This form following mobile clinical visit will be forwarded by the Mobile clinical trial nurse to the Study Manager for review before submission via email to the investigator site.
Laboratory requisition forms will be completed by the mobile clinical trial nurse. Original copies will be shipped to central laboratory and investigator site.

Study questionnaires will be administered, collected by the mobile clinical trial nurse, and shipped to the investigator site.

Mobile clinical source documents will be shipped to the investigator site via royal mail special delivery service/ recorded mail within 5-7 business days from the date of the homecare visit.

All study related source documents will be shipped to the Investigator site for filing and archiving.

Administrative Worksheet

It is a document that initiates and authorises subject's mobile clinical services.

This form will be completed by the mobile clinical trial nurse for each visit conducted along with the mobile clinical trial source documents.

The administrative worksheet will be used by RUMAX LIMITED for billing purposes and will be attached to the invoice and submitted to finance.

4.0 Mobile Clinical Trial Nurse Documentation

Mobile clinical trial nurse Recruitment and Qualification

Each mobile clinical trial nurse will be recruited according to RUMAX LIMITED policies and procedures. Each mobile clinical trial nurse will have the following conducted prior to working on any of the studies:

- DBS checks.
- Right to work in the UK checked and verified.
- Current registration with Nursing and Midwifery Council checks and verification.
- Clinical experience checked and verified via Curriculum Vitae (CV).

Mobile clinical trial nurse Training Documentation

Each mobile clinical trial nurse will be trained on protocol specific procedures prior to

performing study related activities.
Upon completion of study training, the following documents will be provided to the Investigator Site and must be filed at the site:

- Curriculum Vitae.
- Mobile clinical trial nurse proof of NMC registration.
- Site Delegation / Responsibility Log.
- Training Completion and Confidentiality Form.

5.0 Communication

RUMAX LIMITED

To ensure that there is seamless continuity of care, RUMAX LIMITED will assign a Study Manager. RUMAX LIMITED Study Manager will ensure that there is seamless communication between RUMAX LIMITED, study patient and the investigator site team and this will be maintained throughout the duration of the study.

RUMAX LIMITED Study Manager and the Investigator Site will be communicating on the following:

- Physician Order Form and once received, a confirmation will be emailed to the site team. If confirmation is not received within 24 hours from the Study Manager, the Investigator Site will follow up with a phone call.
- Study Manager will provide notification that a mobile clinical trial nurse has been identified and trained.
- Study Manager will contact the subject to confirm homecare visit date and time. Once confirmed with the subject, then the investigator site will be notified.
- If the subject is not reachable after three attempts, then the investigator site will be engaged to assist in reaching out to the subject.
- Any issues observed or reported by the subject during the mobile clinical visit will be reported to the investigator site team during the visit. The mobile clinical trial nurse will facilitate a call between the subject and the investigator site team to ensure that information is gathered directly from the subject.

Study Subject

RUMAX LIMITED Mobile clinical trial nurse will contact the subject directly to schedule each visit date and time as per protocol and Physician Order Form.

- Mobile clinical trial nurse will remind the subject visit expectations and agree on a date and time of the visit.
- Inform subject the approximate duration of the visit.
- Inform the subject that homecare will need access to a sink (to wash hands etc.).
- Mobile clinical trial nurse will give the subject contact details including name in case the agreed date and time of the visit changes.
- On arrival mobile clinical trial nurse will display an ID badge with name, company, and photo (ID) for every visit.
- Inform the subject mobile clinical trial nurse will clean-up with all waste removed and disposed of at the end of each visit.

6.0 RUMAX LIMITED Contact Information

Please contact RUMAX LIMITED at any time should you have any questions:

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7.0 Mobile Clinical Trials Service Overview