Home Care Service Site Agreement

Study Details	
Protocol Number	HMB-001-CL101
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Sponsor	Hemab Therapeutics
Contract Research Organisation (CRO)	Marken
(Lead) Home Care Company, Country	T-Care (Italy)
Hospital Name, Site, Country	Fondazione IRCCS Ca'Granda Ospedale Maggiore Policlinico di Milano – Italy 380-02
Principle Investigator	Andrea Artoni

Introduction and Description

This form documents the agreement between the site (principal investigator (PI)) and local home care company engaged by Marken, that for this clinical trial is contracted. Marken's nursing agency can perform home care visits, conducting protocol specific activities in alignment with the local regulations, contractual commitment with the Sponsor or CRO or Marken, site requirements and Marken's nursing agency procedures. Activities being performed must be reviewed and updated when any amendments have been made to the study protocol, local regulations, contractual commitment with the Sponsor or CRO, site requirements and Marken's nursing agency procedures. Where there is no impact on the activities performed by the Research Nurse this form may remain effective.

List of Activities Performed by the Research Nurse

Visit Type
Vital Preparations (Introductions & PPE)
Vital Signs
IP Administration
Post Observation
IP Vial Count
Study Diary Check
Completion of Source Documentation

Responsibilities Principle Investigator/ Site

Principle Investigator/ Site Responsibilities	Actions
The PI is responsible for the patients, their medical care and reporting to the Sponsor	Completion and signing of the Physician Order Form (POF), which specifically orders the Home Care visit and provides details regarding the specific patient, their (medical) health and activities to be performed at the patient home. Site must always be available for advice on safety issues during Home Care visits.
The PI is responsible for obtaining Patient Informed Consent, including consent on any Home Care related activities, prior to any Home Care visit.	Informed Consent date must be clearly documented on the POF. Site staff discusses the home care service with the patient.
The PI is responsible for the oversight of the external Research Nurses	Review and approval of Research Nurse CV and training records (to be filed in the site trial master file as well), counter signing of the Delegation of Authority Log. The PI can always request more information regarding a Research Nurse or reject to take responsibility for a specific Research Nurse.
The PI / Site is responsible for Investigational Medicinal Product(s) (IMP)management	IMP preparation, storage and transport according to protocol. IMP administration, dosing and details important for Home Care visits are documented on the POF.
The Site is responsible for maintaining Home Care Visit source documents	Source documents will be provided digitally and will be considered the original source document. In the event electronic documents cannot be provided electronically, they will be provided on paper to the site.

Responsibilities Local Home Health Care Company/Research Nurses

Marken's Nursing Agency Responsibility	Actions
Marken/T-Care is responsible for screening, selection and training of Research Nurses	CV and qualification documents of Research Nurses are collected, teleconference calls or face-to-face meetings organized. The Research Nurse will be trained on the study specific activities, with the use of the Sponsor approved Training Manual, which is based on the study protocol. CV and training record are provided to the PI / Site for review and approval.
Marken/ T-Care is responsible for safety reporting and communication with the site / PI	Scheduled visits (between patient and Research Nurse) will be communicated with the site. Visit specific details will be documented on a Home Care Visit Source Document (Patient Specific Source Document, PSSD) and other related source documents, provided to the site after the visit. Any protocol deviation will be documented and communicated with the site. Any safety related issues will be communicated with the site directly during the visit.
Marken/T- Care is responsible for providing correct completed Home Care Visit source documents to the Site	Source data documented by the Research Nurse should be attributable, legible, contemporaneous, original, accurate and complete. Changes should be traceable, should not obscure original entry and should be explained when necessary. After the visits, the Country Study Manager will review the Home Care Visit source documents. Source documents are provided to the site digitally. If the source document cannot be provided digitally, it will be provided in paper form.

Home Care Service Site Agreement

Signatures

Investigator

Name:

Title: Signature:

Date:

Home Health Care Agency

Agency Name:

Name:

Title: Signature:

Date:

Site

Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

Name:

Title: Signature:

Date: