Trial Master File: Note to File

Section 3: Site information and research personnel, *and*

Section 18: Monitoring and Training

Chief Investigator: Dr Edward Carlton **Trial Manager:** Dr Amanda Lewis

PARTICIPANT I.D / STUDY TOPIC:	**Delegation Log and Training Requirements for "Prescribers" within the RELIEF feasibility trial.**

Describe procedure/issue and any preventative actions that have been taken:

Initial RELIEF training materials advised that *"Treatment (study medication) can be prescribed by a registered medical practitioner or prescribing nurse who is listed on the Site Delegation Log."* The Sponsor (North Bristol NHS Trust) confirmed that because RELIEF is *not* a Clinical Trial of an Investigational Medicinal Product (CTIMP), there is no requirement for prescribers of study medication to be listed on the RELIEF Delegation Log. This means **any registered medical practitioner or prescribing nurse at the site can prescribe**, increasing pragmatic operations for the trial, 24 hours a day, 7 days a week. We do, however, need to ensure that any prescriber has appropriate knowledge about the study and that this is monitored at a site level. As such, the Central Trial Team have produced a brief training presentation for prescribers, ***Training Module 7: Prescriber Information_template, v1.0, 10SEP2021***.

Local site Teams (Principal Investigator (PI) and/or appropriate delegate) are responsible for:

(1) updating the ***Prescriber Information*** slide set with local prescription information (see slides for highlighted instructions);
(2) making as many prescribers as possible (at their site) aware of the trial and relevant information. For example, prescribers can be trained at local clinical governance or education meetings. Every department will have these meetings (e.g. weekly or monthly) and this training can be delivered by local PIs (and/or appropriate delegates) to reach as many prescribers as possible.
(3) recording attendance (training) using the latest version of a topic-specific training record (***RELIEF Site Training Record for "Prescribers"***), which should be maintained and kept in the local Investigator Site File (ISF).
(4) providing the Central Trial Team (Study Office) with a copy of the localised slide set and training records, once available.

Prescribers can also access the protocol and any of the other study training materials via the study website if they wish, although those won't be mandated for this particular role.

-END-

PRINT NAME:	AMANDA LEWIS	**SIGNATURE:**	Amanda Lewis Digitally signed by Amanda Lewis Date: 2021.09.13 12:19:35 +01'00'
POSITION:	TRIAL MANAGER	**DATE:**	13SEP2021

Site File Note Guidance

Notes to the Study File are written to identify a discrepancy or problem in the conduct of the clinical research study, note the root cause of the identified problem, identify the corrective action taken to prevent recurrence of the problem, and document that the corrective action has resolved the problem.

A note to Study File may be appropriate to:

- Clarify or add information regarding site specific regulatory file requirements,
- Clarify or add information regarding source document standards,
- Document and address any issue that is protocol- and/or site-specific that cannot be resolved without a change from previous procedures.

Retention and Distribution: All Notes to the Study File should be signed by the author, kept on file in the site regulatory file and made available to the clinical site monitors reviewing the site's documents and procedures.