UMC Utrecht

Note to File Form

Site number		**Study Name**	REMAP-CAP
Site name		**Protocol number**	NCT02735707
PI name		**Sponsor**	UMCU
		Note to File number	

1a What is the scope of the issue

☐ A single participant
Complete section 1b, (local) Investigator to sign, original to be filed in ISF, copy to be filed in TMF

☐ Multiple participants or general conduct at a single site
Complete section 1b, (local) Investigator to sign, original to be filed in ISF, copy to be filed in TMF

☐ Multiple sites or study management
Complete section 1c, Central Principal Investigator to sign, to be filed in TMF

☒ Other

1b Participant(s) number: N/A

1c Site numbers: See site number above

2 Description of the issue

Date discovered: n/a **Date occurred:** n/a

It is difficult to have sufficient staff available at some sites for study eligibility assessment of patients - staff such as junior doctors may change often and cannot all be study trained in advance. This affects ability to recruit patients.

3 Action Taken

Clinicians who wish to assess study eligibility for patients, will complete training using the latest version of the 'eligibility assessors' training slide set and then sign an electronic or paper training log and delegation log. A combined paper Eligibility Assessors Training & Delegation Log has been created for sites if they prefer to use this template for ease.

An eligibility assessor for this study must be a clinician, defined here as any role who has prescribing rights i.e. doctor, practitioner. The electronic of paper training log will capture their clinical registration number (applicable to their role i.e. GMC) as proof of this.

CVs/GCPs are not required to be filed in the ISF for those who have completed the training and delegation logs and provided a registration number.

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By signing this file note, a PI is confirming that they are happy for the study team to ensure that only qualified clinicians will be completing the eligibility assessors training and relevant logs, after which they can conduct their eligibility assessment role immediately.

The PI will then periodically sign off the eligibility assessors for their delegated duty when available to do so. Alternatively, a PI can provide email approval for named staff, prior to being able to sign off the delegation log, which must be filed in the ISF.

	NAME, POSITION	DATE	SIGNATURE
Author Note to File form	**Aisha Anjum, Clinical Trial Manager**	**12th Dec 2025**	Aisha Digitally signed by Aisha Anjum Date: 2025.12.12 15:21:08 Z
Principal Investigator			