

Document Referral Note

Study name:	REMAP-CAP
Protocol number (Eudract):	2015-002340-14
Site number and name	
Sponsor:	UMCU
Applicable File:	ISF for COVID sites
Tab number:	N/A

The following study documents covering the pandemic period of the study can be located in the REMAP-CAP electronic Trial Master File (Florence), as applicable:

- Regulatory and Ethics/HRA documentation for initial and amendment approvals
- Core protocol and amendments
- Domain specific appendices and amendments
- Investigator brochures, IMPDs and SmPCs, as applicable
- IMP labels, Pharmacy manual and administration guides
- Other Pharmacy documentation (CoA, QP etc.)
- Lab manuals/guides
- Approved Patient Information Sheet and Consent Form (PIS/CF) templates
- Study poster/leaflet templates
- Study Questionnaire templates
- Insurance policy and certificates
- Paper SAE report template
- Annual Progress Reports (APR) and Safety reports (DSURs, ASRs)
- eCRF data completion guidelines and Spiral database guides
- Database updates correspondence
- Data score calculation instructions/guides
- Eligibility checklist templates
- Newsletters, FAQs, ITSC letters, recruitment updates
- Training slides/documentation incl. SIV materials
- Investigator Meetings, Q&As and other study/site wide meeting documentation
- General study/site wide correspondence
- All study log templates and form templates

Are located File name _____ Tab _____

Alternate location: **Electronic Trial Master File (Florence)**

These documents will remain there:

Permanently, for the study duration and archiving period

Until the end of the study

Other, specify: _____

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<i>(signature)</i>	<i>(date: ddMmmyyyy)</i>
Aisha Anjum – Trial Manager <i>(name and function)</i>	

A Document referral note can be filed in the specific study file (ISF or TMF) in case documents are filed in another file or at another location.