SITS Open

Physician's verification form of patient data

Version 1.0

The main objective of this verification form is to confirm that the information collected during study is complete, accurate, reliable and verifiable for each patient in the study.

This form will be completed by the treating principle investigator/physician or the treating sub-investigator/physician of the patient in the SITS Open study. The form is to be signed when the patient is completed in the study and locked in the eCRF. Failure to complete this form in its entirety may lead to patient exclusion from the study.

CENTER INFORMATION	PATIENT INFORMATION
Centre code:	Enrollment ID:

INFORMATION ABOUT PHYSICIAN	
First name:	
Last name:	
Street address:	
P.O Box:	
City:	
State:	
Zip Code:	
Telephone:	

I certify that:

- I am a principle or a sub investigator in the SITS Open Study and I have signed the delegation list.
- I have the correct training and education for participation as a treating principle or treating sub investigator/physician in SITS Open
- I am the treating principle or a sub investigator/physician for this patient.
- The patient is registered and documented in the hospital patient file according to clinical practice.
- A registration call has been made and patient has received an enrolment ID in eCRF.

Returned the signed document to: Karolinska University Hospital, Att: SITS Open Coordination Team, Department of Neurology R2:03, SE-171 76 Stockholm, Sweden

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- Inclusion/exclusion in the study and the enrolment ID is documented in the hospital patient file.
- Obtained Informed consent is documented in the hospital patient file.
- All patient data in the hospital patient file and other source documents are valid and correct.
- All data entered in eCRF is correct and equivalent with patient hospital file and other source documentation.
- All patient source documents are filed and stored according to local requirements.
- Protocol requirements are followed for the patient. If any excursion from the protocol is notified this has to be reported to sponsor immediately for judgement.
- All Adverse events and serious adverse events are reported and documented according to clinical practice. In addition, adverse reactions and serious adverse reactions are reported in eCRF.
- If requested, principle investigator (or local clinical coordinators) will send source data to SITS NCs (SITS National coordinator) for monitoring purposes. Hospital patient file extracts are scanned and sent by email to the SITS NC who compare the eCRF with hospital patient file for basic information (hospital patient file in local language, thus the SITS NC is best suited to monitor).
- If requested, a representative for the study coordination (or, in some cases, NC) may visit the centres for monitoring that the documentation is complete and stored appropriately.
- I am aware that Regulatory Inspections may occur during or after the completion of the study and may include auditing of study records. That all studies are subject to inspection by regulatory agencies worldwide. Regulatory Inspections involves comparison of study data with the source documentation on which they are based.

Physician's Signature	Physician's printed name	City and Date

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