Source Data Location Agreement

ISF/ TMF section 8.2

Site number: **Hospital:** **Principal Investigator:**

*) Comment or use the following codes for description of location:					
SHR:	Subject Hospital Record	LAB:	Laboratory data	Diary	Subject Diary
NN:	Nurses notes	MAC:	Machine print-out (e.g. ECG, CGM)	NA:	Not Applicable
SSDD:	Subject Source Data Document	e-CRF:	Data entered directly into the e-CRF	WS:	Work Sheet

Specific for the ENFORCE trial the form "*Subject Source Data Document*" (SSDD) must be used for participants who do not have a Subject Hospital Record (SHR)

MANDATORY INFORMATION	Where to be found *)
Details of the trial in subject hospital record	*SHR*
Date and visit number	*SHR or SSDD alternative WS*
Date of telephone contacts	*SHR or SSDD alternative WS*
Subject's date of birth / CPR	*SHR or SSDD*
In- and exclusion criteria fulfilled	*SHR or SSDD*
Systemic and local reactions to vaccines	*SHR or SSDD*
Serious Adverse Reactions (SARs) or Suspected Unexpected Serious Adverse Reactions (SUSARs)	*SHR or SSDD*
Subject withdrawal from the trial	*SHR or SSDD*
The following data may be entered directly in the e-CRF	
Medical history	*e-CRF*
Concomitant medication	*e-CRF*
Plasma and Serum samples drawn	*e-CRF*
PAXgene and CPT citrate samples drawn	*e-CRF*
AE and SAE	*e-CRF*

Documentation, assessments and their clinical relevance of Laboratory Results etc. must be kept in subject notes - signed and dated by a person from the team at the Investigational Site.

NB! All evaluations of test-results must be made by an Investigator.

SIGNATURE OF AGREEMENT

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Signature Principal Investigator Date