Appendix 1: Tasks list (Version n° VF 03 March 2016)

DISCHARGE_TAL_Sponsor_ECRIN_ECRIN

Enclosure 1: Task Delegation List (Version VF 03 March 2016)

Responsibility Split with obligations of SPONSOR, ECRIN and ECRIN partners institutions

	Obligations of the SPONSOR/ ECRIN with its Scientific Partners	Sponsor [1] (= Coordinating Investigator; CI)	ECRIN-ERIC	ECRIN partner Institutions	Comments
1	**Submission**	**Necessary activities are under the responsibilities of the sites**			The CI defines all tasks in writing (within the consortium contract) for signature by the sites
2	**Vigilance**	Pharmacovigilance activities according Dir 2001/20/EC are not applicable so that a modified and appropriate system (as required in ICH-GCP) will be established.			The CI defines all tasks in writing for signature by the sites (within the consortium contract); SAE Manual will be set up by the sponsor
	Obligations of the SPONSOR/ ECRIN with its Scientific Partners	**SPONSOR**	**ECRIN-ERIC**	**ECRIN partner institutions**	**Comment**
3	**CLINICAL TRIAL Conduct**				The CI assures that all tasks and responsibilities are defined and/or are delegated in writing for signature by the sites (within the consortium contract) and/or assures that these are described in detail in the description of work (DoW) of the EU proposal);

[1] Since in this clinical study no medicinal products or medical devices are investigated no sponsor in the meaning of Dir 2001/20/EC is required. The responsibilities of a sponsor according to ICH-GCP are taken over by the coordinating investigator (CI). The responsibility of the CI is to assure that all tasks are adequately delegated and defined either in the official documents of the EU project (Description of Work (DoW) /or Consortium Agreement) or in additional study specific documents, if applicable.

	Obligations of the SPONSOR/ ECRIN with its Scientific Partners	Sponsor [1] (= Coordinating Investigator; CI)	ECRIN-ERIC	ECRIN partner institutions	Comments
3.1	Ensure the equipment and personnel required to conduct the CLINICAL TRIAL in accordance with the protocol, the regulations, this AGREEMENT, written instructions of the sponsor and the terms of the approval for the CLINICAL TRIAL from the CA/EC	x			
3.2	Ensure that RECRUITING CENTERS shall complete CRF, provided by the Sponsor. The site shall make available any source documents and/or documentations related to the CLINICAL STUDY to representatives of the Sponsor (e.g. monitor, auditor)	x			
3.3	Ensure that RECRUITING CENTERS shall allow DELEGATED personnel to monitor the CLINICAL STUDY	x			
4	**Monitoring**				The CI has delegated defined tasks to the KKS Charite (lead monitoring CRO)
4.1	Development of a monitoring strategy defined in a Monitoring Manual and template documents for on-site monitoring, including updates, whenever necessary	x			

	Obligations of the SPONSOR/ ECRIN with its Scientific Partners	Sponsor [1] (= Coordinating Investigator; CI)	ECRIN-ERIC	ECRIN partner institutions	Comments
4.2	Providing training material for on-site monitoring (for web-based training) and performing initial training for ECRIN coordination and monitors	x			
4.3	Based on the training material provided by the sponsor performing subsequent trainings for ECRIN monitors		X		
4.4	Providing information to ECRIN whenever a site has fulfilled all prerequisites to start with the monitoring visit and oversight about EC approvals, recruitment state, internal list of other requirements	x			
4.5	Providing a template for the Investigator´s site file (ISF) to ECRIN-partners	x			
4.6	Selection of partners for monitoring in ECRIN and non-ECRIN countries (except Germany)		X		
4.7	Ensure that each monitor (except Germany) has been trained based on material provided and training session conducted by lead CRO for monitoring (KKS Charite)		X	X	
4.8	Performing on site monitoring in participating countries (except Germany) according			X	

Commentaire [NA1]: Switzerland does not take part anymore

[redacted]