Title:	**Template for recording delegation of HOVON sponsor responsibilities**	
Version:	01	
Effective date:	15-MAY-2014	
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Approver name	*Signature*	*Date*
G.J. Ossenkoppele		14.4.2014

This template should be used to create a trial specific document that specifies which tasks and responsibilities are delegated by HOVON to another party.

Such a document is required for trials where HOVON is the primary sponsor.

The document has to be completed and signed for approval by all parties involved prior to start of the trial, i.e. before the first patient can be enrolled in the trial.

The delegation of responsibilities as outlined in this document can be included as an appendix in contracts with co-sponsors and vendors.

The template includes pre-printed assignments of tasks as an example, based on the most common distribution of responsibilities in a HOVON trial. It should be adapted for each individual trial.

The purpose of this document is to ensure that the delegation of the sponsor tasks and responsibilities of each individual trial is recorded and to ensure that each party involved is aware of the distribution of responsibilities in the trial.

It is the responsibility of the Principal Investigator to have the document completed and signed prior to the start of the trial. HOVON Data Center, if assigned the task of global trial management and coordination, will assist the PI and will review if the document is present.

The responsibility to enforce this policy lies with the HOVON board.

In case a new party enters into the collaboration after the trial has started, this may be recorded in an additional delegation document to be signed by HOVON, the PI and the new party. If the addition of the new party influences the distribution of tasks between the existing parties (e.g. a task is transferred from HDC to a new vendor), this should be clearly recorded in the additional delegation document. The influenced existing party will need to sign that document as well.

Please note that assigned tasks in this document are an example and have to be adapted for individual trials.
Trial specific tasks may be added for individual trials.
Please add additional columns for trials with multiple co-sponsors and/or vendors. "Vendor" can be any sub-contracted party such as a central lab, central pharmacy, translation agency, etc. In the trial specific document, the terms co-sponsor X and vendor X need to be replaced by the name of the actual institution or company involved.

	Activity	Principal Investigator	HDC	Co-sponsor X*	Vendor X*
	TRIAL MANAGEMENT				
	Global trial management and coordination		X		
	National trial management and coordination Benelux		X		
	National trial management and coordination [country]			X	
	Medical and scientific supervision global	X			
	Medical supervision [country]			X	
	SITE MANAGEMENT				
	Site selection Benelux	X			
	Site initiation (including training) and site document collection Benelux		X		
	Site activation Benelux		X		
	General site management Benelux		X		
	Site selection [country]			X	
	Site initiation (including training) and site document collection [country]			X	
	Site activation [country]		X		
	General site management [country]			X	
	PROTOCOL				
	Supervision of protocol content	X			
	Preparation of draft protocol	X			
	Preparation of final protocol (editing and version control)		X		
	Preparation of protocol amendments		X		

	Activity	Principal Investigator	HDC	Co-sponsor X*	Vendor X*
	(editing and version control)				
	Sponsor approval of final protocol and amendments	X			
	PATIENT INFORMATION AND INFORMED CONSENT (ICF)				
	Preparation of draft ICF Netherlands (Dutch)	X			
	Preparation of final ICF national template Netherlands		X		
	Translation of ICF Netherlands into global template (English)		X		
	Preparation of final ICF national template [country]			X	
	Sponsor approval of final ICF national template Netherlands (Dutch) and amendments	X			
	Sponsor approval of final ICF global template (English) and amendments	X			
	Sponsor approval of final ICF national template [country] and amendments			X	
	INSURANCE				
	Prepare application for clinical trial insurance Benelux		X		
	Prepare application for clinical trial insurance [country]			X	
	BUDGET AND FUNDING				
	Prepare study budget	X			
	Global budget control	X			
	Acquire global funding	X			
	Preparation of KWF funding application forms (Netherlands)		X		
	Preparation and submission of dossier for KWF funding application (Netherlands)		X		
	Preparation and submission of end of trial report for KWF funding (Netherlands)		X		
	Completion of end of trial report for KWF funding (Netherlands)	X			

	CLINICAL TRIAL APPLICATIONS Competent Authorities (CA) and Ethics Committees (EC)				
	Request of EUDRACT protocol number		X		
	Preparation of master clinical trial application forms		X		
	Completion of national clinical trial application forms: Netherlands		X		
	Completion of national application forms or files: [country]			X	
	Preparation of general documentation		X		
	Preparation of country-specific documentation: Netherlands		X		
	Preparation of country-specific documentation [country]			X	
	Submission of dossier for initial approval and amendments to CA: Netherlands		X		
	Submission of dossier for initial approval and amendments to CA: [country]			X	
	Submission of dossier for initial approval and amendments to EC: Netherlands		X		
	Submission of dossier for initial approval and amendments to EC: [country]			X	
	DATA MANAGEMENT				
	CRF design		X		
	Preparation of CRF completion guidelines		X		
	Preparation of data management plan		X		
	Sponsor approval of CRF and data management plan, and amendments	X			
	Design, build and maintain study database		X		
	Design, build and maintain enrollment/randomization system		X		
	Enrollment and randomization/treatment allocation		X		
	Data collection from all sites		X		
	Data cleaning (queries) for all sites		X		

	SAFETY MANAGEMENT				
	Design of SAE reporting form(s)		X		
	Preparation of SAE report completion guidelines		X		
	Preparation of safety management plan		X		
	Design, build and maintain safety database		X		
	SAE data collection from all sites		X		
	SAE data cleaning (queries) for all sites		X		
	SAE evaluation for SUSAR criteria		X		
	Medical review of safety reports	X			
	Reporting safety information to CA Netherlands (individual SAEs, individual SUSARs, SAE or SUSAR line listings, according to national regulations)		X		
	Reporting safety information to CA [country] (individual SAEs, individual SUSARs, SAE or SUSAR line listings, according to national regulations)			X	
	Reporting safety information to EC Netherlands (individual SAEs, individual SUSARs, SAE or SUSAR line listings, according to national regulations)		X		
	Reporting safety information to EC [country] (individual SAEs, individual SUSARs, SAE or SUSAR line listings, according to national regulations)			X	
	Reporting SUSARs in EudraVigilance database		X		
	Reporting safety information to investigators Benelux (individual SAEs, individual SUSARs, SAE or SUSAR line listings, according to national regulations)		X		
	Reporting safety information to investigators [country] (individual SAEs, individual SUSARs, SAE or SUSAR line listings, according to national regulations)			X	
	Ongoing evaluation of overall safety	X			

	MONITORING ACTIVITIES				
	Preparation of monitoring plan		X		
	Sponsor approval of monitoring plan	X			
	Site monitoring visits Benelux [or Site Evaluation Visits]		X		
	Site monitoring visits [country]			X	
	Review of visit reports and follow up of issues Benelux		X		
	Review of visit reports and follow up of issues [country]			X	
	STUDY DRUG MANAGEMENT				
	Arrange sponsor approval of master study drug label and translations		X		
	Preparation of study drug manual (supply, accountability, study drug handling and preparation)		X		
	Study drug packaging, labeling and supply to sites				X
	REGULATORY REPORTING				
	Preparation of Annual Progress Reports (APR)		X		
	Completion of APRs	X			
	Preparation of Annual Safety Reports (ASR)		X		
	Completion of ASRs	X			
	Preparation of End of Trial Report (ETR)		X		
	Completion of ETR	X			
	Submission of ASR and ETR to CA Benelux		X		
	Submission of ASR and ETR to CA [country]			X	
	Submission of APR, ASR and ETR to EC Benelux		X		
	Submission of APR, ASR and ETR to EC [country]			X	
	FILING AND ARCHIVING OF TRIAL DOCUMENTS				
	Filing of essential documents in Trial Master File		X		
	Archiving of Trial Master File after end of trial		X		
	Filing of site documents Benelux		X		
	Archiving of site documents Benelux after end of trial		X		
	Filing of site documents [country]			X	

	Archiving of site documents [country] after end of trial			X	
	STATISTICAL ANALYSIS				
	Statistical analysis and reports		X		
	Preparation of data reports for DSMB		X		
	Preparation and transfer of data sets		X		
	CENTRAL LAB AND CENTRAL REVIEWS				
	Preparation of lab manual / instructions for sites				X
	Preparation and distribution of lab kits for sites				X
	Arrange courier service for transport of materials / samples				X
	Collection and storage of materials for [central review]				X
	Collection and storage of samples for [central lab]				X
	Execute [central review]				X
	Execute [central lab assays]				X
	Data collection of [central review] outcomes		X		
	Data collection of [central lab assay] results				X
	Preparation and transfer of data sets from [central review] results for statistical analysis		X		
	Preparation and transfer of data sets from [central lab] results for statistical analysis				X

Signatures	Name	Function	Date	Signature
Sponsor representative				
Principal Investigator				
HOVON Data Center (Clinical Trial Center, Erasmus MC Cancer Institute) representative				
Co-sponsor X representative				
Vendor X representative				