

## Guidance for fees, reimbursements and time spend for the performance of *nWMO* studies (NIS) with prescription medicines initiated or sponsored by pharmaceutical companies.

*-activities and costs related to regular care may not be charged to the initiating company-*

*Deviations from the guidance must be justified.*

<b>General/overhead cost hospital or research institute (this part does not contain hourly fees for physicians, nurses and/or other research personnel)</b>	
Per participating centre the initiating company can choose one of the following options:	
<b>Option I</b> (will be submitted to the nWMO advisory committee in order to review the appropriate hourly fees for the performing disciplines) Substantiation of the overhead and cost for the facilities, like: Start up fee (setup) <sup>1</sup> Contract negotiations Legal review, signing contract and start study Budget, review financial feasibility and risks Coordination between departments in institute including CTCM intake with investigator Communication with initiating company (sponsor)  Use of Digital infrastructure of the institute (e.g. Hosting, administration and data management systems, EPD account if applicable etc.)  Cost for archiving in case of <u>external</u> archive  Financial management Closure dossier and prepare for archive	invoice 2 hrs 2 hrs 2 hrs 2 hrs 2 hrs  invoice  invoice  2 hrs per year 2 hrs
<b>Option II</b> Cost for archiving in case of <u>external</u> archive	<b>fixed amount</b> <b>€1500</b> invoice
<b>Option III</b> <b>15% of the original budget of initiation and performance of the study with a maximum of</b> Cost for archiving in case of <u>external</u> archive	<b>€5000</b> invoice

<b>Initiation - Close out</b>	
<i>E.g. (principal) investigator and possibly delegate investigator (maximum honorarium for specialist €140 or professor €200/hour, all physicians €100/hour):</i>	

<sup>1</sup> Fixed cost for start up of the study for the in-house research institute including general services (housing, energy, telephone, quality assurance systems, dossiers etc.)

	Reading protocol	2 hrs
	Training on CRF including passwords etc.	2 hrs
	Initiation visit	2 hrs
	Close out visit	2 hrs
Total (also for delegate if applicable)		8 hrs
<i>E.g. Research coordinator / nurse and possibly delegate (€75/hour, other nurses €60/hour).</i>		
	Reading protocol	2 hrs
	Handling administrative tasks	2 hrs
	Training on CRF including passwords etc.	2 hrs
	Initiation	2 hrs
Total (also for delegate if applicable)		8 hrs

<b>Execution study (fee per participant or visit)</b>		
	Screening and informing participant first visit	1 hr
	Completing CRF first visit including queries	1 hr
	Completing CRF follow-up visits including queries	0,5 hr
	Notification SAE (per SAE)	1 hr
	Monitoring activities (per visit):	
-	research coördinator / nurse	1 hr
-	investigator	0,5 hr

#### **Substantiation cost**

All parties should be aware that one should be able to provide a plausible substantiation of the reimbursed cost in case of an investigation by the Inspectorate.

#### **Local feasibility**

Administrative costs for the approval of the study in the participating Centre commissioned by the Board of Directors do not fall under the scope of the Review framework nWMO.

#### **Note:**

Parties are requested to agree on one of the three options for the reimbursement of general/overhead costs per study. Reimbursements will be reviewed only once, which will spare time and efforts. Communications towards external parties can be clear and unambiguous.