

Guidance on reimbursement and time commitment for the conduct of nWMO studies initiated or sponsored by pharmaceutical companies

-work and costs attributable to regular care may not be charged to initiating company-

Deviations from this guidance must be justified.

General / overhead costs research center (NB this section does not include hourly allowances to doctors, nurses and/or other research staff)	
For each participating centre, a choice must be made from the following options:	
Option I (is submitted to advisory committee for assessment of hourly rates related to performers)	
Breakdown of overhead and facility costs, such as:	
Start-up rate (setup) ¹	invoice
Contract negotiations	2 hours
Legal coordination, signing and preparing study	2 hours
Preparing budgets, assessing financial feasibility, risks	2 hours
Coordination between different departments within the institute incl. CTCM intake with the researcher	2 hours
Communication with initiator/sponsor	2 hours
Use of digital infrastructure research institute (e.g. hosting costs administration and data management systems, EPD account if desired etc.)	invoice
Archive costs only if there is an external archive	invoice
Financial Management	2 hrs per year
Closing file and preparing archive	2 hours
Option II	Fixed amount From €1500 Invoice
Archive costs only if there is an <u>external</u> archive	
Option III	
Surcharge of 15% on the budget of the initiation and implementation of the research with a maximum of	€5000 Invoice
Archive costs only if there is an <u>external</u> archive	

Initiation - Close out	
<i>E.g. doctor-researcher and any back-up (maximum fee for specialist €140 or professor €200 per hour, every other doctor €100/hour):</i>	
Protocol reading	2 hours
CRF training including passwords etc.	2 hours
Initiation	2 hours
Close out visite	2 hours
<hr/> Total (possibly also for the rear guard)	<hr/> 8 hours

¹ Fixed costs for starting a study for the benefit of in-house research institute including general services (housing, energy, telephony, quality systems, files etc. ,)

<i>E.g. research coordinator / nurse and any back-up (€ 75 euro/hour, other nurses €60/hour).</i>	
Read protocol	2 hours
Taking care of administrative tasks	2 hours
CRF training including passwords etc.	2 hours
Initiation	2 hours
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Total (possibly also for the back-up)	8 hours

Conducting research (fee per participant or visit)	
Screening and informing participant first visit	1 hour
Input in CRF first visit including queries	1 hour
Input in CRF subsequent visits including queries	0.5 hours
Per SAE notification	1 hour
Monitoring activities (per visit):	
– research coordinator / nurse	1 hour
– doctor-researcher	0.5 hours

Substantiation of costs

The parties must be aware that all costs charged must be substantiated during an inspection by IGJ.

Local feasibility testing

The approval of the research in the participating centre on behalf of the Board of Directors (and the associated administrative costs) does not fall within the scope of the nWMO Assessment Framework.

NA:

There is a preference for agreeing on one fixed fee for each study. Price negotiation is then no longer necessary, which saves time and effort. When this is the case, communication towards external parties/sponsors is clear and unambiguous.