

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

Deviations from the guidance must be justified.

Initiation - Start up fees

E.g. (principal) investigator and possibly delegate investigator (maximum honorarium for specialist €140 or professor €200/hour, all physicians €100/hour):

Reading protocol	1 hour
Informing partnership/institute, in-house trial office, communication with initiator/sponsor/internal legal department	3 hour
Training on CRF including passwords etc.	2 hours
Initiation visit	1 hour
Close out visit	1 hour
Total (optional also for delegate)	8 hours

E.g. Research coordinator / nurse and possibly delegate (€75/hour, other nurses €60/hour).

Reading protocol	1 hour
Handling administrative tasks	2 hours
Training on CRF including passwords etc.	2 hours
Initiation	2 hours
Total (optional also for delegate)	7 hours

General

Contract negotiations	0.5 hours
Cost for <u>external</u> archive	Invoice
Cost local feasibility assessment	Invoice

Execution study (fee per participant or visit)

Screening and informing participant first visit	1 hour
Completing CRF first visit including queries	1 hour
Completing CRF follow-up visits including queries	0.5 hours
Notification SAE (per SAE)	1 hour
Monitoring activities (per visit)	
<i>research coördinator / nurse</i>	1 hour
<i>arts-onderzoeker</i>	0,5 hour

Overhead

The advisory committees increasingly notice that so-called overhead cost (as a percentage surcharge on the entire budget) are being charged by institutions. The percentages vary widely, from 10% to 25%. Such surcharges are not considered acceptable.

Institutes can charge reasonable/fair overhead cost for the use of the infrastructure or facilities of the institution (e.g. use of rooms, IT systems). In principle, these costs should be made transparent (rather than a percentage of the entire budget). This only applies to cost incurred on top of the regular cost of care due to the performance of the nWMO study (NIS).

All parties should be aware that all reimbursed cost should be specified in case of an audit.

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.