

FIGURE 1. MANAGEMENT AND ADMINISTRATIVE START UP COSTS

EVALUATOR Ethics committee(*), acting as Reference Committee/ADVISOR Ethics Committee (Local suitability), not acting as Reference Committee										
DIRECT COSTS, NON-REFUNDABLE		CLINICAL TRIALS			NON-INTERVENTIONAL STUDIES WITH DRUGS and/or DEVICE STUDIES			BIOMEDICAL RESEARCH PROJECTS		
Management Costs	Entity	Industrial Sponsor	Cooperative Group (with/without CRO)	Independent Sponsor of Competitive projects (FISS, La Marató TV3, ...)	Industrial Sponsor	Cooperative Group (with/without CRO)	Independent Sponsor of Competitive projects (FISS, La Marató TV3, ...)	Industrial Sponsor	Cooperative Group (with/without CRO)	Independent Sponsor of Competitive projects (FISS, La Marató TV3, ...)
Ethics Committee evaluation / Single EC	EC	Figure 2	Figure 2	Consult Ethics Committee	800 €	400 €	150 €	300 €	150 €	150 €
Suitability of the facilities / file processing	Site	800 €	600 €	150 €						
Ethics Committee evaluation for LOCAL suitability	Site				600 €	300 €	150 €			

COSTS FOR AMENDMENTS AND MODIFICATIONS TO THE PROTOCOL

DIRECT COSTS, NON-REFUNDABLE		CLINICAL TRIALS			NON-INTERVENTIONAL STUDIES WITH DRUGS and/or DEVICE STUDIES			BIOMEDICAL RESEARCH PROJECTS		
Management Costs	Entity	Industrial Sponsor	Cooperative Group (with/without CRO)	Independent Sponsor of Competitive projects (FISS, La Marató TV3, ...)	Industrial Sponsor	Cooperative Group (with/without CRO)	Independent Sponsor of Competitive projects (FISS, La Marató TV3, ...)	Industrial Sponsor	Cooperative Group (with/without CRO)	Independent Sponsor of Competitive projects (FISS, La Marató TV3, ...)
Amendments and modifications of the protocol	EC	Figure 2	Figure 2	Consult Ethics Committee	300 €	200 €		200 €		

CEIm START UP COST

CLINICAL TRIALS (not acting as reference Committee)

* The SITE manages the suitability of facilities, once the MEMORY OF RESOURCES is presented

* The DIRECCIÓ TERRITORIAL D'INNOVACIÓ, RECERCA I DOCÈNCIA will inform to the EC of all the suitabilities signed monthly in order to receive the corresponding advice.

FEE WAIVER

* For projects without funding and without use extra resources

* For Independent Sponsors who do not obtain competitive project financing

TABLA 2. TASAS CEIm / AEMPS ENSAYOS CLÍNICOS con medicamento

	AEMPS	CERm
IMP for human use not authorized in the EU	2.633,14 €	3.108,13 €
IMP for human use authorized in the EU	658,29 €	2.952,78 €
Substantial Modification	210,65 €	1554.06 €

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