
	Nom document	FP	Codi	Data	Rev.	Pàgina
	Opening rates of Clinical Studies	FP002	RG006	09/05/2024	01	Pàg 1 de 1
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Code	Services	CLINICAL TRIALS			OBSERVATIONAL STUDIES / BIOMEDICAL PI			STUDIES NOT INCLUDED IN PREVIOUS CATEGORIES
		Industrial Promoter	Cooperative Group Promoter	Independent Promoter	Industrial Promoter	Cooperative Group Promoter	Independent Promoter	
1	Contract management and administrative opening	1.000 €	800 €	0 €	1.000 €	800 €	0 €	50 €
2	Trial Pharmacy fees	600 €	600 €	0 €	0 €	0 €	0 €	0 €
3	Contract amendment management	300 €	200 €	0 €	300 €	200 €	0 €	0 €
4	Dismissal of the contract	600 €	600 €	0 €	600 €	600 €	0 €	0 €
5	Start-up fees	800 €	700 €	0 €	800 €	700 €	0 €	0 €
6	Close-out fees	400 €	300 €	0 €	400 €	300 €	0 €	0 €
7	File fees	1.000 €	800 €	0 €	1.000 €	800 €	0 €	0 €
8	Kits custody fees	250 €	200 €	0 €	250 €	200 €	0 €	0 €

TYPE OF STUDY

- **CLINICAL TRIALS:** Experimental evaluation of a product, substance, drug, diagnostic or therapeutic technique that, through its application to humans, aims to assess its efficacy and safety.
- **OBSERVATIONAL STUDIES / BIOMEDICAL PI:** Studies designed to observe and collect data from participants without intervening or altering routine clinical practice.
- **STUDIES NOT INCLUDED IN PREVIOUS CATEGORIES:** Other biomedical research studies or projects with limited funding that require a contract.

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	Opening rates of Clinical Studies	FP002	RG006	09/05/2024	01	Pàg 2 de 1
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TYPE OF PROMOTER

- **Industrial Promoter:** Promoter of the Pharmaceutical Industry (laboratories, private companies, ...).
- **Cooperative Group Promoter:** Foundations, Associations, Groups or other organizations.
- **Independent Promoter:** Hospital Centers and/or Hospital Center Foundations, and Hospital researchers.

DESCRIPTION COSTS/FEES

1. **Contract management and administrative opening:** Communications with the affected parties, review of the contract and economic report, and its negotiation, signing circuit, registration and records in the system for economic control and monitoring.
2. **Trial Pharmacy fees:** Initial costs (review of protocol, preparation of work procedures, attendance at selection and initiation visits, receipt of drugs, ...), and closing costs (closing visit, preparation, delivery or destruction of excess medication and closure of the file).
3. **Contract amendment management:** Communications with the affected parties, review of the document and the changes applied, negotiation, signing circuit, updating of records in the management system and corresponding adjustments for economic control and monitoring.
4. **Dismissal of the contract:** Costs for the procedures carried out and filing of the file.
5. **Start-up fees of the research team:** Protocol review, preparation of clinical coordination, establishment of circuits, assessment of possible patients to be included, and selection and initiation visit.
6. **Close-out fees:** Final reconciliation of activity carried out and invoicing, payment control, communications, data updating, records and administrative filing of the file.
7. **File fees:** Storage, custody and traceability of the researcher's file, once the trial/study is completed, during the time established by the regulations.
8. **Kits custody fees:** Reception, storage, custody, and traceability of the laboratory kits.

FEE EXEMPTION

- Studies without financial funding.
- Independent Promoters (Researchers, Hospital Centers and/or Hospital Center Foundations), with or without funding.