



TARIFES FUNDACIÓ
INSTITUT HOSPITAL DEL
MAR
D'INVESTIGACIONS
MÈDIQUES 2023

Aprovades pel Patronat de la Fundació IMIM en data 13 de desembre de 2022

TARIFES UNITAT DE RECERCA CLÍNICA (URC)

CLINICAL RESEARCH UNIT IMIM

Certificate of Good Clinical Practice (GCP) compliance of a phase I clinical trials unit by Government of Catalonia

SERVICES AND FEES

PRE-START	UNIT	INTERNAL PRICE	PUBLIC EXTERN CENTER PRICE	CERCA CENTER PRICE	EXTERNAL CENTER PRICE
Technical scientific assessments on clinical trials	Hour(s)	36,00	42,00	42,00	65,00
Protocol (writing or revision)	Hour(s)	36,00	42,00	42,00	65,00
Patient information form and Consent (writing or revision)	Hour(s)	36,00	42,00	42,00	65,00
Elaboration of the recruitment materials	Hour(s)	36,00	42,00	42,00	65,00
Structure, content and validation of the CRF (paper)	Hour(s)	24,00	28,00	28,00	43,00
eCRF development	Hour(s)	24,00	28,00	28,00	43,00
eCRF validation	Hour(s)	24,00	28,00	28,00	43,00
Data Base development	Hour(s)	24,00	28,00	28,00	43,00
Feasibility procedure (evaluation of centers)	Hour(s)	24,00	28,00	28,00	43,00
Insurance Questionnaire and offers selection	Hour(s)	24,00	28,00	28,00	43,00
IMP documentation	Hour(s)	36,00	42,00	42,00	65,00
Additional Documents Part I	Hour(s)	36,00	42,00	42,00	65,00
Additional documents Part II	Hour(s)	36,00	42,00	42,00	65,00
CTIS Submission	Hour(s)	36,00	42,00	42,00	65,00
Management of payments related to AEMPs and CEIm (IRB) fees	Hour(s)	24,00	28,00	28,00	43,00
Questions and answers document to Health Authority and CEIm (IRB)	Hour(s)	36,00	42,00	42,00	65,00
EUDRACT register	Hour(s)	24,00	28,00	28,00	43,00
Clinicaltrials.gov / ENCEPP register	Hour(s)	24,00	28,00	28,00	43,00
REEC register	Hour(s)	24,00	28,00	28,00	43,00

Support for local management	Hour(s)	24,00	28,00	28,00	43,00
Initial Sponsor 's file	Hour(s)	24,00	28,00	28,00	43,00
Initial Investigator's file (per center)	Hour(s)	24,00	28,00	28,00	43,00
Initial Pharmacy's file (per center)	Hour(s)	24,00	28,00	28,00	43,00
Monitoring Plan (MP)	Hour(s)	24,00	28,00	28,00	43,00
Project Management Plan (PMP)	Hour(s)	36,00	42,00	42,00	65,00
Safety Management Plan (SMP)	Hour(s)	36,00	42,00	42,00	65,00
Laboratory manual	Hour(s)	36,00	42,00	42,00	65,00
Risk management Plan (RMP)	Hour(s)	36,00	42,00	42,00	65,00
Data management plan (DMP)	Hour(s)	36,00	42,00	42,00	65,00
Statistical Plan (SAP)	Hour(s)	36,00	42,00	42,00	65,00
Sample size estimations	Hour(s)	36,00	42,00	42,00	65,00
Randomization list	Hour(s)	36,00	42,00	42,00	65,00
Centralized randomization	Hour(s)	24,00	28,00	28,00	43,00
Management of materials' purchases	Euros(s)	1,04	1,23	1,23	1,23
Displacement (travels and diets) management	Euros(s)	1,04	1,23	1,23	1,23

STUDY DEVELOPMENT	UNIT	INTERNAL PRICE	PUBLIC EXTERN CENTER PRICE	CERCA CENTER PRICE	EXTERNAL CENTER PRICE
Coordination: project management, review of monitoring visit reports, supervising, risk management follow up, meetings with Sponsor,...	Hour(s)	36,00	42,00	42,00	65,00
Center opening notification to AEMPs and CEIm (IRB)	Hour(s)	24,00	28,00	28,00	43,00
First recruited patient notification to AEMPs and CEIm (IRB)	Hour(s)	24,00	28,00	28,00	43,00
INITIAL MONITORING VISIT: Preparation, visit, report and follow-up related (x n centers)	Hour(s)	24,00	28,00	28,00	43,00
FOLLOW-UP MONITORING VISIT: Preparation, visit, report and follow-up related (x n centers)	Hour(s)	24,00	28,00	28,00	43,00
CLOSE MONITORING VISIT: Preparation, visit, report and follow-up related (x n centers)	Hour(s)	24,00	28,00	28,00	43,00
INITIAL PHARMACY MONITORING VISIT: Preparation, visit, report and follow-up (x n centers)	Hour(s)	24,00	28,00	28,00	43,00

INITIAL PHARMACY MONITORING VISIT Preparation, visit, report and follow-up (x n centers)	Hour(s)	24,00	28,00	28,00	43,00
INITIAL PHARMACY MONITORING VISIT Preparation, visit, report and follow-up (x n centers)	Hour(s)	24,00	28,00	28,00	43,00
Files updating	Hour(s)	24,00	28,00	28,00	43,00
Management of payments for volunteers	Hour(s)	24,00	28,00	28,00	43,00
Volunteer's payment (euros)	Euro(s)	1,18	1,38	1,38	1,38
Sample processing	Hour(s)	24,00	28,00	28,00	43,00
Sample storage	Day (s)	0,16	0,16	0,16	0,16
Diet management	Hour(s)	24,00	28,00	28,00	43,00
Breakfast	Breakfast	3,00	3,00	3,00	3,00
Snack	Snack	5,00	5,00	5,00	5,00
Lunch	Lunch	16,00	16,00	16,00	16,00
Dinner	Dinner	16,00	16,00	16,00	16,00
Request and/or storage of medicines	Hour(s)	24,00	28,00	28,00	43,00
Security medical contact for volunteers (guard located)	Day (s)	257,50	257,50	257,50	257,50
Data entry (HOST, IMASIS, CRF, eCRF, questionnaires...)	Hour(s)	24,00	28,00	28,00	43,00
Protocol amendment /informed consent	Hour(s)	36,00	42,00	42,00	65,00
Center expansion amendment (Part II documents)	Hour(s)	24,00	28,00	28,00	43,00
Management of protocol deviations or protocol breaches	Hour(s)	24,00	28,00	28,00	43,00
Pharmacovigilance (validation, medical assessment, codification, conciliation of SAE, SUSARS notification to AEMPS and local government)	Hour(s)	36,00	42,00	42,00	65,00
Annual report	Hour(s)	36,00	42,00	42,00	65,00
Safety anual report	Hour(s)	36,00	42,00	42,00	65,00
Pre-screening of volunteers (questionnaires, telephone calls, follow-up until medical visit)	Hour(s)	24,00	28,00	28,00	43,00
Outpatient medical visit (1 hour)	VM 1	28,00	42,94	42,94	65,00
Ambulatory nursing visit (1 hour)	VE 1	24,00	28,00	28,00	43,00
Neuropsychologist and nutritionist visit (1 hour)	VM 1	24,00	28,00	28,00	43,00
Evaluation of the Screening	Hour(s)	36,00	42,00	42,00	65,00

Experimental session 4 hours doctor	Session 4M	112	171,76	171,76	260
Experimental session 4 hours nurse	Session 4E	96	112	112	172
Experimental session 8 hours doctor	Session 8M	224	343,52	343,52	520
Experimental session 8 hours nurse	Session 8E	192	224	224	344
Experimental session 12 hours doctor	Session 12M	336	515,28	515,28	780
Experimental session 12 hours nurse	Session 12E	288	336	336	516
Doctor guard	Guard	According to IMIM agreement	According to IMIM agreement	According to IMIM agreement	According to IMIM agreement
Nursing night shift	Night	According to IMIM agreement	According to IMIM agreement	According to IMIM agreement	According to IMIM agreement
Measurements of BP/HR/SatO2 (added to personnel costs)	Measurement	0,07	0,08	0,08	0,10
Measurements of Temperature (added to personnel costs)	Measurement	0,38	0,45	0,45	0,45
Measurements and report of Body composition (Added to personnel costs)	Measurement	5,40	6,35	6,35	6,35
Measurements weight and height (Added to personnel costs)	Measurement	0,13	0,15	0,15	0,15
EKG (Added to personnel costs)	EKG	22,00	26,00	26,00	30,00
EEG personnel	Hour(s)	24,00	28,00	28,00	43,00
Hemogram (laboratory)	Tests	1,66	1,95	1,95	1,95
Basic biochemistry (laboratory)	Tests	14,40	16,94	16,94	16,94
Serology (VHB, VHC, VIH) (laboratory)	Tests	40,80	48,00	48,00	48,00
Standard Coagulation test (laboratory)	Tests	2,77	3,26	3,26	3,26
Other analytical parameters	Euro(s)	1,04	1,23	1,23	1,23
Urine drug test (20 units)	Box	67,71	79,66	79,66	93,71
EtG urine test (20 units)	Tests	2,50	2,94	2,94	2,94
Urine collection	Bottle	0,94	1,11	1,11	1,11
COVID19 Antigen test	Box	150,00	150,00	150,00	150,00
COVID19 PCR testing	PCR	90,00	105,88	105,88	105,88
Breathalyzer	Tests	2,50	2,95	2,95	2,95
Urine pregnancy test (20 units)	Box	25,00	29,41	29,41	29,41
Venous catheter placement (Added to personnel costs)	Procedure	2,08	2,45	2,45	2,45
Venipuncture (added to personnel costs; type of tubes not included)	Procedure	2,76	2,88	2,88	2,88
Capillary blood collection (added to personnel costs)	Procedure	1,50	1,76	1,76	1,76
Nasal Exfoliation (Human Olfactory Neuroepithelium) (added to personnel costs)	Procedure	45,00	55,00	55,00	65,00

Saliva sampling (added to personnel costs)	Procedure	1,25	1,47	1,47	1,47
Stool collection (added to personnel costs)	Procedure	7,12	8,37	8,37	8,37
Hair collection (added to personnel costs)	Procedure	1,25	1,47	1,47	1,47
Sweat collection (added to personnel costs)	Procedure	1,50	1,76	1,76	1,76
Nails collection	Procedure	1,00	1,18	1,18	1,18
Centrifugation of samples	Hour(s)	2,00	3,00	3,00	5,00
Labelling of tubes	Packs of 50	5,00	6,00	6,00	7,00
Other procedures	Euro(s)	1,04	1,23	1,23	1,23
Drug management	Euro(s)	1,04	1,23	1,23	1,23
Oral drug administration (added to personnel costs)	Admin	1,16	1,37	1,37	1,37
Intravenous/intramuscular/subcutaneous (added to personnel costs)	Admin	1,25	1,47	1,47	1,47
Sampling shipment management	Euro(s)	1,04	1,23	1,23	1,23
Annual report notification to AEMPS and CEIm (IRB)	Hour(s)	24,00	28,00	28,00	43,00
Other follow up report to AEMPS and CEIm (IRB)	Hour(s)	24,00	28,00	28,00	43,00

END OF STUDY	UNIT	INTERNAL PRICE	PUBLIC EXTERN CENTER PRICE	CERCA CENTER PRICE	EXTERNAL CENTER PRICE
Visits for Queries resolution before close monitoring visit	Hour(s)	24,00	28,00	28,00	43,00
Clean up/Lock Data base	Hour(s)	24,00	28,00	28,00	43,00
Notification of the last patient recruited to AEMPS and CEIm (IRB)	Hour(s)	24,00	28,00	28,00	43,00
End of study notification to AEMPS and CEIm (IRB)	Hour(s)	24,00	28,00	28,00	43,00
Pharmacokinetic analysis	Hour(s)	36,00	42,00	42,00	65,00
Statistical analysis	Hour(s)	36,00	42,00	42,00	65,00
Final no ICH report	Hour(s)	36,00	42,00	42,00	65,00
Final ICH report	Hour(s)	36,00	42,00	42,00	65,00
Data entry EUDRACT register	Hour(s)	36,00	42,00	42,00	65,00
Report submission	Hour(s)	36,00	42,00	42,00	65,00
File storage in MDA (documents request not included)	Year(s)	24,00	28,00	28,00	43,00