HOSPITAL DEL MAR RESEARCH INSTITUTE FEES 2024

Approved by the Board of Trustees of IMIM Foundation on December 12th, 2023



MARTrials CLINICAL RESEARCH UNIT (URC)

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

CODE	PRE-START	UNIT	Internal	CERCA	Public	Private
			users	users	users	users
SCT230	Technical scientific assessments on clinical trials	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT231	Protocol (writing or revision)	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT232	Patient information form and Consent (writing or revision)	Hour(s)	36,0 €	42,0€	42,0€	65,0€
SCT233	Elaboration of the recruitment materials	Hour(s)	36,0 €	42,0€	42,0€	65,0€
SCT234	Structure, content and validation of the CRF (paper)	Hours)	24,0 €	28,0€	28,0€	43,0€
SCT235	eCRF development	Hour(s)	24,0€	28,0€	28,0€	43,0€
SCT236	eCRF validation	Hour(s)	24,0€	28,0€	28,0€	43,0€
SCT237	Data Base development	Hour(s)	24,0€	28,0€	28,0€	43,0€
SCT238	Feasibility procedure (evaluation of centers)	Hour(s)	24,0 €	28,0€	28,0€	43,0 €
SCT239	Insurance Questionnaire and offers selection	Hour(s)	24,0 €	28,0€	28,0€	43,0€
SCT240	IMP documentation	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT241	Additional Documents Part I	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT241	Additional documents Part II	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT243	CTIS Submission	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT244	Management of payments related to AEMPs and CEIm (IRB) fees	Hour(s)	24,0 €	28,0€	28,0€	43,0€
SCT245	Questions and answers document to Health Authority and CEIm (IRB)	Hour(s)	36,0 €	42,0€	42,0€	65,0€
SCT246	EUDRACT register	Hour(s)	24,0 €	28,0€	28,0€	43,0€
SCT247	Clinicaltrials.gov / ENCEPP register	Hour(s)	24,0 €	28,0€	28,0€	43,0 €
	REEC register	Hour(s)	24,0 €	28,0€	28,0€	43,0€
SCT249	Support for local management	Hour(s)	24,0 €	28,0€	28,0€	43,0€
SCT250	Initial Sponsor 's file	Hour(s)	24,0 €	28,0€	28,0€	43,0€
SCT251	Initial Investigator's file (per center)	Hour(s)	24,0 €	28,0€	28,0€	43,0€
SCT252	Initial Pharmacy's file (per center)	Hour(s)	24,0€	28,0€	28,0€	43,0€
SCT253	Monitoring Plan (MP)	Hour(s)	24,0 €	28,0€	28,0 €	43,0€
SCT254	Project Management Plan (PMP)	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT255	Safety Management Plan (SMP)	Hour(s)	36,0€	42,0€	42,0€	65,0€

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SCT256	Laboratory manual	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT257	Risk management Plan (RMP)	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT258	Data management plan (DMP)	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT259	Statistical Plan (SAP)	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT260	Sample size estimations	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT261	Randomization list	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT262	Centralized randomization	Hour(s)	24,0€	28,0€	28,0€	43,0€
SCT263	Management of materials' purchases	Euros(s)	1,04€	1,23€	1,23€	1,23 €
SCT264	Displacement (travels and diets)	Euros(s)	1,04 €	1,23€	1,23€	1,23€
	management					

	STUDY DEVELOPMENT	UNIT	Internal	CERCA	Public	Private
			users	users	users	users
SCT265	Coordination: project management, review of monitoring visit reports, supervising, risk management follow up, meetings with Sponsor,	Hour(s)	36,0€	42,0€	42,0 €	65,0€
SCT266	Center opening notification to AEMPs and CEIm (IRB)	Hour(s)	24,0 €	28,0 €	28,0 €	43,0 €
SCT267	First recruited patient notification to AEMPs and CEIm (IRB)	Hour(s)	24,0 €	28,0 €	28,0€	43,0 €
SCT268	INITIAL MONITORING VISIT: Preparation, visit, report and follow-up related (x n centers)	Hour(s)	24,0€	28,0€	28,0 €	43,0€
SCT269	FOLLOW-UP MONITORING VISIT: Preparation, visit, report and follow-up related (x n centers)	Hour(s)	24,0€	28,0€	28,0 €	43,0€
SCT270	CLOSE MONITORING VISIT: Preparation, visit, report and follow-up related (x n centers)	Hour(s)	24,0 €	28,0 €	28,0 €	43,0€
SCT271	INITIAL PHARMACY MONITORING VISIT: Preparation, visit, report and follow-up (x n centers)	Hour(s)	24,0€	28,0€	28,0 €	43,0€
SCT272	INITIAL PHARMACY MONITORING VISIT Preparation, visit, report and follow-up (x n centers)	Hour(s)	24,0€	28,0€	28,0 €	43,0€
SCT273	INITIAL PHARMACY MONITORING VISIT Preparation, visit, report and follow-up (x n centers)	Hour(s)	24,0€	28,0€	28,0 €	43,0€
SCT274	Files updating	Hour(s)	24,0€	28,0€	28,0€	43,0€
SCT275	Management of payments for volunteers	Hour(s)	24,0 €	28,0 €	28,0€	43,0 €
SCT276	Volunteer's payment (euros)	Euro(s)	1,18€	1,38€	1,38€	1,38€
SCT277	Sample processing	Hour(s)	24,0€	28,0€	28,0€	43,0€
SCT278	Sample storage	Day (s)	0,16€	0,16€	0,16€	0,16€
SCT279	Diet management	Hour(s)	24,0€	28,0€	28,0€	43,0€

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CCT200	Drookfost	Breakfast	206	206	206	206
SCT280	Breakfast		3,0€	3,0€	3,0 €	3,0€
SCT281	Snack	Snack	5,0€	5,0€		5,0€
SCT282	Lunch	Lunch	16,0 €	16,0 €		16,0€
SCT283	Dinner	Dinner	16,0€	16,0 €		16,0 €
SCT284	Request and/or storage of medicines	Hour(s)	24,0 €	28,0 €		43,0 €
SCT285	Security medical contact for volunteers (guard located)	Day (s)	257,5 €	257,5 €	257,5€	257,5 €
SCT286	Data entry (HOST, IMASIS, CRF, eCRF, questionnaires)	Hour(s)	24,0€	28,0€	28,0 €	43,0€
SCT287	Protocol amendment /informed consent	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT288	Center expansion amendment (Part II documents)	Hour(s)	24,0€	28,0€	28,0€	43,0€
SCT289	Management of protocol deviations or protocol breaches	Hour(s)	24,0€	28,0€	28,0€	43,0€
SCT290	Pharmacovigilance (validation, medical assessment, codification, conciliation of SAE, SUSARS notification to AEMPS and local government)	Hour(s)	36,0€	42,0€	42,0€	65,0€
SCT291	Annual report	Hour(s)	36,0€	42,0€	42,0 €	65,0€
SCT292	Safety anual report	Hour(s)	36,0€	42,0 €	42,0 €	65,0 €
SCT293	Pre-screening of volunteers (questionnires, telephone calls, follow-up until medical visit)	Hour(s)	24,0€	28,0€	28,0€	43,0€
SCT294	Outpatient medical visit (1 hour)	VM 1	28,0€	42,94€	42,94€	65,0€
SCT295	Ambulatory nursing visit (1 hour)	VE 1	24,0€	28,0€	28,0 €	43,0€
SCT296	Neuropsicologist and nutritionist visit (1 hour)	VM 1	24,0 €	28,0€	28,0€	43,0 €
SCT297	Evaluation of the Screening	Hour(s)	36,0€	42,0 €	42,0 €	65,0€
SCT298	Experimental session 4 hours doctor	Session 4M	112,0€	171,76€		260,0€
SCT299	Experimental session 4 hours nurse	Session 4E	96,0€	112,0€	112,0€	172,0€
SCT300	Experimental session 8 hours doctor	Session 8M	224,0€	343,52€	343,52 €	520,0€
SCT301	Experimental session 8 hours nurse	Session 8E	192,0€	224,0€	224,0€	344,0€
SCT302	Experimental session 12 hours doctor	Session 12M	336,0€	515,28€	515,28€	780,0€
SCT303	Experimental session 12 hours nurse	Session 12E	288,0€	336,0€	336,0€	516,0€
SCT304	Doctor guard	Guard	According to IMIM agreement	According to IMIM agreement	According to IMIM agreement	According to IMIM agreement
SCT305	Nursing night shift	Night	According to IMIM agreement	According to IMIM agreement	According to IMIM agreement	According to IMIM agreement
SCT3	Measurements of BP/HR/SatO2 (added to personnel costs)	Measure ment	0,07€	0,1€	0,1 €	0,1€

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SCT307	Measurements of Temperature (added to personnel costs)	Measure ment	0,38€	0,45 €	0,45 €	0,45€
SCT308	Measurements and report of Body composition (Added to personnel costs)	Measure ment	5,4€	6,35 €	6,35 €	6,35€
SCT309	Measurements weight and height (Added to personnel costs)	Measure ment	0,13€	0,15€	0,15 €	0,15€
SCT310	EKG (Added to personnel costs)	EKG	22,0€	26,0€	26,0€	30,0€
SCT311	EEG personnel	Hour(s)	24,0€	28,0€	28,0 €	43,0 €
SCT312	Hemogram (laboratory)	Tests	1,66€	1,95€	1,95 €	1,95€
SCT313	Basic biochemistry (laboratory)	Tests	14,4€	16,94€	16,94 €	16,94€
SCT314	Serology (VHB, VHC, VIH) (laboratory)	Tests	40,8€	48,0 €	48,0 €	48,0€
SCT315	Standard Coagulation test (laboratory)	Tests	2,77€	3,26€	3,26 €	3,26€
SCT316	Other analytical parameters	Euro(s)	1,04€	1,23€	1,23 €	1,23 €
SCT317	Urine drug test (20 units)	Box	67,71€	79,66€	79,66 €	93,71€
SCT318	EtG urine test (20 units)	Tests	2,5 €	2,94€	2,94 €	2,94€
SCT319	Urine collection	Bottle	0,94€	1,11€	1,11€	1,11 €
SCT320	COVID19 Antigen test	Вох	150,0€	150,0€	150,0€	150,0€
SCT321	COVID19 PCR testing	PCR	90,0€	105,88€	105,88 €	105,88€
SCT322	Breathalyzer	Tests	2,5 €	2,95€	2,95 €	2,95€
SCT323	Urine pregnancy test (20 units)	Box	25,0€	29,41€	29,41€	29,41€
SCT324	Venous catheter placement (Added to personnel costs)	Procedure	2,08€	2,45€	2,45 €	2,45€
SCT325	Venipuncture (added to personnel costs, type of tubes not included)	Procedure	2,76€	2,88€	2,88€	2,88€
SCT326	Capillary blood collection (added to personnel costs)	Procedure	1,5 €	1,76€	1,76 €	1,76€
SCT327	Nasal Exfoliation (Human Olfactory Neuroepithelium) (added to personnel costs)	Procedure	45,0€	55,0€	55,0 €	65,0 €
SCT328	Saliva sampling (added to personnel costs)	Procedure	1,25€	1,47€	1,47 €	1,47 €
SCT329	Stool collection (added to personnel costs)	Procedure	7,12€	8,37€	8,37 €	8,37€
SCT330	Hair collection (added to personnel costs)	Procedure	1,25€	1,47 €	1,47 €	1,47€
SCT331	Sweat collection (added to personnel costs)	Procedure	1,5€	1,76€	1,76€	1,76€
SCT332	Nails collection	Procedure	1,0€	1,18€	1,18€	1,18€
SCT333	Centrifugation of samples	Hour(s)	2,0€	3,0€	3,0€	5,0€
SCT334	Labelling of tubes	Packs of 50	5,0€	6,0€	6,0€	7,0€
SCT335	Other procedures	Euro(s)	1,04€	1,23€	1,23 €	1,23€
SCT336	Drug management	Euro(s)	1,04 €	1,23€	1,23 €	1,23 €
SCT337	Oral drug administration (added to personnel costs)	Admin	1,16€	1,37 €	1,37 €	1,37€
SCT338	Intravenous/intramuscular/subcutan eous (added to personnel costs)	Admin	1,25€	1,47 €	1,47 €	1,47 €
SCT339	Sampling shipment management	Euro(s)	1,04€	1,23€	1,23€	1,23€

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SCT340	Annual report notification to AEMPS	Hour(s)	24,0€	28,0€	28,0€	43,0€
	and CEIm (IRB)					
SCT341	Other follow up report to AEMPS and	Hour(s)	24,0€	28,0€	28,0€	43,0€
	CEIm (IRB)					

	UNIT	UNIT	Internal users	Cerca users	Public users	Private users
SCT342	Visits for Queries resolution before close monitoring visit	Hour(s)	24,00 €	28,00€	28,00€	43,00€
SCT343	Clean up/Lock Data base	Hour(s)	24,00€	28,00€	28,00€	43,00€
SCT344	Notification of the last patient recruited to AEMPs and CEIm (IRB)	Hour(s)	24,00 €	28,00€	28,00€	43,00€
SCT345	End of study notification to AEMPS and CEIm (IRB)	Hour(s)	24,00€	28,00€	28,00€	43,00€
SCT346	Pharmacokinetic analysis	Hour(s)	36,00€	42,00€	42,00€	65,00€
SCT347	Statistical analysis	Hour(s)	36,00€	42,00€	42,00€	65,00€
SCT348	Final no ICH report	Hour(s)	36,00€	42,00€	42,00€	65,00€
SCT349	Final ICH report	Hour(s)	36,00€	42,00€	42,00€	65,00€
SCT350	Data entry EUDRACT register	Hour(s)	36,00€	42,00€	42,00€	65,00€
SCT351	Report submission	Hour(s)	36,00€	42,00€	42,00€	65,00€
SCT352	File storage in MDA (documents request not included)	Year(s)	24,00€	28,00€	28,00€	43,00€

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