

RATES 2018

1.- SCIENTIFIC COUNSELING: METHODOLOGICAL, EPIDEMIOLOGICAL, STATISTICAL, IT AND TELEMATIC	RATES
A) Rates for members of the Institute	
Counseling	Free
Scientific counseling	30 €/hour
B) Rates for staff from other Hospitals/Public Institutions	
Counseling	35 €
Scientific counseling	45 €/hour
C) Rates for Private Institutions	
Counseling	60 €/hour
Scientific counseling	80 €/hour

2.- TRAINING	RATES
Interns	150 €/hour
Graduates and Staff	350 €/hour

3.- RESEARCH PROJECTS (RP) (Including CLINICAL TRIALS SUBJECT TO NATIONAL AND INTERNATIONAL CALLS. DOCTORAL THESES)	i+12 RATE
Technical counseling on the design and methodology of the research project	550 €*
Technical counseling on the clinical development of medication/research study projects	3,100 €
Study start-up	
Study feasibility survey (per center)	75 €
Counseling and/or review of the methodology described in the research protocol	650 €*
Drafting and adaptation of the protocol	1,850 €
Drafting and adaptation of the patient information leaflet and informed consent	105 €
Design of the paper version of the case report form (CRF). Consult the price for the electronic eCRF	1,900 €
Design of IT support software (BASE). Consult the price for the electronic eCRF	1,900 €
Preparation of the general documentation related to the clinical trial application (EudraCT, annexes 1A and A1) to be submitted to the Spanish Agency of Medicines and Medical Devices (AEMPS)	500 €
Preparation of the documentation related to the local clinical trial application to be issued to the Research Ethics Committees (RECs), prepared by our REC	220 €
Creation of the randomization list	250 €
Requesting of the civil liability insurance policy	145 €

3.- RESEARCH PROJECTS (RP) (Including CLINICAL TRIALS SUBJECT TO NATIONAL AND INTERNATIONAL CALLS. DOCTORAL THESES)	i+12 RATE
Management of the medication (identifying suppliers, negotiating, purchasing, managing the secondary packaging, storing and controlling the stock)	900 €*
Preparation of the investigators' brochure	330 €
Replication of the investigator's brochure (per researcher)	150 €
Preparation of the sponsor file	330 €
Submission of the protocol or amendment request to the AEMPS	105 €
Submission of the protocol or amendment request to the REC (per Committee)	105 €
Responding to the REC's request for clarifications	250 €
Responding to the Research Agency's request for clarifications	250 €
Responding to corrections or clarifications requested by the AEMPS	250 €
Clinical trial registry (www.clinicaltrials.gov or REec)	190 €
Preparation of a specific monitoring plan	180 €
Drafting of the statistical methods section/Data Management Section	300 €
Sample size calculation	110 €
Data analysis plan	650€
Data Management Plan (DMP)	850 €
Drafting of the Data Validation Plan	450 €
Database preparation and validation	1,950 €
Annotated CRF	450 €
Query programming and validation (100 queries)	2,150 €
Study implementation	
Initial Visit (Study Site Opening) and Study Site Opening Report (Principal Investigator and Pharmacy Department)	690 €
Semi-annual maintenance of the clinical trial registry (www.clinicaltrials.gov or REec)	85 €
Maintenance of the documentation archive	300 €
Annual management of severe adverse events (SAE) or of suspected unexpected serious adverse reactions (SUSAR)	750 €
Expeditious notification of SUSARs to the relevant authorities (Annex 1D)	440 €
Drafting and Submission of Development Safety Update Reports (DSURs) to the REC and AEMPS	550 €
Data Management/Loading	1,500 €
Periodic monitoring visit - Drafting of the monitoring report and query resolution	620 €
Preparation of documentation related to protocol amendments	650 €
Drafting of the annual monitoring report	560 €
Review of data consistency and sanitation	300 €
Interim statistical analysis	450 €
Final statistical analysis	600 €

Study completion	
Final Visit (Study Site Closure)	670 €
Drafting of the end of study Report (Notification to the AEMPS-REC)	3,000 €
Publication of results (medical writing)	3,000 €
File archiving and custody (for 10-15 years, according to the legal requirements)	Consult price

* Consult the rates for this service with the Unit.

4.- OBSERVATIONAL STUDIES	i+12 RATE
Counseling on the design and methodology of an observational study	440 €
Drafting and adaptation of the protocol of an observational study	1,200 €
Drafting and adaptation of the patient information leaflet and informed consent	105 €
Design and drafting of the paper version of the CRF. Consult the price for the electronic eCRF	1,050 €
Processing of authorizations: REC, AEMPS and the Autonomous Region (1 Autonomous Region)	500 €
Processing of authorizations (for each additional Autonomous Region)	200 €

5.- OTHER RESEARCH PROJECTS	i+12 RATE
Preparation of the general documentation related to the Research project application (e.g., Foundation for International Services [FIS], Mutua Madrileña, etc.)	500 €*

* Consult the rates for this service with the Unit.

6.- APPLICABLE TO ANY TYPE OF STUDY	i+12 RATE
Drafting of the statistical data analysis strategy	650 €
Descriptive data analysis	900 €
Inferential analysis (bivariate and multivariate)	1,600 €
Analysis of the cause of the refusal of rejected projects	900 €
Other statistical techniques (Bayesian analysis, meta-analysis, genetic epidemiology, longitudinal data analysis, etc.)	>2,600 €
Assessment of diagnostic tests, their sensitivity and specificity, predictive values and receiver operating characteristic (ROC) curves	1,600 €
Shared drafting of the study results with the principal investigator for the final document	1,000 €
Drafting of the specific materials and methods section of the final document	1,000 €
Counseling on the presentation of the study results for their scientific dissemination	600 €
Review of scientific articles	200 €

6.- APPLICABLE TO ANY TYPE OF STUDY	i+12 RATE
Database preparation and validation (Access and RedCap)	800 €
Drafting and validation of other databases or applications	1,900 €
Data imports	200 €
Data exports (CSV, R, SAS, SPSS)	400 €
RedCap user registration and access maintenance (per user)	15 €
Database sanitation	600 €*
Cloud storage	Consult price
Data standardization in the CDISC format	600 €
Coding of adverse events, procedures, medications, etc. (medical dictionaries such as Medra, WhoDrug, CTC and similar ones)/per each term	15 €
Reconciliation of SAEs	150 €
Other activities	Consult price

* Consult the rates for this service with the Unit.

7.- TRAINING	i+12 RATE
Training in Research Methodology	150-350 €/hour
Training in the critical reading of scientific literature	150-350 €/hour
Training in the preparation of a scientific manuscript for publication in peer-reviewed scientific journals	150-350 €/hour
Specific training courses based on the researcher's needs	150-350 €/hour
Training in the use of free access software for statistical analyses	150-350 €/hour
Training in advanced statistics	150-350 €/hour