

ESID Registry Research Study Project Fees / Reimbursement Structure 2023

Aug 16, 2023, Markus Seidel, Stefano Volpi, Fabio Candotti on behalf of the ESID Board

All research projects conducted with ESID registry data require some, at least a minimum, amount of work that exceeds the routine maintenance of the registry (*e.g.*, announcements of the study, data extraction and filtering, data linking to study CRFs, sometimes additional programming, statistical analyses, etc.). Therefore, barring extenuating circumstances, a financial contribution that depends on the project complexity and sponsor to reimburse these costs and to support the registry financially will be required. The following outline should serve as a guideline and is published for transparency without liability; this policy is subject to individual changes without prior public notice.

Packages to finance ESID registry projects

1. **SMALL:** a small academic study with a mere pre-evaluation on how many patients with XY disease are in how many centers, and then linking a RedCap survey to existing ESID-R data with extraction of the latter (raw), would, *e.g.*, ask for:
 1. small start-up fee or none: 0-1000€
 2. administrative tasks and IT-service tasks, *e.g.*, directing calls/survey distribution to the respective patients / centers: 1500-5000€
 3. varying consultation and data extraction and analytical services: 0-5000€
 4. overheads of 8% for ESID-R, legal and accounting administrative work→ range: 1620-12.000€

2. **MEDIUM or LARGE:** a larger academic study: higher amount of work, thus higher fees
 1. like “SMALL” plus optional additional programming needed in Freiburg or elsewhere,
 2. plus statistical analyses, other cost factors, calculated on hourly fee estimation (see example below)...→ range: 10-50.000€

3. **INDIVIDUAL:** an “investigator-driven” academic but industry-supported, or a pure commercial / pharmaceutical collaborator / industry study:
 1. a minimum, non-refundable fee for a feasibility check and setting up a non-disclosure agreement and a pre-contract, *e.g.* 2.500€, which could later be deducted from the start-up fee, once the full contract is established and the study project is launched
 2. a defined start-up /set-up fee including a contribution for the setting up (existence) and maintenance of the registry: 10.000€
 3. personnel costs for study management: liaison with documenting centers, quality control, protocol advice, legal assessment, regular reporting, medical experience, statistical analyses etc., overseeing the final report; 50-150€/hour
 4. personnel costs for a study coordinator / study nurse to support data acquisition and quality control at ESID or PI’s center ...?
 5. (Optionally, if documenting workload is high: “per-patient fees” for data acquisition and entry paid to participating centers → need separate legal contracts with financial compensation with each participating center!)
 6. publication fees, meeting (travel) costs, ...
 7. overheads of 12% for ESID-R maintenance, legal and accounting administrative work [much higher workload than merely academic studies].→ range: ≥30.000€

The funds should be transferred to ESID with the label of the registry project, the individual fees should be estimated by Dr. Gerhard Kindle (workload Freiburg), optionally also by the mainly involved center(s), AND the treasurer, and approved by the registry chairperson. The final amounts will depend on a final calculation and sums of work hours of personnel and subcontractors (e.g., legal, statistical services...) made by the ESID administration office upon collection of all invoices. VAT might be required depending on national laws. In general VAT should not be due if the service provided is within the scope of ESID constitution and between academic institutions and ESID. It will be important to specify in the service agreement/contract that the services are within ESID scope.

See an example calculation (with person and company names blackened out) below. The cooperation between research teams, their principal investigator, and the ESID registry representatives will be on an academic collegial basis, aiming to serve all parties as soon as possible, and is subject to undisputable ESID-internal prioritization, e.g., of running projects over new projects. No guarantee of data delivery in a certain time frame or completeness will arise from payment of these financial reimbursements. To this end, individual/larger studies will have specific study protocols and contracts for clarification of terms. With the submission of a project proposal form, the applicant agrees to these general terms of study project fees and the reimbursement structure.

Example for a small “INDIVIDUAL” or “LARGE” project:

Cost	Description	Unit Type	Number of Units	Currency	Type of cost	Accepted Unit Price	Accepted Total Cost	supported
Personnel	ESID Board, ESID registry chair - design overseeing and project managing the study operation. Prof. Dr. [redacted] with more than 20 years of experience. Tasks comprise oversee outcome and reporting interim report Q4 2022 (retrospective patient findings, only), Final Report Q2-2023 (both retrospective and prospective findings reported)	Hourly rate	30	EUR	Direct cost	EUR 150.00	EUR 4,500.00	Yes
Study set-up fee	ESID registry development, setup and operation. ESID Registry team Freiburg with more than 20 years of experience. Tasks comprise registry database programming and data extraction. Hours	Hourly rate	200	EUR	Direct cost	EUR 50.00	EUR 10,000.00	Yes
Personnel	Project management and coordination. ESID Executive Director [redacted] with 20 years of experience. Tasks comprise coordination, management, reporting and liaison with [redacted]	Hourly rate	40	EUR	Direct cost	EUR 50.00	EUR 2,000.00	Yes
Personnel	Legal assessment - Data Protection Officer. ESID DPO, [redacted], with 4 years of experience. Tasks comprise consent forms development and legal/regulatory oversight	Hourly rate	15	EUR	Direct cost	EUR 65.00	EUR 975.00	Yes
Personnel	Registry team coordination. [redacted] Infectious Disease specialist, ESID Registry officer. With more than 20 years of experience. Tasks comprise liaison with DCs, follow-ups, data extraction oversight and quality control.	Hourly rate	35	EUR	Direct cost	EUR 50.00	EUR 1,725.00	Yes
Personnel	Researcher - data analysis and compiling data for the report. Expert in the field of immunology with more than 10 years of experience. Tasks comprise analysis of population's variables extracted from ESID registry and necessities to answer to primary endpoint and secondary endpoint.	Hourly rate	116	EUR	Direct cost	EUR 50.00	EUR 5,800.00	Yes
Publication open-access and journal fees	A place holder equivalent to 10,000 USD (9,350.58 EUR oanda.com 20 Feb 2023) will be included by default in each Collaborative Research budget to support the costs for the publication of one or more papers in peer-reviewed journals in open access and for the registration fees to present the results in one or more scientific congresses according to the publication plan that will be decided	Fee	1	EUR	Other cost-no overhead (provisional)	EUR 9,350.58	EUR 9,350.58	Yes

EUR	Total direct costs	EUR 25,000.00
	Overhead rate: 25%	EUR 6,250.00
	Total other costs	EUR 9,350.58
	Total study cost	EUR 40,600.58
	supported	EUR 40,600.58