LLC "Eco-safety Research Centre"
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ЭКО БЕЗОПАСНОСТЬ
НАУЧНО-ИССЛЕДОВАТЕЛЬСКИЙ ЦЕНТР

PRICE LIST FOR DRUG DEVELOPMENT RESEARCH SERVICES 2024

I. Conducting clinical bioequivalence trials of drugs

II. Development and validation of analytical methods:

- ✓ Development of HPLC-MS/MS methods for the quantitative determination of biologically active substances
- ✓ Validation of analytical methods and preparation of validation reports
- ✓ Development of non-standardized sample preparation protocols
- ✓ Preparation of analytical reports according to the regulations of the EAEU and the Federal State Budgetary Institution "SCEEMP" of the Ministry of Health of Russia
- ✓ Processing of statistical data, preparation of statistical reports in accordance with EAEU regulations

III. Medical writing and statistics:

- ✓ Development of initial trial-specific documentation for conducting all phases of clinical trials
- ✓ Statistical data processing, preparation of statistical/final reports based on research results in accordance with EAEU regulations.
- ✓ Review of results/reports of preclinical and/or clinical studies at various stages, risk assessment

IV. Data collection and processing:

- ✓ Electronic data capture form (EDC)
- ✓ Interactive web randomization system (IWRS) and drug accountability

V. Development and registration of drugs:

- ✓ Developing regulatory strategies at every stage of drug development and circulation
- ✓ Planning, creation and/or refinement of preclinical and clinical trials programs for any drug class of any complexity.
- ✓ Preparation and finalization of instructions for the medical use of drugs (SmPC, drug substances)
- ✓ Preparation of registration dossier modules in CTD format according to EAEU regulations
- ✓ Writing scientific reviews of preclinical and clinical trials

VI. Post-registration services:

- ✓ Preparation of scientific/review articles for publication in scientific journals listed in Web of Science, Scopus, RSCI.

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- ✓ Development of research and development (R&D) programs for the post-marketing use of medicines
- ✓ Statistical data processing, preparation of statistical/final reports based on the results of research work

VII. Development of documents within the pharmacovigilance system:

- ✓ Preparation of drug safety review reports (DSRP)
- ✓ Preparation of periodic safety update reports (PSURs)
- ✓ Preparation of pharmaceutical risk management plans (RMPs)
- ✓ Creation and maintenance of the organization's pharmacovigilance system.
- ✓ Providing QPPV with all functions
- ✓ Audit of the pharmacovigilance system

VIII. Development of documents within the Quality Management System:

- ✓ Development of documents for the organization's quality management system (Standard Operating Procedures - SOPs, regulations, instructions, etc.)

IX. Review of clinical trial and scientific research materials by the Ethics Committee of the LLC "Eco-Safety Research Centre":

- ✓ Reviewing a package of documents and conducting an examination of materials from clinical trials of bioequivalence and phase I-IV drugs, observational studies, dissertations

X. Review of clinical trial materials and research papers by an independent data monitoring committee:

- ✓ Reviewing a package of documents on materials from clinical trials of bioequivalence and phase I-IV medicinal products as part of the assessment of safety data and the formation and provision of an opinion by the Independent Data Monitoring Committee.

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PRICES

I. CONDUCTING CLINICAL BIOEQUIVALENCE TRIALS OF DRUGS:

Service description	Price	Timeframe, months
Clinical part of the trial		
Bioequivalence study with a simple crossover design • **2 periods** • Up to 40 subjects • Washout period –up to 4 weeks	from 70 000 RUB/subject	2
Bioequivalence study with replication design • **4 periods** • Up to 40 subjects • Washout period – up to 4 weeks	from 100 000 RUB/subject	3
Analytical part of the trial		
Bioequivalence study with simple crossover design • **2 periods** • **1 analyt**	from 50 000 RUB/subject	1
Bioequivalence study with a simple crossover design • **2 periods** • **2 analyts**	from 65 000 RUB/subject	1
Bioequivalence study with replication design • **4 periods** • **1 analyt**	from 80 000 RUB/subject	2
Bioequivalence study with replication design • **4 periods** • **2 analyts**	from 90 000 RUB/subject	2

II. DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS:

Service description	Price	Timeframe, days
Development and validation of analytical methods*		
Development of HPLC-MS/MS methods for the quantitative determination of biologically active substances in a biological matrix (plasma, serum, whole blood, urine, saliva).	200 000 RUB**	7-14
Validation of the analytical method and preparation of the validation report	150 000 RUB	3
Non-standard sample preparation protocol	100 000 RUB	7
Analytical report preparation	200 000 RUB***	3
Statistical report preparation	100 000 RUB****	7
Cost of one biosample	from 900 RUB*****	-

* the price does not include consumables (plastic) and reagents (substances and internal standards)
** for one substance in a matrix; two substances - coefficient 1.2, three substances - coefficient 1.3, etc.
To determine substances in different matrices, calculations are performed for each method.

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Service description	Price	Timeframe, days
*** up to 2500 biospecimens; more than 2500 biospecimens – coefficient 1.5 **** one BAS, two BAS - coefficient 1.5, three BAS - coefficient 2.0, etc. ***** the cost and time of measuring the concentration of biologically active substances in samples and other services provided by a chemical analysis laboratory are also calculated. ***** the price does not include the purchase of standard biospecimens.		

III.MEDICAL WRITING AND STATISTICS:

Service description	Price	Timeframe, days
Development of Initial trial-specific documentation *		
Initial trial-specific documentation “BIOEQUIVALENCE” • Protocol • Subject information sheet and consent form • Investigator’s Brochure	250 000 RUB	14
Initial trial-specific documentation “LATE PHASE” • Protocol • Subject information sheet and consent form • Investigator’s Brochure • - All materials for the subject/researcher	from 250 000 RUB**	21-28
Statistical data processing, preparation of statistical/final reports		
Final report “BIOEQUIVALENCE” • - Safety/Tolerability statistical report • - Bioequivalence statistical report • - Final report with supplements	230 000 RUB***	14
Final report “LATER PHASE” • - Statistical report on safety/tolerability • - Statistical report on efficacy/immunogenicity • - Final report with supplements	270 000 RUB****	21-28
*it is possible to develop each document separately from the Initial trial-specific documentation. **cost and time may vary depending on the type of drug, the need to involve experts/experts in the clinical field. ***one active substance, each additional one increases the amount by 50,000 rubles. ****cost and timeframe may change depending on the number of efficacy/immunogenicity points and the scope of statistical analysis.		

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IV. DATA COLLECTION AND PROCESSING:

Service description	Price	Characteristics of the trial
Electronic data capture form (EDC)*		
EDC package "Bioequivalence STANDARD"	170 000 RUB	• simple crossover study • 1 site • up to 3 months • up to 40 subjects
EDC package "Bioequivalence PLUS"	200 000 RUB	• replicative / adaptive design • more than 3 months • more than 40 subjects
EDC package "Bioequivalence PROFESSIONAL" • EDC package "Bioequivalence" • Biostatistics • Final research report	400 000 RUB	• any bioequivalence study
EDC package "ADVANCED"	from 450 000 RUB	• late phase • multi-centre studies** • up to 250 subjects***. • up to 6 months****

* **own validated CTcloud software**

Documentation package for EDC

- General package of validation documents for the system (NOT project specific documents, general for CTcloud EDC)
  - validation plan
  - data management plan
  - requirements specification
  - user manual
- Project documents (for a specific CT)
  - design validation (Database Design Qualification)
  - EDC template
  - references (Standards/Rules)
- Upon completion:
  - Uploading a database in Excel format
  - PDF listings for each subject
  - MedDRA data coding of the current version (adverse events, antecedent and concomitant diseases) and ATC (antecedent and concomitant therapies)

**up to 5 sites; 6-10 sites - coefficient 1.2; more than 10 sites - coefficient 1.4

***251-350 subjects - coefficient 1.1; 351-500 subjects - coefficient 1.2; 501-700 subjects - coefficient 1.3; 701-1000 subjects - coefficient 1.4; more than 1000 subjects are estimated separately.

**** 6-8 months - coefficient 1.1; 9-10 months - coefficient 1.2; 11-12 months - coefficient 1.3; 12-18 months - coefficient 1.4; more than 18 months - estimated separately.

Randomisation and drug accounting (IWRS)*		
Connection of IWRS (+ drug accounting module) to the ADVANCED EDC package	from 100 000 RUB	-
IWRS and Drug Accounting Module	from 300 000 RUB	-

* **own validated CTcloud software**

- Documentation package for IWRS
- General package of validation documents for the system (NOT project-specific documents, in general for CTcloud IWRS)
- Project documents (for a specific CT):

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Service description	Price	Characteristics of the trial
○ validation plan ○ requirements specification ○ design validation (database design qualification) • Upon completion: ○ uploading a database in Excel format ○ PDF listings for each subject		
Extra services (EDC/IWRS)		
Project specific validation documentation	30 000,00 RUB	Project-specific validation documents - validation plan - data management plan - requirements specification - project qualification - database structure
Project-specific user guides	30 000,00 RUB	Project specific instructions by role
Additional/project log management	5 000,00 RUB	available
	10 000,00 RUB	timing by database (deployment, opening, closing, unloading)
	20 000,00 RUB	Change log (audit log)
User training (light)	5 000,00 RUB	Presentation Distance learning with instructions
User training	20 000,00 RUB	Case study presentation Full-time introductory training Ongoing training on updates (if required)
Maintenance and hosting	20 000,00 RUB	For each month thereafter, from the 4th
Long-term database storage on server equipment (with the ability to fully deploy the database as an EDC and back up all data)	50 000,00 RUB	Up to 3 years
Deploying a database on a dedicated server and then dumping the entire database	500 000,00 RUB	Service life up to 6 months.
Dedicated server hosting and support	50 000,00 RUB	For each month thereafter, starting from the 7th

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V. DEVELOPMENT AND REGISTRATION OF DRUGS:

Service description	Price	Timeframe, days
Developing a regulatory strategy		
Literature review and assessment • Evaluation of available data from preclinical trials • Evaluation of available clinical trial data • Summary of the evaluation results and conclusion on the sufficiency and required extent of preclinical and clinical trials	83 000 RUB	14
Development of a research (clinical) strategy: • - Estimated number of studies • - Proposed research phases • - Estimated research timeframe • - Estimated research budget	33 000 RUB	7
Development of the study design(s): • Target population • Goals, objectives • Sample size (power calculation) • Primary (secondary) endpoint	99 000 RUB*	7-14
* the cost of work may vary depending on the type of drug, the amount of active ingredients, etc.		
Preparation of instructions for medical use of drugs (SmPC, drug substance)		
Leaflet development (drug substance)	79 000 RUB*	14-21
Development of general characteristics of a medicinal product for medical use (SmPC)	87 000 RUB*	14-21
* the cost of work may vary depending on the amount of active ingredients		
Preparation of registration dossier modules in CTD format		
One-component drug Section 2.4. Preclinical review Section 2.5. Clinical review Section 2.6. Summary of preclinical data Section 2.7. Summary of clinical data	250 000 RUB	28
Two-component drug Section 2.4. Preclinical review Section 2.5. Clinical review Section 2.6. Summary of preclinical data Section 2.7. Summary of clinical data	350 000 RUB	28
*for three or more component drugs the cost is calculated separately **the final cost of work may change depending on the type of drug (generic/original drug), availability and quality of available source documents		

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VI. POST-REGISTRATION SERVICES:

Service description	Price	Timeframe, days
Preparation of scientific/review articles *		
Scientific article	70 000 RUB.	14-21
Review article	50 000 RUB	7-14
Abstracts	30 000 RUB	7
Formatting of the article according to the requirements of a specific journal. Editing/rendering of figures and tables. Preparation of a list of references as required.	from 13 000 RUB	7
Scientific research (R&D)		
Research programme	from 70 000 RUB	7
Subject information sheet with consent form	20 000 RUB	2
Report on the results of the research	from 100 000 RUB**	14-21
*Cost and timeframe may vary depending on the type of drug, the need to involve clinical experts/reviewers. **Cost and timeframe may vary depending on number of safety/efficacy/immunogenicity points and scope of statistical analysis.		

VII. DOCUMENTATION DEVELOPMENT WITHIN THE FRAMEWORK OF THE PHARMACOVIGILANCE SYSTEM:

Service description	Price	Timeframe, days
Pharmacovigilance services for marketing authorization holders in the Russian Federation and abroad		
Preparation of a drug safety report (DSR) for a drug under development	100 000 RUB	14-21
Periodically updated safety report (Periodic Safety Update Report, PSUR) • every 6 months from the international date of registration for the first 2 years; • annually for the next 2 years; • further – every 3 years.	120 000 RUB	14-21
Risk management plan for the development/use of a drug (RMP)	120 000 RUB	14-21
Establishing and maintaining the organization's pharmacovigilance system		
Establishment and maintenance of the Pharmacovigilance System Master File • writing of Standard Operating Procedures (SOPs) • outsourcing of literature monitoring • providing QPPV with all functions • weekly screening of regulatory websites to identify safety reports • monthly screening of safety reports in scientific and medical	400 000 RUB	14-21

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Service description	Price	Timeframe, days
literature • reconciliation of safety data with client • identification and reporting of safety alerts • responding to regulatory requests		
Inclusion of 1 drug in the Pharmacovigilance System Master File	60 000 RUB per year	-
Pharmacovigilance system audit		
Pharmacovigilance system audit	150 000 RUB	14-21

VIII. DEVELOPMENT OF DOCUMENTS WITHIN THE FRAMEWORK OF THE QUALITY MANAGEMENT SYSTEM:

Quality management system	Price	Timeframe, days
Quality management system		
Development of Standard Operating Procedures - SOPs	negotiated	from 14
Development of regulations, instructions, etc.	negotiated	from 14

IX. PREPARATION FOR CONSIDERATION OF DOCUMENTS AND CONDUCTING AN EXAMINATION OF MATERIALS BY ETHICS COMMITTEE OF LLC "ECO-SAFETY RESEARCH CENTRE"

Service description	Price	Timeframe, days
Bioequivalence and Phase I-IV clinical trials		
Primary application, one site	40 000	from 4
Reapplication, one site	25 000	from 4
Emergency application*, one site	50 000	from 1
Unscheduled meeting**, one site	60 000	from 1
Acceptance of documents for approval of a clinical trial	0	from 4
Observational trials		
Primary application, one site	40 000	from 4
Reapplication, one site	25 000	from 4
Dissertations		
Examination of materials	10 000	from 4
*Submitting documents less than three days before the meeting. **Holding EC meetings outside the approved meeting schedule.		

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X. Examination of materials from clinical trials and research papers by an Independent Data Monitoring Committee

Service description	Price	Timeframe, working days
Independent Data Monitoring Committee meeting		
One meeting (including review of data from up to 2 patients)	10 000 RUB	2
*payment according to the issued act based on the number of actual meetings held **payment quarterly		