# Шаблон для оформления рукописи, содержащей результаты ОРИГИНАЛЬНОГО ИССЛЕДОВАНИЯ

При написании статьи просим Вас руководствоваться актуальными версиями международных рекомендаций для описания соответствующего типа исследований, размещенными на [ресурсе EQUATOR](https://www.equator-network.org/reporting-guidelines/) (Enhancing the Quality and Transparency of Health Research), в частности:

|  |  |
| --- | --- |
| **Тип исследования** | **Рекомендации** |

**Template for an ORIGINAL manuscript**

Please follow the appropriate current versions of international recommendations published on [EQUATOR](https://www.equator-network.org/reporting-guidelines/) (Enhancing the Quality and Transparency of Health Research) when preparing a manuscript, i.e.:

|  |  |
| --- | --- |
| **Type of research** | **Recommendations** |
| Randomized (RCT) and non-randomized prospective controlled trial | [CONSORT](http://www.equator-network.org/reporting-guidelines/consort/)[, additions](https://www.equator-network.org/?post_type=eq_guidelines&eq_guidelines_study_design=0&eq_guidelines_clinical_specialty=0&eq_guidelines_report_section=0&s=+CONSORT+extension&btn_submit=Search+Reporting+Guidelines) |
| [Observational](http://www.equator-network.org/?post_type=eq_guidelines&eq_guidelines_study_design=observational-studies&eq_guidelines_clinical_specialty=0&eq_guidelines_report_section=0&s=+&eq_guidelines_study_design_sub_cat=0) study | [STROBE](http://www.equator-network.org/reporting-guidelines/strobe/), [additions](https://www.equator-network.org/?post_type=eq_guidelines&eq_guidelines_study_design=0&eq_guidelines_clinical_specialty=0&eq_guidelines_report_section=0&s=+STROBE+extension&btn_submit=Search+Reporting+Guidelines) |
| Study of diagnostic or screening tests | [STARD](http://www.equator-network.org/reporting-guidelines/stard/) |
| Multivariable prediction model for individual prognosis or diagnosis | [TRIPOD](http://www.equator-network.org/reporting-guidelines/tripod-statement/) |
| [Animal](http://www.equator-network.org/?post_type=eq_guidelines&eq_guidelines_study_design=animal-pre-clinical-research&eq_guidelines_clinical_specialty=0&eq_guidelines_report_section=0&s=+) reseach | [ARRIVE](http://www.equator-network.org/reporting-guidelines/improving-bioscience-research-reporting-the-arrive-guidelines-for-reporting-animal-research/) |
| [Health Economic](http://www.equator-network.org/?post_type=eq_guidelines&eq_guidelines_study_design=economic-evaluations&eq_guidelines_clinical_specialty=0&eq_guidelines_report_section=0&s=+) Evaluation | [CHEERS](http://www.equator-network.org/reporting-guidelines/cheers/) |

**TEMPLATE USE GUIDE**

All manuscript materials should be placed in a single \*.docx file (exception - the rules for providing certain types of figures are given below).

The manuscript section headings are highlighted in black.

Recommendations regarding the content of this section/subsection are indicated in blue. Some recommendations may not apply to your research.

**Replace** the blue text with the text of your manuscript (black), saving the section headings.

Upload the completed manuscript to the journal's website.

***(Delete this page in the final version of the manuscript)***

**ИНСТРУКЦИЯ ПО ИСПОЛЬЗОВАНИЮ ШАБЛОНА**

Все материалы статьи следует разместить в одном файле формата \*.docx (исключение - ниже см. правила предоставления некоторых видов рисунков).

**Черным цветом** выделены заголовки разделов статьи.

**Синим цветом** обозначены рекомендации относительно содержания данного раздела / подраздела. Некоторые рекомендации могут оказаться неприменимы к вашему исследованию.

Сохраняя заголовки разделов, **замените** текст **синего цвета** на текст Вашей статьи (черный).

Заполненный шаблон статьи следует загрузить на сайт журнала.

***(Эту страницу следует удалить в финальном варианте рукописи)***

### manuscript title

The manuscript title should be as specific as possible, reflecting the main study result. It is also recommended to include in the title an indication of the target patient population and medical intervention (if applicable). If the manuscript describes a RCT, it is necessary to specify this in the title. For other designs, it is desirable to indicate it in the title.

### Authors

Author's full name1\* Author's full name2, Author's full name3,..., ....

### Affiliation

1Author's affiliation (official name of the university/institute), city, country

2Author's another affiliation (official name of another university/institute), city, country

3Author's another affiliation (official name of another university/institute), city, country

### abstract

The abstract volume is **150-350** words.

***BACKGROUND*** (1-3 sentences). Justify the relevance and novelty of your study based on the importance of the problem (e.g., use epidemiological parameters) and remaining gaps in the research area.

***AIM.*** Formulate as specific as possible the research question for which the study was conducted. Specify the target population, medical intervention (if applicable), main assessed variable (or group of variables).

***MATERIALS AND METHODS.*** This section of the abstract **should** provide a summary of the target population (one or more), the study design, the intervention characteristics (if applicable), the main estimated variables, and methods of their assessment. This section ***should not*** contain characteristics of study subjects (the groups size, conclusions on their comparability, etc. - this information is presented in the RESULTS section);

If the study is in a clinical trials registry, please provide the registration number.

***RESULTS.*** Specify the number of patients (included in the study, completed the study (for prospective studies), the most significant characteristics of the groups). Provide the main study outcomes - descriptive statistics, the results of hypotheses testing, 95% confidence intervals for the main results. *P*-values must be presented with three or more decimal places. It is necessary to provide frequencies of adverse events in study of a medical intervention.

***CONCLUSION*** (1-3 sentences). Briefly and as accurately as possible formulate conclusions based on the results obtained. Discussion of the results and any generalizations should be avoided here.

### Key words

term 1; term 2; term 3.

It is necessary to provide 3-7 keywords that best reflect the essence of the presented work. The keywords should be selected from the MeSH thesaurus. Exceptions are allowed only if the required term is missing.

\*Corresponding author.

### Rationale

Justify the relevance of the study based on the importance of the problem. Use for this, e.g., epidemiological parameters (prevalence, morbidity, mortality, disability, lethality, quality of life, QALY, DALY, etc.), social and economic burden of disease, etc. The values of these parameters at the global, continental, country, regional levels may be demonstrated.

Justify the novelty of your study by describing the remaining gaps in the research area. Identify the resolved and unresolved (or resolved low methodological level) aspects of the problem (another population, another intervention, another criteria or methods, etc.) with an analysis of previously published results (Russian, foreign).

Each author's statement, except for the most well-known, must be provided with references to sources of information. In general, **no more than 3 references** should be used for each statement.

### aim of the STUDY

Formulate as briefly and accurately as possible the aim of the study. If there are several aims (that is undesirable within a single manuscript), formulate each in a separate sentence.

Include in the purpose statement the information about the target population, interventions (if applicable), the main assessed variable (outcome) or group of variables.

For experimental (hypothesis testing) studies of medical interventions, formulate the purpose as a hypothesis of superiority, non-inferiority, or equivalence to a comparator for a fixed primary outcome.

Make sure that the statement of aim in the main text and in the abstract is the same.

**MATERIALS AND METHODS**

This section should be divided into the subsections described below. This section ***should not*** contain characteristics of study subjects (the groups size, conclusions on their comparability, etc. - this information is presented in the RESULTS section);

**Site and time of the study**

*Study site.* Specify the sites that participate in the study (including localities and departmental affiliation or form of property).

*Time of the study.* Specify the calendar time period (accurate to within a month) between the first visit of the first subject and the last follow-up of the last subject analyzed in the study.

**Study populations (one or more)**

Specify the number of study populations (e.g., two of them - sick and healthy subjects).

Separately for each population, specify the inclusion criteria (sex, age, etc.) and exclusion criteria (e.g., comorbidities). If the exclusion criteria for all study populations are the same, specify them once.

*Population "...":* (if more than one)

*Inclusion criteria:* criterion 1, criterion 2,… (note: sex and age are usually indicated as the first inclusion criteria).

*Exclusion criteria:* criterion 1, criterion 2,…

The withdrawal criteria (if any) should also be specified separately for prospective studies.

**Sampling method from the study population (or several sampling methods from several study populations)**

Specify the applied sampling method (arbitrary, consecutive, random, matching, etc.). Various sampling methods can be used for different samples in the same study, e.g., one sample can be formed by consecutive inclusion of observations, and the other one by the matching to the observations of the first sample. For more information on sampling methods, see [here](https://en.wikipedia.org/wiki/Sampling_%28statistics%29).

**Study design**

A description of the study design may be performed by listing the study design characteristics:

* single-center or multicenter,
* *observational* (routine patient management practices) or interventional, *i.e. experimental*, (patients are prescribed any (not necessarily new) medical interventions (therapeutic, preventional, diagnostic, screening), **in the interests of study**),
* dynamic (patients are observed at least twice at different time points) or cross sectional (patients are observed once),
* for dynamic studies: prospective (groups are formed according to the exposure factor or to some initial criterion) or retrospective (groups are formed according to the outcomes occurred during the observation),
	+ for prospective studies: specify the period of patients’ follow-up (or the minimal and maximal periods if patients were followed for different periods), the visit schedule,
	+ for retrospective studies: specify the minimal and maximal period between the start and end of follow-up,
* one-sample (one study population) or two (or more)-sample
	+ for one-sample studies: controlled (including placebo controlled) or uncontrolled, or comparative (subgroup comparison),
	+ for studies with two or more samples: comparative or non-comparative,
	+ for one-sample and two-sample studies of diagnostic and screening methods: controlled (with a reference test) or uncontrolled, comparative (with a test other than the reference) or non-comparative,
* for controlled studies: randomized or non-randomized, blinded or non-blinded,
	+ for randomized studies: describe in detail the randomization procedure,
	+ for blinded studies: describe in detail the masking methods.

If there is a study protocol, please provide a reference to it or attach it to the manuscript as appendix. If the study is in a clinical study registry, please provide the registration number.

In some manuscripts the authors describe two or more different study fragments that are performed in different aims (that, in general, is not desirable within a single manuscript). In this case, it is necessary to describe separately the design of each study fragment.

**Description of medical intervention (for interventional studies)**

If the studied interventions (therapeutic, preventional, diagnostic, screening) are not a part of routine medical practice, but are prescribed in the interests of study, they should be described in detail. For therapeutic interventions, describe the doses, titration schedule, administration routes, duration of use, conditions for discontinuation of therapy. For surgical interventions, describe the details of preoperative assessment, the operation, including anesthesia and postoperative management of patients. Non-invasive medical interventions (e.g., questionnaire survey), as well as management technologies (e.g., patient routing) also require descriptions.

**Methods**

Specify methods of inclusion and exclusion criteria detection. For example, if patients with liver pathology were excluded, specify the relevant documents or examinations.

List all the studied clinical, laboratory, instrumental and other parameters for which the results are presented in the manuscript. Specify or describe the assessment methods for each of these. For clinical diagnoses, disease forms and stages, complications, relapses, remissions and other clinical events, provide detection criteria (or references to such criteria). Specify the method and the equipment for laboratory and instrumental findings.

When describing experimental studies, specify the primary outcome for assessing the intervention effect, and describe its criteria.

**Statistical analysis**

Use [SAMPL](https://www.equator-network.org/wp-content/uploads/2013/03/SAMPL-Guidelines-3-13-13.pdf) guidelines to correctly describe the procedure and the results of the statistical analysis.

Specify the statistical software package (including its version), parameters of distributions of quantitative and qualitative data; statistical methods and criteria, the significance threshold and methods of its correction in case of multiple hypothesis testing. Specify the methods for calculating confidence intervals for the main study outcomes (proportions, absolute and relative risks, odds ratios, sensitivity, predictive value, etc.).

When describing hypothesis testing experimental studies, **it is necessary** to provide a complete statement of the tested hypothesis (type of hypothesis, clinically significant effect size) and describe the procedure and results of calculating the required sample size. For other study designs, describe the sample size calculation, if any.

**Ethical expert review**

Please provide information on the results of the study protocol review by the ethics committee, with the indication of:

1. the ethics committee official name;
2. conclusion;
3. protocol number;
4. the date of signature.

### Results

Specify total number of study subjects, the size of each group. When describing the prospective study, describe the subject attrition at each study phase (if there was no attrition, specify it). A flowchart of subject selection and follow-up is desirable.

Provide descriptive statistics for each group for all parameters at each study phase. If there were missing data, specify the actual number of measurements.

Provide the results of statistical hypotheses testing (if any). *P*-values must be presented with **three or more decimal places**.

Illustrative (tables, figures) presentation of results is desirable. At the same time, duplication of information in tables and figures in the text is not allowed.

The "Results" section **should** **not** contain discussion of the results, expression of the authors' opinions.

Describe any adverse events that occur during the medical intervention study. Any medical events (diseases, injuries, unplanned surgical interventions, etc.), laboratory and instrumental observations should be considered as adverse, if the association with the medical intervention (preventional, diagnostic, therapeutic, screening) cannot be excluded. The absence of adverse events should also be noted.

### Discussion

**Representativeness of Samples**

Estimate the representativeness of samples to the target populations based on the results of other epidemiological and clinical studies. Explain any specific factors (social, economic, cultural, etc.) that may affect the external validity (generalisability) of the study findings, i.e. the possibility of their extrapolation to the target population (e.g., indicate that the study subjects were recruited only from national level medical center or a private health care center, or that the study subjects recruitment was performed only under polar night conditions, etc.). The main factors that determine low representativeness are: sampling method (non-random selection), sources of cases (single center studies), case inclusion period (short), sample size (small).

**Comparison with other publications**

Consider the results in the context of similar or related studies (with references to them). Describe the advantages and disadvantages of your study compared to others.

**Clinical significance of results**

Assess the clinical significance of the results regardless of their statistical significance.

**Study limitations**

Provide an analysis of factors that may have caused systematic biases and variability of the results and therefore influenced the study findings. Limitations may be attributed to each study phase, from its aim, methods (study conditions, design, sampling method, sample size, intervention, estimation techniques and methods, statistical analysis) and to the interpretation of results (clinical significance of the effect, applicability of study outcomes when changing conditions of use, etc.). Conclude which way the results of the study may be biased due to the limitations of the study.

It is recommended to use the [Catalog of Bias](https://catalogofbias.org/biases/) when describing possible limitations.

**Next studies**

Specify what kind of study you plan or consider to be appropriate next.

### Conclusion

Formulate conclusions briefly and as accurately as possible based on the obtained statistically significant results. Discussion of the results and any speculations should be avoided.

### Additional information

**Funding.** Specify the funding source(-s) for the study (grant, planned R&D, contract with a sponsor, etc.), using the wording: "The study was supported by grant ..." or "The study was carried out with financial support, medical supplies, technical support ..., etc. ...from …"

If the work was performed proactively, without any funding, and was analytical (e.g., analytical work with the use of available sources of information), specify: "No funding."

**Conflict of interest.** Specify the presence of obvious and potential conflicts of interest, i.e. conditions and facts that may influence the study outcomes or their interpretation (e.g., funding from stakeholders and companies, their participation in the discussion of study outcomes, writing a manuscript, etc.). If not available, use the following wording: "The authors declare no obvious and potential conflicts of interest related to the content of this article."

**Contribution of authors**. It is necessary to describe the contribution of each author to the study and preparation of the manuscript, using ICJME criteria for authorship:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

2. Drafting the work or revising it critically for important intellectual content; AND

3. Final approval of the version to be published; AND

4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Each author must meet **all four criteria** for authorship.

A description of the compliance of the contribution with the first and the second criteria of authorship should be presented as follows:

“**Full name of author 1 - contribution of author 1 according to criterion 1, according to criterion 2;**

**Full name of author 2 - contribution of author 2 according to criterion 1, according to criterion 2 ... "**

To confirm the authors' compliance with criteria 3 and 4, it is necessary to specify at the end that

"All of the authors read and approved the final version of the manuscript before publication, agreed to be responsible for all aspects of the work, implying proper examination and resolution of issues relating to the accuracy or integrity of any part of the work".

**Acknowledgment**

Thank those whose contributions to the writing of the manuscript were insufficient to be recognized as authors (e.g., they met only three of the four criteria for authorship), but are still considered significant by authors. Specify what was this person’ impact (advises, technical assistance, translation, etc.)

### ReferenceS

The reference list include publications only (references to Internet resources are also allowed).

References to theses, conference abstracts, textbooks, and anecdotal overviews should be avoided. References to original scientific publications and systematic reviews are desirable.

Self-citation should be avoided unless it is necessary (e.g., if there are no other sources of information, or the present work was performed on the basis of or as a continuation of cited studies). Self-citation should be limited to 3 references.

For details of citing, see [here](https://www.omet-endojournals.ru/index.php/index/pages/view/references/).

### Tables

Tables should have a numbered heading and legible clearly marked columns. The tables’ content should correspond to that in the text, but should not duplicate the information presented in it. References to tables in the text are required. If there are no tables, leave this section blank.

If necessary, add a "**Note**" section under each table and add explanatory information: abbreviations (even if they are presented in text), presentation format, statistical significance tests, etc.)

### Figures

The volume of graphic material is minimal (with the exception of works where this is justified by the nature of the study). Each figure must be with a numbered caption. References to figures in the text are required.

1. **Illustrations** (graphs, diagrams, schematic illustrations, sketches) drawn with MS Office tools should be contrast and clear. Illustrations should be converted in a separate file and saved as an image (in \*.jpeg, \*.bmp, \*.gif format), and then placed in the manuscript file as a fixed figure. It is unacceptable to apply any elements (arrows, captions) over the figure inserted in the manuscript file by means of MS Word due to the risk of their loss at the stages of editing and layout.
2. **Photographs, screenshots** and other non-drawn illustrations should not only be inserted in the text of the manuscript, but also uploaded separately in a special section of the manuscript submission form as \*.jpeg, \*.bmp, \*.gif files (\*.doc and \*.docx - if additional markings are applied to the image). The image resolution should be >300 dpi. The image files should be named according to the number of the figure in the text. The file description should include a separate caption, that should correspond to the name of the photo placed in the text (e.g.: Figure: 1. Louis Pasteur).
3. If a manuscript contains previously published figures (even if their parts have been translated from a foreign language into Russian), the author must provide the editorial office with consent of the copyright holder to publish this image in another journal (with the correct indication of the corresponding journal), otherwise it will be considered plagiarism (see "[Ethics of Scientific Publications](https://www.omet-endojournals.ru/jour/about/editorialPolicies#custom-2)" in detail).

If there are no illustrations for the manuscript, leave this section blank.

### Information about the authors

Information about EVERY AUTHOR should be given as follows:

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