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Authors' guidelines

1. CONDITIONS OF SUBMISSION AND COPYRIGHT ISSUES

I. Manuscripts are considered for publication with the understanding that they do not contain previously published material, have not been published previously and are not currently under review at another journal or elsewhere. **Conference presentations (including summaries, abstracts and posters) and doctoral (PhD) or master (MSc) theses are exempt but should be acknowledged in the title page**.

II. The Authors of manuscripts that include illustrations, tables and/or sections of text that have been published previously elsewhere must request permission to reproduce the material from the copyright holder. This permission must be presented in written form during submission of the manuscript. In the absence of such permission, all material received will be regarded as the Authors' own work.

III. All the manuscripts that do not respect the Authors' Guidelines will be resent to the Author.

IV. Studies must adhere to the ethical standards established in the **The Code of Ethics of the World Medical Association** (**Declaration of Helsinki**) and have to be conducted in accordance with these. Submitted manuscripts should be compatible with the **International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals** and aim for the inclusion of representative human populations (*i.e.*, sex, age and ethnicity) as per those recommendations.

V. All **animal experiments** must follow the **ARRIVE guidelines** and should be conducted in accordance with the **National Research Council's Guide for the Care and Use of Laboratory Animals**. Authors will have to state this in the Ethics paragraph. The sex of animals must be indicated, and where appropriate, the influence (or association) of sex on the results of the study.

VI. For the studies involving patients and animals Authors must indicate **the name of the approving committee and the approval number or code protocol**. Indeed, they must guarantee that the enrolled participants (or who stands in for – *e.g.*, legal guardians, next of kin in case of death, animal owner) signed an informed consent with the awareness of being part of a scientific publication.
Finally, the patients' names or the needless references related to personal aspects or sensitive data that could reveal the identity of a patient must be omitted from the text and all the iconographic materials.

VII. The Publisher's conduct must be in accordance with the **ICMJE recommendations about the responsibilities in the submission and peer-review process**.

VIII. **No fees** are required to submit the manuscripts.
Authors publish **open access** under the terms of the **Creative Commons License**, type **CC BY-NC** (**Creative Commons Attribution-NonCommercial License**).
In order to grant this License, If your paper is accepted, the Author identified as the formal Corresponding Author will receive an email with the Journal Publishing Agreement (as explained in the paragraph 2). The form must be compiled and signed by each Authors of the manuscripts.

2. ONCE A MANUSCRIPT IS ACCEPTED FOR PUBLICATION

I. Each Author must complete and sign a **Conflict of Interests disclosure form**, which specifies all economic, personal and professional relationships that could become a conflict

of interests, that could be perceived as a possible conflict of interests, or that could influence the work of the Author described in the manuscript. All the declarations will appear after the **Acknowledgements** section of the article, in the specific paragraph entitled **Ethics**.

II. Under proofreading before the publication, the Editorial Office will send you the **Conflict of Interests** disclosure form, alongside with the **Journal Publishing Agreement** to the Editorial, which you will return compiled and signed to: **editorialoffice@pharmadvances.com**.

III. The Authors will be held responsible for any false declarations or noncompliance with the instructions specified above.

IV. The Editorial Office reserves the right to reject any manuscript that does not conform to the above-described instructions.

3. SUBMISSION PROCEDURE

To submit the articles each author needs to register at the official platform, available at the following link: https://www.editorialmanager.com/phadv/default1.aspx. It will be possible to upload the manuscript, which must be in Word **format and with the word line numbers** to facilitate the reviewers.

4. PEER-REVIEW TIMING

The Journal is committed to evaluate articles as quickly as possible, while maintaining scientific excellence and rigor. **Expected time to the decision after each (re)submission**: 30 days.

5. PEER-REVIEW PROCEDURE

The decision to publish a manuscript is based on the **peer-revision** and acceptance of an article will be based on criteria of originality, relevance, and scientific content of the contribution. Manuscripts are rapidly, strictly, and fairly peer- reviewed by international experts on our **Board of Reviewing Editors** and other members of the international Scientific Community.
Specifically, *Pharmadvances* applies a **single-blind**, **transparent**, and **constructive review process** in which both the Authors' and the reviewers' identities, gender and affiliations are concealed.
Each manuscript will be thoroughly evaluated by **at least two expert referees** beyond our Editors.
Authors may be requested to modify the text based on the comments of reviewers, to which they should respond point by point.
Statements made in the manuscripts are the responsibility of the Author and not of the Editors. The opinions expressed in the articles are those of the Authors and may not reflect the position of the Editors.

EDITORIAL WORKFLOW		
Steps	**Editorial Office (OE) /Editor in Chief (EIC) /Section Editor (SE)**	**Comments**

1	Author submits paper	Only Word format papers are accepted. **Word line numbers are needed.**
2	EO receives new submission	
3	EO executes Technical Check	
4	EO initiates discussion	
5	EO assigns the manuscript to the EIC. According to the topic, EIC assigns the manuscript to the appropriate SE.	Editors discuss the manuscript and decide on: - Removal (like "Rejection") - Sent back to author: paper returns to author who may revise it and resubmit Assignment: paper will be assigned to an editor
6	The SE decides together with the EIC if the submitted manuscript should be accepted for further revision or rejected.	The assigned SE will then follow the manuscript in the subsequent steps and might require consultation with the EIC or other editorial board members for specific issues
7	SE identifies and invites the reviewers	**2 Reviewers** (default) or more in case assessment requires multiple expertise. 10/15 days to review (original manuscripts)
8	Reviewers send in their comments and recommendation	EO/SE sends reviewers reminders if necessary
9	SE/EO receives reviewer comments	Only assigned editor receives
10	SE makes a recommendation accordingly	SE decides (revise, accept, reject) and shares its decision with the EIC. EO receives notification
11	In case of revision, EO notifies the Authors	
12	In case of revision, Authors submit revised manuscript to EO	Author submits revision (deadline: 10 days default; flexibility depends on the amount of work required to address the editor/reviewer comments)
13	EO assigns manuscript to previous SE	

14	In case of revision, SE sends revised manuscript to the Reviewers (if necessary or requested by Reviewers)	7 days to review (revised manuscripts). Reviewers can see comments from authors
15		Reviewers send their recommendation
16	SE receives recommendation	Only assigned editor receives
17	SE sets a (final) decision	SE decides (revise, accept, reject) and shares its decision with the EIC. EIC confirms.
18	EO notifies the Author	
19	EO sets final disposition	Publishing editor receives manuscript

6. PREPARATION OF THE MANUSCRIPT

6.1 Article types

Article description	Abstract	Word limit	Tables/Figures	References
Research articles Research Articles report on primary research. They must describe significant and original observations. Consideration for publication is based on the article's originality, novelty, and scientific soundness, and the appropriateness of its analysis. The article must be subdivided into the following sections: introduction, materials and methods, results, discussion, conclusions.	Unstructured abstract, max. 350 words.	The text should be 3000-5500 words (8 to 16 typed, double-spaced pages) not including abstract, tables, figures, references.	Min. 4 Max. 6-8	Max. 120-150
Review article Reviews are summaries of recent insights in specific research areas of a topic that has direct relevance in the field. Key aims of Reviews are to provide systematic and substantial coverage of mature subjects, evaluations of progress in specified areas, and/or critical assessments of emerging technologies. They should discuss a topic of current interest, outline current knowledge of the subject, analyze different opinions regarding the problem discussed in a balanced manner, be up to date on the latest data in the literature. Normally these are authored by individuals who have themselves made a significant contribution to the original literature on the topic under review and are acknowledged authorities in the field.	Unstructured abstract, max. 350 words.	The text should be 2000-4000 words not including abstract, tables, figures, references.	A minimum number of 3 display items is required including figures and tables or boxes for important but marginal topics.	Max. 150-180.
Systematic Reviews, Meta-Analysis Please select "Systematic Review" as Category. A systematic review identifies, selects, and gives a critical appraisal of the relevant research to a given issue/question including a structured analyses of the data that are cited in the review.	Unstructured abstract, 250 words max.	The text should be 3500 words maximum, excluding abstract, figure legends and references.	Total of no more than 6 figures and/or tables.	Max. 150. If more, justification should be provided.

Brief reports Brief Reports are short announcements of research results. They must contain data derived from cutting-edge research and be of potential interest to a large proportion of the readership. They are independent, concise reports representing a significant contribution to the field. Such communications should represent complete, original studies and should be arranged in the same way as full-length manuscripts.	Unstructured abstract, max. 200 words.	The text should be limited to 2500 words not including abstract, tables, figures, references.	Max of 2 figures and/or tables (combined total).	Max. 20
Perspectives Perspectives are intended to review concepts in a field of interest to PhAdv based on the writer own assessment. They should provide a new view with the goal of sparking debate and open up future research avenues.	Unstructured abstract, max. 200 words.	The text should be between 2000 and 3500 words not including abstract, tables, figures, references.	A minimum number of 2 display items is required.	Max. 50-100
Opinions Opinions are short articles intended to convey the author's viewpoint: on an issue that is critical to the research community; on the strengths and weaknesses of a hypothesis or scientific theory; on a research study. In the latter cases they should provide constructive criticism and be supported by available evidence. Opinion articles should not contain unpublished or original data.	Unstructured abstract, max. 200 words.	The text should be limited to 2500 words not including abstract, tables, figures, references.	A minimum number of 2 display items is required.	Max. 20
Commentaries A commentary is a thorough analysis referred to a work already published in the field of interest to PhAdv, written to draw attention to its possible impact. They should be written by expert in the field.	No abstract	The text should be between 1500 - 2000 words not including tables, figures, references.	Max of 2 figures and/or tables (combined total).	Max. 20
Meeting Reports	No abstract	The text should be between 2000 and 3500 words not including tables, figures, references.	Max of 2 figures and/or tables (combined total).	Max. 20
Letter to the Editor Letters are encouraged if they directly concern articles recently published in the journal. If accepted, the editors reserve the right to submit such letters to the authors of the articles concerned prior to publication, in order to permit them to respond in the same issue of the journal. In exceptional cases, Letters may also address data published in another journal or general subjects related to matters discussed in the journal.	Unstructured abstract, max. 200 words.	The text should be limited to 2500 words not including abstract, tables, figures, references.	Max of 2 figures and/or tables (combined total).	Max. 20
Editorials Editorials are discussions related to a specific topic, article or issue written by an editor or other member of the publication staff.	No abstract	The text should be between 1500 - 2000 words not including tables, figures, references.	Max of 2 figures and/or tables (combined total).	Max. 20
Interviews These types of articles are usually written by the editors who use a question/answer format to interview leading scientists or eminent characters to provide an authoritative view on a particular aspect related to	No abstract	The text should be limited to 2500 words not including tables, figures, references.	Max of 2 figures and/or tables (combined total).	Max. 20

the field of interest to PHADV .				
Case report Accurate and transparent data collection from episodes of care informs the delivery of high-quality individualized healthcare. Therefore, case reports submitted to *PharmAdvances* should make a contribution to medical knowledge, must have educational value, highlighting the need for a considerable change clinical practice or diagnostic/prognostic approaches. The ones that describe preventive or therapeutic interventions are discouraged, as these generally require stronger evidence. Should adhere to **international case report guidelines** supporting the measurement of: (1) **clinician and patient-assessed outcomes**, (2) effectiveness of **Clinical Practice Guidelines** (CPGs), and (3) **the return on investment** (ROI).	See *PHADV* 's Case report format below	limited to 1500-1800 words	Max of: 1-2 tables and 3 figures..	See *PHADV* 's Case report format below
Clinical Trial Description of the results of interventional studies related to health. They can include pilot studies, safety and efficacy trials, surrogate endpoint studies, and proof-of concept studies. Clinical Trials Articles should have the following format: 1) Abstract, 2) Introduction, 3) Materials and Methods, 4) Results, 5) Discussion.	Abstract with the clinical trial registry number	The text should be limited to 12000 words.	Max. 15 tables and figures.	Max. 120-150

6.2 Adherence to research reporting standards

Pharmadvances encourages authors to make every attempt to adhere to recognized research reporting standards for many study types, such as:

- **CONSORT** for randomized trials
- **STROBE** statement for observational studies
- **PRISMA** guidelines for systematic reviews and meta-analyses Authors are encouraged to refer to and follow available guidelines from **EQUATOR Network** (https://www.equator-network.org).

6.3 Case Report format

i. **Title** – The diagnosis or intervention of primary focus followed by the words "case report".
ii. **Key words** – 2 to 5 key words that identify diagnoses or interventions in this case report (including "case report").
iii. **Abstract** – (unstructured)
iv. **Introduction** – Briefly summarizes why this case is unique and may include medical literature references.
v. **Patient information**:
   - primary concerns and symptoms of the patient.

- Medical, family, and psychosocial history including relevant genetic information.
- Relevant past interventions and their outcomes.
- De-identified patient specific information.

vi. **Clinical findings** – Describe significant physical examination (PE) and important clinical findings.

vii. **Timeline** – Historical and current information from this episode of care organized as a timeline (figure or table).

viii. **Diagnostic assessment**
- Diagnostic methods (PE, laboratory testing, imaging, surveys).
- Diagnostic challenges.
- Diagnosis (including other diagnoses considered).
- Prognostic characteristics when applicable.

ix. **Therapeutic intervention**
- Types of therapeutic intervention (pharmacologic, surgical, preventive). o Administration of therapeutic intervention (dosage, strength, duration).
- Changes in therapeutic interventions with explanations.

x. **Follow-up and outcomes**
- Clinician- and patient-assessed outcomes if available.
- Important follow-up diagnostic and other test results.
- Intervention adherence and tolerability. (How was this assessed?)
- Adverse and unanticipated events.

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xv. **Follow-up and outcomes**

- Clinician- and patient-assessed outcomes if available.
- Important follow-up diagnostic and other test results.
- Intervention adherence and tolerability. (How was this assessed?)
- Adverse and unanticipated events.

xvi. **Discussion**
- Strengths and limitations in your approach to this case.
- Discussion of the relevant medical literature.
- The rationale for your conclusions.
- The primary "take-away" lessons from this case report (without references) in a one paragraph conclusion.

xvii. **Patient perspective** – The patient should share their perspective on the treatment(s) they received.

xviii. **Informed consent** – The patient should give informed consent.

6.4 COVER LETTER

A cover letter must be included with each manuscript submission. It should be concise and explain why the content of the paper is significant, placing the findings in the context of existing work and why it fits the scope of the journal. Confirm that neither the manuscript nor any parts of its content are currently under consideration or published in another journal.

6.5 ESSENTIAL TITLE PAGE INFORMATION

6.5.1 Full title

The title of the manuscript should be concise and specific. Manuscripts must be submitted with both a full title (maximum of 100 characters) and a short running title (maximum of 40 characters), abbreviations are not allowed in the titles.

6.5.2 Author names and affiliations

Authors names should be listed in the following order: First name, middle initial, last name.

Each author should list a department, university, city and country (please avoid writing your academic position such as resident, fellowship, assistant or associate professor). The PubMed/MEDLINE standard format is used for affiliations: complete address information including city, zip code, state/province, country, and all email addresses. At least one author should be designated as corresponding author, and his or her email address and other details should be included at the end of the affiliation section. It is also advisable to indicate the **ORCID identification**.

6.5.3 The name, the affiliation, the e-mail address of the Author responsible for correspondence about the manuscript

At least one Author should be designated as Corresponding Author (identifying the corresponding Author with an asterisk), and his or her email address and other details should be included at the end of the affiliation section. It is also advisable to indicate the ORCID identification. In the case of

joint first Authorship, a footnote should be added to the Author listing, *e.g.*, 'X and Y should be considered joint first Author' or 'X and Y should be considered joint senior Author.

7. MAIN TEXT FILE

The text file should be presented in the following order and be line numbered throughout:

i. **Abstract and key words;**
ii. **Impact statement;**
iii. **Main text;**
iv. **Acknowledgments;**
v. **Compliance with Ethical Standards (see the paragraph below);**
vi. **References;**
vii. **Tables (each table complete with title and footnotes);**
viii. **Figure legends;**
ix. **Appendices (if relevant).**

NOTE: Figures, Tables and supporting information should be supplied as separate files

i. **Abstract and key words**

A concise and factual abstract is required, not exceeding 300 words. The abstract should recapitulate in an abbreviated form the Purpose of the study, Results (along with the main methods used) and Conclusions. Vague, uninformative statements and too basic, general sentences should be avoided. Important terms relevant to the content of the manuscript should be incorporated into the abstract to assist indexers and searchers. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, references should be avoided. Also, non-standard or uncommon abbreviations should be avoided, but if essential they must be defined at their first mention in the abstract itself.

Immediately after the abstract, provide a **maximum of 5 keywords**, avoiding general and plural terms and multiple concepts (avoid, for example, 'and', 'of'). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

ii. **Impact statement**

The impact statement is single sentence (typically 15-30 words) that summarizes the most important finding of the work: it needs to complement (rather than repeat) the title and should avoid acronyms that are not well known to a broad readership.
The style of writing should conform to English usage and syntax. Authors whose mother tongue is not English are urged to have their manuscripts checked for linguistic correctness before submission. Slang, technical jargon, obscure abbreviations and abbreviated phrasing should be avoided.

iii. **Main text**

1) **Introduction**
Should establish the rationale for the research and contain only the essential information and citations.
2) **Materials and methods**
Provide a detailed description of the materials and methodologies used.
Indeed, new sequence information must be deposited to the appropriate database prior to submission of the manuscript.

New high throughput sequencing (HTS) datasets (RNA-seq, ChIP-Seq, degradome analysis…) or other high throughput data must be deposited in public databases such as the GEO database, the NCBI's Sequence Read Archive (SRA), or others.
Clarify all the ethical aspects related to your research (see instructions on the Ethics paragraph below) including availability of data and materials. Copy of all the uncropped original experimental data at publishing resolution must be retained for five years and shown upon request by the journal. Failure to produce such data on request can constitute a reason.

3) **Results**
Present the results of the research clearly and exhaustively. Should give answers to the aim/s aforementioned in the introduction and provide main findings and trends.

4) **Discussion**
Analyze critically the results obtained and their possible translational and clinical implications. Should compare and contrast the results with relevant research, provide possible alternate explanations to interpret the results and include possible limitations and shortcomings. It should make clear whether the hypothesis mentioned in the article is true, false or no conclusions can be derived.

5) **Conclusions**
Present the significance of the results, their potential impact and, if possible, future perspectives.

NOTE: Acronyms, abbreviations, units of measurements
Pharmadvances recognizes the adoption of the **International Systems of Units** (**SI-Units**). Acronyms, abbreviations and units of measurements without a legend and/or incomprehensible are not permitted. When necessary, a list of abbreviations may be inserted after the abstract.

iv. **Acknowledgments**

v. **Compliance with Ethical Standards**
Complete the paragraph with the following items:

1) **Fundings:** in addition to a list of the sources of funding, Authors are also expected to provide the relevant grant numbers, where possible, and list the Authors associated with the specific funding sources.
Authors are also required to state whether the funding sources were involved in study design, data collection and interpretation, or the decision to submit the work for publication.
2) **Conflicts of interests:** Authors must include financial relationships (such as employment, consultancies, stock ownership or options, honoraria, patents, and paid expert testimony), personal, political, intellectual (organizing education) or religious interests, according to the **ICMJE recommendations**. A competing interest should not prevent someone from being listed as an author if they qualify for authorship (see below). If there is doubt about whether interests are relevant or significant, it is prudent to disclose.
Also state if no conflict was present by writing "The Authors have declared no conflict of interests".
3) **Availability of data and material:** each manuscript should provide a standardized format to specify the availability of data underlying the research results of the article.
The statement may refer to original data the research generated or to third-party data, which have been analyzed. The statement should expresses: the means of access, where applicable, providing their link to the data or the required unique identifier. Some examples:

AVAILABILITY OF DATA	STANDARDIZED STATEMENT
Available in a repository accessed with the DOI link.	*The data underlying this article are available in (repository name), at the following link: https://dx.doi.org/[doi]*
Available in a repository accessed using a unique identifier other different from a DOI.	*The data underlying this article are available in (repository name) at the following link: (URL), accessed with a unique identifier, (e.g. deposition number, accession number).*
Incorporated into the article (and its online supplementary material).	*The data underlying this article are available in the article (and in its online supplementary material).*
Cannot be shared for reasons due to ethics and privacy.	*The data underlying this article cannot be shared publicly due to (describe why, e.g. for the privacy of research participants). The data can be shared just before a reasonable request to the corresponding author.*
Available just before a reasonable request.	*The data underlying this article can be shared just before a reasonable request to the corresponding author.*
Owned by a third party.	*The data underlying this article were provided by a third party (specify who/which) under an approrpiate licence or permission. Data can be shared on request to the corresponding author after the permission of the third party.*
Generated at a large-scale facility.	*The data underlying this article were accessed from (indicate the name with the URL and unique identifier for dataset). The derived data generated in this research can be shared after a reasonable request to the corresponding author.*
Derived from a source in the public domain.	*The data underlying this article are available in (repository name), at the following link: https://dx.doi.org/[doi]. The datasets were derived from sources in the public domain: (indicate the list sources, with the URLs).*
Subject to an embargo.	*The data underlying this article are subject to an embargo of (specify the period of embargo). Once the embargo expires the data will be available (specify the availability, e.g. after a reasonable request, etc.).*
No new data associated with this article.	*No new data were generated or analysed in this research.*

4) **Code availability**: indicate if it is applied.
5) **Authors' contribution**: *PharmAdvances* follows the **International Committee of Medical**

Journal Editors which state that, in order to qualify for authorship of a manuscript, the following criteria should be observed:

- ✓ substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work;
- ✓ drafting the work or revising it critically for important intellectual content;
- ✓ provide approval for publication of the content;
- ✓ agree 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.

Contributors who do not meet these criteria, but nonetheless provided important contributions to the final manuscript, should be included in the **acknowledgements** section. The responsibility is related to the author, who will get written approval by persons named in the acknowledgments section.
Manuscripts prepared and written by commercial entities (fake-paper factories, "paper mills") on behalf of researchers listed as authors on the manuscript do not meet *PharmAdvances* policies and will not be considered for publication. *PHADV* will reject suspicious manuscripts before the peer-revision.
All the individual contributions should be specified as an Author Contributions statement, that is mandatory and needed at the time of the submission. It should describe each Authors' tasks.

NOTE: list only 2 initials for each author, without full stops, but separated by commas (*e.g.*, JC, JS). In the case of two authors with the same initials, please use their middle initial to differentiate between them (*e.g.*, REW, RSW) or second letter of the last name (*e.g.*, RWe, RWa).

6) **Ethical approval**

Human studies and subjects

The study must be conducted in accordance with the ethical standards established in **The Code of Ethics of the World Medical Association** (**Declaration of Helsinki**). The manuscript should be compatible with the **Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals** and aim for the inclusion of representative human populations (*i.e.*, sex, age and ethnicity) as per those recommendations.
Authors must provide the name of the approving committee and the approval number or code protocol. Furthermore, they must guarantee that the enrolled participants (or who stands in for – *e.g.*, legal guardians, next of kin in case of death, animal owner) signed an informed consent and that are aware they will be part of a scientific publication. Patients' names and unnecessary references to personal aspects (*e.g.*, occupation, residence) or sensitive data (*e.g.*, political preference, etc.) that could reveal the identity of a patient must be omitted from the text and iconographic materials.

Animal Studies

If experiments have been conducted on animals, the Authors should declare that the study have been conducted in accordance with the **ARRIVE guidelines** and should be carried out in line with the **National Research Council's Guide for the Care and Use of Laboratory Animals**. The sex of animals must be indicated, and where appropriate, the influence (or association) of sex on the results of the study.

NOTE: if some of the Ethics' items are not applied, please, write **N/A**.

Clinical Trials Registration

Pharmadvances follows the **International Committee of Medical Journal Editors (ICMJE)** policy about **Clinical Trial registration** and adopts its definition of clinical trial: "Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration".
PHADV requires the registration of clinical trials in a public registry, before or at the time of first patient enrollment, to be considered for the publication.
The ICMJE allows publicly accessible registration in any registry that is a primary register of the **WHO International Clinical Trials Registry Platform (ICTRP)**, including the minimum acceptable 24-item trial registration dataset or in **ClinicalTrials.gov** (a data provider to the WHO ICTRP).
During the submission, Authors must provide the registration identification number and the URL for the trial's registry. The studies involving applicable clinical trials should be complied with the FDAAA of 2007 and the results should be reported to **clinicaltrials.gov** within 1 year of study completion. Author's results can be shown in clinical trials registries without it being considered previously overlapping or published publication.

Clinical Trial submissions

The quality of data reporting on randomized clinical trials will be evaluated following the rules and checklist of the **CONSORT statement** (**CONSORT 2010 Statement**: Updated Guidelines for Reporting Parallel Group Randomized Trials. Schulz KF, Altman DG, Moher D et al. Ann Intern Med 2010;152: 1-7).
PHADV requires a clear and accurate description of the study design, conduct, and analysis methods used to obtain the results of clinical trials.

Phase I studies

Phase I studies of single agents will be considered only where there are additional translational research components. Instead, where a remarkable response rate was observed, translational research is not required.
Phase I studies of single agents could be considered if they have the following features:

- has compelling preclinical rationale.
- Includes a new drug class that has not been studied before in the phase I. Comprehends pharmacokinetics in order to determine whether potentially therapeutic blood levels have been achieved, based upon preclinical studies.
- Demonstrates tolerability of the drug at the maximum-tolerated dose, preferably associated with inhibition of a relevant pharmacodynamic end point.
- Demonstrates that the drug has entered phase II or III testing, because of its sufficient interest to investigators.
- Derivative phase I studies of the same drug, but now investigated in a different schedule compared to what was previously reported, will receive lower priority.
- Derivative phase I studies of a new drug of the same class as was previously reported, without compelling evidence of novelty compared to what is known

about this drug class, will receive lower priority.

Phase I studies of combination could be considered if they have the following features:

- compelling preclinical rationale for the combination with the inhibition of intersecting pathways.
- Includes novel drug classes that have not been previously combined.
- Comprehends pharmacokinetics in order to determine whether potentially therapeutic blood levels have been achieved for each drug, based upon preclinical studies, and importantly whether an interaction exists between the two agents.
- Demonstrates tolerability for the combination at the maximum-tolerated dose, preferably associated with inhibition of a relevant pharmacodynamic end point.
- Demonstrates that the drug has entered phase II or III testing, because of its sufficient interest to investigators.

Phase II trials

Phase II studies should be considered if they include:

- a clearly expressed definition of the primary end point.
- Hypothesized value of the primary end point that justified the planned sample size.
- Analysis of the weakness or of any comparison to historical controls.

7) Publication Ethics

PHADV's Publication Ethics are in accordance with the **ICMJE Publishing and Editorial issues related to publication in Medical Journals**.

1) ***Plagiarism***

Authors should declare any potentially overlapping publications on submission. Any overlapping publications explicitly identified should be cited.
In case of doubt, the Editors shall require explanations and the full access to the used documents, such as the signed consent forms. The Editors can also proceed with an independent revision of the manuscript to ascertain if the manuscript meets the ethical standards. If any problem emerges, the Authors and the institution where the study was conducted will be consulted and updated about the results of such review. The manuscripts could be rejected in case of serious misconduct.
Furthermore, in case of serious proven misconduct, all Authors of the indict article shall be banned from future publication in PHADV.
A fraudulent article or an article previously published elsewhere could be improperly published. In this case, the article will be retracted. Readers will be informed with a notification on the journal web site, and the Authors' institution will be contacted by Editors and/or the Publisher. In case of publication on indexing systems, every appropriate step to identify the fraudulent article will be undertaken, including adding the word "Retraction" in the title.

2) ***Data falsification and fabrication***

Data falsification means to manipulate data, images, not convenient results, with the intention of giving a false impression, for example increasing the scientific quality of the study.
Any doubt regarding data integrity will be referred to the Editor. The Editor may request the data for inspection or verification. If the original data cannot be provided, the manuscript will be rejected or retracted, depending on the cases.

3) ***Manipulation of images***

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  For example: Bodtger U, Linnegerg A. Remission of allergic rhinitis: An 8-year observational study. J Allergy Clin Immunol 2004;114(6):1384-8.

Books

Name of the author/editor, title, publisher/institution, town where published, first and last page number of the work.

For example: Paupe J, Scheinman P (Eds). Allergologie Pédiatrique. Flammarion, Paris, 1988:pp:324-42.

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For example: The Mouse Tumor Biology Database. Available at

http://tumor.informatics.jax.org/mtbwi/index.do. Accessed May 20, 2013. If an author or group of authors can clearly be associated with a web link, such as for weblogs, then they should be included in the reference.

Article within a journal

Smith JJ. The world of science. Am J Sci 1999;36:234-5.

Article within a journal (no page numbers)

Rohrmann S, Overvad K, Bueno-de-Mesquita HB, Jakobsen MU, Egeberg R, Tjønneland A, et al. Meat consumption and mortality - results from the European Prospective Investigation into Cancer and Nutrition. BMC Medicine 2013;11:63.

Article within a journal by DOI

Slifka MK, Whitton JL. Clinical implications of dysregulated cytokine production. Dig J Mol Med 2000; doi:10.1007/s801090000086.

Article within a journal supplement

Frumin AM, Nussbaum J, Esposito M. Functional asplenia: demonstration of splenic activity by bone marrow scan. Blood 1979;59 Suppl 1:26-32.

Book chapter, or an article within a book

Wyllie AH, Kerr JFR, Currie AR. Cell death: the significance of apoptosis. In: Bourne GH, Danielli JF, Jeon KW, editors. International review of cytology. London: Academic, 1980:pp. 251-306.

Online First chapter in a series (without a volume designation but with a DOI)

Saito Y, Hyuga H. Rate equation approaches to amplification of enantiomeric excess and chiral symmetry breaking. Top Curr Chem. 2007. doi:10.1007/128_2006_108.

Complete book, authored

Blenkinsopp A, Paxton P. Symptoms in the pharmacy: a guide to the management of common illness. 3rd ed. Oxford: Blackwell Science 1998.

Online document

Doe J. Title of subordinate document. In: The dictionary of substances and their effects. Royal Society of Chemistry. 1999. http://www.rsc.org/dose/title of subordinate document. Accessed 15 Jan 1999.

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FTP site

Doe, J: Trivial HTTP, RFC2169. ftp://ftp.isi.edu/in-notes/rfc2169.txt (1999). Accessed 12 Nov 1999.

Organization site

ISSN International Centre: The ISSN register. http://www.issn.org (2006). Accessed 20 Feb 2007.

Dataset with persistent identifier

Zheng L-Y, Guo X-S, He B, Sun L-J, Peng Y, Dong S-S, et al. Genome data from sweet and grain sorghum (Sorghum bicolor). GigaScience Database. 2011. http://dx.doi.org/10.5524/100012.

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