Clinical Trials scope – Blood Journal

Reporting clinical trials in *Blood*

Blood welcomes submission of manuscripts reporting on clinical trials whether phase 1, 2, 3 or 4. Reports should include a full description of the study design, patient population, methodology and conduct, and statistical plan. In all cases, the report will undergo peer review and will be evaluated for technical merit, novelty, clinical and scientific impact, and other measures to determine suitability for publication. Fast-track peer review is offered for clinical trial studies that deserve to be brought out to the public with maximum expediency.

As defined by the International Committee of Medical Journal Editors (ICMJE) (www.ICMJE.org), a clinical trial is 'any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome'.

Blood follows the trial registration policy of the ICMJE and considers only trials that have been registered before submission, and **before the onset of patient enrollment.** Acceptable registries must be ICMJE-approved (see more information in the section below).

For authors reporting phase II and phase III randomized controlled trials it is recommended to consult the CONSORT Statement and Checklist (http://www.equator-network.org/reporting-guidelines/consort-2010-statement-updated-guidelines-for-reporting-parallel-group-randomised-trials/) to facilitate the complete and transparent reporting of trial findings. In addition, including a Patient Flow Diagram in the manuscript is recommended for randomized studies.

Registration number and name of the trial registry must be provided at the end of the article abstract.

Phase 1 studies are welcome in *Blood* provided the results are sufficiently novel, clinically or scientifically significant and of high impact to merit publication in *Blood*. Criteria that may determine suitability for publication include the following:

- First-in-class molecules with important mechanistic information emerging from the study

- Safety information that is novel and important for patient care
- Important dosing, pharmacokinetic or pharmacodynamic information
- Unexpected efficacy for the patient population with a novel agent or a novel combination of agents
- Ground-breaking information about the biology of the disease in question, including biomarker development, or about the mechanistic activity of a particular drug

In all cases, phase 1 studies should have been completed and should have met the objectives based on the planned study design before they can be considered for publication.

Phase 2 studies are acceptable for publication with the following guidelines:

- Results of a completed phase 2 study with proper design and sample size (as delineated in the statistical section) to answer an important clinical or biological question
- An interim analysis may be considered provided this is a planned interim analysis according to the design of the study and the results merit publication. This may include an unexpected or high level of efficacy, important safety information that may impact the use of the agent(s) in question, or important biologic information learned from the study at the time the report is being proposed
- Single-arm, uncontrolled studies can be considered provided the results are significant enough on their own (based on efficacy, safety or translational information). When historical cohorts are used for analysis, the statistical and scientific validity and design of such a comparison should be clearly described.

Phase 3 studies are welcome in *Blood* with the following guidelines:

- The results are presented after completion of the study as planned according to the statistical design of the protocol
- Studies that are terminated early are acceptable for publication if a proper justification is provided for the early termination. Such justification may include a decision by a Data Safety Monitoring Board or regulatory authority. In these cases, this information should be added to the submission to support publication.

- Interim analyses are generally only acceptable when planned according to the statistical design of the trial and provided there is important new information generated that warrants release of early data. Proper description and justification of such scenarios needs to be included, and the report cannot represent only a subset analysis.

Phase 4 studies may be accepted for publication in *Blood* if they meet the following criteria:

- They provide important efficacy and/or safety information and are not merely confirmatory but provide important new insight into the disease and/or the treatment
- They are properly designed and conducted in a prospective manner
- Studies that provide important new data pertaining to survivorship are welcome

Follow-up reports of previously published studies can be submitted to *Blood* when the follow-up report provides additional new information not previously available. This may include the following:

- Significant additional follow-up on a trial of a novel agent or combination of agents where the additional information is valuable to assess issues such as duration of response, survival, safety, etc. For a follow-up report to be acceptable, there has to be either a significant change in the efficacy or safety information, or it has to include clinically relevant prolonged follow-up information regarding response duration or survival as compared to any prior publication.
- Long-term follow-up data that may provide valuable survivorship information (e.g., late complications, long-term survival, etc) or new insights into the disease or the drug(s)

Clinical trial registry

In accordance with the guidelines published by the International Committee of Medical Journal Editors (ICMJE) that all clinical trials be registered in one of five ICMJE-approved public trials registries (i.e., ClinicalTrials.gov, www.actr.org.au, www.ISRCTN.org, www.umin.ac.jp/ctr/index/htm, or www.trialregister.nl). Trials **must be registered at or before the onset of patient enrollment**.

In addition to accepting registration in any of the above five registries, *Blood* will accept registration of clinical trials in any of the primary registers that participate in the WHO International Clinical Trial Registry Platform (ICTRP) or in EudraCT. Registration in a partner register only is insufficient.

The ICMJE and *Blood* implement the WHO definition of clinical trials for all trials that began enrollment on or after **July 1, 2008**. This definition states that a clinical trial is "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."

Following ICMJE, *Blood* will not consider results posted in the same clinical trials registry in which the primary registration resides to be previous publication if the results are presented in the form of a brief, structured (< 500 words) abstract or table.

For more information, see ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals.