Editor's Note ... *Clinical Trial Reports: A New Section*

There is no doubt that much more clinical experimentation in cancer patients occurs than is reported; even well-conceived, well-designed and well-conducted clinical experiments are not reported. Results deemed negative, uninteresting, incomplete, of lower priority, or of less value because the rationale became less attractive over time, and occasionally studies with positive results, are amongst those not reported. All too often our busy schedules keep us from finding the time to get it done and get it done in a timely manner. Unfortunately, the effect is that valuable information is not shared, and undoubtedly, this at some level eventually leads to redundancy, waste, and less optimal patient care.

Enter Clinical Trial Reports, a new section of *The Oncologist* that we hope will provide many of you the ideal venue for reporting clinical trials. While the hope is that clinical studies that would otherwise not be reported will now be published, we also recognize that the easy online format and the rapid publication will prove attractive as an ideal venue to rapidly disseminate information. We welcome all trials and look to have a broad range of clinical trials and results appear in Clinical Trial Reports.

All accepted manuscripts will appear as a one-page extended abstract in the print version of *The Oncologist*, with more detailed data available online. The one-page print version allows for maximum flexibility, with an abstract, a brief discussion, and a figure or table of choice, chosen to capture the salient points of the study. The online database will eventually be searchable, providing access to the extensive archive of reports that will appear in *The Oncologist*. The format accepts data from phase II or III trials; pharmacodynamic or pharmacokinetic trials with fixed dosing are also compatible. Phase I trials should not be published in the abbreviated format of Clinical Trial Reports. We also note that this new section will not preclude publication of full articles on phase II trials of primary interest in their full form in other sections of the Journal.

We have tried, with the help of many, to construct a portal that is welcoming and easy to navigate, and that will not stop you from proceeding because one small item has been omitted. The initial offering has been vetted with the kind patience of those whose work appears in this "inaugural issue," but we consider it a work in progress that will only become better and easier with time.

We hope you will try this format, and we welcome your feedback. Together we can make our efforts at treating cancer even better.

Tito Fojo
Section Editor

Susan Bates
Section Editor

Bruce A. Chabner
Editor-in-Chief

Clinical Trial Reports publishes not only positive phase II trials in brief but also phase II trials that do not have positive therapeutic outcomes but provide valuable insight into pharmacology, drug interactions, and reasons for drug failure. This information should not be lost to the community of investigators and practitioners.

Clinical Trial Reports and all supportive documentation will be published online at <http://clinicaltrialreports.theoncologist.com/reports/>. In these reports, we ask that the sponsor, coordinating site, participating sites, and investigators be clearly identified. Extended abstracts of approximately 400 words and a single salient graphic, such as a table, schema, waterfall plot, image, or graph will also be published in the Journal's print edition. Each abstract should consist of four sections: Background, Methods, Results, and Discussion.

REVIEW PROCESS

Only well-executed studies, as attested by peer review, will be accepted for publication. These manuscripts will be rigorously reviewed by *The Oncologist's* internationally recognized

editorial board (www.TheOncologist.com/misc/edboard.dtl), as well as by ad hoc reviewers with relevant expertise.

The criteria used by reviewers to evaluate the potential value of the study include the number of patients in the study, differences or trends seen in patient subsets, *p*-values, primary outcome(s) of the study, and statistical analyses.

TIME FROM SUBMISSION TO PUBLICATION

Since it is essential that the results of these studies be reviewed and published with dispatch, peer review will be completed within 3 weeks of manuscript receipt. Accepted papers will then be published ahead-of-print online within 2 weeks. Hence, the gestation from manuscript submission to online publication will be approximately 5 weeks.

NOTE: As standard practice, submitting authors will complete a Potential Conflict of Interest and Financial Disclosure.

DISCLAIMER: The redacted online and print version may differ from the full Clinical Trial Report available at <http://clinicaltrialreports.theoncologist.com/reports/>.

INSTRUCTIONS FOR SUBMISSION

We hope you find the process user-friendly. As this is a new process, we anticipate making changes and welcome your feedback.

Some of the pull-down menus must be chosen before you can proceed. Because the goal was to make this as user-friendly as possible, many of these pull-down menus need not be chosen if they do not apply, and you will not be stopped from continuing the submission process. Therefore, please be careful that you do not overlook anything that might be relevant or important.

REPORT OVERVIEW

Please provide all details in this section to properly identify the trial

- Abstract (structured abstracts requested)
- ClinicalTrials.gov identifier
- Sponsor
- Collaborators
- Principal Investigators and co-authors

REPORT INFORMATION

- All are optional pull-down menus, with exception of Additional Details of Endpoints or Study Design.

PATIENT CHARACTERISTICS

- A combination of pull-down menus and fill-ins.

PRIMARY ASSESSMENT METHOD

- A combination of pull-down menus and fill-ins.
- Note: If you choose to have a waterfall plot drawn, it will automatically appear in the Figures/Tables Section, and you will be able to assign it the figure number you choose.

SECONDARY ASSESSMENT METHOD

- To be used for secondary methods such as PSA or CA125 values, secondary imaging methods, or other novel assessments.
- A combination of pull-down menus and fill-ins.

ClinicalTrialReports.TheOncologist.com

ADVERSE EVENTS

- Generally, adverse events occurring in 5%–10% of enrolled patients should be included.
- Enter the number of patients who experienced or did not experience the adverse event, and the program will calculate the percentages in a summary table provided in the report.
- NA/NC: No adverse event or no change from baseline.

PHARMACOKINETICS/PHARMACODYNAMICS

- Report PK/PD information in text box format.

FIGURES/TABLES

- If a waterfall plot was selected in the Primary Assessment Method section, it will appear here.
- Please include, beside the figure, a relevant figure legend.

ASSESSMENT/ANALYSIS/DISCUSSION

- Choose from the pull-down menus to describe whether the study was completed, considered active or inactive, and the investigator's analysis of that assessment.
- Discussion — A brief discussion addresses the findings of the study, shortcomings, if any, and reasons why the results might have been negative, and explores possible next steps regarding how and why this study may be useful to patient care and further research. Include in the discussion a response to this question: "If this could be done over again, would you use the same or different design?" If the trial did not complete planned accrual, a calculation of the statistical power of the incomplete trial to answer the question posed should be provided.
- Key references, defined as those that are essential for the review process or for reader understanding, can be included. References should be in *The Oncologist* format and inserted in the Discussion text box at the end of the brief discussion.