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Guest Editorial

# Analysis and Reporting of Clinical Trials

**Bruce Pihlstrom**
Emeritus, University of Minnesota, Bethesda, Maryland

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The Author Guidelines for the *Journal of Clinical Periodontology* encourage using the CONSORT guidelines for reporting clinical trials (available at: www.consort-statement.org), pre-trial registration in public clinical trials registries, and the inclusion of data from all randomized subjects by using an intention to treat (ITT) analysis. The following letter to the editor from Drs. Van der Weijden and colleagues addresses ITT analysis. This issue has obvious impact on the reporting and publication of clinical trials in general and, specifically on the analysis and reporting of oral health clinical trials. Accordingly, an independent biostatistician from the larger clinical trial research community with experience in oral health clinical trials was asked to comment on this matter. The letter from Dr. Van der Weijden and subsequent commentary from Dr. James Hodges is published for the benefit of the readers of the *Journal of Clinical Periodontology* and for the broader oral health research community.

As stated by Drs. Van der Weijden et al., ''the handling of dropouts, (protocol) adherence, and missing data should be openly described.'' They also state that ''Editors and reviewers should both be critical of the description of these items and unprejudiced to the choice of analysis in the context of obligations set down by GCP.'' However, as Dr. Hodges correctly points out, the burden of proof for using a ''per protocol'' analysis lies with the investigator and he recommends that plans and the rationale for any per-protocol analysis be registered before beginning randomization of subjects in a clinical trial. As stated in its Author Guidelines, the *Journal of Clinical Periodontology* recommends public registration of clinical trials; such registration, including the protocol for statistical analysis, would do much to address the issues raised by Dr. Van Weijden and his colleagues regarding the need to openly disclose the handling of dropouts, protocol adherence, and missing data in reporting clinical trials. Dr. Van der Weijden and colleagues are correct to point these issues out but to avoid any perception of bias, these matters must be addressed and openly disclosed in a public format before beginning the trial, not after the trial is completed.

## References

Hodges, J. S. (2008) Comment: intention-to-treat has implications for study planning and execution, not just subject retention and follow-up. *Journal of Clinical Periodontology* **35**, 683–684.

Van der Weijden, G. A., Rosema, N. A. M., Slot, D. E. & Timmermann, M. (2008) Letter to the editor: ITT in respect to GCP – a matter of diligence. *Journal of Clinical Periodontology* **35**, 681–682.

Address:
*Bruce Pihlstrom*
*Associate Editor*
*Emeritus*
*University of Minnesota*
*Bethesda*
*Maryland*
E-mail: bpihls@umn.edu