sample withdrawal. It might be asked whether the results, following analysis by physicians and statisticians, were the same or different. The publication provided an answer. The results of the ITT analysis and PP analysis were essentially the same.

b. ITT analysis vs. PP analysis – the Sethi study

In a study of bronchitis infections, Sethi et al. (24) used both ITT analysis and PP analysis, and defined the PP population to exclude patients who violated any aspect of the study protocol to a degree that might affect assessment of treatment efficacy. Protocol violations that might affect assessment were determined prior to beginning of study and included violation of exclusion criteria (including age), serious or complicating infection or disease, active alcohol or drug abuse, use of prohibited concomitant medication, compromising adverse event, medication or visit non-compliance, failure to meet the inclusion criterion of acute exacerbations of chronic bronchitis, and an outcome of "unable to determine."

c. ITT analysis vs. PP analysis – the Abrial study

In a study of chemotherapy for breast cancer, Abrial et al. (25) used both ITT analysis and PP analysis. PP analysis was conducted because a large fraction of the study subjects did not receive the entire treatment. Eight subjects, out of 50 subjects, did not receive the entire treatment because of allergy or toxicity. Hence, the clinical results and data from mammograms and ultrasound were calculated on both an ITT basis (50 subjects) and per protocol basis (42 subjects).

Data from per protocol analysis were somewhat more favorable than with ITT analysis. Regarding clinical evaluation of efficacy, complete response was found in 26% of the ITT subjects and in 31% of the PP subjects. Regarding the objective evaluation of efficacy (mammograms), complete response was found in 18% of the ITT subjects, while complete response was found in 21.4% of the per protocol subjects. ITT analysis and PP analysis showed similar efficacy results.

d. ITT analysis vs. PP analysis – the Berthold study

In a study of a natural product tested for lowering cholesterol, Berthold et al. (26) defined the PP population. Patients were classified as non-adherent if they failed to take

[24] Sethi S, Breton J, Wynne B. Efficacy and safety of pharmacokinetically enhanced amoxicillin-clavulanate at 2,000/125 milligrams twice daily for 5 days versus amoxicillin-clavulanate at 875/125 milligrams twice daily for 7 days in the treatment of acute exacerbations of chronic bronchitis. *Antimicrob Agents Chemother.* 2005;49:153–160.

[25] Abrial C, van Praagh I, Delva R, et al. Pathological and clinical response of a primary chemotherapy regimen combining vinorelbine, epirubicin, and paclitaxel as neoadjuvant treatment in patients with operable breast cancer. *The Oncologist*. 2005;10:242–249.

[26] Berthold HK, Unverdorben S, Degenhardt R, Bulitta M, Gouni-Berthold I. Effect of policosanol on lipid levels among patients with hypercholesterolemia or combined hyperlipidemia. *J Am Med Assoc.* 2006;295:2262–2269.