To the Editor: The May 2005 issue of the *Journal of Oncology Practice* contained an article titled “ASCO Clinical Trials Workshop Provides Guidance for Community Practices” and a subsection called “Treating Trials as a Business,” which describes cooperative group trials as “cost neutral.” Unfortunately, when considering clinical trial participation, multiple other expenses, as described below, were excluded from the article.

Cited as an example of cost neutrality was a \$1,500 trial reimbursement, with 42 patients enrolled each year, covering a staff salary of \$50,000 plus \$12,000 in benefits. Additionally, the section titled “Hiring Adequate Staff” mentioned key personnel: oncologist, research nurse or clinical research associate, data manager, and part-time research pharmacist. The formula for staffing is 25 to 30 patients enrolled per full-time employee (FTE) with one more additional FTE for long-term follow up.

The administration of cooperative group trial participation requires oversight and direct participation of the principal investigator; administrative-savvy Web user administration for cooperative group Web site access; Web navigation assistance; human resource management; constant vigilance of ever-changing federal and institutional regulatory standards and documentation of their compliance; computers with Internet access to download continuous reams of protocol updates and significant adverse event (SAE) reports; office supply acquisition and payment; paper copier, fax, long-distance phone access, voicemail, and e-mail; mailing costs and express shipping costs; ambient boxes, dry ice, Department of Transportation (DOT)/ International Air

Transport Association (IATA)—appropriate insulated specimen shipment packages, and DOT/IATA labels; specimen collection and processing, cryotubes, a freezer available for specimen storage/opening/closing/dispensing charges from the investigational pharmacy; duplication of radiation planning films/paperwork, and a freezer for drugs; processing travel reimbursement requests; and more. All of these overhead expenses must either be absorbed by a local sponsoring institution or paid out of the \$1,500-per-patient fee.

Industry-sponsored studies may have higher reimbursement rates as a result of documentation demands, but do often provide study-specific specialized training, fees for patient screening, specimen collection kits (tubes and insulated mailers, appropriately labeled), shipment costs, and direct information to the local study coordinator and their research staff (protocols, updates and case report forms or software). Unlike cooperative group-sponsored trials, industry sponsors do not require research staff to provide constant cyberspace surveillance to identify and download protocol changes, SAE reports, or administrative announcements.

I believe that the conduct of the cooperative group clinical trials can be considered cost neutral only if a local sponsoring institution has absorbed the administrative and regulatory costs and also allocates related professional services (investigational pharmacy, pathology, radiology, etc.) within a supportive infrastructure. Someone must pay for the use of these resources.

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