

## SUMP Studies

By Norman M. Goldfarb

It is common for research sites to conduct studies that were expected to be profitable, but end up being unprofitable. They may also decide to conduct studies with the conscious expectation that they will be unprofitable. Their reasons may include:

- The study supports a mission of the institution such as patient care, advancement of scientific knowledge, or improvement of community health.
- The site anticipates that good performance on an unprofitable study will open doors to future profitable studies.
- The study supports a personal objective of the principal investigator, ranging from the opportunity to co-author an important scientific article to currying favor with a person of influence.

At the end of the year, the research site's financial statements will show a profit or loss based on the aggregate performance of all studies conducted. Unfortunately, the performance of the clinical research unit may be substantially understated because "management" and principal investigators consciously elected to lose money on certain studies. There is nothing wrong with subsidizing clinical research, but the clinical research unit may be penalized for decisions outside its control. In addition, study coordinators and other staff members will have labored on studies that were doomed to failure, hard duty for anyone.

If a research site decides to subsidize unprofitable studies, it should establish policies that govern which studies deserve subsidies, how many studies should be subsidized, and how large the total subsidy should be. Like any other significant business activity, these subsidies can and should be managed. Without a defined budget and established policies, the research site may find itself wasting its scarce resources.

The research site can establish a fund for subsidized unprofitable medical projects ("SUMP"). It can then appoint a committee to manage the fund, allocating its budget to the most-deserving studies and monitoring their performance. The SUMP committee thus takes on the role of "customer," demanding results like any other customer. "Customers" are more likely to receive value for their dollars than "donors" that write blank checks.

With a defined SUMP budget and governing policy, the committee can ask an investigator, for example: "You spent \$50,000 of SUMP funds on your last project with nothing to show for it; why should we trust you with another \$50,000 now?" Or, it can say: "Despite spending only 80% of your \$50,000 SUMP budget, you made major contributions to our mission last year. We invite you to submit a new proposal for this year."

### Author

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or [ngoldfarb@firstclinical.com](mailto:ngoldfarb@firstclinical.com).