

The Division of AIDS of the National Institutes of Health (DAIDS) houses various networks that fund assorted HIV/AIDS-related clinical trials across the world—and is the largest funder of vaccine and other prevention studies in the world.

All of the AIDS-related clinical trial networks funded by DAIDS have time-limited funding from grants, which generally last five years. This year, as part of the ongoing “recompetition” process, DAIDS considered applications from existing and proposed networks, all seeking funding for the next seven years.

The six networks were announced in June and will each address a different priority: vaccines (HVTN); microbicides (MTN); other prevention research (HPTN); maternal, pediatric and adolescents (IMPAACT); strategic initiatives (INSIGHT); and therapeutic clinical trials (ACTG.)

Clinical trial sites and research organizations around the world were able to apply to one or more of these networks, and so could potentially work with multiple networks at the same time doing different types of studies. Under this arrangement, DAIDS—which has its own, increased centralized budget for trials activities—offers a lump sum to a site, which covers core operations for all of the networks that it is working with. Each network then funds the direct protocol and study operations costs for the site. Sites were free to apply to as many networks as they liked, and the networks could approach promising sites as well.

This arrangement is one strategy for realizing the vision of “pluripotent” or multifunctional sites which can do multiple types of research simultaneously or in sequence. It’s a vision that has gained a lot of traction in conference-room conversations about clinical trial-site capacity. In theory, it offers a cost-effective approach to maintaining sites, using trained staff and infrastructure effectively, and ensuring that there is less “down time” between trials.

But how does the reality look on the ground?

As a first step towards answering this question, AVAC spoke to seasoned investigators in South Africa about how their sites are faring under this system.

At press time, most sites were waiting to hear the outcomes of their applications, and most had applied to more than one network, in hopes of broadening from areas of proven experience (be it prevention of mother-to-child transmission, ARV delivery, vaccines or microbicides) into newer activities.

Overall, we heard good news and some cautionary notes. There was broad consensus that multi-tasking was a cost-effective approach, but there was also concern that some essential activities might be under-funded. Most sites also felt that they would need to find additional funding resources for trial-related activities from a limited local and international pool.

Staffing was a major concern. Because staff funding is often related to specific protocols, salaries have to be apportioned across different projects and sometimes even different funders, as no single funder is really prepared

to support entire, long-term staff structures. Instead, they prefer to pay for part of an individual staffer’s time. The result is a juggling act, which can sometimes fall short. One investigator, who, like many interviewed, asked to speak anonymously, said that this could become a “huge problem.” Another site reported losing a fairly senior and experienced investigator as a result.

Another area of concern was capacity development—the catch-all phrase which includes developing, training (and re-training) staff; maintaining and expanding infrastructure; and building and sustaining strong relationships in the community and at multiple levels of government and the media.

Here, too, human resource issues loom large. “Capacity development will need further funding from the outside,” says Glenda Gray of the Perinatal HIV Research Unit at the Chris Hani Baragwanath Hospital in Soweto. “No one is willing to pay to develop scientists or researchers. We will need to be innovative to ensure that capacity development occurs.”

Gita Ramjee of the South African Medical Research Council says that the sites that are best positioned to become multifunctional are ones that already have strong capacity, raising the question of whether and how new, additional capacity can best be developed. “The [DAIDS] funding will be for research within clinical trial sites with trained staff and infrastructure,” she says.

Other areas of concern include long-term and essential issues of social marketing and communication about the site’s activities, HIV research and services such as counseling, testing or treatment. Community mobilization, recruitment and retention are also time- and labor-intensive and can be under-funded through protocol-specific budget lines, as well.

“The big issue is that funding occurs on specific protocols, so money only flows when you are enrolling or have activated a protocol. There is very little money to develop sites’ community relations. Sometimes it can take up to 18 months to get real community buy-in and no one is prepared to pay for the preparations sites need to do before trials are started,” says Gray.

Balanced against these concerns is the over-riding sense that working with the NIH is a truly collaborative exercise, and that there are many benefits—from training opportunities and infrastructure development to information exchange with colleagues in other countries—that come from working within the DAIDS networks.

Given the range of trials that are ongoing or planned for the coming years, it will be critical to build on these strengths and to pay close attention to unmet needs, including ongoing community work, development of new sites, and expanded relationships with existing treatment and care infrastructure. Addressing these issues is critical to making the idea of multifunctional sites a credible and sustainable reality.

“But,” says Gavin Churchyard, a principal investigator at Aurum Health Research, which is working in South Africa’s mining communities, “our complaints are small in comparison to the good work being done with the networks and the NIH. It is mostly a very positive experience.”