

## In this Chapter:

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# Data and Materials

## *A “to do” list for the future*

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Data shape the vaccine science agenda and vice versa. The agenda is framed around hypotheses that guide the samples that are collected and the assays that are conducted. The interpretations assigned to the data that are generated shape the agenda. It’s an intricate cycle that’s influenced by a range of factors—politics, prevailing wisdom, funding, technology and, at almost every turn, the legal and intellectual property frameworks that govern the institutions, trial networks and consortia conducting the research.

It’s been five years since the *AVAC Report* that last analyzed intellectual property (IP) and data and materials management as they relate to AIDS vaccine research. A lot has happened since. For this year’s Report, we have returned to the issue, with a focus on data and materials. Data and materials are the bricks and mortar of research. (For definitions of these terms see p. 38.) With a licensed AIDS vaccine still many years away by almost all estimates, questions about how data are generated, compared, stored and interpreted are of the utmost importance. Based on conversations with a range of stakeholders, review of documents and presentations or discussions at recent conferences and public forums, AVAC believes the field is at a critical juncture, with existing systems that need to be expanded for the field to achieve its next set of goals.

The good news is that there are strong structures to build upon. We heard that access to data is widely regarded as far easier than it had been in the past. There is more collaboration on many levels, facilitated by various consortia that can be used as models going forward.

The Center for HIV/AIDS Vaccine Immunology (CHAVI), Collaboration for AIDS Vaccine Discovery (CAVD), the International AIDS Vaccine Initiative’s (IAVI) Neutralizing Antibody Consortium (NAC), and other entities have made great strides in creating

collaborative, big science-oriented approaches to tackle some of the field’s major scientific questions. Researchers at different institutions are sharing information and ideas in unprecedented ways. Larger quantities of samples than ever before are being collected and mined for clues to guide AIDS vaccine development. On the clinical trials front, first Step and then the Thai Prime-Boost trial yielded surprising, valuable results that underscore the irreplaceable value of human studies in advancing the field.

The fact that progress has been made is no reason for complacency. As important as these advances are, today’s systems for collecting, storing and sharing data are insufficient for some of the goals of upcoming AIDS vaccine research. More can be done to ensure that data from various trials are comparable and to broaden access to data and materials even further.

These steps are critical as the field moves in the direction of an expanded and iterative array of exploratory trials in humans. These trials propose to look at specific scientific questions using particular candidates, without presuming that the candidate would advance for further development. Such trials are often, though not necessarily, small. And the only way for a suite of these trials to be truly useful is if the results across studies are, to some degree, comparable.

As Ron Germain of the US National Institute of Allergy and Infectious Diseases said at an open forum on the Global HIV Vaccine Enterprise Scientific Strategic Plan at the Paris AIDS Vaccine Conference in 2009, “You can have many small trials but unless you know each trial will collect comparable and comprehensive data sets, they will not be comparable and you will not be able to use them as a basis for going forward.” These systems are perhaps even more problematic for larger experimental Phase IIb or proof-of-concept trials.

Improving the current systems for managing data and materials will require some substantial up-front investments in infrastructure and operations management. But over the medium and long term, systems that make data more consistent and widely available will also help the field optimize its resources. “I think at the moment everyone collects and stores data in different ways. It makes it almost impossible for one trial to be compared to another,” said Robin Shattock of St. George’s, University of London, at the same Paris forum. Shattock suggested that one easy way for the field to “do less with more” is to ensure that data are even more comparable and accessible than they have been to date.

Many people we spoke to echoed Shattock and expressed the need for more centralized repositories of data and more transparent and coordinated approaches to data collection and analysis.

We also heard a strong call to address issues of assay selection and comparability and to strive for more globally accessible systems for data storage. A new combined initiative of CHAVI and the CAVD to establish an “HIV vaccine relational dataspace” could help address this. The initiative will allow many databases that contain different types of information (e.g., data on genomics, antibody and cellular responses) to be relationally queried.

Many of these opinions have been voiced in discussions about what belongs in the updated version of the Global HIV Vaccine Enterprise Scientific Strategic Plan (see p. 18). Indeed, the ability of the Enterprise to shape the way the field collects, stores and shares data and materials may be its most important impact in the next few years. At the Paris meeting, HVTN head Larry Corey said, “The original Enterprise article was all about reorganizing what we

do. I think we’ve not done such a great job in that.” Many of the priorities identified below have been noted before and may appear in the next Enterprise plan. This time next year, all Enterprise members—including AVAC—will be responsible to show that we’ve moved from words to action.

### **Broaden, and increase the flexibility of, materials transfer agreements**

When we last explored these topics five years ago, CHAVI, CAVD, IAVI’s NAC and its consortia for vectors and live-attenuated vaccines were just emerging. Today it’s possible to measure how they have moved the field. Although each has a different structure, they share the goal of facilitating collaboration among researchers working in different institutions and disciplines. These consortia have aimed to reduce duplication and harness the power of their membership to gather and analyze data from large numbers of samples. They have prioritized approaches for enhanced comparability. They have resulted in new institutional linkages, such as IAVI’s partnership with the Scripps Research Institute.

Each consortium has Materials Transfer Agreements (MTAs), centralized repositories of specimens and reagents and information-sharing systems that allow rapid dissemination of results to other consortia members. This increases the efficiency with which other scientists can make course corrections or conduct independent analyses. These innovations have slashed through much red tape and legal roadblocks that have stymied inter-institution collaboration in the past.

The discoveries that have emerged from these consortia include CHAVI collaborators’ work on identifying genetic signatures associated with improved control of HIV in acute infection, understanding infection by founder virus and its difference from chronic replicating virus, breakthroughs in identifying novel neutralizing antibodies from IAVI’s NAC collaborators, and CAVD’s work on teasing out critical aspects of humoral and cellular immunity to target in vaccine design.

We looked at the MTAs being used by different consortia. Material requestors must promise to:

- Conduct only non-commercial pure research or research solely focused on HIV and not other diseases (NIH transfers are an exception).
- If commercial use is permitted, prices for products sold in the developing world or where research was conducted must be set at “reasonable”, at cost or cost-plus terms. Given the uncertainty around cost and pricing for hypothetical products, it is difficult to estimate what these would be or whether this condition is useful in guiding decisions about whether a project will be feasible over the long term.
- Abide by consortia restrictions regarding material use and transfer to others.
- If products can be made and sold, negotiate future revenue-sharing with research and trial consortia.

This may involve determining a fixed share of revenue payment.

- Transfer technical knowledge or manufacturing skills to countries that participate in trials, so that products can be locally produced for their populations.

The existing agreements seem to work well enough for scientists within the consortia, but we heard that the process for engagement by outside collaborators is still time-consuming and somewhat “creaky”. Approaches to engaging innovative thinkers outside consortia—and outside the AIDS vaccine field—need to be streamlined through revised, flexible MTAs and other related agreements. There are other models that could be explored, such as California’s

## Intellectual Property and Access: Revisiting our 2005 recommendations

AVAC Report 2005 contained a number of recommendations regarding intellectual property (IP) and access agreements.\* These are reviewed and updated below.

- Develop consortium agreements that appeal to all capable stakeholders including the private sector. The consortia must address: how participants will value, protect or be proportionately rewarded for their existing IP provided to and used by the consortium; and how participants will be allocated rewards for the new IP the consortium creates from its work.

*The private sector is largely missing from consortia efforts including CHAVI, CAVD and IAVI’s initiatives. There is still little in existing IP agreements regarding valuation and allocation of future rewards.*

- Adopt a “Covenant Not to Sue” as a mechanism to reduce preclinical and early-stage research risks from IP uncertainty, while preserving potential economic rewards should the research prove to be successful later. The covenant can also apply to research tools.

*Features of current MTAs used by AIDS vaccine consortia help to serve a similar function as the model covenant that AVAC proposed in 2005, even though that specific model has not been adopted.*

- The US Government should extend its “authorization and consent” language to reduce IP research risks for projects funded by government grants.

*No modifications to government language have been made.*

- Include plans for eventual product access in clinical trials for the participants in AIDS vaccine and other prevention trials.

*Access commitments continue to be determined on a trial-by-trial basis, with differing levels of clarity, ranging from the relatively detailed “road map” generated by the RV144 team in advance of their data analysis, to much more open-ended questions about post-trial access for the microbicide candidate PRO 2000 (see Chapter Four). Much more can be done to ensure that every trial has a clear plan for next steps regarding access for placebo recipients, expanded manufacturing, launch of confirmatory trials, introductory studies and other issues.*

- Set up secure, encrypted, licensed database systems to allow authorized users to share trade secret data under carefully controlled circumstances.

*CHAVI and CAVD have online lists of completed studies and available data. An expanded “bibliography” of similar information should be created. Access could be by application or password-protected.*

\*To read the full article visit [www.avac.org/download/reportarchive](http://www.avac.org/download/reportarchive)

<sup>1</sup> Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Available at URL: <http://www.cirm.ca.gov/Files/Regulations/100604.pdf>

state government-funded stem cell research program, through which biomedical materials are shared without the requisite of consortia membership.<sup>1</sup>

The current MTAs tightly restrict ownership and use of data and materials. Restrictions on non-commercial use specify that the sample and any progeny or derived materials are owned or controlled by the consortium in question and cannot be used for commercial purposes unless specifically negotiated. This restriction may serve to keep the resulting research in line with a public benefit agenda and avoid diversion to non-AIDS-vaccine-related priorities. However, this provision needs to be considered as a potential disincentive to industry and some academic involvement since it leaves great uncertainty as to whether the costs of research could be recouped by selling unrelated products or producing funds for a university transfer office at any later date through multiple use of transfers.

Here are some ways in which MTA conditions of sharing should be more flexible.

- Permit non-AIDS-vaccine-related commercial uses of derived materials, providing that users are first able to meet the consortia's AIDS vaccine-related research directions and that these other uses do not delay or take away any resources from meeting that obligation.
- Produce GMP (Good Manufacturing Practices) lots to share vaccines and reagents more widely.
- For entities that must recoup costs, establish up-front arrangements for revenue-sharing for any of their income related to the materials. Because all of this work is still considered early-stage research and future revenues are speculative, we also believe—as we said back in *AVAC Report 2005*—that valuation of the shares must not be

## I am an advocate because...

**How am I an advocate? After 20 years you think the answer would be simple. I don't speak the "I" any more. After creating an organization, the work is done through a constellation of people. We teach about the cross section of HIV and human rights, engage in prevention research and its implications for women and work with women living with HIV to become part of the leadership.**

**Dazon Dixon Diallo, Founder of Sister Love,  
USA**



overinflated and could adjust only as milestones of success are achieved.

- Specify that a portion of any revenue generated by using a material or sample would be returned to the consortia as a reinvestment in the AIDS vaccine research agenda.

Stakeholders and entities that control data can reserve control over its release to outsiders. CHAVI, for example, has collaborators sign an internal confidentiality agreement that ensures non-disclosure of results discussed within the consortia for up to three years.<sup>2</sup> “That policy was essential for building trust in CHAVI so that we could get out of the traditional mode of not talking to our colleagues and revealing data until the data are published. Now large numbers of scientists working together are being completely open and telling what happened that day in the lab,” says CHAVI head Barton Haynes of Duke University. Ways to structure such policies so that trust gets built and data are released more quickly for legitimate public use should be identified.

The MTA agreements we reviewed set principles that allow commercial use of materials in a future AIDS vaccine in exchange for reasonable but undetermined cost pricing. This is probably as specific as the language needs to be, given the long timeframes for development of products. Specific efficacy trials, like RV144, have gone ahead with more detailed access agreements in place

<sup>2</sup> Quay J. *Intellectual Property and Legal Issues*. CHAVI Annual Meeting 2007. Available at: [https://chavi.org/wysiwyg/downloads/CHAVI\\_Annual\\_Meeting\\_2007\\_legal\\_and\\_IP\\_update.pdf](https://chavi.org/wysiwyg/downloads/CHAVI_Annual_Meeting_2007_legal_and_IP_update.pdf)



### I am an advocate because...

I engage communities in Kisumu, Nyanza province, where the male circumcision clinical trials research went on. They still lack information, but I bring them into the fold through photo documentaries passing on correct knowledge and information on where to seek medical male circumcision services.

**Simon K'Ondiek**, Coordinator, HIV/AIDS Research and Advocacy Programme, Kisumu, Kenya

We have heard positive reviews of the sample sharing arrangements established by Step sponsors (see box, p. 37), which have been adapted for samples owned by the Thai government for RV144 analysis.

To further facilitate exchange of data and

(see Chapter Two). AVAC maintains its strong endorsement of lowest-cost pricing for any vaccine in a low-income country.

### Increase global exchange of samples and reagents

The results from both the Step and RV144 AIDS vaccine trials have reaffirmed the utility of evaluating vaccine candidates in humans. These trial results were not fully predicted by preclinical challenge trials in animals or by Elispot assays measuring interferon-gamma production by vaccine-induced T cells. The unexpected finding, in RV144, of an impact on HIV acquisition by a vaccine that did not induce traditional neutralizing antibodies underscores the need to measure a range of innate, mucosal and non-traditional antibody effects. Some of the assays to measure these parameters exist, others will need to be developed, and still others will need to be standardized and validated. All of this needs to happen at the same time as the clinical trial agenda advances.

While there's scientific merit in an expanded array of exploratory clinical trials, including small Phase I, Phase IIb or trials with adaptive designs, there's also a real risk that these trials won't achieve their own goals if they are conducted in the field's current context. A proliferation of small trials will be greater than the sum of their parts only if the data these trials gather are comparable and, to some extent, accessible to researchers not directly involved in the study or who are working in other, related fields. Confusion surrounding interpretations of data from non-human primate studies is an object lesson in this problem.

samples, centralized "curators" of both samples and data could be established, either as new entities or by giving resources to existing entities such as SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). These entities would serve as single points of contact and would have the resources to manage and honor requests for sophisticated data sets or analyses. Based on our interviews, there can be a bottleneck in obtaining this type of information, even when raw data are more readily available.

Different types of data raise different issues. As discussed at the 2010 Conference on Retroviruses and Opportunistic Infections (CROI), there is no central clearinghouse to share the increasingly large volumes of data from HIV genomics and microarray expression, which examines gene activity. This can impede data analysis. In a discussion of genomics research and HIV at CROI 2010, John Ioannidis of Tufts University, described a recent effort requested by the journal *Nature Genetics* and carried out by various researchers to replicate the results of selected gene-expression studies it had published.<sup>3</sup> More than half the repeated studies yielded results different from the original. In addition, other studies had discrepancies because of differences in the software used to mine the data.

The challenges with genetic data illustrate the complex interplay of technical, institutional, legal and ethical factors affecting many types of information. Compatible computer frameworks are needed to store the data. Institutional agreements are needed to facilitate sharing and comparison. Technical fine-tuning is needed to generate reproducible results. And ethical and legal issues need to be addressed. For example, in the US, a

<sup>3</sup>Ioannidis JPA, et al. Repeatability of published microarray gene expression analyses. *Nat Genet.* 2009 Feb;41(2):149-55. Epub 2008 Jan 28.

## Turning the Page: Engaging new talent in the search for an AIDS vaccine

New minds and new ideas are critical for the future of the AIDS vaccine field. Researchers in the early stages of their careers—e.g., post-doctoral students and clinical instructors—need support and resources to help them establish and advance careers as AIDS vaccine scientists. One recent initiative that aims to provide this support is the Early Stage Investigator Scholar Award (ESI), which is funded by the National Institute of Allergy and Infectious Diseases (NIAID).

The program offers three to eight awards, which include up to US\$450,000 over two years plus mentorship from established researchers working in clinical trials and primate research. Participating organizations include the Center for HIV/AIDS Vaccine Immunology, the HIV Vaccine Trials Network, the

National Center for Research Resources, the Global HIV Vaccine Enterprise and NIAID.

The award program's twin aims are to attract and retain promising early-stage investigators and to foster increased collaboration between clinical and non-human primate scientists working on AIDS vaccine discovery. Integrating the non-human primate and clinical agenda is one of the field's top priorities. The program's strategy of targeting funds to early-stage investigators to engage them in this work should be evaluated over the long term by tracking the career paths of grant recipients. Because evaluating such a program can take time, in the near term its funding should remain in the NIAID AIDS vaccine budget. The model should also be investigated for other key areas.

For more information, visit <http://www.hvtn.org/science/esi.html>.

tribe of Native Americans in Arizona recently won a lawsuit brought against the University of Arizona after genetic samples from the community were mined for information that was beyond the scope of the research project the community had originally agreed to participate in.<sup>4</sup> Questions and controversies like this one are sure to arise again as new technologies or new questions are brought to bear on samples that may have been given for more narrowly specified research projects.

On the data-sharing front, there are emerging approaches in other arenas that could be considered by the AIDS vaccine field. For example, the National Academy of Science and others have started to design a “microbial research commons”.<sup>5</sup> Its features include standardization of data and software, developments in “cloud computing” (internet-based computing that provides a platform for sharing software and other resources on demand)

and governance of clearinghouses that facilitate wide sharing. A similar approach could be used to positive effect in the burgeoning field of HIV genomics as well as for the large sets of other immune function information being generated.

### Develop clear, coordinated plans for data collection and analysis

The data from RV144, though tantalizing, did not establish a correlate of protection or a clear set of criteria for advancing candidates. No one knows which assays will measure the parameters that could turn out to be predictive of benefits. Assays specified at the outset of a protocol may be outmoded by the time the trial is over. Even with all of these caveats, the field can and must do better at developing clear, coordinated plans for sample collection and measurement and data analysis associated with clinical trials.

<sup>4</sup> Designing the Microbial Research Commons: An International Symposium. 2009 Oct 8-9. Available at URL: [http://sites.nationalacademies.org/PGA/brdi/PGA\\_050859](http://sites.nationalacademies.org/PGA/brdi/PGA_050859)

<sup>5</sup> Harmon A. Indian Tribe Wins Fight to Limit Research of its DNA. *New York Times*. 2010 Apr 21. Available at URL: <http://www.nytimes.com/2010/04/22/us/22dna.html>

These could include newer assays for mucosal immunity, signatures of innate protection, cell-killing ability, avidity and other parameters of immune function. The most robust of these assays should be standardized across trial networks, in the way that Elispot for *gag* responses and neutralization assays were several years ago. As one investigator said, “If you don’t believe in [the predictions of a competitor’s] assay you won’t say it’s valid.”

As the field works towards consensus, it should expand the conversation about the strengths and weaknesses of any given assay. Published studies typically have limited discussions of the variability of their assay methods even though they often acknowledge when their scope is limited by alternative biological models or assumptions.

The range of assays that can be conducted is limited by the quantity of samples collected from trial participants. Sample quantity is, in turn, limited by a range of factors including cost, consideration for participants and site collection capabilities.

There will always be limitations, but some of these can be avoided. RV144 is hampered by the small number of biological samples collected during the trial. The initial plans for blood draws were scaled back during the debate over whether the trial should happen at all. The consequences are still felt seven years after the trial started. Trials need to be sufficiently funded to collect the samples needed to optimize scientific discovery. Participants give time, energy, blood and tissue to studies, with the understanding that each trial will be able to answer the questions it has laid out—and to engage unexpected questions that may emerge when the trial is over. The next generation of trials must honor this expectation.

### **Maintain and expand mechanisms to engage and facilitate “smaller science”**

IP and MTA agreements like the ones outlined above may fail to entice innovative participation from smaller entities that need revenue today—not 30 years from now. Private-sector involvement in AIDS vaccine development is still minimal—within and outside the main consortia—and the existing agreements may not be optimal for

engaging smaller biotechs or scientists who are outside the mainstream of AIDS vaccine research. There need to be additional structures in place to nurture and facilitate such “smaller” science. These could include innovation grants and approaches to intellectual property that balance public and private benefit with expanded access to data and materials.

### **Ensure engagement of early-career investigators and explore a consortium specifically for this group**

Access to data determines, and drives, careers. The consortia-based approach to data management and sharing assists young and early-career investigators who need to publish on experiments they have designed and led. Working within a consortium like CHAVI allows young investigators the opportunity to collaborate with more senior scientists outside of their primary institution and to access reagents and materials that might be difficult to obtain otherwise. However, the experiments conducted with these samples may be constrained by the goals of the consortium and/or the scope of the MTAs. Young investigators need access to the samples, reagents, and materials to advance their training, gain recognition and explore their ideas. (Mature investigators do too, but there’s a particular urgency around this when it comes to fostering the next generation of scientists.) Since an effective vaccine is still decades away, the field needs to provide incentives for young scientists to make this their life’s work.

### **KEEP THE BIG PICTURE IN FOCUS**

If the Global HIV Vaccine Enterprise secretariat, or any other entity, takes on key tasks like developing a set of guidelines for sharing data and material, such guidelines are meaningful only if they are followed.

Big-science management and the work of hundreds of investigators and of thousands of participants have advanced our understanding of this virus in ways that could not have been predicted in 1981, when AIDS was first reported. The field requires adjusted ways to produce, control and disseminate the data and materials to finish the work finding an AIDS vaccine. 🧪

## Sharing the Search for Clues: Step and RV144 post-trial analysis

A collaborative effort is swiftly being launched to understand the result of RV144. This effort is modeled directly on the approach taken to understanding the Step result. The Step trial team set up a committee of leading scientists who evaluated requests for samples and also made recommendations about which assays to carry out. After approval and completion of a materials transfer agreement, researchers who hadn't worked on the study had access to data and samples. Each researcher agreed not to share specimens or data, and publication and presentation of data were permitted subject to review by HVTN and Merck, the trial sponsors.

The consensus is that this committee-based approach granted data access to scientists affiliated with big-science consortia and those who were working more independently. With Step, 27 proposals were submitted, of which 19 were approved.

As *AVAC Report* went to press, more than 30 proposals for studies of RV144 samples had been approved. More than 20 institutions and 35 investigators will work on these studies, which were selected in a review process involving topic-specific working groups (humoral and innate immunity, T-cell immunity, host genetics and animal models) and a scientific steering committee, chaired by Barton Haynes of Duke University. To put these proposals into action, 26 MTAs had to be negotiated. These had to be fully compliant with pre-existing agreements between the Thai and US governments. While this process was complex and time consuming, more than 80 percent of the agreements were fully executed within two months. The MTAs were facilitated by the Walter Reed Army Institute for Research and the Henry M. Jackson Foundation for the Advancement of Military Medicine, a non-profit organization that supports the US Military HIV Research Program.

Both the Step and RV144 processes for post-trial analyses appear to be strong models for sharing trial samples and data with researchers not involved in the original trial. It will be important to evaluate these processes in more detail and look for areas that could be improved, such as the scope of researchers engaged in follow-up (in terms of institutional affiliation and area of expertise) and the degree to which sample availability was a limiting factor in approving proposals.

In conversations about Step data analyses, we were told that although scarcity of samples was not a factor in rejecting any proposals, it was a factor in modifying some of the proposals that were approved. However, there were additional samples from participants in other trials of MRK-Ad5, the vaccine tested in Step. There are no other trials of the ALVAC-AIDSVAX combination tested in RV144 so far, so the only available samples are those obtained during the trial—and any potential follow-up studies. When plans for RV144 developed, sample-collection plans were dramatically scaled back so that fewer blood draws were done on participants over the course of the study.

Scaling back sample collection can be a cost-saving measure in the near term. But initial savings can take a long-term toll on efforts to understand a trial result. This isn't an area where future trials should cut corners.

## Data and Materials: Defining the terms

### *What are data and materials?*

Two important US agencies (the National Institutes of Health and the Office of Management and Budget) define “data” as recorded information, regardless of the form or media on which it may be recorded, or as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings.<sup>6,7</sup> Research data consist of a set of numbers or information resulting from measurements or analyses, or of materials such as chemical and biochemical molecules, cells or genetically modified organisms. In the case of genomics, data consist of trillions of bytes located on multiple computer servers that often are not connected to each other. Materials can refer to biological samples, usually blood and blood products or tissue, reagents or standard biological materials against which viruses or vaccines are tested and “progeny” materials that are derived, grown or made from source materials.

### *Who Owns or Controls Data and Materials?*

Ownership of biomedical data and materials is like having title to a house or a car—if you own them legally, you alone control them, which includes having the right to share them with someone else freely, with conditions, or for payment. In biomedical research, responsibility and stewardship for the data and materials also settles on a number of other stakeholders who could be called “co-owners” in the sense that they have control over the data even if they do not hold the title for them. The difference between the legal possessors of data and the individuals or entities who have control over its management is not always clear. Legal distinctions regarding these different types of owners vary from country to country and may be negotiated by agreements specific to a trial or product. Possible “owners” with power to control, either fully (by

permission or assignment) or because they assert ownership rights that others dispute, include:

- The funded grantee to conduct a trial, usually an institution, university, agency or group
- The party that creates or generates data, such as a principal investigator, a team, an individual or a company
- The study sponsor, joint parties such as two governments in RV144 or a sole sponsorship as with Merck in Step
- The supplier of test vaccines, such as Sanofi or VaxGen/Global Solutions for Infectious Diseases
- Funders who pay for all the work or make in-kind contributions such as the NIH, the Thai government, the military or philanthropic foundations
- Participants in a trial who give their samples to be used. Trial coordinators might recoil at the idea that participants may own their samples, the data or rights derived from them, but almost every trial requires an individual’s release of those rights in consent forms. In some countries, such as Brazil, those rights are not transferred.

### *Why might access to data and materials be restricted?*

Access to data and materials may be restricted, withheld or negotiated due to many considerations: best use of resources for science, commercial rewards from future patents, consequences of first publication and analysis of data, effects on individual careers, equity concerns between developed and developing countries or long-term benefits to affected populations. As one person we spoke to said, “People who hold data have an edge in competition.”

<sup>6</sup> U.S. Department of Health & Human Services. NIH Grants Policy Statement. 2003 Dec 1. p. 114. Available at URL: [http://grants1.nih.gov/grants/policy/nihgps\\_2003/](http://grants1.nih.gov/grants/policy/nihgps_2003/)

<sup>7</sup> Office of Management and Budget. Circular A-110. 19 Nov 1993. Further Amended 1999 Sep 30. Available at URL: <http://www.whitehouse.gov/omb/rewrite/circulars/a110/a110.html>