THE CENTERWATCH MONTHLY

December 2008

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Demand for Medical Writing Continues to Rise

Source: CenterWatch estimates 2004, 2008

According to CenterWatch analysis, the medical writing market has more than doubled in size during the past five years, increasing from an estimated $345 million in 2003 to $694 million in 2008.

Medical writers have taken on more responsibility, often performing jobs previously done by statisticians or clinical researchers. They have become an important part of the drug development process.

The medical writing market has grown 15% each year over the past five years, to nearly $700 million, thanks in part to a rise in the volume of work outsourced by drug sponsors hoping to meet regulatory requirements and convert clinical study data into manuscripts for scientific and medical publications.

Demand for medical writing services is rising at a time when many major pharmaceutical companies have cut jobs as part of restructuring plans and when experienced medical writers have left positions in drug companies to work as freelancers. As a result, those doing medical writing on a contract basis, including full-service contract research organizations (CROs), medical communications firms and freelance writers, report strong demand for their services.

As demand for their services continues to grow, medical writers have taken on more responsibility, often performing jobs previously done by statisticians or clinical researchers, and have become an important part of the drug development process.

"Medical writers understand the studies, protocol, data, statistics and what they mean, and are able to interpret the data and write about it in a way that is transparent and easy for anyone who has to review it to understand. Medical writers play a pivotal role in telling the story about a product—if you don't interpret the data and tell the story effectively, you will not secure approval," said Melanie

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Making the Business Case for Accreditation

When the Association for the Accreditation of Human Research Protection Programs (AAHRPP) launched in 2001, its first accredited organizations comprised a few market segments. Today, AAHRPP has accredited 138 parent organizations, representing more than 600 entities from almost every type of human research organization.

As the number of accredited organizations continues to grow, the big question is whether the business benefits of accreditation will continue to grow as well.

When representatives from seven non-profit agencies combined in 2001 to create an accreditation program for human subject research, they faced what some viewed as insurmountable challenges.

First, this new accreditor, the Association for the Accreditation of Human Research Protection Programs (AAHRPP), wasn't the only accreditation option. That same year, the Department of

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Veterans Affairs (VA) and the National Committee for Quality Assurance (NCQA) created an accreditation program for VA hospitals that eventually became the Partnership for Human Research Protection (PHRP). Although backed by leaders from some of the nation's top universities, teaching hospitals, institutional review boards (IRBs) and patient and disease advocacy programs, AAHRPP didn't have the advantages of PHRP's VA contract.

Perhaps of more concern, however, was that accreditation was completely voluntary, so, although most research organizations viewed accreditation as valuable, they weren't required to seek it. The new accreditor faced two big questions: How will two accreditors survive in a relatively small market and will any but the largest, most forward-thinking research organizations invest the time and money needed to achieve accreditation?

Fast forward to today and AAHRPP is not only surviving but thriving. Rather than struggling to prove its viability, AAHRPP is increasingly recognized as the seal of approval in human subject research, and the 2005 dissolution of PHRP has only increased AAHRPP's influence.

When AAHRPP launched, its first accredited organizations comprised several market segments (e.g., teaching hospitals, universities, and IRBs) based on the association's founding members. Today, those markets have expanded and grown to include 138 parent organizations, representing more than 600 entities from almost every type of human research organization.

Universities and Teaching Hospitals

AAHRPP accreditation in academia was a natural fit early on because many of AAHRPP's founding members were leaders of universities, medical schools and teaching hospitals.

Of the 138 AAHRPP-accredited organizations today, 49 are universities. Almost one-third of the country's medical schools and nearly 40% of the clinical research-intensive universities are AAHRPP-accredited, according to AAHRPP president and CEO Marjorie Speers. Based on the number of these organizations that have committed to seeking accreditation in the coming years, Speers estimates that by the end of 2010, almost 80% of eligible universities will have completed the accreditation process.

"If you talk to most universities today, most of them feel the need to get accredited because they see that this is the way of the future and they want to be part of this group. Certainly among the universities, peer pressure is driving this process now as much as anything," Speers explained.

Mid-size universities that conduct behavioral and social science research are among the academic institutions that are now feeling that peer pressure, Speers said. She estimates that there are 300 mid-size universities eligible for accreditation, several of which are already in the process of applying. This segment of academia is expected to be a growth area for AAHRPP, especially as more and more mid-size universities become accredited.

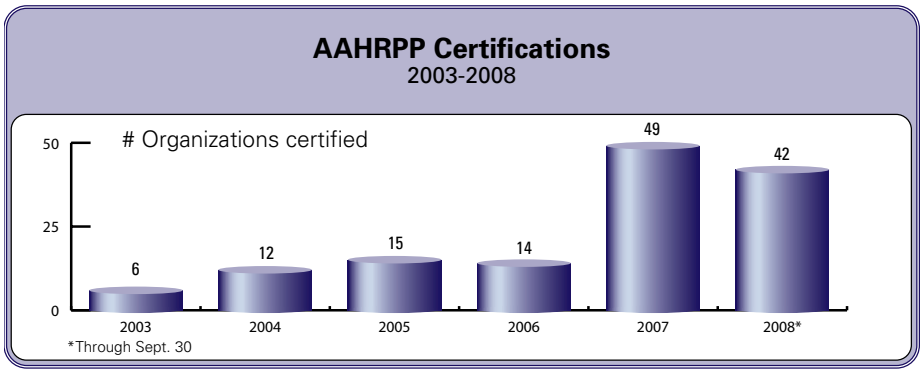
Teaching hospitals earn accreditation in one of two ways: either as part of an affiliation with an accredited university or by seeking accreditation independently. To date, AAHRPP has accredited 16 independent teaching hospitals. When combined with the

AAHRPP Application Fees
Based on annual volume of protocols reviewed

	Active Protocols	2009 Application Fee			Active Protocols	2009 Application Fee
Level 0	*	$6,400		Level 9	3,501 - 4,000	$47,800
Level 1	1-100	$10,200		Level 10	4,001 - 4,500	$52,500
Level 2	101-500	$15,400		Level 11	4,501 - 5,000	$57,200
Level 3	501-1,000	$19,700		Level 12	5,001 - 5,500	$61,500
Level 4	1,001-1,500	$24,400		Level 13	5,501 - 6,000	$66,000
Level 5	1,501 - 2,000	$29,000		Level 14	6,001 - 6,500	$71,000
Level 6	2,001 - 2,500	$33,600		Level 15	6,501 - 7,000	$73,500
Level 7	2,501 - 3,000	$38,500		Level 16	7,001+	$79,500
Level 8	3,001 - 3,500	$43,000				

*Organization that relies entirely on the services of one or more external IRBs that are accredited by AAHRPP. Source: AAHRPP 2008

number of teaching hospitals that are accredited through a university, Speers estimates that AAHRPP has accredited 60% of the hospitals conducting research, and she expects to see that number grow in the future.



Source: Association for the Accreditation of Human Research Protection Programs, 2008

Community Hospitals

Another market in which AAHRPP hopes to grow is community hospitals, which are often smaller and therefore lack the resources necessary to pursue accreditation.

Newton-Wellesley Hospital (NWH) in Newton, Mass., was one of the first community hospitals to seek accreditation, and it was one of the first 14 organizations of any type to be accredited by AAHRPP. Although accreditation was relatively new (especially for smaller community hospitals), NWH executives saw it as a business necessity if they wanted to compete with bigger research programs.

"We wanted to make sure that, as we were growing our program, we were growing it in a way that was going to protect our human subjects," said Hope Violette, manager of NWH's Office of Research. "We wanted to assure ourselves, we wanted to assure our investigators, we wanted to assure our sponsors that even though we aren't large in terms of numbers we certainly have the infrastructure to provide the same protections as a larger program."

NWH's application process took almost 18 months to complete. Much of that time was spent completing AAHRPP's required self-evaluation, a process in which organizations are encouraged to find—and fix—organizational shortcomings.

"We looked for big gaps first, and, once we thought we got some of those things resolved and had systems in place to address those, we went back and went standard by standard by standard through the process," Violette said.

This step-by-step self evaluation (also required as part of AAHRPP's triennial reaccreditation process) is one of accreditation's biggest benefits, Violette said, because it provides organizations with a systematic method for reviewing policies and procedures on a periodic basis—a review that might not otherwise occur if not required by AAHRPP.

Accreditation gives NWH a slight advantage when dealing with clinical trial sponsors, Violette said, an advantage that is especially important as a smaller organization.

"I don't know that we're at the point yet where the sponsors are just going to the accredited organizations and not going to other organizations … But I do know the other way around, when the sponsor comes to us, they are pleased by the fact that we're an accredited organization, and I do think it holds some weight," Violette said.

Independent IRBs

To earn AAHRPP accreditation, a research institution must use only accredited institutional review boards (IRBs) or be able to demonstrate that the IRBs they use meet all the standards of an accredited IRB. This is fairly simple for universities or teaching hospitals, which often have their own IRBs, but independent research sites or contract research organizations (CROs) usually work with numerous independent, or central, IRBs, many of which may not be accredited.

To these organizations, the process of seeking accreditation and switching all their work over to the handful of accredited IRBs may be overwhelming or prohibitive—unless more independent IRBs become accredited. Therefore, increasing the number of accredited independent IRBs was one of AAHRPP's earliest strategic goals.

Speers estimates that there are approximately 35 independent IRBs (a number that she said changes almost daily), nine of which are accredited. AAHRPP's eventual goal is to accredit 80% of the country's independent IRBs.

Wellesley, Mass.-based New England Institutional Review Board (NEIRB) and Columbia, Md.-based Chesapeake Research Review (CRRI) were among the first independent IRBs to be accredited by AAHRPP.

Although only one other IRB (Western IRB in Olympia, Wash.) had achieved AAHRPP accreditation in 2003, the CEO of NEIRB at that time saw accreditation as an opportunity to improve the IRB's processes, said NEIRB director of operations Erin Bowers. A number of programs and procedures now in place at NEIRB resulted from the process of pursuing AAHRPP accreditation.

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"Before 2003, we didn't have a site-visiting program, so if we thought a site was out of compliance, we didn't have any ability to actually go there and see what was going on," Bowers said. "We implemented a nationwide program where we can go check out compliance at sites. That was required for us [by AAHRPP]."

CRRI, accredited in 2004, was one of the only independent IRBs to seek and achieve both AAHRPP and PHRP accreditation. Although a stringent believer in the safety and quality assurance benefits of an accreditation program, CRRI founder and CEO Dr. Felix Kihn-Maung-Gyi said organizations like his have only just begun to see the business benefits of accreditation.

"Whereas five years ago, I think most folks were saying, 'We're not interested because it doesn't translate to increased business opportunities,' I think today they are starting to realize that there may be better business opportunities if they are accredited," Gyi said.

CROs and Private Research Sites

CRRI saw one of those business opportunities come to light in 2006 when it partnered with Montreal-based contract research organization (CRO) ethica Clinical Research to deliver ethics review services to both Canada and the United States.

ethica is the only CRO to be AAHRPP-accredited, but others are going through the application process, according to Speers. AAHRPP's ultimate goal is to have 80% of CROs be accredited.

"If you focus on who in the research enterprise potentially poses the most risk to research subjects—who has the greatest influence over research subjects—it would be independent IRBs because they review so much of the research for industry and it would be CROs because CROs are managing so much of the research."

In September, AAHRPP accredited its first independent investigative research facility, HOPE Research Institute of Arizona. As the first private research site to be accredited, HOPE undertook a challenging year and a half process of documenting procedures and reorganizing relationships with IRBs, according to HOPE's managing partner Patricia Adams.

"We do 40 to 50 trials at any given time, and we were using a number of IRBs that weren't AAHRPP-accredited. We had to evolve our studies and, as we started new studies up, encourage our sponsors to use only accredited IRBs," Adams said.

Speers believes the accreditation process for CROs and independent research facilities will get easier as more organizations go through it and as more independent IRBs achieve accreditation.

Government Agencies

Although the U.S. government doesn't require all human research programs to be accredited, it does require accreditation for all the medical centers within the Department of Veterans Affairs. The dissolution of PHRP opened the door for AAHRPP to move in and accredit those medical centers.

Of the 93 VA medical centers that are separately eligible for accreditation, all have applied and undergone site visits, and, to date, 57 have achieved accreditation. (None have been denied, but some are still undergoing the process.) The National Institutes of

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Level 2	101-500	$6,900		Level 11	4,501 - 5,000	$18,900
Level 3	501-1,000	$8,800		Level 12	5,001 - 5,500	$20,500
Level 4	1,001-1,500	$10,200		Level 13	5,501 - 6,000	$22,000
Level 5	1,501 - 2,000	$11700		Level 14	6,001 - 6,500	$23,500
Level 6	2,001 - 2,500	$13,500		Level 15	6,501 - 7,000	$24,400
Level 7	2,501 - 3,000	$13,800		Level 16	7,001+	$26,000
Level 8	3,001 - 3,500	$14,200				

*Organization that relies entirely on the services of one or more external IRBs that are accredited by AAHRPP. Source: AAHRPP

Health and the Centers for Disease Control, both part of the Department of Health and Human Services, are undergoing the accreditation process now, as are the national laboratories of the Department of Energy (one national laboratory is already accredited).

"The one department that is not accredited is the Department of Defense," Speers said. "We're hoping that they will come on board and seek accreditation over the next couple of years."

Room to Grow

Although Speers is pleased with AAHRPP's progress to date, she says there are still market segments in which to grow.

Opportunities for growth beyond the United States remain to be seen. AAHRPP has accredited one organization each in Canada, Singapore and Korea, and Speers says the association is working in a number of other countries in Asia, Europe and South America.

"With the exception of Canada, the attraction to AAHRPP [for institutions outside the United States] is that AAHRPP accredits a foreign institution according to the U.S. regulations as well as to any in-country code. A number of institutions want to attract industry sponsors to their institution, and AAHRPP is a very good way for them to show that they can meet the U.S. standards for conducting research," Speers said.

One state department of health—in Florida—has achieved AAHRPP accreditation, and Speers sees state government agencies as a critical market for AAHRPP's growth.

"It's important for state health departments to get accredited because they generally perform research on vulnerable populations—people of lower income or lower educational achievement…I think it's really important for state health departments to have good protection programs in place," Speers said.

Another potential market segment for accreditation is sponsors, but pharmaceutical companies have been slow to seek accreditation for their own research. One sponsor is currently in the process of applying for accreditation, Speers said, and she expects to see others.

Industry leaders such as Hope Violette at Newton Wellesley Hospital say sponsors still have much to learn about AAHRPP accreditation and what it really means.

"[Sponsors] don't understand the difference between the whole program is accredited versus just the IRB. Most of them really do believe that it's just your IRB that is accredited and they don't understand the scope of accreditation. We're making progress, but I think we have a ways to go in terms of the sponsors really understanding what that means," she said.

Looking Ahead

Regardless of how many organizations say accreditation is a good idea, the fact remains that it is voluntary and it takes valuable resources. Conducting the initial self-evaluation required to apply for accreditation can take a significant amount of time—anywhere from a few months to two years—and, according to the AAHRPP web site, application fees start at $6,900—a number that goes up depending on the size and complexity of the human research protection program. That price doesn't include the annual accreditation fee that organizations must pay once they are accredited or the time involved in seeking initial accreditation, submitting the required annual reports, and applying for re-accreditation every three years.

"Until we really see a demonstration from the part of the sponsors seeking only accredited organizations, I think smaller research groups are going to have a hard time justifying return on investment based solely on mission and value statements as opposed to true dollars and enhanced revenues. I think that that's where the real crux is: What makes [accreditation] valuable for a small organization other than to have that stamp of good-housekeeping approval?" said CRRI's Gyi.

AAHRPP highlights several benefits to AAHRPP accreditation, including partnership and marketing opportunities, competitive advantages and improved performance in FDA audits, but accredited organizations themselves say they've seen more of the internal benefits of accreditation—benefits that can't always be seen in revenue statements.

As the number of accredited organizations continues to grow, the big question is whether the business benefits of accreditation will continue to grow, as well.

— Molly Rowe