JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 7, No. 3, March 2011 "Can You Handle the Truth?"

Site Profiles

By Shae Owens

If you have ever used a resume or curriculum vitae (CV) in a job search, you understand the advantages of compiling your professional profile in one place. Not only is a resume an efficient way to convey information to other people, it is also an effective memory aid for yourself. In addition, it forces you to think about your strengths and weaknesses, so you can accentuate the positives and address the gaps.

Similarly, a site profile can serve the same functions for a research site. A site profile is useful in marketing, site qualification visits, and getting acquainted with site monitors and other sponsor (and CRO) personnel throughout a study. A site profile can serve as a marketing brochure, but a typical profile will include more information than a brochure. The site's website may include some or all of the information.

Some sponsors — with a bit of persuasion — will accept a site profile as an attachment to a feasibility questionnaire, so it is not necessary to enter the same information over and over and over. Just write in, "See attached." The sponsor benefits by receiving the completed questionnaire faster and gaining more information.

Most sites already have all of the information needed for a site profile at their fingertips. All that's necessary is to compile the information and present it in an attractive format.

A site profile should include the following information:

- **Site Contact Information.** Site name, address, phone number, fax number, and email address. If possible, include a photograph of your facility and/or staff.
- **Research Staff.** List of all staff relevant to research: investigators and their medical specialties; study coordinators; pharmacy staff, etc. Include credentials, certifications, research experience, and contact information for each individual, along with the best times and methods for communication. Supplement the profile with one-page bios, as appropriate.
- **IRB.** Local or central, submission schedule, turnaround times, and contact information
- **Medical Records**. Electronic or paper charts, monitor access, and Part 11 compliance, if applicable
- **EDC Experience.** eCRF systems that can be used with little or no training
- **Pharmacy.** Drug shipment address and storage locations, refrigerator specs, temperature monitoring, hours of operation, security measures
- **Laboratory.** Refrigerator and freezer specs, dry ice availability, centrifuge specs, special equipment, lab accreditations, and staff certifications
- **Facilities.** Exam, treatment and procedure rooms, waiting area and amenities for subjects, and emergency equipment and resources
- **Computers.** System capabilities, Internet bandwidth, security measures
- **Radiology.** Available services and locations
- **Pathology.** Note whether tissue release issues exist
- **Special Capabilities.** Tests, assessments and equipment
- **Records Storage.** Locations, access and security measures

- **Quality Systems.** Standard operating procedures, training programs, internal audits, and CAPA programs
- **Contract Information.** Parties to the agreement, payee and signatories
- **Metrics.** Enrollment, retention, data query rates, FDA inspections and outcomes, and process times (e.g., turnaround on regulatory submissions)
- **Monitor Visits.** Location(s), scheduling preferences, amenities (fax, copier, Internet access, sauna, etc.), travel directions, parking, local lodging, and restaurants

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