Logistics of Performing Clinical Research

AN INTERVIEW WITH MICHELE FORMOSO

When members of a retina practice make the decision to take part in clinical research, there are many considerations involved. Will the research be small investigator-sponsored trials (ISTs)? Will the research involve larger populations, as with studies sponsored by the National Eye Institute (NEI) or industry?

Regardless of the type of research that is being performed, it is important to set up an infrastructure that can support the participating physicians and the patients who volunteer to enroll in clinical research studies. This is often where a clinical research coordinator (CRC) comes in. In Responsible Research: A Guide for Coordinators*, the authors refer to the CRC as the "heart and soul of the research study."*[1]

I recently had the opportunity to speak with Michele Formoso, who is the Retina Research Manager for Mid Atlantic Retina and Wills Eye Institute in Philadelphia, to find out more about how this clinical research site has evolved and is currently run.

– Michael J. Koss, MD, FEBO

Dr. Koss: *When was the retina research center that is now Mid Atlantic Retina and Wills Eye Institute founded, and what was the process?*

Ms. Formoso: Other than homegrown retrospective studies, the first large NEI-funded trial in which we participated was the Early Treatment Diabetic Retinopathy Study (ETDRS), which was conducted in the 1980s. Over time, and as industry interest in the retina field has increased, we have expanded our research unit and our collaborative efforts to advance medicine.

There have been many significant advances in retina that have been a direct result of our participation in pivotal clinical trials. Recently, our patient data and study participation directly led to the approval by the US Food and Drug Administration (FDA) of aflibercept (Eylea, Regeneron) for wet age-related macular degeneration (AMD), ranibizumab (Lucentis, Genentech) for retinal vein occlusions, ranibizumab for diabetic macular edema, ocriplasmin (Jetrea, Thrombogenics) for vitreomacular adhesions, and the Argus prosthetic implant (Second Sight) for retinitis pigmentosa. We are fortunate to be able to offer alternative treatments to our patients and contribute to these advances in medicine.

Dr. Koss: *In what retina studies are Mid Atlantic Retina and Wills Eye Institute currently involved?*

Ms. Formoso: We are currently enrolling patients for several studies for dry AMD, wet AMD, uveitis, central serous chorioretinopathy, Stargardt macular dystrophy, and retinal vein occlusions. We have multiple studies that are no longer enrolling but are under way. Some of these trials are sponsored by Wills Eye Institute or the NEI, but the majority are industry sponsored. The studies with which we are involved include both prospective and retrospective designs. Some of these are surgical, but many are evaluating the efficacy and safety of medical treatments. A full listing and status of our clinical trial participation can be found at: http://www.midatlanticretina.com/research.php.

D. Koss: *What is the enrollment process?*

Ms. Formoso: The screening process starts during a routine visit with a retina specialist, after which, if a patient is identified as a potential candidate, he or she is directly referred to our unit. After the informed consent process, a best-corrected visual acuity measurement and screening tests are performed. Depending on study requirements, tests are ordered and reviewed by our physicians prior to enrollment. Enrollment in studies varies based on protocol requirements. Enrollment may involve a masked and unmasked physician, eligibility determination confirmation from a reading center, coor-

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dination with OR and surgeon, preparation of study drug or product on site or coordinated with a pharmacy or laboratory, and calibration of all devices on site.

Dr. Koss: *How have you seen the studies change over time in your center?*

Ms. Formoso: Because of our infrastructure strength and that of our fellowship program, we are able to perform more ISTs than another smaller practice might be able to. For wet AMD, for example, we are performing our own study that will evaluate alternative optical coherence tomography-guided treatment regimens with aflibercept (ATLAS).

Dr. Koss: *What are challenges of research from the perspective of a CRC?*

Ms. Formoso: From my perspective, it can be challenging to complete all the necessary screening procedures in 1 day, so we often split screening visits to make this easier for patients. Additionally, when there is no available treatment option for a particular disease, patients are often desperate to qualify for a clinical trial, and there is a very high degree of disappointment when they cannot be enrolled. Thus, it is important for everyone involved, including coordinators, technicians, and physicians, to provide realistic expectations from the very beginning during the informed consent process.

Once a patient is enrolled into a study, motivation can be challenging if the patient is not experiencing signs of improvement. In this setting, the coordinator can expedite research visits. Each patient who enrolls in 1 of our studies is assigned a coordinator to facilitate extra visits and efficient data collection. Another point to note is that we thank each patient at the end of every visit. It is important to appreciate a patient's willingness to participate in research.

Dr. Koss: *What are some of the benefits of participating in clinical trials for patients?*

Ms. Formoso: Our patients are often the first to receive promising new treatments that would not otherwise be available outside the clinical trial setting. Participants take pride in helping others by contributing to medical knowledge, or helping to identify possible new treatments.

Dr. Koss: *What are the benefits of participation to a practice?*

Ms. Formoso: There are several, and these are not limited to having access to the newest treatments and being able to contribute to changing and improving the standards of care for retinal disease. Our mission at Mid Atlantic Retina and Wills Eye Institute is to provide the highest quality care for our patients and to discover the next best treatments for all patients with retinal diseases. ■

1. Fedor CA, Cola PA, Pierre C, eds. *Responsible Research: A Guide for Coordinators.* London, UK: Remedica; 2006.

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Michael Koss, MD, FEBO, is currently a visiting researcher with the Doheny Eye Institute of the University of Southern California, where he is primarily investigating the potential of human embryonic stem cell transplantation for the therapy of dry age-related macular degeneration. He may be reached at michael.koss@me.com.