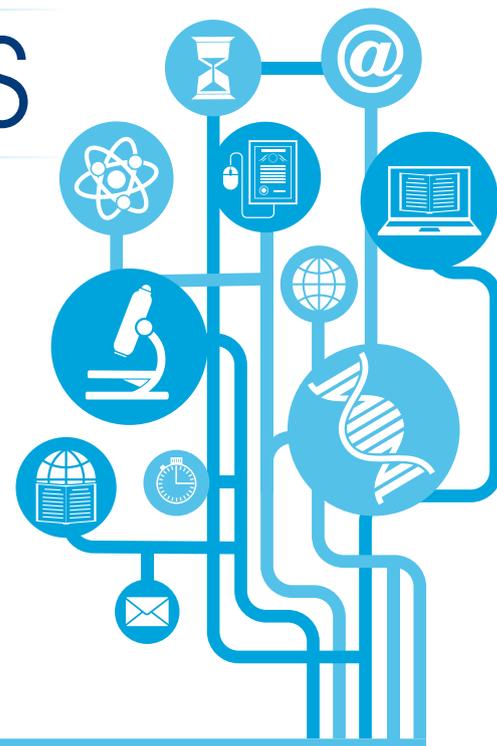


CLINICAL TRIALS

CLINICAL STUDIES IN OCULAR IMAGING

Involvement in diagnostic clinical trials can assist you in bringing a new level of expertise to your staff.

BY RYAN BOUCHARD



In ophthalmology, the area of imaging has continued to develop rapidly, with significant resources focused on bringing more technology to market. From the clinical trial perspective, technological advances can be used to identify a novel endpoint to pair with a new therapeutic or to offer insight into the recruitment of subjects who may benefit the most from the proposed therapy.

In an earlier column, I mentioned the site survey process conducted by sponsors to assess device availability and expertise on behalf of the site's staff in the use of the devices during everyday practice.¹ As technology changes and clinical practices try to adapt, it can be difficult to stay current on the variety of devices and possible techniques used in researching the latest therapeutic advances. In this article, I take a step back and discuss how your potential research site can become involved in another exciting area of investigation that will help bring these concepts to your practice and create new levels of expertise.

DIAGNOSTIC DEVICE CLINICAL TRIALS

The diagnostic device ecosystem continues to face requests for more data on clinical performance in support of US market clearances. Optical coherence tomography devices, new products in corneal biomechanical modeling, and spectral microscopy are some of the areas intersecting with modeling and imaging to provide greater understanding of structural changes in the eye.

Guidance documents and recent approvals in the United States suggest a higher requirement for these products' performance. Larger studies of diverse populations are

“ Sponsors are looking for prospective sites that can dedicate resources and trained staff to consistently perform imaging assessments.”

being considered to judge the effectiveness of new devices. Sponsors are looking for prospective sites that can dedicate resources and staff who are trained in the same manner and who are available to consistently perform imaging assessments. Clinical study designs now focus on eliminating unnecessary variables, such as multiple technicians, to better identify the variability of the devices themselves. Traditionally, these studies have largely been performed in the academic or university research setting, but with the fast pace of innovation, private practice and other multispecialty sites are being considered as well. At Ora, we are always looking for new sites that may be able to offer these characteristics to our sponsors.

ANTERIOR SEGMENT IMAGING

In the anterior segment imaging “revolution,” it will also be important to follow the path of some research in posterior segment imaging with regard to the use of normative databases. Currently, a number of commercially available optical coherence tomography devices include a normative



AT A GLANCE

- Ocular imaging continues to evolve and provide numerous opportunities for additional research by clinicians.
- Staff experience with new imaging techniques should be emphasized on site surveys for potential therapeutic studies.

database as a reference for key ocular structures. Those databases have grown to include more key subgroups (age, ethnicity, and gender, for example), and they now provide a better comparison of individual patients with the general population. As more modalities are explored in the anterior segment arena, a key factor in creating greater clinical utility for the clinician will be the collection of data to help create a similar comparison to the general population. This collection of big data will be critical to the further development of the product category. Opportunities in clinical trials around this area will continue to grow in the coming years.

IMPACT ON SELECTION FOR TRIAL PARTICIPATION

Involvement in diagnostic clinical trials can assist you in bringing a new level of expertise to your staff and an added layer of experience in clinical research that you can speak to on

site surveys. “Tricks of the trade” and the experience gained by staff using the technology while studying hundreds of patients will increase their comfort level with the product. When it comes time for that product to be an important endpoint or to be used in a screening process, you will be able to demonstrate a deep understanding of some of the possible pitfalls and best practices you have developed. This experience speaks to the sponsor during the survey process and onsite visits.

CONCLUSION

Advances in ocular imaging and modeling are taking the industry to the next level. Eye care providers are now able to see different structures with unprecedented precision, transforming the diagnosis and treatment of a number of diseases. Opportunities for clinical practices to get involved earlier in the imaging revolution are numerous, and that experience can be leveraged to allow your participation in other programs. The past few decades have unveiled significant advances in imaging. It seems as though this rapid pace of discovery in ophthalmic imaging devices is only the beginning. ■

1. Bouchard R. The logistics of participating in device clinical trials. *CRST*. 2015;(15)3:80-82. <http://bit.ly/1RSulZT>. Accessed April 7, 2016.

Section Editor Ryan Bouchard

- director of medical devices at Ora
- (978) 332-9574; rbouchard@oraclinical.com