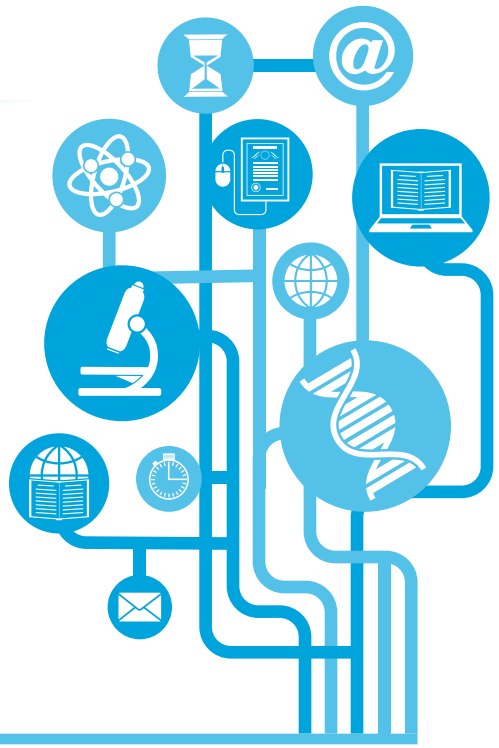
CLINICAL TRIALS



SPEAKING WITH PATIENTS ABOUT PREMIUM IOL CLINICAL TRIALS

Section Editor Ryan Bouchard interviews John Berdahl, MD.

BY RYAN BOUCHARD AND JOHN BERDAHL, MD

The paperwork has been filed, the Institutional Review Board has approved the protocol and study initiation package, you have attended the investigator's meeting, and the study lens inventory is on the shelf in the ambulatory surgical center. Now, it is time to recruit study subjects. What makes the ideal study subject, and how do you speak with him/her about the pros and cons of involvement? I recently sat down John Berdahl, MD, to discuss his thoughts on subject recruitment and some of his tactics on how to approach a potential study participant.
—Ryan Bouchard, section editor

RYAN BOUCHARD: What are the characteristics of an ideal patient for a premium IOL clinical trial?

JOHN BERDAHL, MD: It would be someone who is really interested in the technology but who may not have the means to obtain it. Patients in trials can have access to advanced technologies that they may not have access to otherwise. The challenge is that these studies are controlled, so patients could receive a control IOL; that is therefore a conversation that I always have with the patient. This is a challenge particularly in terms of presbyopia-correcting solutions, because a LASIK enhancement down the road will not correct the patient's vision.

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Many patients, however, find that the potential to receive newer technology and the altruistic angle, that they are helping advance the science, coupled with paying less money, are a good trade-off.

RB: What are some of the benefits to enrolling in a premium IOL clinical trial, and what does that conversation with the patient entail?

JB: First and foremost, I always make it clear to the patient that I am going to do the best thing for his or her eyes and that I would not do anything that I did not think was in his or her best interest. For any given patient, various approaches are reasonable, and the specific choices are based on the patient's visual goals, ocular anatomy and physiology, and psychology. When I talk about the benefits of participating in a clinical trial, I tell patients that they may be receiving a technology that will not be available to

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the general public for a number of years (provided it does indeed receive FDA approval). This idea appeals to many patients. Advances in technology can happen fast, and if people are going to live with an implant in their eyes for decades, getting something earlier than it may otherwise be available can be a real advantage. The next benefit that I talk to patients about is how they are leading a legacy. The lenses that are available in a clinical trial today exist because someone else was in the patient's shoes a decade ago, also in a clinical trial. I talk to patients about how they can be a part of moving science forward. They care about that, and they will appreciate the fact that their contribution makes a meaningful difference to the scientific community.

RB: What might you say to a patient who has reservations about enrolling in a premium IOL clinical trial?

JB: I am candid with my patients in terms of both the pros and cons of enrolling in a clinical trial. As I mentioned previously, I always go over the fact that, if the patient does not receive the study lens, he or she may not have the range of vision associated with that implant. That is probably the biggest sticking point for the patients that I have in clinical trials: they really do not want to be in the control arm. We talk honestly about that, what the chances are of that's happening, and what it means for their quality of vision afterward.

The second thing I talk about in terms of cons is that the technology is not yet FDA approved. I tell them that there are no guarantees, but that, by the time a device is in phase 3, the technology is believed to be very safe. I tell them that, in addition to helping the industry learn more about the safety of the technology, clinical trials also provide information on how effective the technology is. I know that my patients rely on me to help them decide if enrolling in a clinical trial is a risk worth taking, so I am diligent about giving them all of the information they need to make informed decisions.

Although not necessarily a con, the final thing I talk to my patients about is the importance of attending study visits. I emphasize the fact that they need to come back for their follow-up visits, do the appropriate data monitoring, and make sure the lens is functioning properly. Study visits can be time consuming, so I always discuss with the patient the length of the study and the time required.

RB: How do you manage your patients' expectations about clinical trial results?

JB: Generally, what they are most concerned about is how they are doing. That is typically the focus of the conversation and if the patient is happy with his or her results. As human beings, we always want to measure ourselves against other people, and patients are curious about whether or not the device will obtain FDA approval. I tell them that, quite frankly, I do not know. I often say that, regardless of what our experience has been, part of the study design is that numerous trial sites with good surgeons use this technology and all of the data are then pooled for the FDA to review. If it is a technology that I have had positive experience with, I tell patients that I am hopeful that it will get approved so that other people can experience the same benefits.

I have never been part of a trial where there were significant problems associated with the technology, but I think I would talk to the patient about the clinical trial process as whole and let him or her know that we are constantly working to optimize the available technologies to improve the quality of life of our patients.

AT A GLANCE

- An in-depth discussion about participation in a clinical study will improve participants' overall satisfaction with the process.
- Be candid about the time commitment and the need to attend all follow-up visits during the study.
- Access in the practice to the newer technologies can be very beneficial to the right study participant.

CONCLUSION

Involvement in clinical research can help a practice bring new technologies to its patients sooner. It offers the study participants an opportunity to be important members of the clinical product development cycle. In-depth conversations and follow-up early in the process to identify the right study participants can go a long way for participants' overall satisfaction and compliance with the study procedures. ■

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