PEER PERSPECTIVES IN EYECARE · THE ROUNDTABLE

EYEPRENTICE

Why Do the Research?

Four voices on how investigator-initiated trials turn clinical curiosity into a career – and move the field faster than industry can on its own.

William F. Wiley, MD
Medical Director, Cleveland Eye Clinic · Moderator

Nicole R. Fram, MD
Advanced Vision Care, Los Angeles

Robert J. Weinstock, MD
The Eye Institute of West Florida

Diana Pust
Director, Medical Affairs Surgical, Alcon

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Setting the table

The first session of the 2026 Eyeprentice Learning Series opened a four-part arc on clinical research. The premise was deliberately basic – not *how* to run a trial, but *why* a busy surgeon should bother at all. The panel landed quickly on a shared origin story: none of them came out of training wanting to do research.

Wiley: Early in my career I had no interest in research. I just wanted to see patients and do surgery. What changed it was being at a conference, hearing a new lens or laser was coming out, and realizing other docs had early access to the tech and I didn't. I had this jealousy. I'd go to a company and ask to be in the study, and it's an FDA launch, expensive, and they have to trust the investigators. You're just not going to get an FDA study out of the gates.

Fram: Same for me. Research sounded like benchtop and lab coats, very academic, and I just wanted to practice medicine. Then I saw all the innovation happening in ophthalmology and I wanted to be on that leading edge. To get there, research is one of the key things that takes you. You have to start somewhere.

> *You can't speak to a technology with confidence to a patient if you haven't looked at your first fifty cases of it.*
>
> NICOLE R. FRAM, MD

What an IIT actually is

An investigator-initiated trial inverts the FDA model. The investigator – not the manufacturer – is the sponsor.

Fram: It's a study conceived, designed, and led by an independent investigator. You run the show. The company supports you financially, helps you find a statistician, helps make sure data is collected safely. But you come up with the idea, you control the data, you publish it. In an FDA trial the sponsor is the manufacturer, regulatory sets the questions, and the purpose is usually the label. Most of what we do is off-label anyway.

Weinstock: I look at it as two buckets. One is your own idea on your own data – maybe one IOL in one eye, another in the other – that you present at ASCRS or AAO without involving industry at all. The other is partnering with a company on a product they've brought to market, to gather real-world, phase-four data. They can even help you brainstorm and craft it, and give an unrestricted grant that isn't tied to the outcome.

Getting on the radar

Wiley: *Take us through how you actually got into IITs.*

Wiley: Somebody – I think it was Bill Trattler – told me: just start with your own data, do it for free, find something you're curious about. Present twenty eyes at a meeting. Then industry takes note – *we like the trend, do you want to do a hundred-eye study, or pool your data with someone running the same thing?* You have to start with your own data early to get any serious consideration. That sparks the next funded study.

Pust: And enroll quickly. If you underestimate enrollment and someone beats you to it, editors will ask *how is this new?* – and even a great study won't make the highest-impact journal.

4	3	1 yr	6–9 mo
PART SERIES	CLINICIAN INVESTIGATORS	FELLOWSHIP WINDOW	TYPICAL IIT

A real example

Fram: One of my first IITs looked at how OVDs affect intraoperative aberrometry – Bill was part of it. We found viscoadaptive and dispersive OVDs could shift the reading half a diopter to a full diopter in the wrong direction. A simple idea that kept people from picking the wrong lens. That was easy, that was perfect, let's do it again. Most recently Diana and I are running a Unity-versus-Centurion phaco trial – still enrolling.

Building the proposal

Pust: Because Nicole shared the idea, we took it internally, got alignment with the business, and suddenly the topic had funding. Projects start with a concept – hypothesis, primary and secondary endpoints, sample size, rough budget. Run it past a medical-affairs team first; we're clinicians too, so we'll tell you if it'll fly. Then the synopsis is the real work – it's the skeleton of your publication. We think about the ending as the beginning.

> *It is support, not control. The data is the data – if the result disappoints the sponsor, you still publish it.*
>
> THE PANEL, IN AGREEMENT

When the data disappoints

Wiley: *What happens when an IIT doesn't get the outcome the sponsor wanted?*

Pust: Data is the data. Medical affairs is distinct from commercial marketing precisely so we can't be biased. If you found something, you found something – that's your due diligence to patients. It just spurs more questions to discuss.

Fram: I've had studies come back non-inferior – everything performed the same – and that's still useful. "Just as good" is worth publishing. And you design for that honestly: aim for non-inferiority, and if it turns out superior, now you're a hero.

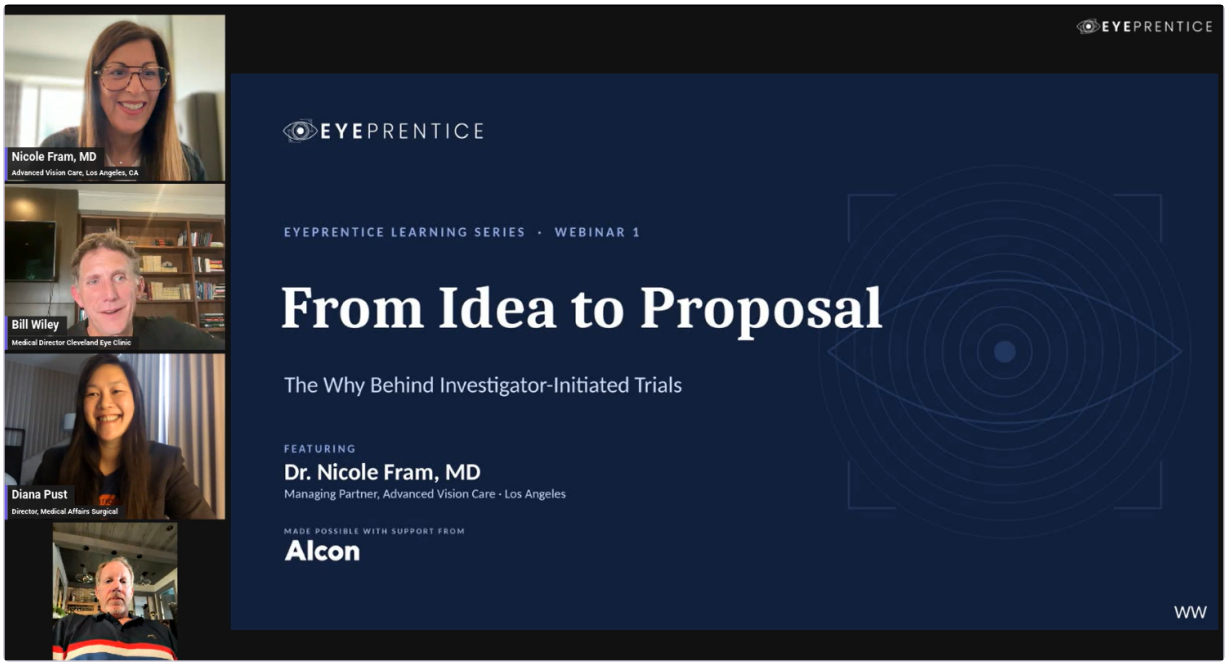
Weinstock: You don't set yourself up for failure. Do a ten-patient pilot on your own dime, see the trend, then design the hundred-patient IIT on top of that and get it funded.

The fellowship window

Weinstock: The fellowship year is a huge opportunity. Your mentor is high-volume and stretched thin – they need help. You're a fresh set of eyes. Go to them and say, *connect me with the MSL from this company, I'd like to put together an IIT.* You submit the practice's data, learn the whole process, and come out of training having already done one. But you have to take the lead – nobody hands it to you.

Three things to take with you

1. **Be curious.** The question is everything – start from a clinical problem you actually care about.
2. **Independence is the point.** You own the design, the data, and the publication; the sponsor supports, it doesn't steer.
3. **Write a proposal they'll fund** – with the help of your MSL and medical-affairs team, not alone.



From the session. *The panel convened live for "From Idea to Proposal," the first webinar of the Eyeprentice Learning Series – featuring Dr. Nicole Fram, with Dr. William Wiley moderating, Dr. Robert Weinstock, and Diana Pust of Alcon. Made possible with support from Alcon.*

About this piece. This Roundtable is an edited synthesis of the Eyeprentice Learning Series webinar "Investigator-Initiated Trials, Part 1: From Idea to Proposal." Remarks have been condensed and lightly edited for clarity from the recorded session; speakers' words are presented in substance as delivered. The webinar was supported by Alcon. Views expressed are those of the individual participants and do not necessarily reflect those of Eyeprentice, Identity Media Group, or Alcon. Faculty affiliations shown are pending final confirmation.