CRITICAL PATH INSTITUTE 20 YEARS OF IMPACT

Advancing Drug Development. Improving Lives. Together.

July 2025

SPOTLIGHT NEWS: eCOA Quarterly Newsletter

Dear Members and Friends:

We are delighted to announce that Veeva Systems and Vector Psychometric Group (VPG) have both joined as members of the eCOA Consortium. We had the pleasure of meeting members of both teams at our 2025 US Face to Face meeting in Rockville, MD, and hope you'll enjoy this New Member Feature with JR Wirth of VPG.

New Member Feature – Vector Psychometric Group (VPG) with RJ Wirth

R. J. Wirth, PhD, CEO

How did VPG come about?

VPG started in 2007. It was originally conceived as a side gig, a way to keep collaborating with friends from graduate school so we could talk about psychometrics, help each other out with small consulting projects, and just pool resources. Early on, we were very fortunate to find collaborators at a large sponsor who were interested in the same things we were, so our first "real" job in industry was developing a large item bank of over 300 items that this sponsor could use in their trials to better understand their products. At the time, FDA had little interest in item response theory or computerized adaptive testing, but the sponsor found the tools extremely useful for their decision making. In fact, I know they are still using those tools today.

What brought you to the world of eCOA?

Funny enough, we started dabbling in eCOA back in 2009 when it was just called ePRO. As I've said many times before, we were young and dumb. We thought if we built a system that was capable of administering measures built on modern measurement theory in a flexible and appropriate way, people would flock to it. We failed to appreciate just how slow this industry is to change. Moreover, we had to learn that just because we had a system that allowed you to administer an assessment using computerized adaptive testing on a Blackberry (yes, I'm that old), a gaming system, or your standard computer, it didn't mean people would use it. Our products could do a lot of advanced things, but they were not the things people needed at the time. Now, after many years of focusing on moving measurement science forward in this industry, we have built a completely new system — one focused on what the industry needs, not just what we think people should use. Although, that's in there as well.

What's a recent project or initiative you've been involved in that you're particularly proud of?

I'll focus on two projects that I am very proud of and that I can actually talk about. First, I'm a co-PI, along with Dr. Richard Lipton, on the FDA-funded MiCOAS grant. This grant was awarded to VPG in 2019, and it focuses on developing a standard set of core endpoints and associated outcome measures for use in migraine clinical trials. It has been wonderful to have the time, resources, and regular FDA interactions to build new tools. We are too often rushed when developing a measure. MiCOAS has been very different in that way. The second is also funded by FDA: the PARCR project. This project is focused on developing and disseminating COA-focused training resources for use both within FDA and for external stakeholders. Members of VPG were asked to serve as subject matter experts on the project. Again, the time and ability to discuss the science underlying COA Guidance with talented researchers, including FDA staff, has been a wonderful experience. PARCR is less than a year old, but we should have some initial papers and training modules coming out in the not-too-distant future.

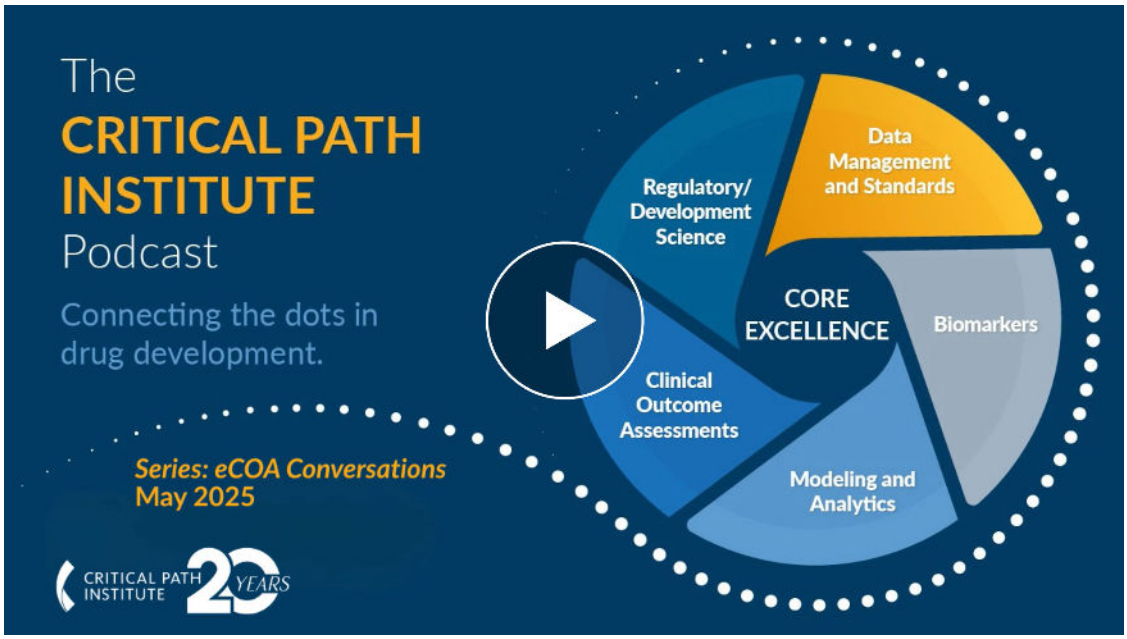
What's one book, podcast, or resource you'd recommend to others in your field?

Anything not work related! I think people spend too much time replying to emails and reviewing reports. It's important for people to step away, relax, and allow themselves a chance to recharge. Overworked people don't do their best work, so to do good work, sometimes you need to not work.

What's one goal you'd like the eCOA Consortium to achieve this year?

Being so new to the Consortium, I'm not sure I know enough to have real goals for the group. For VPG Health, it's already been a very valuable resource. People have been welcoming, and hearing about the successes and challenges facing others in this industry has been invaluable. I'm looking forward to seeing where the Consortium goes and, maybe with a little time, helping us get there.

C-Path Podcast: eCOA Conversations



Listen to the latest Critical Path Institute eCOA *Conversations* series.

This engaging panel features industry veterans reacting to the question, "What makes a good eCOA partner?" In addition to host Scottie Kern, Executive Director of C-Path's eCOA Consortium, this episode's panel includes Dr. Florence Mowlem, PhD, Chief Science Officer at uMotif, YPrime's Vice President of eCOA and Patient Technologies, Dr. Karl McEvoy, and Brian Lillis, Director of Clinical Outcome Technologies at ICON plc.

Each guest shares their unique journey in the eCOA space, their perspectives on the evolving role of technology in clinical trials, and the importance of collaboration between sponsors and providers. The episode explores how meaningful partnerships can drive successful outcomes, enhance the quality of data collection, and ultimately, improve patient experiences in clinical studies. With insights on what constitutes a solid eCOA partnership, the participants discuss trust, transparency, and effective governance structures. The conversation emphasizes that while the challenges of eCOA may seem daunting, a robust public-private partnership grounded in mutual understanding can lead to the successful capture **of trial participant voices in clinical research.**

Listen to the full episode and stay informed on the future of drug development — tune in now: The Critical Path Institute Podcast: eCOA Conversations - YouTube.

Recent Events

2025 eCOA Consortium US Face-to-Face Meeting, Glenview Mansion, Rockville, MD

2025 eCOA Forum, Bethesda North Marriott, Rockville, MD

Upcoming Events

August 12, Virtual eCOA Forum, 12PM US ET, eCOA Data Changes

October 8-9, eCOA Consortium European Face-to-Face Meeting, Dublin, ICON plc HQ

Meet the eCOA Consortium's Industry Co-Director for 2025

What is your core expertise?

Karl McEvoy, PhD
Vice President of eCOA and Patient Technologies

I am a Scientist by training, but I would say eCOA is now my core expertise. In particular I have a focus on the patient centric aspect of what we do, and how eCOA can positively impact how patients interact with Clinical Outcome Assessments within a trial. I've been working with eCOA for about 13 years now and have worked across a variety of indications and diseases. Some of my time was as an eCOA provider, and some as a sponsor. While on the sponsor side, my work was more focused on neuroscience and rare disease.

What is the most rewarding aspect of your job?

I really enjoy the variety day to day, and the ability to meet and work with so many interesting and talented people across the industry. Some indications present more unique opportunities to include patients in the study set up and design, and some patient populations require a different approach. I really enjoy working on those kinds of studies. It's nice to be a part of the drug development lifecycle, even in a small way. In my time as a scientist, my focus was Microbiology and Neuroscience. During my PhD. I was doing research into novel therapeutics against Prion diseases, so while I am no longer based in a lab, it's nice to be part of the process of helping to get drugs to patients with unmet medical needs.

Why is collaboration within the eCOA Consortium important?

I think it's vital. It helps to ensure that despite potential competition between companies, we can still work together to make the industry better. Also, to align best practices and new ways of working, and hopefully show those new to eCOA that there is more to it than just adding technology to a study. There is a science behind it, and the consortium is a

great place to examine what we need to change or do better to improve and support data collection in clinical trials.

What do you want the eCOA Consortium to achieve?

I would like us to get to a place where eCOA is used in every trial without a second thought! I'd like the consortium to be a big part of that, by being a forum for discussion, a place where industry leaders can collaborate, pose questions, and create guidance and new ways to work that help to showcase just how important eCOA is in helping sponsors to collect endpoint data. We are already a great place to go for guidance, webinars, and information on eCOA related content. But I think we can continue to build on this and continue to be thought leaders for the industry.

If you weren't working in eCOA, what career path would you choose?

If I wasn't in eCOA, I'd probably still be in the laboratory and working in drug development. But if I left science completely, I would be a carpenter! I love to build things in my spare time and usually have some kind of project going.

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eCOA Educational Series

Up next: August 4, 2025 | eCOA Exchange #5: Combining sensor-based measurement with patient-recorded data | 9:00-10:25 AM ET. Register here.

On demand: eCOA Exchange #4: eCOA: The COA Measure Owner's Perspective

This eCOA Exchange presented the perspective of COA Measure Owners on the acquisition of licenses to use COA measures electronically in clinical trials and highlighted C-Path's plans to help reduce the friction of eCOA licensing across all stakeholders. Listen to the recording here.

Project Spotlight: Measure Owners Forum

Licensing of COA measures for electronic use has been a perennial point of friction in clinical trial execution, and a pre-competitive, multi-stakeholder effort was considered necessary to address these points of friction. In addition, several C-Path-led projects and forums reinforced the need to engage with a collective of COA Measure Owners (MOs) to discuss challenges and opportunities around eCOA licensing and develop a mutual understanding of the divergence of approaches, requirements and expectations of COA-MOs.

Who or what is a COA Measure Owner?

We needed a term that captured the wide range of individuals and entities that own some aspect of a COA measure's intellectual property. We proposed the term ***Measure Owner***, and define it as:

Any entity that either develops, holds the copyright for or manages the licensing of clinical outcome assessment measures and/or their translations for use in medical product development.

A group of SMEs within eCOA Consortium met in January 2024 to explore how we could potentially convene a COA Measure Owners Forum (COA-MOF). A Steering Committee was formed in February 2024 that incorporated sponsor representation from PRO Consortium.

Objectives

- Identify and engage with a diverse range of COA-MOs
- Convene a series of multistakeholder group meetings to explore pre-identified themes collectively
- Examine published best practices and recommendations and assess their utility
- Identify the additional resources or activities required to further develop the efficiency of eCOA licensing and implementation

Status

Having completed the first wave of COA-MO recruitment, a questionnaire has been issued to all candidate MOs to help prioritize the topics of most interest; example topics include measure of version control, libraries, and license agreements. The Steering Committee will use the results to shape the first wave of COA-MOF meetings which we hope will begin in Q4 2025. Updates will be provided via the normal consortia channels, and a newsletter distributed to both participating COA-MOs and potential new MO recruits.

Upcoming Projects:

eCOA Basics

eCOA Basics is a series of educational videos created by members of the eCOA Consortium. Videos will be topic-specific, less than 10 minutes long, and the product of collaboration between at least two member firms. The videos and associated assets will be published online by C-Path. Topics cover a wide range of eCOA fundamentals such as "What is eCOA" and "Electronic vs Paper" to "eCOA data changes", and "Incorporating sensor-based digital health technologies".

Volunteers are still needed for many categories. Reach out to Alisa Heinzman for additional details.

Recent Publications

Clinical and Translational Science, November 3 | Implementing sensor-based digital health technologies in clinical trials: Key considerations from the eCOA Consortium.

Elena S. Izmailova, Danielle Middleton, Reem Yunis, Julia Lakeland, Kristen Sowalsky, Julia Kling, Alison Ritchie, Christine C. Guo, Bill Byrom, Scottie Kern

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eCOA Connect Reminder

CONNECT WITH US

Have you "connected" with us yet? The eCOA Consortium's LinkedIn Group, *C-Path's eCOA Consortium: eCOA CONNECT!* All eCOA Consortium members and industry colleagues operating in the eCOA space are welcome to join and drive the discussion.

Click here to access the LinkedIn Group.

Member Firm Listing

Help support our mission. **MAKE A GIFT TODAY**

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