



Pediatric
Dermatology
Research
Alliance

Helping children with skin diseases through collaborative research

8365 Keystone Crossing, Suite 107, Indianapolis, IN 46240 | 317-202-0224 | pedraresearch.org

PeDRA CO-CHAIRS

Lawrence Eichenfield, MD

University of California, San Diego
Rady Children's Hospital, San Diego

Amy Paller, MS, MD

Northwestern University Feinberg
School of Medicine, Chicago
Ann & Robert H. Lurie Children's
Hospital of Chicago

PeDRA EXECUTIVE COMMITTEE

Anna Bruckner, MD

University of Colorado
School of Medicine
Children's Hospital Colorado

Ilona Frieden, MD

University of California,
San Francisco
Benioff Children's Hospital

Moise Levy, MD

Dell Children's Medical Center
Dell Medical School, University
of Texas, Austin

Kimberly Morel, MD

Columbia University
Morgan Stanley Children's
Hospital of
New York-Presbyterian

Dawn Siegel, MD

Medical College of Wisconsin
Children's Hospital of Wisconsin

Jeffrey Sugarman MD, PhD

University of California,
San Francisco

Guidelines for Industry

FAQs

June 2015

Background

Launched in 2012, PeDRA is a young but rapidly growing organization, run by leading dermatologists from the U.S. and Canada who give of their time and are active on PeDRA's working committees and Study Groups. Currently, more than 200 investigators and sixty-eight American and Canadian institutions are represented in the Alliance. PeDRA is the research arm of the Society for Pediatric Dermatology (SPD), which has supported PeDRA since inception with generous seed money.

PeDRA goals

The PeDRA **mission**: To promote and facilitate high quality collaborative clinical, translational, educational, and basic science research in pediatric dermatology.

The PeDRA **vision**: To create sustainable collaborative research networks to better understand, prevent, treat and cure dermatologic diseases in children

A highly motivated organization, PeDRA is building a network of pediatric specialists poised to participate in studies and investigations of all types. We bring together scientists with shared interests for investigator-initiated research, and provide a network of eager clinicians who can join forces with scientists to better understand pediatric disease and find new treatments. PeDRA, and the research it fosters, will bring industry closer to new market opportunities while also moving toward potential solutions for children living with underserved, yet demanding and burdensome, dermatology diseases.

PeDRA's success will bring tangible benefits to the field of pediatric dermatology, physicians, patients and industry partners by expanding the scope of research efforts in a variety of important ways. These include training younger physicians in patient-oriented research and inspiring them to see the promise of our research endeavors. PeDRA provides a ready network of both early-career and senior investigators, thus creating an organization capable of responding to new research initiatives and advances in the field.

Industry engagement in PeDRA

Several pharmaceutical and biomedical companies have supported PeDRA's early capacity building and the cadre of companies now interested in PeDRA is growing. To further clarify ways in which industry can affiliate, support, and interact with PeDRA, following are responses to frequently asked questions:

How can industry develop trials & data via the PeDRA network?

PeDRA is a network that exists to augment collaborative research that in turn will generate solutions to meet our young patients' needs. PeDRA investigators, many of whom are clinicians, know their patients and understand the urgent needs of these children. To a large extent, this foundational knowledge has shaped PeDRA's research agenda.

In this orientation, we know there is a clear overlap of interests with companies that are also working to advance new solutions for patients. We want to support and reinforce industry efforts that yield new clinical trials. More than any other clinical or research sector, we pediatric dermatologists in PeDRA understand the inherent challenges in recruiting and managing pediatric subjects for trials and want to see the evolution of successful trials that will bring new answers for patients.

That said, PeDRA stays focused on its prime mission as a research collaborative, serving as a clearinghouse to interest its investigators in participating in new industry trials. This role will be especially important to industry when attempting to fill trials for the rare pediatric dermatology diseases. Through engagement of its members, PeDRA can work with industry to develop and accomplish translational research, assess biomarkers, refine outcomes measures, and assist in bringing the highest impact and value to clinical studies. In the future, PeDRA may consider developing a clinical trials network as an adjunct entity. If so, we will engage our industry partners in informing the development of this trials network to ensure optimal collaboration and effectiveness.

How can industry access the PeDRA network to find investigators for clinical trials?

PeDRA leadership is available to our industry sponsors to discuss the optimal way of informing our network about pending trials and identifying sites that would be best suited for each study. PeDRA will manage assistance in finding investigators on a case-by-case basis, in some instances sending messages out to our network, in others recommending to companies specific communication strategies for reaching investigators. The PeDRA membership list is not available to industry.

For the future, we are considering a portal on the PeDRA website for industry to log upcoming trials and related announcements. For now, just contact Sheila Rittenberg, Acting Executive Director, when you would like to engage PeDRA in your clinical trial plans: sheila.rittenberg@gmail.com, 503-381-5950.



Is it possible for industry to negotiate one agreement for all PeDRA-affiliated sites engaged in a trial?

As a research network, rather than a clinical trial network, PeDRA can't promise "one stop shopping" that would involve one central study coordinator. Depending on the nature of the trials in question, PeDRA may be able to facilitate collaboration among investigators that will ease the negotiation process for industry developing trial sites. The PeDRA Study Group structure (see Addendum) will lend itself as a natural fit for this type of collaboration.

Will there be a fee for industry to access PeDRA's investigator or research outcomes database?

PeDRA is being developed as a research entity to help patients and not as a resource for data purchase. As noted above, the PeDRA membership list is not available to industry. However, we understand that industry sponsors are our partners and will work with you on a case-by-case basis to identify investigators and/or data sets you may require. For industry sponsors, there is no fee for this service. It is as yet undecided if PeDRA will make this type of service available to non-sponsors and, if so, the fee that would be enacted for this service.

How will the PeDRA website interface with industry clinical trials?

There is currently no interface for industry trials on the PeDRA website. However, as noted earlier, PeDRA will be considering this new role in the near future. We welcome industry's perspective on the features such an interface should have in order to be most effective and helpful. Just contact Sheila Rittenberg, sheila.rittenberg@gmail.com.

Will PeDRA have registries that industry can access?

We anticipate that some registries will be created. They are likely to be focused on less common diseases, or less common subsets of common diseases, that without collaborative efforts, would be far more difficult to study. We expect this registry focus to generate a high yield in terms of importance in the field. Industry input will be helpful in focusing these efforts in ways that will help direct further research and clinical trials.

Can industry help with data analysis of PeDRA research?

We anticipate that partnerships with industry for data analysis could occur. PeDRA recognizes that industry is often well endowed in data analysis resources. As the PeDRA network begins to generate data



from its current research projects, we will assess how we can bring industry into this part of the process. This collaboration would have to be defined but we recognize that it is an excellent opportunity for partnership. Similarly, we will provide mechanisms for industry to share its data with PeDRA as this reciprocity can only serve to better support goals for improved patient care.

What are the mechanisms for industry to help define areas of focus for PeDRA's collaborative projects? Can industry be a part of study design?

PeDRA welcomes industry's input on priority areas of research focus. There are a few mechanisms to make your views known: The *Hour for Industry* event is designed exactly for this purpose, and has produced rich input for PeDRA leadership to consider in shaping the Alliance's research and advocacy focus. Your company may want a more focused discussion than the *Hour for Industry* group format provides. PeDRA leaders are always open to holding a teleconference for a focused discussion. Also, we meet with our industry sponsors formally at the winter AAD Annual Meeting, and can find more informal avenues for discussion at various other dermatology events that PeDRA leaders attend. Just make your interests known to Sheila Rittenberg, sheila.rittenberg@gmail.com.

Can industry collaborate with PeDRA on goals for a company's specific studies?

Yes. PeDRA is available to help industry maximize the goals of specific studies. This may involve PeDRA providing input on feasibility and methodology of translational studies, guidance on how to improve study protocols, recruitment methods, or logistical necessities, or define outcome measures. Whether through engaging PeDRA Study Groups or individuals in PeDRA, we can advise industry on specific study design. Similarly, we can open appropriate avenues via the PeDRA Study Groups or Executive Committee for vetting of new study ideas on the part of industry.

Can industry funds be used to support specific research projects?

This has not yet been decided. PeDRA as an organization is in early formative years and we need to focus on broad capacity building that can in turn enable much of the important expansion necessary to be an effective research network. We rely on industry funds in part to fuel this important growth. There may be future avenues for directing some of these funds to specific projects but we are not currently at that point.

We know that most companies have "Investigator Initiated Studies" or similar as a funding vehicle. We will be encouraging our study groups to apply for these grants as appropriate.



Is there a way for industry to learn more about dermatologists' attitudes, beliefs and recommendations?

Certainly industry can learn about dermatologist behavior and attitudes as they work with PeDRA investigators in clinical trials, for guidance on study design, etc. However, PeDRA's focus is patient-centered research so we would not be engaging in surveys of this nature.

Can industry participate in the PeDRA Annual Conference?

Since PeDRA is still involved in determining many of the fundamentals of the Alliance, we have decided to continue to limit attendance for the 2015 Annual Conference to PeDRA investigators and to selected representatives of patient advocacy groups. We will be developing a policy for the 2016 meeting and anticipate that industry will have a role in that conference and beyond. To help us understand what is important to you in terms of conference participation, or other ideas for engagement there, please contact Sheila Rittenberg, sheila.rittenberg@gmail.com.

