

# Current Perspective

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## All About Trust

On September 20, *The New York Times* and ProPublica broke a story about Memorial Sloan Kettering Cancer Center (MSKCC) and its health care data start-up Paige.AI. They detailed how the start-up company had exclusive access to MSKCC tissue resources and that 3 board members and 3 key executives were investors or had equity stakes. This all came on the heels of an investigation into drug industry ties of its chief medical officer (who then resigned). Questions were also raised about using individual identifiable information about patients and physicians without their knowledge. MSKCC in response noted the expense and risk of an enterprise with the potential to change the future of cancer diagnosis. Overall, the report stimulated questions about transparency, optics, and conflicts of interest.

The American Academy of Ophthalmology adheres to a robust set of policies that govern our approach to financial (and nonfinancial) conflicts of interest. These can be found on [aao.org](http://aao.org) and include our internal policies, policies of the Accreditation Council for Continuing Medical Education, and those from the Council of Medical Specialty Societies' Code for Interactions With Companies (which I helped write). Their collective objective is not to eliminate all potential conflicts, but to create a path for disclosure and management, recusal when appropriate, and elimination where necessary. It is meant to give members, and the public, trust in the transparency and integrity of the Academy.

### The IRIS Registry

In the aftermath of the MSKCC debacle, I received questions about the relationship between the Academy IRIS (Intelligent Research in Sight) clinical registry data and Verana Health, the for-profit company to which the Academy has licensed commercialization of IRIS Registry data. Here are the facts.

As you are probably aware, health-related data has significant potential commercial value. One company in the oncology space, Flatiron Health, sold last year for over \$2 billion. Several companies have been founded by Academy members to monetize various subsets of clinical data.

Each Academy member whose electronic health record (EHR) system is integrated with the IRIS Registry has signed an agreement that permits data to be used—but only if it is

stripped of patient and physician identifiers when used for commercial purposes. Further, it can be used for analysis only if it is aggregated with other data to further preclude discovery of personal identification. Additionally, the data can be used only for projects that are scientifically valid and consistent with the Academy's mission.

It became obvious that there was commercial appetite for the data. Accordingly, the Academy decided in 2016 to market some IRIS-derived data to pharmaceutical and device companies under carefully controlled circumstances. I won't go into great detail as to the review and control processes, but suffice it to say that they were drafted by task forces of Academy members, subjected to legal review, and then approved by the Board of Trustees. A Research and Analytics Committee composed of Academy members provided ongoing oversight.

However, marketing data was not the "core business" of the Academy, and the Board concluded that the Academy either had to find a commercialization partner or develop a commercialization arm. At the same time, the need to commercialize the data became critical. Early in the development of the IRIS Registry, we decided to offer it at no cost as a member benefit—which was unusual in the registry space. However, the IRIS Registry's operating costs, due to its size and complexity, grew to exceed \$5 million per year. This meant that to sustain the IRIS Registry, the Academy either had to charge its members or find a revenue stream to offset part of that cost.

### Choosing a Partner

We therefore looked for a partner organization that (at a minimum) fulfilled the following characteristics:

1. Expertise in the health data space
2. Strong technology team



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3. Access to substantive investment capital
4. Knowledge of ophthalmology
5. Expertise with for-profit/nonprofit partnerships
6. Reputation for operational integrity

The Academy found this partner in DigiSight Technologies, a Silicon Valley–based company cofounded by ophthalmologist Mark Blumenkranz. After nearly 6 months of negotiations and constant review by the Board of Trustees, general counsel, outside legal counsel, and extramural advisors, the Board approved licensing commercialization of the IRIS Registry to DigiSight Technologies in early November 2017.

Here are some of the basic terms of that agreement. The Academy continues to own the IRIS Registry. It licenses commercialization to DigiSight. The Academy nominates a member to the DigiSight board. DigiSight is bound to the same restrictions regarding de-identified and aggregated data as is the Academy. The Academy has considerable influence (and at times absolute authority) over many elements of the commercial transactions. In return, the IRIS Registry’s operating costs were reduced by 80%, and there is downstream revenue potential. Overall, the final document runs 70 pages. There were weeks when I spent over 20 hours in document review and negotiation.

**Benefits.** What do the Academy and its members get out of this? First and foremost, it helps to ensure the sustainability of the IRIS Registry—the largest specialty society clinical data registry in all of medicine. The IRIS Registry is transforming our profession, and it also provides a Merit-Based Incentive Payment System quality reporting system that will save our members an estimated \$186 million in avoided penalties next year, when the MIPS payment penalties—based on last year’s performance—start to take effect. It has led to numerous peer-reviewed scientific papers with novel clinical findings that promise to enhance the quality and delivery of care for our patients. And it is an increasingly important vehicle for clinical benchmarking and quality improvement. The IRIS Registry has received accolades from policymakers, public health experts, data analysts, and other medical organizations as “best of breed.”

Second, the Academy will likely now be financially able to continue offering the IRIS Registry at no charge to members. And if it is very successful commercially, IRIS Registry revenue may provide an alternative to dues dollars.

Third, and critically, DigiSight (now renamed Verana Health) makes the data analytic tools and platforms that it develops and uses for commercial purposes available at no charge to the Academy for our own analytic purposes.

Fourth, the Academy retains full authority over noncommercial data projects conducted by members, Academy-affiliated organizations, or the Academy itself. Commercial activities do not interfere with these projects.

Finally, all of ophthalmology retains a high-quality tool that can provide novel insights into real-world evidence—what actually happens in the practice of ophthalmology. It can be a basis for comparing clinical trials to real-world practice, performing postmarket surveillance of drugs and devices, studying rare diseases, comparing outcomes from

treatment alternatives, illuminating disease natural history in large populations, and examining the impact of comorbidities and confounding variables on disease progression.

**Initial steps.** In the year since the relationship was signed with DigiSight what has happened? First, as mentioned earlier, the company was renamed Verana Health. This was intended to signal that the company is now a health care data company—not an ophthalmology company. Second, the company has totally restructured itself around the IRIS Registry—its core asset. Third, it has received a large infusion of capital from some of America’s legendary venture capitalists and companies. Fourth, it has recruited outstanding leadership and beefed up its technology and data science teams. It has had commercial success in its mission to accelerate health care innovation through data insights.

Most important for Academy members, nothing has happened to cast a shadow on the Academy’s reputation for independence and integrity. Rather, we are getting kudos in the medical society space for the way we executed this relationship. Others are trying to emulate us.

### Conflict of Interest

As for potential financial conflicts, these are carefully scrutinized. I sit as the Academy’s Board-designated representative on the boards of FIGmd (our registry software vendor) and Verana Health. I receive no compensation, stock, or stock options for my work representing the Academy. And no member of the Academy Board or staff has any financial relationship with Verana or FIGmd—not even a complimentary T-shirt.

### The IRIS Registry: A Growing Asset

The IRIS Registry had its fifth birthday and is still growing. Over 18,000 ophthalmologists and their employed optometrists use it. It contains more than 200 million patient encounter records. Over 50 EHR companies are mapped to it. It still has problems, however. EHR updates play havoc with data mapping. Every year CMS approves new quality measures, which must be coded into the IRIS Registry’s software. The data must be continuously and carefully curated to ensure quality to avoid the “garbage in/garbage out” dilemma. With time, we hope to ingest more data from images, from genetic testing, and from patients themselves.

Throughout this process, the Academy hopes the IRIS Registry will bring more and more value to its members as a tool to benchmark and judge clinical outcomes and processes of care. We anticipate that ophthalmologists will choose to employ the IRIS Registry to report their quality outcomes to CMS, commercial payers, and health systems as means of avoiding payment penalties, garnering bonuses, and demonstrating their value. It will continue to support our advocacy and policy objectives. And we anticipate that it will become a robust source of generating new scientific information that will change the way we care for patients.

At all times, the Board of Trustees and senior staff pledge to oversee the IRIS Registry and Verana Health to protect the reputation of the Academy for integrity, independence, and trustworthiness. It may be our most important asset.