

MEMBER SPOTLIGHT



MICHAEL C. MONTALTO, PHD

Executive Director, Pathology & Clinical
Biomarker Laboratories, Bristol-Myers Squibb
President, Digital Pathology Association

TELL US ABOUT YOURSELF – WHERE YOU COMPLETED YOUR UNDERGRADUATE/POSTGRADUATE, FAMILY, WHAT A TYPICAL DAY LOOKS LIKE FOR YOU, ETC.

I received my PhD in tumor biology from Albany Medical College and completed post-doctoral training in anti-inflammatory drug discovery and whole animal physiology at Brigham and Women's Hospital, Harvard Medical School. I live on the New Jersey shore, where I'm in the ocean surfing most mornings before work. My wife and I have three children and we are extremely passionate about supporting them and helping them understand their true potential.

I'm usually at work by around 8:30 a.m. (depending on surf conditions) but that's about all that's typical in any given day. I'm fortunate to be working in a cutting-edge field that is evolving alongside the growing demand for precision immuno-oncology medicine. I have the opportunity daily to explore technology platforms that have the potential to yield a complete picture of patient biology, help in the discovery of innovative biomarkers and, I hope, ultimately speed the delivery of medicines to more patients.

HOW LONG HAVE YOU BEEN WORKING WITH DIGITAL PATHOLOGY?

I started my career at Memorial Sloan-Kettering Cancer Hospital in the lab of Dr. Lloyd J. Old, who is considered by many to be one of the founding fathers of modern day immuno-oncology. It was here that I discovered my deep interest in pathology. We conducted monoclonal antibody screenings for different tumor types, and I often ran down to the operating room multiple times a day to collect patient samples in order to process them into histological slides for research.

This hands-on experience motivated me to pursue a career in deconstructing the complexity of cell and tissue samples visually – and illustrated for me how pathology had not kept pace with technological innovations. I wanted to modernize pathology and bring the field to the digital age to enable scientists to see more and glean more insights.

My work in digital pathology truly began in 2003, when I took a position at General Electric within their Global Research and Development Center, alongside the 2013 winner of the Nobel Prize in Physiology or Medicine, Dr. James Rothman, who shared my fascination with digital pathology. He challenged me and my team to find a way to see as many tissue biomarkers as possible at one time on standard pathology samples; we succeeded in inventing technology to see up to 100 biomarkers in a single histological specimen. The technology, known as "high-level multiplexing" (MultiOmyx™) was patented and published in the Proceedings of the National Academy of Science in 2013. Over my career I've had the privilege to develop and commercialize general digital pathology technology for diagnostic use that allows pathologists to see more than ever thought possible.

HOW LONG HAVE YOU BEEN WITH YOUR CURRENT EMPLOYER AND WHAT IS YOUR ROLE?

I have been with Bristol-Myers Squibb since 2016, and I am the executive director of Pathology & Clinical Biomarker Laboratories, Translational Medicine. I have responsibility for genomics, genetics, flow cytometry, and pathology and it is my great privilege to lead a talented group of researchers in developing and applying methods to measure biomarkers across all of our clinical programs.

HOW HAS DIGITAL PATHOLOGY DIRECTLY AFFECTED YOUR BUSINESS?

We're applying digital pathology to our research efforts across disease areas. In immuno-oncology, by combining the power of digital pathology with other clinical technology platforms, we're able to generate quantitative, accurate views of the tumor microenvironment, allowing translational scientists to see multiple disease markers at once, repeatedly and at scale. The data collected by digital pathology computers can be combined with deep learning and artificial intelligence technology to learn from and build upon – a digital “brain” that informs digital “eyes.”

Our digital pathology capability – combined with our genomics and genetics efforts – is enabling us to generate unprecedented insights into patient biology that are helping to guide our research.

HOW IS DIGITAL PATHOLOGY IMPACTING THE HEALTHCARE AND DIAGNOSTICS INDUSTRIES AS A WHOLE?

I believe digital pathology has the potential to provide critical scientific answers that could make a real-world impact. The healthcare industry is increasingly focused on precision approaches that will help us find the right treatment for the right patient at the right time. Digital pathology and deep learning are increasingly important tools in our arsenal to identify biomarkers that can enrich patient populations. In immuno-oncology, where we have learned that there is no one-size-fits-all approach, digital pathology helps us to see the complete story of cancer biology, paving the way toward predictive diagnostics in our research. Beyond oncology, I believe that this technology will help us understand the biology of many other diseases, ultimately informing more personalized medicine development and treatment approaches.

FROM YOUR PERSPECTIVE, WHAT IS THE MOST IMPORTANT REASON FOR YOUR USE OF DIGITAL PATHOLOGY?

The emergence of digital pathology and, more specifically, its recent application to translational science, has allowed us to see disease differently: literally and figuratively. Just as next-generation sequencing has created volumes of insights to inform our translational research, so too will quantitative image analysis and multiplexing generate new insights. These data will ultimately inform the approach to rational combinations, patient selection and clinical trial design across therapeutic areas.

WHAT DOES THE FUTURE OF DIGITAL PATHOLOGY LOOK LIKE TO YOU? PARTICULARLY, WHEN DO YOU SEE, OR DO YOU SEE ITS ADOPTION AS AN EVERYDAY OCCURRENCE?

The more we use these technologies in our research to identify biomarkers that can enrich patient populations, the more important it becomes to translate this technology into a complementary or companion diagnostic. For the market to be ready to embrace an image-based companion diagnostic, we need market access to this technology. We are not there yet, but there are encouraging signs of change. The FDA approval of whole slide imaging shows that the investment community, regulatory authorities and clinicians are willing to entertain its potential to change clinical practice.

As I look ahead, I believe we need to train the next generation of pathologists, develop the necessary tools and protocols, and – most importantly – generate usable data to demonstrate the value of digital pathology.

HOW LONG HAVE YOU BEEN A MEMBER OF THE DIGITAL PATHOLOGY ASSOCIATION (DPA) AND WHAT FIRST ATTRACTED TO YOU TO THE ASSOCIATION?

When I was at GE Healthcare/Omnyx, we were among the first group of benefactor companies when the DPA opened membership to the broader community. I became more active in 2011 when I joined the regulatory taskforce and eventually led that team to influence the FDA to change its classification of whole slide imaging (WSI) devices to a de novo class II device.

HOW DID YOU INITIALLY GET INVOLVED WITHIN THE ASSOCIATION AND WHAT IS YOUR CURRENT INVOLVEMENT?

I am currently the President of the Digital Pathology Association. My first involvement with the DPA was during my tenure at Omnyx, and we recognized the important work of the DPA to help educate about and raise awareness of digital pathology applications.

WHAT DO YOU ENJOY MOST ABOUT THE DPA?

The DPA is truly a collaborative environment. It is rare to find an organization of leaders from industry, academia and community healthcare settings all working as a single body to promote the education and awareness of digital pathology. The DPA has made tremendous progress over the years, including working closely with the FDA, partnering with The National Society for Histotechnology (NSH) on the first WSI certificate program, and hosting the most successful connect-a-thon to promote interoperability. The DPA has made very positive and lasting impacts on the WSI community.

June, 2018