# Digital Pathology Implementation at Massachusetts General Hospital

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**Becca Battisfore:**

Welcome to the latest edition of the College of American Pathologists' CAPcast. I'm Becca Battisfore, Content Specialist with the CAP. In this episode, Dr. Joe Sirintrapun will be talking with Dr. Joe Lennerz about his experience with implementing digital pathology. Before we get into the questions, let's learn more about our guests. Dr. Sirintrapun, would you like to introduce yourself?

**Dr. Joe Sirintrapun:**

Thanks, Becca. So I'm Joe Sirintrapun, and I am the Director of Pathology Informatics here at Memorial Sloan Kettering Cancer Center in New York City. I've been around for a little bit, been involved with CAP on the Digital and Computational Pathology Committee. I'm actually leading or co-leading the implementation work group, and just happy to be here.

**Becca Battisfore:**

Great. And Dr. Lennerz?

**Dr. Joe Lennerz:**

Hi. Yeah, my name is Joe Lennerz. I'm a pathologist. I work at the Massachusetts General Hospital. I direct the molecular lab and work in the Center for Integrated Diagnostics. I'm a CAP member and part of the newly introduced CIPI council. Thank you.

**Becca Battisfore:**

Great. And thank you both for joining the podcast today. Dr. Sirintrapun, I'll let you take it from here.

**Dr. Joe Sirintrapun:**

Thanks, Becca. So this is going to be a fun one because you can never have enough Joes. So you have myself and you have Joe on the other side, but ... so Joe, I'm going to ask you some questions that I pretty much ask all the guests, but we'll start with the first one here. What were your challenges in getting your institutional leaders in laboratory to agree to digital pathology implementation?

**Dr. Joe Lennerz:**

That's a very good question. So I think the first part is, of course, leadership buy-in usually means you have to have good arguments. To have good arguments, you need to know what you're trying to accomplish with it. So I would say the first part is that you need to distinguish whether you implemented digital pathology for, let's say, research for education, or for clinical workflows. And I think the arguments you need to bring for each one follow completely different paradigms. You have a research impetus, you want to probably see or tie it to publications or funding mechanisms that would cover for the cost. And then you can offer it as a service or a core laboratory. When you do it for education, I think courses, CME and maybe your institutional approach is probably slight different, but you can do slide conferences or there's like a portability associated with that.

And then of course, probably the most relevant and the most challenging currently is clinical implementation. So you have to make certain promises and the arguments around reimbursement that function for other, let's say new tests or technologies may not be as applicable for that. Now once you have your arguments ready, I think some of the challenges that you face is related to funding and value propositions, not only that they differ drastically, but different people of course with their individual interests might be more amenable to one versus the other. And then of course, if you have other components related to that in let's say in a clinical space, you have to figure out what the validation would cost, what other aspects you need there.

So simply put, what challenges I personally faced is figuring out which one is the best initial step to get your feet wet. So we started definitely more on the educational and research side because the funding can be obtained through regular mechanisms, and then having that experience makes it a lot easier to talk about other clinical implementations. I think probably the biggest challenge from a clinical rollout is you have to be accountable for it, meaning it's one thing to ask leadership about certain components and funding and let's say support, but I believe the most important part is then if you want to own it and if you want to run it, you have to be accountable for it. So you have to have good SOPs, validations, et cetera. So in other words, the one word answer is you have to have really good arguments.

**Dr. Joe Sirintrapun:**

No, that's great. And I really appreciate you going through all the different ... because all these arguments are individual and everybody has to, as an institution, sort of has to take a look introspectively about which argument really works for them. So it's really great that you're able to share that. So maybe along the same lines, what pushback did you face in terms of getting your colleagues to accept digital as it was proposed?

**Dr. Joe Lennerz:**

Oh, I mean over the years, yes. I remember one particular attending, and I think it's still echoing to this day. He came in and said, "Oh, what's that? That's as useless as the moon landing." And I was just thinking like, "All right, good. That's an interesting opinion to have." And sometimes the pushback comes from out of nowhere, where you think that some people are extremely technophile and they want all the new stuff, but then when it comes to, "Oh you want me to do this for sign out? Oh, no." So I think it's mostly a surprise in a way sometimes, but I think by now most people have some experience with digital pathology.

So I think currently it's more those that are absolutely married to their microscope, they love it and they find it okay. And the most pushback I think is if you start interfering with their day-to-day practice and with their time. And I think some really high throughput surgical pathologists, they cannot tolerate if you change the outline of the report. And it's all optimized for efficiency. So I think a little bit of change management is probably helping with that. And maybe the key element from the pushback that I experienced is the real high throughput surgical pathology disciplines. Whether that's really possible to completely digitize, I think that's probably the area where I see most pushback currently.

**Dr. Joe Sirintrapun:**

Yeah. Along the same lines, I mean what advice would you give yourself if you had to do this over, to get a redo?

**Dr. Joe Lennerz:**

Oh, that's a good question. I would say I would just do it. That's the quick answer, not hesitate too long, not overthink the various different things. Settings differ, of course. I've helped set up a digital pathology in three different institutions and the settings were completely different. The use case is different. Each individual decision can be pondered, met about, and having hundreds of meetings about, for example, which scanner to buy. And each individual decision is not as important as starting it, just getting started. Sometimes it's not worth discussing whether it's a five, a 10, a 50, or a 500 slide scanner. It's just important to have one. I'm sure there have been meetings about which fax machine to buy and I think those were probably extremely meaningful meetings at the time, but at some point it's just like, "Let's just do it."

**Dr. Joe Sirintrapun:**

I really like that. I mean yeah, don't let analysis paralysis really take the better of you. I really like that spirit of just go and just dive right in. I mean just you can't learn swimming unless you're just in there in the pool. So I was wondering if I was going to ask you this, but what are your wins so far with it? You mentioned you implemented for education, other things. What can you take away in terms of some of the victories that you've had?

**Dr. Joe Lennerz:**

So I think one victory is of course that we have access to files. And I used to say that digital pathology or the histology is actually the one missing image from the medical record. Now, while the images are not yet in the medical record, I think we have access to the files and that opens up a gigantic set of benefits that is hard to capture or enumerate, but if you want to look at a prior case, you can search it, find it, open it. It takes 20 seconds. That is extremely convenient and you don't need to pause, put it on your list or request it, wait to get the slides to then rethink why you wanted the case to re-review. "Ah, I just wanted to compare morphology."

So I think those, let's call it tangible or intangible benefits, are extremely prevalent. So I learned to recognize that that is actually one of the key things. So we rolled out digital pathology, went completely digital just shy before the start of the pandemic in our molecular lab, where it's arguably a unique setting where you have typically one representative slide for an entire tumor, but then having that morphology and being able to correlate molecular findings with morphology is just a very educational and scientific endeavor, but it's there. Now, the other win is that once you start doing this in some systematic capacity ... in one of the institutions we had to rule of putting a sticker on the diagnostic slide, for example, of consult cases. And then those slides were scanned individually, but you had a permanent record.

That doesn't sound like it's that complicated, but over the years you built a database, you have these files available for all the use cases that we discussed earlier. So I think we might need to realize that digital pathology is not the one thing that will change everything or the one use case that is suddenly unlocking this as if some sort of knot opens up and then everyone goes digital. It might be that this is just like back in the seventies and eighties, the automatic cover slipper. It's just a thing that adds value on multiple levels, but dissecting it out for the one win might not be possible. So a lot of diverse wins, but not one specific one. But I think the ability to work remotely shouldn't be underestimated. I think that's a huge win that we at least booked in the molecular side.

**Dr. Joe Sirintrapun:**

I appreciate that too because ... and I've brought this up in several other interviews with other folks too, this archival was very big. And I always bring up the feeling. When I'm on frozens, and in fact I was on frozens yesterday, the ability to pull something without actually having to request from the slide file room, it's just priceless. There's so many add-ons that you don't have to think about to be able to compare at the instantaneous of ... at the end of your fingertips, that feeling. And I can tell you that if we were to take that away, "Oh you know what? Sorry, scanners, sorry," I think we would revolt. I'm positive we would revolt. Not just me, the entire department. That feeling is something else. And the ability to do remote, that was very big during the pandemic. I still have my little home office. So those are some of the big wins also. So your wins sound very similar to ours as well.

**Dr. Joe Lennerz:**

Yeah.

**Dr. Joe Sirintrapun:**

So let me ask you a question that's a little bit different from some other folks I've had on the podcast, and you how much I love participating, but the PICC alliance, tell me a little bit about that. Maybe just tell us a little bit about this story of behind basically the organization that you've founded and all that stuff.

**Dr. Joe Lennerz:**

Sure, thank you for asking that. It's very near and dear to my heart. So maybe just as sort of ... the beginning is basically through chance and circumstance, I was the PI on the first instrument precision study of a scanner, a whole slide scanning system and realized that the FDA thinks about devices quite different from, let's call it the practicing pathologist. And at first it was sort of a gap and I just thought, "What are they talking about?" And over the years, through many different people that I was exposed to, I learned to see it slightly different. And the field is called regulatory science, which is the science about regulation. At first I thought, "How can there be science about regulation? That doesn't make sense, because regulation is human made," but then after a while it dawned on me that, well, if there's a new technology, there cannot be regulation around it because it didn't exist. Otherwise it wouldn't be new.

So then the question is, well, how do you apply the scientific method to inform regulatory decisions or regulatory guidance? The field itself became suddenly very interesting to me. So one of the people that I was exposed to was Esther Ables, at the time a regulatory person in one of the major companies. And through her I met Brent Galles, who's on the FDA side, a scientist within the FDA. And the three of us conceptualized sort of how could we tackle this field that is apparently, or at least it seemed, almost completely ignored by many of the other societies? And we said, "Well, this may need some initiative behind it." And it resonated really well with I think a broad range of stakeholders, CAP, the Digital Pathology Association, the Association for Pathology Informatics, and you name them. Currently, over the years once we started we realized that there are so many different stakeholders.

So in very brief, a regulatory science initiative is just like any other collaboration, an interest group, but what's different with PICC, or the Pathology Innovation Collaborative Community, is that this grassroots movement at some point became a little more formal because the FDA has a certain program that's called Collaborative Communities, which has to fulfill certain criteria. I won't cover that, but just to outline a few is the vision and a charter has to be drafted and it should be open to all and it shouldn't be restricted. So there's no membership fee, there's no talking about pricing or antitrust monitoring has to happen. So there's a couple of rules around it, but the main point is it should be a community for the community, meaning everything is open, everything is shared. And the interesting part is it creates a platform to ask all kinds of interesting questions.

Now, Joe, I know you posed some fascinating questions over the years, but it is almost like a little bit of a treasure chest, where you put all the things that don't fit into the typical rubrics. And I thought that that was something fascinating. By now we have about 600 members. So a lot of people receive emails, many join the monthly steering committees, and it is really sort of a community where you can interact across the various stakeholders, but with FDA participation. Notably the FDA or the agency participates actively and they speak also on their own behalf. Now that is something very unique because normally the FDA is not really informing anything in terms of outside the realm of a specific submission. And even within that it's usually confidential. And just hearing what the reviewers or the scientists behind that curtain think about certain topics I think is probably to some of them liberating to hear and run some of their ideas by us, meaning the field and vice versa. So long story short, it's an interest community that enables something that wasn't there before. So it's irrespective being public or private. And if you haven't seen it, pathologyinnovationscc.org. And yeah, just check it out.

**Dr. Joe Sirintrapun:**

Yeah, we should put that in a link somewhere if we can, but let me add a couple of things to that being on this. If you told me 10 years ago that regulatory, even the science of it, that I would actually want to participate, I'd be like, "What the heck?" Because nobody thinks of regulation as being fun, but I can tell you being part of PICC, you make regulation fun. It actually makes your mind ... it bends your mind, it makes you think, it stretches it, it gets you outside your bubble because it's not just academic folks, it's everybody there. You got regulators, you got the FDA, you got government, you got vendors, you got everybody on there. So you're outside a bubble, it makes you really think it. It not only tackles digital pathology, but it tackles genomics. So it's a great place to even have ... who would've thought regulatory science can be fun and thought-provoking? But somehow you pulled it off. And that's why I said it's pretty unique. It's pretty unique.

**Dr. Joe Lennerz:**

Thank you.

**Dr. Joe Sirintrapun:**

That was a nice tangent, but ...

**Dr. Joe Lennerz:**

I couldn't do it without the help of many folks like you. Ula Green is amazing. We try to be as transparent as possible and it is very interesting because we also ask from the people who participate to be active, which I think is in some settings or meetings. It's more that you passively digest things, but I think the ability to ask people to actively contribute and they want to contribute, they want to actively provide information, for example, to the agency, so I think it's fairly cool. So it's also a lot of fun to make it fun.

**Dr. Joe Sirintrapun:**

And you help digest things for me. I forgot to mention that too. Sometimes when it gets very wonky and complicated, I sort of go to you and get stuff in digestible bits.

**Dr. Joe Lennerz:**

Thank you.

**Dr. Joe Sirintrapun:**

So let me ask you something. Let's get a little ... I might know this story, but what was your first personal experience with digital pathology?

**Dr. Joe Lennerz:**

Oh, well Mike Isaacs at Wash U.

**Dr. Joe Sirintrapun:**

I thought you'd mentioned him.

**Dr. Joe Lennerz:**

Oh no, he's a great friend and collaborator over the years. So at some point I remember that I was a resident at the time and I ran into his office and he was sort of like, "What's going on? Why is a resident coming to me?" And he's the IT director and he was immediately sort of hooked with this idea, "Why aren't the slides scanned? Well we should do that." And then at the time, I think it was 2007, we had a north campus and the north campus didn't have all the offices. It was just renovated and it just so happened that I was the molecular fellow and I didn't have a microscope, but we had a scanner.

So then I switched over to just be fully digital for at least the slides that I needed to review. And it was very interesting when I went to GI fellowship, I had to switch back to the microscope and it took a few weeks to get back into using the microscope. So definitely big props to Mike Isaacs, who also, I remember we worked for a long time to get our LIS system to be able to open the slides and that was a big breakthrough to be able to have that. Yeah, so it's been a few years.

**Dr. Joe Sirintrapun:**

I figured you’d mentioned Mike. Yeah, so we all have kind of a mutual network connection. And also that was probably the time when we probably met. We're all from around St. Louis area anyway, so it's a small world, but -

**Dr. Joe Lennerz:**

Absolutely.

**Dr. Joe Sirintrapun:**

Well let me ask you the last part. So I'm going to ask you to put a crystal ball, break out the crystal ball. Where do you see digital pathology heading in the next five to 10 years?

**Dr. Joe Lennerz:**

That is a very, very speculative thing to say, but I think there will be a lot of things happening over the next five years. First of all, I think a change that is probably coming and it's a harsh wind, is that for the first time a technology is not entirely just owned by pathologists. So many of the other innovations I would say were internal developments, but I believe there's a new sort of vector in the equation and that's an external force. People will want our data, and in particular the histology. It's images. A lot of people know that one of the big applications of AI is image analysis. And in radiology the field is booming and a lot of the ground truth is actually in our slides.

So I believe that we have so far, I don't want to use the word enjoyed, but that comes to mind, the element of internal development for all of our progress, but I believe that there is now a tendency in the field that we will face an external force. And I would go as far as saying that over the next five years we will have to adopt to that, meaning that outside entities will come with all risks and benefits and say, "Look, we want this." And then you either be ready or you be not actively influencing that. So in addition to that, I believe what will happen in parallel is that for selected, let's call it care pathways for specific applications, digital pathology will probably be more amenable than others. So a lot of people think that, for example, mutation prediction from H&E slides will enable a diverse set of populations. And I mean with the patients, but I also mean settings in terms of health care settings, the ability to prescreen, let's say, certain cases.

Of course there's regulatory aspects to that, but I believe that the progress will diversify and it will come from all ends and all directions. I do not think that that has happened like that in pathology. Usually we square things off and we box it into specific functional modules, but I believe this will touch us sort of in the middle of our workflow, which is where the microscope sits. In terms of other sort of trends that I can see or perceive is I believe data sharing will be absolutely critical. As you know, CMS just released the guidance that we are allowed to continue exercising what we've done during the pandemic, but what that will lead to is basically more remote work, more second looks, more effectively image and data sharing that will be enabled.

So we need to have really good policies around that, we need to come up with the regulation around slide retention, digital slide retention, and then overcoming some of the key challenges related to diverse patient population, minorities, et cetera. We really need to harvest the metadata as well. So I believe pathology will undergo a complete data revolution. The beautiful thing that we always say, our LIS systems looked like in the eighties, that will be unacceptable. I think it will morph into a data-driven field, and the digitization of slide is one component of that, but with, let's call it the data structures that we have in pathology and the extreme high value and reliability of pathology, I believe is not even ... people are not quite aware yet, but that will, in my opinion, definitely happen and probably change the face of pathology quite a bit.

**Dr. Joe Sirintrapun:**

That is quite a remarkable answer. A lot of that stuff I wasn't even expecting or wasn't even on my radar. So I really appreciate that. I'm going to drill down in some of the points you mentioned. In some ways it reminds me, there's an old saying I think in the consumer industry, if you don't really ... when you're dealing with AI, if you don't really know what they're trying to sell you, you're most likely the product. And I think when you mentioned that the third party and these external ones, it almost makes it sound like pathology might be the product because they're generating so many data, not necessarily pathologists, but the outputs or results, the other interpretations. That's all part of the product and people will find it valuable. They will want it now that it's digitized, but that can be seen possibly negatively.

But one thing you mentioned in the second part, you said that legacy technologies won't suffice. One of the issues is that meanwhile who's going to pay and build all these technologies? It might be the external forces because they see the value of the product itself. You might see that the LIS's that we had before just aren't capable. So these third parties are going to say, "You know what? To capture data better, to be able to allow us as the product to be a better product, we need to have better systems out there." And that part I think is very profound. I didn't think of that, but I think that's actually ... that will be very interesting, because it's a business case in itself. Yeah, there might be the product, but as a byproduct you can see a lot of massive advancements and improvement in technology around the practice of pathology. For pathology to be a better product, we must have everything around it be better. And that might be the onus for that. So I think that's a very fascinating philosophical answer, so I appreciate that. Did I kind of sum it up, maybe what you're thinking? Or anything to add?

**Dr. Joe Lennerz:**

Yeah. No, I fully agree. I think that the part that is ... and I know you've been part of that conceptual study that's capturing what I believe people consider diagnostic quality is that it's not just a test. A microscopic review is not an essay, it's an interpretation, but that's the test level. And then we have the procedure level around that, which is entailing in the future the scanner and AI tools, but it's the procedural layer surrounding that. And then the outside layer around all the procedures is what an individual, let's call a department division or pathology practice offers in terms of service. So it's test, procedure, and service, and all the three things have to be in unison to make something a high-quality product to use your analogy.

So I think you're spot on, but I don't believe that most pathologists consider themselves a product or that they deliver a service that has to have a certain external facing marketing aspect and it has to be digestible or it has to be interoperable, but that will be a force in the field of medicine pointing at pathology to say, "Well, maybe not everyone can read an x-ray or a CT scan, but the data is available in the medical record." At some point there will be a group that says, "Look, we're going to put our H&E slides in the medical record," even if it's just that you can quickly pull up something during a tumor board. I mean, the interpretation of the CT scan is still the domain of radiologists despite the image as a service being available in the medical record. So I foresee what you just said. I didn't think about it as a product, so that's a great analogy, but we are all service providers, and customer service in terms of being a good collaborator for our clinical colleagues and exercising what is our clinical practice is absolute key.

**Dr. Joe Sirintrapun:**

Yeah. I mean it wasn't my intent, but I mean I can see this being a very provocative thought experiment with this discussion. But yeah, it's something that I would've never thought of and I appreciate you answering that question. That was a very unique perspective.

So with that in mind, Becca, I guess I'll turn it back to you.

**Becca Battisfore:**

Great. I think we covered the past, present, and future of digital pathology. So I want to thank you both for joining again to talk about your experiences. And I want to thank you all for listening to this CAPCast. To learn more about digital pathology, the Digital and Computational Pathology Committee has a great resource center on the CAP's website. The link to that will be in the episode description. And for more information about the CAP, visit cap.org.