UAB and MIC: Using Data for Predictive Modeling

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Customer Spotlight Webinar

Mary Killelea: Welcome, everyone. Thank you for joining us for Intel's Customer Spotlight Series. This series highlights innovative, industry-leading companies that are undergoing digital transformation, have tackled business and technology challenges, and created new opportunities using Intel data centric technologies and platforms. Today's conversation focuses on healthcare technology, scaling up care and capacity, and the opportunities for artificial intelligence.

Today's host is Tim Crawford. Tim is the Strategic CIO Advisor that works with enterprise organizations. Tim, I'm going to turn it over to you now to kick off today's conversation.

Tim Crawford: Great. Thanks, Mary, and welcome to our audience for taking part in this really interesting conversation that we're about to have. I'm joined by a couple of folks that are really going to put a spotlight on some of the really innovative work that they're doing, both in a technology setting, but then also within the healthcare environment.

So, let me first introduce our two guests. So, Dr. Emma Fauss is the CEO of Medical informatics Corporation. Emma, welcome to the program.

Dr. Emma Fauss: Thanks for having me.

Tim Crawford: And I'm also joined by Dr. Dan Berkowitz, who is the Professor and Chair at the University of Alabama at Birmingham. Dan, welcome to the program.

Dr. Dan Berkowitz: Thanks. Delighted to be here and to share our experience with the audience.

Tim Crawford: Excellent. So why don't we start off maybe setting a foundation for our audience, in terms of who Medical Informatics is, and who the University of Alabama at Birmingham is, and the work that you're doing, Dr. Berkowitz.

We have about 25 minutes of discussion that we're going to go through with both Dr. Fauss and Dr. Berkowitz, and then we'll get to a Q&A session. So**,** Dr. Fauss, why don't you kick us off? Who is Medical Informatics Corporation?

Dr. Emma Fauss: Well, we're a company—we're actually located in Houston, Texas. We're a software company that specializes in what we call clinical surveillance in the hospital sort of inpatient environment.

So what that effectively means is, we enable solutions around remote patient monitoring, so being able to access data around your patients coming from the disparate medical devices that are connected to

that patient outside of that room, as well as leverage that data for building and deploying predictive analytics at scale.

Tim Crawford: So, maybe talk a little bit about how you got started, because I think this is a fascinating aspect as we get into who the company is, and how the company got started, but I think that will also set the stage for Dr. Berkowitz too.

Dr. Emma Fauss: Yes. It is actually very interesting. We got started about 10 years ago. I was actually doing my graduate doctoral work at University of Virginia. And my co-founder had been just recently recruited after finishing his PhD to be an engineer in the pediatric environment over at the hospital at UVA.

And one of the things that they were trying to do, you know, 10 years ago was, they were trying to take the data coming from typical cardiac bedside monitoring equipment, and see if they could look at those wave forms and physiological indicators coming off of patients, to detect imminent catastrophic events.

So basically, teaching machines to recognize these types of critical events, or—and then also go a step further and then looking at the precursors and predicting that—those and foreshadowing them when they would occur.

And one of the crazy things was is that if you look back at that time, you know, very—it's not too different from where we are today still, but a lot of the bedside medical devices speak proprietary languages. There's not a lot of interoperability.

And so physically, just getting access to that data, was very challenging. And once you had access to the data, being able to store it in mass so that you could leverage it for the development of those analytics, became very important.

And what you saw is you saw a lot of people rolling around carts. And, you know, my co-founder looked at that and said hey, you know, we have supercomputers. We have parallel processing. We should be able to not lose this valuable data and leverage it to improve clinical care.

And I guess just a little bit of a snapshot is that when I came into the picture, I actually happened to be going by his lab and I noticed there was a line of physicians out his doorway. And I asked him. I said, "What's—why are all these physicians, you know, outside your door?"

And he's like, "Well, they're coming because they don't have access to this data, and they saw something that sparked their curiosity that they said, there's a problem here with this patient, and I need to go back and look at it."

And it was just that simple, you know, looking at that situation, I said, you know, "Craig, you have a scaling problem here. We might need to think about creating a company that allows us to not only just get access to this data, but then provide this as a tool to clinicians so that we can look at improving how clinical care is delivered." So that's—yes, that's a little bit of a snapshot of where it came from. Yes.

Tim Crawford: That's great. And I do want to kind of double click on that, but before we do, let's bring Dr. Berkowitz into this. And Dr. Berkowitz, maybe you could talk a little bit about the work that you're doing at the University of Alabama at Birmingham.

Dr. Dan Berkowitz: Absolutely. So just to give people perspective, this is—the University of Alabama in Birmingham is the largest academic center, what's really the only academic center in Alabama. And the hospital is probably the fifth largest academic public hospital in in the country. So, this is a large operation.

And as the chairman of the department of anesthesia, we have tried to be visionary as the department really has inroads, particularly obviously in the operating room with monitoring of patients, but more importantly, in all of the surgical ICUs. That's the neuro intensive care unit, the surgical intensive care units, and some of our performer and cardiac intensive care units.

And so really one of my visions is or my primary vision is, integration of data, the whole perioperative journey and the ability for us to gain and to utilize data for not only risk stratification of patients in the preoperative stages of their operative journey, but also the development and utilization of tools for not only precision medicine management of patients in the operating room and in the ICU, but also as Emma had talked about, for predictive modeling, because really that is where we rule as number one as a specialty in critical care and in anesthesia, to create value for the institution.

The ability to analyze in a very sophisticated way, data that has come out of the machine in a way that is essentially agnostic to the kinds of devices that are actually generating voltages out, the ability to actually utilize that data, time align it, is essentially priceless.

Because I was like Emma. I was one of those guys that was rolling around carts, you know. I was rolling around carts with the analog digital converters plugging in these plugs into the back of devices, and trying to time align arterial waveform, EKGs, cardiac output devices. And it was clunky, and it was really very difficult to re-access the data.

This platform really has provided, I would say, just a tremendous leap forward in the ability to actually acquire and as I said, in a company agnostic way, and integrated so that it's actually used by physicians.

Tim Crawford: Sure. And I want to hold off on talking about Sickbay first. Let's jump into a deeper dive into the challenges. And Dr. Fauss, you touched on these. And Dr. Berkowitz, you also mentioned, you know, challenges around getting access to that data, and the wave forms, and just the sheer scale problem.

Can we maybe dive a little deeper into the experience that the physicians, and the clinicians, and the nurses were having? And kind of what their experience is, so that we can set that stage in understanding clearly what the problem is that this is solving? Dr. Fauss, you'd like to start with us?

Dr. Emma Fauss: Do you want me to go with that? Okay. I was going to let Dr. Berkowitz go first on that one, but the ...

Tim Crawford: Either way.

Dr. Emma Fauss: So just to say, I'm clearly not a physician and I don't live on the front lines, but I think over all these years, it's working very closely with people that do live and breathe this every day. I think that if you're not on the front lines, you often are not aware, especially like if you're in some of the IS part of the house, you don't necessarily recognize the gaps in data that a lot of the people in the frontline have.

A lot of the medical—and just from a technical standpoint, a lot of these medical devices or biomedical devices at the bedside, they speak all different languages. If any data gets outside of them, sometimes that gets into the EMR through manual data entry.

Sometimes a portion of that is automated, but things like waveforms where you can see arrhythmias, things where device settings, like when did you change the ventilator settings—those type of second to second, minute to minute pieces of information, are often lost.

And then when you step back a little bit further and look at that journey that Dr. Berkowitz talks about, from admission to discharge, what people also don't realize is that often these medical devices are set up so that they lose the data every time you transfer the patient to one area—one carrier to the other.

So, there's this sort of continuity of data that also gets lost and makes it—it creates a lot of challenges for care providers as they're trying to treat a patient as they go through that journey within the healthcare system. So, Dr. Berkowitz, you could talk to the real-world applications of that, but that's what we see from our perspective. Yes.

Dr. Dan Berkowitz: Right. Yes. I mean, I think, you know, you've obviously highlighted some of the important points. Some of the important points again are, as you've stated Emma, are the disjointedness of the data, the multiple platforms that are necessary for providers to access in order to integrate the data, and also the fact that a lot of the information that is downloaded onto sheets, payables, whatever, into formats that can be seen, are intermittent.

They don't give you continuous assessments. And that can be challenging when one has an event and doesn't know—and you don't have any sense of what—in a sort of a temporal relation, in a temporal way, you don't know what preceded that event, whether it was an acute hypoxic event, an arrhythmia, all of those things, you can analyze that in a sophisticated way to know what happen—you know, what occurred.

And importantly also, the ability of some of the new technology, the problems that we have, is actually the access remotely. So as we get into things we talk about, where one—particularly in the era of COVID, where there is the ability—you know, where we have access to monitors, if monitors are in the patient's rooms, how can that information be observed and seen in a remote location so that management can be—so that there is less access—less necessity for access to risk developing or defining access problems.

So, these are some of the problems that sort of occur with—in the real world, clinical world.

Tim Crawford: Great. And I want to …

Dr. Emma Fauss: I want to make one more point.

Tim Crawford: Go ahead.

Dr. Emma Fauss: One more point is that, I do see the two types of deterioration really suffer from this in the clinical care environment. One is the rapid, you know, very acute deteriorations that can happen, where you miss—there's limited documentation. So, for instance, if you have a code event or some sort of rapid deterioration, the care team deals with that in the immediate, you know, timeframe.

But then when you're trying to go back and understand what happened, sometimes that happens in between the documentation that is already integrated, right? So, you could actually—an arrhythmia might be missed, arrhythmia might not be documented, or an arrest event may not be—you may not have all the data around that.

The other type of deterioration that happens that the current documentation systems don't really deal with, is long term deteriorations that happen over multiple shifts. So again, the format in which the data is presented today, and the lack of granularity, create things like long term deterioration on a ventilator, to be difficult to pick up in the current way that the data is visualized.

So, I don't know if Dr. Berkowitz, I mean just—there are clinical impacts. There's a clinical result of not having this data that it can be life threatening to people, right? I just want to make sure people understand the severity of this.

Dr. Dan Berkowitz: Yes, absolutely, and I think that this—you know, I think that certain changes which—it's the accumulation of small, subtle changes that ultimately lead to a state, what we would call a state change in the patient. And it's that state change, whether it's from a patient that is septoid, to developing septic shock, that is what we would like to determine or definitely predict in advance.

Tim Crawford: Sure. No, this is great. So, Dr. Fauss, I want to shift back to you, and maybe you can give us kind of a brief overview of the Sickbay platform, and how it addresses some of these challenges.

Dr. Emma Fauss: So again, I'm sure our audience has a varied background, but for all intents and purposes, I'll sort of try to give the 30,000-foot view. So, most people are familiar with, if you've seen an ICU environment, or any sort of clinical monitoring environment, whether that's an OR, or even some med-surg or low acuity, you'll typically have a bedside monitoring device, like an SpO_2 monitor, an actual patient monitor for vital signs or a cardiac monitor.

These are devices that are hooked up to the patient. They generate continuous signals. They have device settings. And what you find in the infrastructure today is that portions of that data, very small, like less than 0.01% of that data, will actually be documented in what's called the electronic medical records.

And that's usually, you know, you think of systems like Epic, Cerner. But there's really—there's nothing really been in between that, that allows like a system, a process or a brain, that allows the utilization of this data from these multiple devices that might be hooked up to a patient.

And as you get in higher in acuity in these environments, you have more and more devices at the bedside. So, by the time you get to the OR, you might have 15 devices that might be connected to that patient. And as you can imagine, each of those devices have different screens. They're each doing their own thing.

And so at the end of the day, one, just from a practical standpoint of being able to see this data, whether you're in the room or outside of the room at a remote location, whether that's in your office or at home, becomes a technical challenge.

And then if you're trying to make use of that data, whether it's for better documentation, better reimbursement activity for automated event recognition, or whether you're trying to introduce more intelligent alarms that help transform that data so that you can actually have a precursor warning to some imminent deterioration.

That's really where Sickbay was built and created. It was built and created to fuse data from—we're vendor gnostic. So we fuse data from a lot of different medical devices that you might see in that clinical environment, and we combine that data with often inputs from the EHR, like laboratory and medication results, and make it—and put it in a place where we have standard SDKs and APIs so that you can visualize this data.

You can compute this data. You can push this data to downstream systems. It takes away, in many ways, a lot of the—how can you think about it? If you looked at it from an infrastructure standpoint, if I were to—a lot of systems have single use, and we're essentially allowing a common infrastructure for this type of data that's traditionally been lost, to be leveraged in these downstream applications.

For all intents and purposes, a lot of things we have—as a platform, we have different applications that stand on top of that platform. Dr. Berkowitz mentioned some of the remote monitoring capabilities. So, the ability, like especially in the COVID world, to remotely view that data outside of the room.

We push our data to web-based interfaces. So, from a technical standpoint what that means, is it means that we're very flexible at embedding our analytics and our visualizations in existing workflows. So, we can, for instance, put our remote monitoring in your EHR workflows.

We can put it in your alarm notification workflows that exist today without having to disrupt the clinical environment, but providing that extra layer of information. So that's just a technical thing—yes. That's just a 30,000-foot view of what we do.

Tim Crawford: No, that's great. And maybe you could talk a little bit about the partnerships, because there were some key partnerships that you shared in our previous call that I think would be important for folks to understand.

Dr. Emma Fauss: Yes. Well, we work very closely with Intel, and we also work with other partners. We work with a lot of micro device manufacturers, and then also partners like Cisco. Recently actually, we started working with Cisco on medical device integration solutions, where we can actually leverage your existing investment in your Cisco infrastructure, to basically augment and help with medical device integration.

So, traditionally, if you wanted to connect to those 15 devices, if they were not already networked, and they didn't have their own gateways or ways to connect with them on the network, you would have to connect them putting hardware in the room. And what we found is that that can actually be cost prohibitive to organizations.

So, they might have invested in DI solution, but they only put it in the OR, but they can't get it in their lower acuity settings. They can't get it in their med-surg because it's too expensive.

So, we came to Cisco and we said, how can we make this cost effective at scale, and make this easy to get the data, plug and play essentially so that really organizations could start leveraging that data across the entire patient journey, which is something we heard from our customers, because it wasn't just enough to have the ICU.

It was, I want to know what happens when they come in the ED, when they go to the OR, when they go to the ICU, the step down, and then lower acuity settings. We need to have that entire history in order to start to look at optimization at different levels for risk analytics, you know, up transfers, down transfers, operational aspects of patient flow, right.

Tim Crawford: Dr. Berkowitz, you know, this story is much bigger than just access to data.

I mean, access to data is a huge piece of this. Let's not minimize that, but the story is much bigger than that. How do you see innovation and things like artificial intelligence coming in to impact the patient experience, and ultimately patient care?

Dr. Dan Berkowitz: Sure. So just to give sort of—and to jump off on what Emma had said, and to sort of just give an analogy of how critically important this platform—this kind of platform is. I'd like to sort of have people envision two points, all right? A point A and a Point B.

Now, if you think about it, if we in a standard, say standard medical device that is downloading data, you know, you would download Point A, you know, whatever information you have at Point A and Point B over here. But if you think about it, the way that you can pick Point A and B is by a line, by a circle, by a squiggle, by whatever.

And so if you're just looking at Point A, and then you're looking at Point B, you're missing out all of the information that might occur, or the events that might have occurred between Point A and Point B. So if you think about it in that sense, that is the power of not only obtaining and visualizing it, but storing that data for later analysis.

So, from the perspective of the greater picture, well if we think about all of this kind of line physiologic data, what can you use it for? Well, most importantly, from a physiologic standpoint and from a precision standpoint, all patients are different. You know, when we think about—when we try and monitor or keep things like blood pressure constant, we know that everyone is not the same.

So, if we can utilize transformed data or data where we look at specific variables, not just in their raw form, but in a form that is transformed and gives us even more insight or more information, that is going to be even better for our patients, and will enable us to actually institute much more precision-based therapies.

A very good example of where Sickbay has utilized this, is in specific analytic platforms that allow one to measure the blood pressure that is critical for maintaining adequate cerebral perfusion pressure.

And if we can measure surrogates of cerebral blood flow, and blood pressure together, and get information about the relationship between blood pressure and blood flow together, then we can predict what blood pressure is good for that particular patient, and can manage that patient appropriately. So, this is so important for precision physiologic management of patients.

The next and most important, I thought, is actually in the ability to predict events, okay? And what is beautiful about the platform for prediction is that number one, one can store this information and can say well, let us look at all of the physiologic variables, the EKG, the—all of the physiologic variables that we're recording in high precision.

What are the subtle changes, not the big changes of blood pressure goes from 140 to 120, but what are the subtle changes that occur in the waveform, or subtle changes that may occur in the waveform of the EKG, that might predict that this patient is going to have an event.

So, we can mark the event, if we have an event. We can mark the event, and then look back and say okay, well we can or we can get a machine that is able to look at subtle changes, because our eyes can't see a lot of what's—and we can say, and this machine can say well, you know, in the 50 patients that did not have this event, the EKG looked like this.

In the 50 patients in which there was this event, you know, there was this very subtle change. And so, we can utilize that kind of information to build in algorithms that can actually give us information and enable us to predict events that are going to happen long before they occur.

And so, we can intervene, whether it is low blood pressure, hypertension, arrhythmias like atrial fibrillation, the development of sepsis— this is being done by MIC and Sickbay. They have developed some of these algorithms.

They have deployed some of them, some of these risk prediction algorithms, and they are going to continue to do more, hopefully, you know, in partnership with people like us, and with academic institutions that sort of sum up the bigger picture.

Tim Crawford: That's great, and I appreciate the detail there. Dr. Fauss, I know, you know, Dr. Berkowitz is a key client for you, and you do a lot of really detailed work with Dr. Berkowitz and his team at the University of Alabama, Birmingham. Are there any other points that you would add that maybe you've seen with other clients that you could briefly add to the conversation?

Dr. Emma Fauss: I think I would just like to add that, you know, there's a spectrum of value creation in getting this data, right? We've talked about access to data. we've talked about the other end of predictive analytics. But even just going through that journey, there's a lot that an institution can learn and take in the process of that journey, to improve their service lines today.

And I do think that's important, because I think, you know, this isn't the type of research or activity that, you know, oh, let's do this, and we'll invest in this now, and maybe 10 years down the road, we might get an improvement. No, this is something where you deploy and there's value right away to the clinical people on the ground, especially in this COVID environment, where clinical distancing is so important.

An example of that I'd just like to talk about is, you know, some of the work we're doing around event recognition, right? Part of doing AI and machine learning—if you sort of abstract it to what is that is really? It is about—any ML or AI is about pattern recognition.

So effectively, what you're doing is you're training a computer algorithm to recognize certain things that maybe you can't see yourself. And when you're able to get this data, you're able to do that at a scale that has never been done before.

So, for instance, we're working on a number of projects right now where we're, you know, either teaching algorithms to recognize particular types of arrhythmia events, particular types of events that are needed for clinical documentation, right.

And so, what this does is, one, it—right off the bat, it allows access to the data so people can see those events and actually get an accurate representation of how much those events are occurring at their institutions.

The secondary benefit, as you go down that journey is, when automated event recognition becomes available, you can start to improve your documentation reimbursement activities, right? So maybe it's something that ties in directly to the acuity of a patient. That's way before you even get to a predictive analytic.

Now, once you're able to accurately label that data, now you start to be able to build those algorithms, and test those algorithms, that then recognized the precursors to those events. And that's when you start to get into that really sweet spot of leveraging predictive analytics in your clinical environment.

But I wanted to make that point because I want to let people know who are listening to this, that this is a journey, even as, you know, adopting this kind of technology, but it's something that even if you start where you are today, there are ways that you can leverage this data to improve clinical care and operations, and eventually build a competitive edge, and build a flexibility and response in your

organization, to allow you to react and evolve, and improve your service lines so that you're very competitive within the marketplace as well.

Tim Crawford: No, and that's—Dr. Fauss, that's great, and I think that's an important transition, you know, as we talk about next steps and kind of where we go from here. So, Dr. Berkowitz, how do you see this playing out in terms of next steps, in terms of what you're looking for next? And maybe you can briefly kind of summarize your thoughts, and then I'll move to Dr. Fauss and ask her to do the same.

Dr. Dan Berkowitz: Sure. I mean ultimately, it's my goal to have this deployed, as Emma said, for—throughout the whole institution, both in the ICUs and which we have started to deploy now, the intent—the operating rooms, which we have also—where we have also deployed it, and then ultimately to all of our care beds, because if you're in the hospital, you're sick enough to be monitored at this level. Otherwise, you shouldn't be in the hospital.

So, I think that's one of our—that's one of the important things that we, you know, obviously would like to do, is sort of deployment at scale, as we were talking about. And, you know, we have created a team at UAB that will be able to work with this data.

We've actually hired a machine learning expert that's going to be part of our team. He just started, and will be able to work together with the Sickbay, you know, looking at some of these algorithm development predictive analytic stuff that we were talking a bit, that Emma was talking about and that I've talked about before.

And I think the most important thing is for us to demonstrate, as we've said, as Emma has said, that we can show improvement in outcome and at such enhanced value, because all of these things are really ultimately what our goal is, is to improve patient care, improve outcomes, reduce lengths of hospital stay, and prevent events from happening, particularly if we can see them coming the patients' way. So, I think that's where we are heading towards.

Tim Crawford: No, that's great. Dr. Fauss, just a couple of brief thoughts on what's next for you.

Dr. Emma Fauss: Well, right now, we're very much focused on the Scale to Serve program that we're actually working on with Intel. This is a program which was originally spun up to help address some of the immediate COVID challenges that was actually inspired by some of the work we're doing with UAB.

And the intention is really to help 100 hospitals turn on remote monitoring and basic Sickbay capability, to help address some of the more immediate concerns of, you know, creating that clinical distancing. Just to give you a quick sort of, you know, just a snapshot I think is interesting, we actually just got some results back from one of the sites we had scaled up on.

And it was is very interesting that one of these institutions came to us and asked, you know, in the middle of the COVID response, you know, can you help us scale up? And so, we turned on a number of beds at their main facility, and they sent out a generic, you know, hey, this resource is now available to you.

And within a couple of weeks, we had 900 clinical users sign up across the institution. And within three weeks, we were up to utilization rates of 40,000-page views because we're—you know, they access the website, right? So that's how you access the utilization, but it was up to 40,000 hits per week, and that continues to climb.

But I just, I wanted to put that out there because I think it helps illustrate there are gaps, and there are—there is a demand from the people on the ground that are on the front lines that need access to this data, just to be able to do their jobs effectively, and it's currently missing.

And so, when you do make it accessible, it becomes a very powerful tool in the hands of people in your organization. So that's how this ...

Tim Crawford: Wow, that's impressive. Yes. No, that's impressive. And you mentioned the partnership with Intel, and we just briefly touched on this earlier, but I want to circle back with that, because I think it's important for folks to understand where Intel fit into the picture for you, for Sickbay and how MIC is leveraging that partnership.

Before we go to the Q&A, can you maybe just take just a brief minute and talk about that?

Dr. Emma Fauss: Well, yes. You know, Intel—you know, we've known Intel for a few years. We originally started working with some of the IoT groups, you know, in the world of devices and integration of things, Internet of things. But we eventually did get an investment from Intel Capital, which we have very much enjoyed working with them very closely.

The Intel Capital Group just basically opened the doors to the resources at Intel. And so just to give an example, we were able to work with some of the top security professionals at Intel, and leverage their experience in terms of consulting on our product, right?

We were able to leverage some deep resources in AI and machine learning to look at some of the problems we're facing in new and different ways. And that has been extremely valuable for us, and a valuable partnership. And through that, really those relationships that we've developed over the years, when COVID came around, I think there's a lot of cultural alignment.

Intel has been very much—they've sort of put their money where their mouth is, and had gone out there and said, we really want to help people in need, hospitals in need, care providers in need. And they have put a number of different programs, in addition to the Scale to Serve forward, to help get technologies like ours into the hospitals, to help them in this sort of time of uncertainty. So yes.

Tim Crawford: Sure. Okay, let me quickly get us to Q&A. we only have a few minutes left. So I'm going to suggest that we maybe hit this as more of a lightning round between the two of you, and try and get through as many questions as we can in the few minutes that we have left.

So, the first question is, and I think this is something that you touched on earlier in the conversation, but it probably bears restating, which is, why doesn't most of this data in the patient's room, already go into the EMR? And you touched on that, but why isn't it going into the EMR?

Dr. Emma Fauss: Well, just simply put that the architecture of the EMR is not structured to handle the fidelity and the load of the data. I think when most people think of like oh, we'll put this in a database, the amount of—the 870,000 data points that are generated every hour, are—they just don't store in an SQL database. You would—your SQL database would break.

So when we really came at this problem, you had to re-architect how you were going to store and manage the data from basically the basics, right? And so that Sickbay was built from the ground up to be optimized to handle that load of data, and leverage it in real time at scale. So, it required a different architecture, is the answer to that question.

Tim Crawford: Okay, great. Next question. Actually, we've had a couple of questions along these lines. Where does the FDA come into the mix when it comes to Sickbay and the work that's being done?

Dr. Emma Fauss: So very quickly, Sickbay is a class 2 medical device. Its indication is for use for active patient monitoring and alarm distribution. So, you can, you know, use our product as a medical device. In terms of the novel analytics, this is where the FDA has really come down.

If you were transforming data in real time and it's using the diagnosis and treatment of a patient, it is considered a medical device. And so, as such, any device that we helped create or that our partners create and does that in real time, needs to be taken to the FDA as its own medical device. And we're actually in the process of doing that with a number of different applications.

Tim Crawford: Great. Dr. Berkowitz, I think this next one I'm going to send to you. And it follows a couple of questions here around COVID. How has Sickbay kind of changed the game for you in the era of COVID?

Dr. Dan Berkowitz: So predominantly, what it involves is distribution of data and web-based monitoring, and the ability of people to be outside of the environment, providing a PPE exposure of high-risk physicians, maybe older physicians that are working in the critical care areas. And I think that's the most important.

There is also, you know, advantages of having information, and we haven't utilized it at this point yet, but having information from ventilators that are essentially down—that are monitored by the platform, integrated into the information download that we have and easily monitored in a single space. So, I would say that's the predominant use.

Tim Crawford: Excellent. Dr. Fauss, next one for you. Is Sickbay—is the Sickbay solution only useful for hospitals of a large scale?

Dr. Emma Fauss: Most definitely not. If you're monitoring patients, Sickbay will be useful, especially around the remote monitoring applications as well. I think that, because it is a modular system, basically it allows institutions to select the applications that they need to leverage.

So as where UAB might be interested in working with a lot of our research-based applications, so it allows them to then do that machine learning and AI. A smaller hospital might be focused on more of the clinical applications that directly impact their service lines.

Tim Crawford: Great. The next question. So are—is Sickbay making recommendations—maybe this is for both of you. And so, is Sickbay making recommendations for nurses and physicians to take? Dr. Fauss, do you want to start with that, and maybe we'll switch to Dr. Berkowitz and get his perspective as well on this?

Dr. Emma Fauss: So as of right now, our applications themselves, the ones that we host on the Sickbay platform, do not currently make recommendations. Those type of applications need to go through the FDA, as they're impacting through the clinical care direction of the care staff.

But that does not mean that institutions like UAB, cannot leverage the platform to incorporate the data and analytics into decision support tools for visualization.

Tim Crawford: Okay. Dr. Berkowitz?

Dr. Dan Berkowitz: Yes. I mean, I think that pretty much answers it. I think that, you know, the information can potentially be used for—if we make decisions about how we—you know, if we've got pathways that we develop for utilizing the information in decision-making.

But the utilization, as Emma has said, and deployment of sort of novel monitors, will need FDA clearance i.e., data that has been transformed from its original data, and then used as a “device” will need FDA clearance.

Tim Crawford: Excellent. Dr. Fauss, Dr. Berkowitz, thank you so much for taking your valuable time to share your insights with our audience, and your experiences and some information around Sickbay and the work that's being done there. I want to thank both of you for taking part in the conversation.