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MTI START-UPS SEE BEYOND THE DATA

MedTech Innovator cohort companies RIVANNA, IMVARIA, and Anumana apply AI-driven solutions across a range of medical specialties.

COLIN MILLER

In every major technological field today, artificial intelligence (AI) is more ubiquitous than ever before. No longer confined to software engineers and roboticists, large language models like ChatGPT have turned AI into a household product that laypeople can use to learn and create, saving time and effort in the process. In the medical industry, AI is perhaps most advanced in the imaging sector.

According to various estimates, among AI/machine learning medical device approvals, radiology applications account for 70-80%, far more than cardiology and neurology.

Medical images, often the first line of a diagnostic workup, have always been a rich source of information and patterns, much of which is not visible to the human eye. Here, AI lends additional expertise to facilitate screening for early detection and diagnosis, and not just that. In many cases, by streaming workflows to save time and create consistency for both image acquisition and interpretation, AI can increase radiology capacity in ways that both increase patient access and hospitals' bottom lines. But the same arguments apply to surgical or other specialties to which AI is applied, where it brings time savings,

predictability, accuracy, and a leveling of expertise that increases capacity.

As the medical industry becomes increasingly overloaded with patient demand, a burden that AI tools may help to relieve by streamlining workflows and fast-tracking diagnostics and care, logistical and regulatory barriers have made adoption a more deliberate process. Looking to improve clinical outcomes in different areas of medicine are three MedTech Innovator cohort companies, **RIVANNA**, **IMVARIA**, and **Anumana**, whose AI solutions are designed to increase practices' accuracy and efficiency. Rivanna aims to improve the placement of epidural needles for spinal anesthesia, while IMVARIA and Anumana are focused on extrapolating diagnostic insights from the most accessible imaging formats.

RIVANNA Has Anesthesiology's Back in Epidural Injections


Will Mauldin

For RIVANNA, AI can help clinicians metaphorically see through walls by layering information on top of ultrasound to achieve X-ray-like performance without radiation. Co-founded in 2010 by CEO Will Mauldin, PhD, the company emerged when the first handheld ultrasound devices were emerging onto the market during a large-scale push for miniaturized electronics. Mauldin, who specialized in ultrasound technologies as a doctoral candidate and later served as an assistant research professor at UV, saw that trend as an opportunity to address an unmet need in spinal anesthesia, particularly for childbirth. Since X-rays cannot be used around a fetus, epidural needles are placed without any image guidance, entailing serious risks.

The bony environment of the spine and ribcage is obstructive to ultrasound imaging, a modality more suited for soft tissue and one that anesthesiologists only use in limited contexts. This anatomical challenge has traditionally made real-time visualization of the anesthesia needle entering the epidural space impossible when clinicians are used to seeing the entire path of the needle to its target when administering vascular access and regional anesthesia. However, more recent advancements in ultrasound probe technology have given way to a safer, albeit more painstaking, guided methodology. Managing the positioning of the probe and needle so that one doesn't block the other is a three-handed task, as the anesthesiologist needs to handle both the needle and syringe separately, thus requiring a second personnel member for the job.

Spinal, or neuraxial, anesthesia is only effective if it is delivered to the right location, the epidural space. According to Mauldin, up to 1 in 5 patients in labor go without pain relief due to inaccurate placement. Plus, multiple attempts to access the epidural space can traumatize the peripheral nerves near the spine, causing paresthesia. In non-obstetric applications such as lower limb surgeries, doctors may need to opt for general anesthesia over neuraxial, which carries its own risk factors. Patients with spinal implants or scar tissue from previous injuries or surgery may be contraindicated for epidurals altogether if needle access is too complicated.

Because the epidural space is not a solid structure, but a region beyond the ligamentum flavum in the posterior complex adjacent to the dura, anesthesiologists use a "loss of resistance" technique to determine when the needle pierces the ligament into the space and stop advancing before reaching the dura. If the needle extends too far and punctures the dura of the spinal cord, debilitating headaches can result from a leak of spinal fluid that requires a separate procedure to resolve and might lead to lasting consequences downstream. With nearly 5 million epidural injections performed annually across obstetric, surgical, and chronic pain settings, "even though these are low single-digit rates, we're still talking about tens of thousands of patients left with chronic neurological conditions," Mauldin says.

The CEO describes RIVANNA's debut device *Accuro* as "a stud finder for the spine." Using relatively basic AI developed in the 2010s for enhanced signal processing and bone mapping, *Accuro* provided physicians with a view of the needle's position relative to the epidural space using B-MODE ultrasound. The second generation, *Accuro 3S*, started development in 2021, was FDA-cleared in 2025, and is slated for a limited market release toward the end of this year. The updated model has more powerful AI that provides "a true, automated, real-time image guided technique" according to Mauldin and a modified design to solve the three-hand problem without the need for a second clinician (*see Figure 1*).

As a member of the 2025 MedTech Innovator cohort and a top-five finalist for the Grand Prize at The MedTech Conference powered by AdvaMed, **RIVANNA** has received vital exposure to industry leaders and stakeholders. CEO Will Mauldin notes, "One big benefit we've gotten from the relationship with MTI has been the connections to resources that were instrumental in forming strategic partnerships, raising money, and commercialization," adding that participation in MTI's investor forum at the JP Morgan conference earlier this year has brought the company closer into the fold of the overall medtech ecosystem.

When anesthesiologists place a central line using ultrasound guidance, their targets are fairly shallow, within a few centimeters of the skin surface. The needle is placed at an oblique angle to the probe that can't be replicated with epidural procedures since the needle and probe must both be perpendicular to the access point. To make this configuration possible, *Accuro 3S* has an opening in the center of a patented *Dual-Array* probe that the needle can pass through without disrupting the field of view or compromising the image. This innovation addresses key challenges in current procedural guidance, and the company recognizes the foundational research of Dr. Charles Y. Kim (Duke University), whose work in ultrasound-guided interventions was instrumental in this advancement.

The core IP behind *Accuro* and its underlying software *SpineNav3D* is exclusively licensed from the University of Virginia, and while the first iteration included a disposable attachment that made a temporary marking on the patient's skin indicating the alignment of the needle, the *Accuro 3S* system replaces that component with a different consumable that secures the probe to the patient's back.

Compared with the "rules-based" AI found in *Accuro*, *Accuro 3S* incorporates *SpineNav-AI*, a more robust neural network that Mauldin says is "much more performant in terms of raw accuracy" and conveys more annotated information, including locations of the ligament, spinal canal, muscle tissue, and more. Since spinal ultrasound data was not abundant, RIVANNA had to collect its own algorithm training data prospectively, gathering between 10,000 and 15,000 scans of patients ranging in age, sex, ethnicity, and body mass index.

Figure 1
The *Accuro 3S* Device

Source: RIVANNA

SpineNav-AI software is included in the 510(k) clearance of *Accuro 3S* as a diagnostic ultrasound system as opposed to being regulated as a standalone medical device because it is not intended for pairing with any other ultrasound hardware. Still, the algorithm requires an additional battery of clinical testing for validation, and Mauldin is not opposed to the possibility of licensing it as an independent product.

"There's a compelling business case to leverage [the software] that we've created, and to deploy it on a leading point-of-care ultrasound manufacturer's system," Mauldin states. "One segment of the market prefers an all-in-one solution, but we also know that emergency medicine constitutes a large segment of the market that does a lot of lumbar punctures and POC ultrasound scans that would value the technology on the devices they're already familiar with." The CEO also anticipates opportunities for future applications in thoracic epidurals, paravertebral blocks, and chronic pain solutions that tend to use more capital-intensive and radiation-requiring fluoroscopy.

Reviewed by an independent panel of radiologists, *SpineNav3D*—the foundational algorithm powering the first-generation *Accuro* and predecessor to *SpineNav-AI*—proved to be more than 94% accurate relative to the ground truth within 3mm. Clinical trials comparing the *Accuro* system with epidurals performed without guidance demonstrated an 81% higher first-insertion success rate, 83% fewer instances of paresthesia, and a 90% reduction in patients reporting a satisfaction score of less than 4 out of 5 with their pain management experience.

In addition to being able to utilize an existing CPT code that Mauldin says is "uniquely applicable" to *Accuro 3S procedures*, RIVANNA is also in communication with CMS regarding a new ICD-10-PCS code that will help with tracking healthcare economics and outcomes when using the devices. The company has raised a total of $9.5 million through its Series B, primarily from family office shareholders, and has received $52 million in cumulative funding from BARDA under a contract to advance its musculoskeletal imaging platform for fracture detection and soft tissue diagnostics, unrelated to its epidural product line.

With FDA clearance secured, an existing reimbursement pathway, and a licensable AI platform that could reach well beyond its own hardware, Mauldin sees RIVANNA at a commercial inflection point: "We've de-risked the technology—now it's about scaling it across a market where millions of procedures are still performed blind every year."

IMVARIA Tackles Pain Points in Lung Diagnostics

IMVARIA co-founders Joshua Reicher and Michael Muelly had a lot in common even prior to starting a company together, from training at Stanford before going into clinical radiology to researching AI technologies at Google. "We were both learning the R&D side of AI along with the tech deployment side and wanted to bring what we learned back into the clinic," Reicher recalls about the origin of IMVARIA.

The start-up's CEO explains that two main bottlenecks limit the update of AI in clinical medicine, creating a rift between research and practice. One is determining what areas of focus will yield the greatest impact on patient care. The other is understanding the healthcare system and workflow to create something ready for clinician adoption that wouldn't be an overly onerous change to implement. "Even today, we're still only seeing a handful of AI technologies deployed here and there, but we think now is the time for things to scale up substantially," Reicher says.

According to Reicher, clinical skepticism is not a major barrier to AI proliferation. About a decade ago, when AI was a relatively new buzzword in the industry, rumors circulated that radiologists would be out of jobs within five years, yet now radiologists are in greater demand than ever. "Doctors have followed these trends enough to know that there is a difference between hype-filled headlines and reality on the ground," Reicher assures, adding, "As an example, there's a growing awareness that LLMs are something that will be part of people's lives."

IMVARIA's algorithm platform centers around a combination of computer vision and risk modeling that Reicher aims to make scalable and applicable across a diverse range of use cases and clinical practices. What makes IMVARIA's software unique is the hands-off approach (from the clinician's perspective) that should alleviate workflow burdens rather than add to them. As Reicher explains, "Often with AI tools, clinicians have to increase the amount of time spent on each case because they have to manually manipulate the data as they run it through the system.

Ours is truly automated processing without a human in the loop for running the analysis, and it is supported by most major insurers around the country."

The company's first FDA-cleared product *Fibresolve*, a De Novo software-as-a-medical device (SaMD), is an adjunct in the diagnosis of idiopathic pulmonary fibrosis (IPF), a severe yet somewhat enigmatic pathology with vague symptoms such as cough, fatigue, and shortness of breath. Currently, patients presenting with these symptoms may require a fairly invasive lung biopsy, which itself correlates with a nearly 6% mortality rate despite being part of the gold standard diagnostic. *Fibresolve* can improve noninvasive diagnosis, not to mention shorten patient journeys to pulmonologist referral (a process that may take visits with four or five different doctors), by analyzing multimodal data such as CT images and functional tests for subtle patterns. Such analysis is reimbursed via novel CPT codes specific to the way *Fibresolve* works.

IMVARIA's algorithms are built on data sets compiled from pharmaceutical partners, private and public health centers, registries, and more. In addition to *Fibresolve*, the company offers an early detection module for lung disease called *ScreenDx,* which was cleared as a 510(k) SaMD in 2025. *ScreenDx* integrates into a health system's IT and works in the background without dedicated clinician interaction, flagging signs of underdiagnosed disease states as data comes in. Reicher compares the product to detection tools for "high-acuity" conditions like stroke, but in IMVARIA's case the focus is on chronic, underdiagnosed conditions. Outside of pulmonology, IMVARIA has published pivotal data on early-stage lung cancer and is exploring liver and kidney diseases as well as inflammatory and rheumatological conditions.

Reicher hopes to address some of the roadblocks to scalability that affect the adoption of medical software, whether or not it includes AI. Applications often need to be installed locally within an organization, or semi-locally in the case of cloud-based solutions, and require specific training for users to operate them and perform regular upkeep. In larger institutions, newly purchased software, like capital equipment, often must be approved by multiple budgeting committees.

Access to data that includes outcomes and quality information is another common obstacle. Reicher explains, "Today, most AI systems get deployed in such a way that data remains cordoned off within each health system, and it's very hard to combine these systems, which limits the upside of what you can learn and build." With *Fibresolve*, IMVARIA handles all analysis off-premises, acting as a contracted laboratory and returning diagnostic results within 72 hours of receiving relevant records for a patient. The algorithm has a built-in feedback loop that becomes more generalizable the more it's used, improving its performance.

Reicher expects disease detection to trend toward less invasive methods for increased home use before symptoms send patients to the doctor. To reach that point, tooling must be extremely

accurate to avoid false-positives. IMVARIA's strategy is to "work backwards" from the last stages of patient workups, where diagnostic questions remain, to early, proactive screening of patients who may be in the healthcare system for other reasons.

Like any medical device, SaMD tools are validated ahead of time, but AI is known to make unique and sometimes unpredictable errors, so IMVARIA performs continuous monitoring of its algorithms with an internal quality system designed to promote consistent performance across patients and institutions with increasingly heterogenous sources of data. Reicher intends for IMVARIA's core platform to be broadly applicable with fine-tuning adjusted to the particular combination of medical data and analysis techniques needed to reach a conclusion in any given use case.

IMVARIA has published close to 40 combined abstracts and studies investigating performance of its computing models for lung disease, as well as health economic studies demonstrating the software's utility for insurers. The company closed its seed round led by Creative Ventures in 2020 and its Series A is upcoming, supported by Labcorp, InHealth Ventures, Cedar Crest Ventures, and others. It has also received a Phase I SBIR grant of $400,000.

Anumana Makes Educated Inferences in Heart Failure

anumana


Simos Kedikoglou

Anumana was founded in 2021 as the culmination of a joint effort between the Mayo Clinic and **nference**, an early entrant to the field of machine learning for cardiology-focused clinical solutions. By leveraging large stores of deidentified data that span full patient journeys from physician notes to medications and imaging files, Anumana develops cardiac AI-based solutions that can glean pertinent disease information from electrocardiogram (ECG) waveforms. The company's first FDA-cleared cardiac ECG-AI algorithm detects low ejection fraction (LEF), and two additional algorithms for pulmonary hypertension and cardiac amyloidosis are under review.

"Our vision is to get patients diagnosed earlier in a way that is simple and inexpensive for clinicians and for the system," says Simos Kedikoglou, chief operating officer of Anumana. The standard 12-lead ECG was selected as an entry point to the market because it can be done less resource-intensively and in settings with less infrastructure than those for MRI, CT, or echo while still yielding more than 60,000 data points for assessment. In large clinical studies, Anumana has shown that its ECG-AI can pinpoint telltale signs of LEF, an early sign of heart failure, in ECGs enabling clinicians to identify patients who may be at risk before experiencing symptoms.

Kedikoglou highlights three of the company's value points: an extensive and diverse data set from major academic medical centers, advanced analytics, and thorough validation of the software's sensitivity and specificity that compares favorably with well-established tests. "Our flagship product has an area under the curve of 0.94, meaning it coincides very closely with the ground truth," Kedikoglou says.

There are approximately 7 million heart failure patients in the US, with that number projected to grow to more than 11 million by 2050. The condition can occur downstream of many other cardiac issues; for example, an acute myocardial infarction (or heart attack) may get a patient rushed to the hospital for a stent, but once the damage begins, heart failure can occur over the next five to 10 years. Kedikoglou explains that when heart failure is diagnosed and treated early enough, the progression of the disease can be slowed with pharmaceutical intervention; prompt treatment affords patients greater longevity and a higher quality of life. Likewise, the overall cost to the healthcare system can be minimized with early treatment.

The label of indication for the *ECG-AI* LEF model, designated as a Breakthrough Device, is "reasonably broad," according to Kedikoglou, and applies any time a clinician has a suspicion of LEF, which could include adult patients with cardiomyopathies, patients who are post-myocardial infarction, aortic stenosis, and chronic atrial fibrillation, those who are post-partum, and those undergoing cardiotoxic drug therapies. Patients who are asymptomatic at the time of diagnosis have the most treatment pathways as options, which can limit damage to the myocardium, along with impact to quality of life.

Using *ECG-AI* LEF, clinicians have additional, valuable clinical information to evaluate and make decisions about their patients' course of care, including whether to order additional testing, such as echocardiography. The algorithm only requires ECG as an input and is compatible with newly generated ECGs as well as ECGs taken in previous sessions, both covered by separate CPT

codes. *ECG-AI* LEF is simple to use and returns results in seconds in the form of a report posted within the electronic health record and ECG management system, with the data processing occurring on-site.

Anumana's *ECG-AI* LEF solution has been validated in a multicenter retrospective study of 16,000 patients. The technology was evaluated in a randomized controlled trial of 22,000 patients, demonstrating its performance in a typical community care setting. Anumana recently completed another validation study, including more than 2.8 million ECG and echocardiogram pairs from more than 676,000 patient encounters, which Kedikoglou points out is "above and beyond the minimum of regulatory clearance."

The second pair of clinical indications Anumana is targeting, pulmonary hypertension and cardiac amyloidosis, can coincide with heart failure or develop independently. Anumana's eventual vision is for patients to receive an ECG-AI evaluation with a routine ECG and be tested for various conditions right away to better defined the care pathway.

Beyond the technology that was initially licensed from the Mayo Clinic, Anumana has subsequently filed original IP, totaling more than 300 patents filed and more than 100 granted. The full suite covers the way the neural networks operate, practical implementation, and other aspects of the software.

In the standard of care, nearly 40% of patients with heart failure get diagnosed in acute care settings, such as the emergency department. These patients need to be managed according to guideline-based care and assessed for myocardial damage. Asymptomatic patients or those with HF risk factors can be managed effectively with medications. Eventually, Kedikoglou foresees a multi-algorithm cardiac panel, analogous to a blood panel today, that can detect multiple biomarkers at once.

For reimbursement, outpatient clinics can use an ambulatory patient code, APC 5734, which can tangibly defray the expense of the service, especially since it is performed at the point of care rather than an external lab. Having worked in the development of medical technology for more than 20 years, Kedikoglou says, "Our reimbursement outlook has been a lot more favorable than many other new technologies, and that reflects both the providers' and payors' interest in seeing this AI implemented in day-to-day practice."

With clinicians eager to use *ECG-AI* LEF, Anumana's priority is delivering seamless implementation into hospital IT systems. A distribution partnership with **Philips** has been publicly announced, and more strategic agreements are in the works. Meanwhile, a separate branch of the business uses the same data set for perioperative or intraprocedural guidance using modalities beyond ECG, and the company has forged an agreement with **Boston Scientific** to offer that service for Boston Scientific's procedures. To date, Anumana has raised more than $100 million from Mayo Clinic, nference, Boston Scientific, and more, which is being used for further R&D and validation. MTS