Nicholas Borys â?? CEO and CMO, MedTrace

We are delivering innovation that is scientifically grounded, clinically meaningful, and ultimately transformative for patient care.

03.09.2025

Tags:

Denmark, Medtrace, Medtech, Diagnostics

With decades of experience across nuclear medicine, oncology, and clinical development, Dr Nicholas Borys now leads MedTrace through a pivotal phase as interim CEO and Chief Medical Officer. The Danish company is advancing a novel platform that enables real-time production of oxygen-15 labelled water â?? a tracer long considered the gold standard for measuring blood flow â?? for clinical use in cardiac imaging and beyond. In this conversation, Borys discusses the technologyâ??s potential to reshape diagnostic practice and MedTraceâ??s path from Denmark to the US market.

How has your professional journey shaped your current leadership role at MedTrace?

I joined MedTrace just over a year ago, initially as a consultant, bringing with me a career spanning developing medicines in nuclear medicine, neurology and oncology. I trained as an internal medicine physician and moved into the pharmaceutical industry early on, joining Hoffmann-La Roche at a time when it was developing a new generation of nuclear imaging agents through its Medi-Physics division. One of my first projects involved IMP (SPECTamine), an I-123-labelled tracer for stroke diagnosis and one of the earliest SPECT imaging agents to receive FDA approval. I supported the team through the final stages of the Phase III trial and contributed to the successful registration and launch, an exciting entry into the world of nuclear brain imaging.

Following that, Medi-Physics was acquired by Amersham International, a major player in nuclear medicine. There, I became involved in cardiac imaging and led an international Phase III programme for a new agent, MyoviewTM, securing approvals in both the United States and Europe. That experience cemented my expertise in nuclear cardiology and broadened my exposure to oncology. Over the next 15 years, I focused on oncology drug development, primarily in small biotech companies, and progressed into the role of Chief Medical Officer. I spent over a decade at Celsion, where we advanced therapies for breast, liver, and ovarian cancers, including a gene-based treatment, guiding programmes from Phase I all the way through to Phase III. That kind of continuity is rare and something I take pride in.

Working in smaller companies also meant close involvement with executive leadership. At Celsion, I collaborated extensively with the CEO and CFO, and together we raised over USD 400 million to finance our clinical pipeline. That level of operational engagement proved invaluable. It eventually brought me to MedTrace, where I initially focused on the companyâ??s Phase III programme. Returning to nuclear medicine â?? this time in cardiology â?? has felt like a full-circle moment. Now, as interim CEO, I am drawing on the full breadth of my clinical, regulatory, and leadership experience. While the transition has brought new challenges, it is also an opportunity for continued growth, and one I am genuinely excited to embrace.

How does MedTraceâ??s technology work, and what makes it a potential game-changer in cardiac imaging?

MedTrace is entirely focused on a single, transformative innovation: using water as a tracer for nuclear imaging. While anatomical imaging modalities such as CT and MRI provide detailed structural views of the body, nuclear medicine offers functional insight, capturing how organs and systems are actually working. This depends on the tracer used. One of the most widely adopted is fluorodeoxyglucose (FDG), a glucose analogue labelled with fluorine-18, which enables PET scans to measure metabolic activity. FDG is especially useful in oncology, where tumours typically exhibit high glucose uptake.

In contrast, our approach at MedTrace centres on oxygen-15 labelled water (15O-water), long considered the gold standard for quantifying blood flow. The scientific foundation for this tracer has existed for decades, but clinical application has been hindered by its extremely short half-life of just two minutes, which made timely delivery impractical. Traditionally, 15O-water had to be produced in a cyclotron, often located some distance from the imaging site, requiring rapid transport that added logistical complexity and limited its use.

Our breakthrough lies in solving this barrier through the development of a compact device called the P3, that produces 15O-water directly at the patientâ??s bedside, adjacent to the PET scanner. This innovation enables immediate injection and acquisition of high-quality perfusion images, opening the door to real-time, quantitative assessments of blood flow. Our initial clinical focus is in cardiology, where accurate, non-invasive imaging is critical for diagnosing ischaemic heart disease.

In the United States, approximately 30,000 individuals present daily to emergency departments with chest pain. Around half are suspected of having ischaemia, where the heart muscle receives insufficient blood flow. These patients often undergo nuclear stress testing using SPECT (single photon emission computed tomography), which compares perfusion images taken at rest and under stress. If abnormalities are detected, the patient may be referred for coronary angiography, an invasive catheter-based procedure that visualises arterial blockages.

However, data shows that nearly half of these invasive procedures yield negative results, exposing patients to unnecessary intervention and the healthcare system to avoidable cost. This is where we believe our technology can make a substantial difference. While SPECT imaging provides an accuracy rate of around 60 to 70 percent, evidence from earlier studies suggests that 15O-water could achieve accuracy rates above 80 percent. By increasing diagnostic precision, we will improve on identifying which patients need further invasive procedures, enhancing clinical efficiency, reducing patient burden, and optimising outcomes. Up to 40 percent of patients who undergo invasive coronary angiography do not have significant disease in their major arteries. With 15O-water we expect to manage those patients better.

Where is MedTraceâ??s technology currently being used, and what role has Denmark played in its clinical adoption?

Denmark has played a pivotal role in both the scientific origins and early clinical deployment of our technology. 15O-water has a particularly strong legacy in Danish research. Our P3 platform â?? which enables the on-site, real-time production of 15O-water â?? was developed there, and Denmark remains a key proving ground for its clinical application.

One of the most compelling aspects of the technology is its safety profile: it is fundamentally water, labelled with a short-lived isotope, and administered in extremely low doses. Combined with the precision of the perfusion data it generates, this makes it particularly well-suited to cardiac imaging. Recognising this, Danish regulators granted a special exemption allowing hospitals to use the platform under a patient-specific certification. This has enabled early adoption in clinical settings, most notably at Aarhus University Hospital, where over 4,000 patients have already been scanned.

While the initial focus has been on cardiology, the technology is now being explored for broader clinical use. The experience gained in Denmark continues to guide our development efforts and stands as an essential foundation for future expansion into other geographies and therapeutic areas.

What prompted MedTrace to focus on the US market, and how does this align with the companyâ??s continued presence in Denmark?

Prioritising the United States was a strategic and necessary choice. As the largest and most progressive healthcare market globally, the US offers the ideal environment to introduce our 15O-water platform. It combines clinical sophistication with the infrastructure to support innovative diagnostic technologies, particularly in nuclear cardiology, where we believe our approach can deliver significant value. We have already submitted our IND application and are well into our Phase III clinical programme in the US. Given our size, it is essential that we remain focused. Concentrating our resources on a single, high-impact market at this stage allows us to execute effectively and position ourselves for a strong launch. The US is simply the most logical starting point.

However, this emphasis does not alter MedTraceâ??s foundation. We remain firmly anchored in Denmark, where the company was established and continues to be strategically and operationally centred. There are no plans to shift our headquarters or core functions. What we are building in the US is a complementary presence, an extension of our footprint to support regulatory and commercial preparations. We already have a small office in Minneapolis, which we expect will become increasingly important as we approach New Drug Application (NDA) submission and scale up our go-to-market capabilities. In that sense, Denmark remains our centre of gravity, while the US becomes the next frontier.

What are the key milestones MedTrace is working towards over the next two to three years?

Our near-term focus is firmly set on completing our ongoing Phase III clinical trial, which we anticipate concluding in 2026. Following the final patient visit, we intend to move swiftly toward finalising our NDA for submission in the United States. If that process proceeds as planned, we expect to reach both submission and approval within the next two to three years, setting the stage for a commercial launch in the US market.

Cardiology remains our lead indication, and alongside regulatory efforts, we are working to ensure clinical readiness. That includes close collaboration with key stakeholders in the nuclear cardiology space, particularly the American Society of Nuclear Cardiology (ASNC), which plays an important role in shaping the field. We are focused on building relationships with imaging centres, supporting physician education, and preparing for the installation of our P3 production units at high-volume sites.

It is a critical period, where clinical, regulatory, and commercial preparation are progressing in parallel. The next few years will be foundational in transitioning from late-stage development to market realisation.

What final message would you like to share with the healthcare community as MedTrace moves into its next chapter?

Although MedTrace is a small company based in Denmark, our mission is both focused and far-reaching: to advance the field of perfusion imaging by integrating 15O-water into clinical practice for the benefit of patients and physicians. We are confident that this technology has the potential to meaningfully improve how conditions such as chest pain are assessed, delivering a higher level of diagnostic accuracy resulting in better patient care.

Our work in cardiac imaging marks only the beginning. Once established in this space, we intend to explore applications in neurology and oncology, where 15O-water may offer comparable diagnostic precision. The goal is not simply to introduce a new tracer, but to reshape the clinical standard for perfusion imaging across multiple therapeutic areas.

This is a particularly exciting moment for us. We are building on strong foundations in Denmark while preparing for our entry into the US market, an important next step in our growth. I am pleased to share our vision, and proud of what we are working to achieve: delivering innovation that is scientifically grounded, clinically meaningful, and ultimately transformative for patient care.

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