

Rology Earns the First FDA Clearance for a 2-sided and On-demand Teleradiology Platform



CAIRO, [4th of October 2023] – Rology, the leading AI-assisted teleradiology platform in the Middle East and Africa, is thrilled to announce that it has received 510(k) clearance (K231385) from the U.S. Food and Drug Administration (FDA) for its Teleradiology Platform as a Class II Medical image management and processing system (radiological). This establishes Rology teleradiology platform as the world’s premier FDA-cleared on-demand and 2-sided teleradiology solution, according to Rology’s analysis.

With operations spanning across 9 countries, Rology has been a game-changer in saving more than 600,000 lives through its precise and swift radiology reports. The zero-setup and zero-footprint platform boasts comprehensive modules, including an Automatic Image Acquisition Tool (Rology Connect), Automatic Workflow Management System, DICOM Viewer, Reporting Tool, and Peer Review Tool, all of which have received the FDA 510(k) clearance.

Platform Innovation and Challenging Tradition

The platform's dynamic design facilitates the seamless acquisition of DICOM images from various imaging modalities and systems. These images are then encrypted, anonymized, stored, and intelligently matched with top-tier radiologists based on their availability and subspecialty. A notable highlight is that a staggering 69% of all reports undergo a peer-review process prior to delivery, emphasizing quality and accuracy.

Historically, many teleradiology providers have opted for FDA clearances targeting PACS systems and DICOM viewers, systems that can pose financial burdens for many healthcare providers. However, with the dramatic advancements in technology since then, there's been a paradigm shift. Rology's on-demand, two-sided platform melds the capabilities of these traditional systems while also introducing new features. Notably, its dynamic matching system ensures each scan is paired with the most suitable radiologist based on subspecialty and availability. This innovation, offered within a cost-effective pay-per-report model, democratizes access to top-tier teleradiology and guarantees unparalleled quality and precision in every report.

"Without a doubt, this marks a monumental moment for the industry. We've long recognized the need to challenge the traditional bounds, and with the platformization of our services, we're not just integrating technology but reshaping the very fabric of teleradiology. Our platform stands as a testament to innovation and the commitment to deliver only the best to our clients," said Amr Abodraiaa, CEO of Rology.

Commitment to Excellence

This monumental achievement aligns perfectly with Rology's strategic vision of growth and global expansion. Having dominated the MEA market in the past 6 years, this clearance marks a significant milestone in Rology's journey towards establishing a pronounced global footprint, especially in regulated markets. This strategic move follows closely on the heels of Rology's acquisition of the Saudi-licensed teleradiology provider, "Arkan United", further amplifying its presence in the KSA. In July, Rology further fortified its position by securing a strategic investment from industry titan, the Phillips Foundation. The FDA clearance paves the way for some important strategic partnerships with industry leaders worldwide.

"The FDA clearance not only emphasizes our commitment to cybersecurity and regulatory adherence but also paves the way for promising collaborations with major radiology and hospital chains. It is a testament to

our unwavering commitment to providing top-notch, error-free radiology reports to our partners and patients," said Mahmoud Eldefrawy, Chief Medical Officer of Rology.

Empowering Healthcare Providers: Rology's Tailored Solutions for All

This FDA 510(k) clearance not only cements Rology's position as an industry front-runner but also unlocks immense potential for its extensive clientele. Serving over 150 clients in 9 countries, this clearance especially augments the capabilities of SMEs such as imaging centers, which make up 25% of the scans processed. The platform's inclusive design also significantly benefits remote and underserved public hospitals, which account for a commendable 56% of the scans. Such public institutions, often strapped for resources, can now leverage Rology's state-of-the-art solutions to bridge the gap, ensuring their patients receive the same quality of radiological care as those in more privileged settings. Furthermore, the balance of scans from private hospitals at 19% underscores Rology's versatility in catering to diverse healthcare settings.

"As we celebrate this milestone, it's essential to remember its broader impact," says Moaaz Hossam, Chief Business Officer of Rology. "This clearance doesn't just represent technological advancement; it symbolizes hope for countless medical providers, especially SMEs (standalone imaging centers) and the underserved public hospitals. With this platform, they can now provide world-class radiology services, ensuring that every patient, irrespective of their location or the institution's size, receives top-notch care. Our vision has always been about democratizing healthcare access, and this is a significant step towards that goal."

Impact: Six Years of Transforming Teleradiology

Over the past six years, Rology's platform has undeniably made a significant imprint in the teleradiology landscape. Serving an impressive 10,449,212 population, the platform has adeptly managed over 644,003 scans. Its expansive reach spans 387 imaging modalities and collaborates with a

network of 306 dedicated radiologists. Demonstrating its commitment to inclusivity and broad access to healthcare, 35% of scans catered to primary care settings, with 39% reaching rural areas. Notably, nearly half of the scans, at 46%, were directed towards the low-income class, highlighting Rology's dedication to making advanced healthcare accessible for all, regardless of their socioeconomic status.

"Our journey over the past six years speaks volumes about our dedication to the communities we serve. Witnessing the platform facilitating over half a million scans, especially serving the underserved like the rural and low-income demographics, has been a major source of pride for us. At Rology, we believe in leaving no stone unturned, and these numbers are a testament to our commitment to reshaping healthcare to benefit more people in more places," commented Salma Sakr, Chief Growth Officer of Rology.

Revolutionizing the Teleradiology Landscape

Rology's recent FDA clearance is not just a validation of the platform's safety and efficacy, but it also stands as a testament to the unique value proposition the platform offers in the teleradiology sector. Such clearances are pivotal for healthcare platforms, as they signify a level of trust and assurance for healthcare providers and patients alike. In an industry that continues to evolve with technology, receiving this clearance underscores Rology's commitment to setting the highest benchmarks of quality and security.

Understanding the intricacies and complexities of the regulatory landscape, Rology strategically collaborated with Innolitics, a renowned US-based engineering & regulatory consulting firm. This partnership wasn't just about ticking boxes; it was about bringing together two entities dedicated to shaping the future of radiology. Innolitics, with its deep expertise in radiology and regulatory processes, complemented Rology's vision to bring a game-changing platform to the market. Together, their synergized efforts

streamlined regulatory navigation, making FDA clearance an achievable dream.

J. David Giese, CEO and co-founder of Innolitics, remarked, "Our collaboration with Rology exemplifies the power of synergy. Together, we've taken significant strides in the realm of radiology, with the aim of delivering unparalleled healthcare services globally. Rology's dedication, combined with our regulatory and engineering consulting expertise, made the FDA clearance not just a possibility, but a reality. This achievement is a testament to the fact that when vision meets expertise, boundaries are expanded, and genuine, impactful change is realized."

About Rology:

Rology is the leading AI-assisted teleradiology in the MEA region, providing cutting-edge teleradiology solutions to over 150 clients across nine countries. With a presence in Egypt, Kenya, and Saudi Arabia, Rology's mission is to set new standards in radiology through technology and expertise. More details are available at www.rology.health

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