December 16, 2021
JMDC Inc.
Doctor-NET Inc.

First Pharmaceutical Approval in Japan for Chest X-ray AI Algorithm that Supports Diagnostic Imaging of Patients with Infectious Pneumonia, Including COVID-19 Pneumonia

– Commencement of service and sale on the AI algorithm platform "AI-RAD" –

On December 9, 2021, Doctor-NET Inc. (head office: Minato-ku, Tokyo; President and CEO Masako Hasegawa; hereinafter the "Company"), which is a subsidiary of JMDC Inc. (head office: Minato-ku, Tokyo; President and CEO Yosuke Matsushima), obtained pharmaceutical approval (marketing approval under the PMD Act[*1]) for "Chest X-ray Pneumonia Detection Engine DoctorNet JLK-CRP," a service that supports diagnostic imaging of patients with infectious pneumonia, including COVID-19 pneumonia. This is the first time in Japan that marketing approval has been obtained under the PMD Act[*1] for an infectious pneumonia detection AI algorithm that utilizes widely used plain X-ray images.

The Company is an industry leader, having the largest share of the remote diagnostic imaging support market in Japan. It already collaborates with approximately 1,000 medical facilities around the country using its remote networks, and performs diagnostic imaging services for 8,000 cases per day and 2 million cases a year. The Company has been promoting the development of the AI algorithm platform "AI-RAD," which enables the use of AI algorithm on the Company's remote networks. The AI algorithm that has attained pharmaceutical approval on this occasion is employed in examining plain X-rays, which are widely used in Japan, and in diagnosing COVID-19 pneumonia for which there is a strong social need. For that reason the Company has made this area a high priority. Development of this AI algorithm has been jointly undertaken by JLK Inc. in South Korea in cooperation with Kyoto Prefectural University of Medicine and Tsuyama Jifukai Tsuyama Chuo Hospital.

Service provision for, and sale of, "Chest X-ray Pneumonia Detection Engine DoctorNet JLK-CRP" in Japan will commence in December 2021 on the Company's medical imaging AI algorithm platform "AI-RAD." The Company will continue to help prevent the spread of COVID-19 infection.

■ Developmental background of "Chest X-ray Pneumonia Detection Engine DoctorNet JLK-CRP"

The outbreak of novel coronavirus disease (COVID-19) started in China in December 2019 and has since spread across the world. In Japan, the total number of people infected with the disease exceeds 1.7 million and more than 18,000 people have died from the disease as of November 2021. This situation has had an enormous economic and social impact. Even as the vaccination rate has risen, it is still important to take continuous infection control measures due to the appearance of mutant strains. To prevent the spread of infection and so conserve the medical resources of core hospitals in charge of providing medical care to patients with severe diseases, the health system is emphasizing early screening of patients with suspected COVID-19 infection at clinics and local hospitals in charge of providing initial medical care.

In this situation, employing plain X-ray equipment widely used at clinics and local hospitals to properly extract infectious pneumonia findings from X-ray images is, together with PCR testing, etc., expected to lead to the early screening of patients with suspected COVID-19 infection. However, it is difficult for clinics and local hospitals without a radiodiagnosis specialist to accurately detect signs of infectious pneumonia from plain chest X-ray images compared to CT images, and those signs are often overlooked. For that reason, the Company has developed this product with the aim of detecting findings of infectious pneumonia with a detection accuracy equivalent to that of radiodiagnosis specialists. This will assist diagnosis by doctors at clinics and local hospitals who are not radiodiagnosis specialists, thereby helping in the early screening of patients with suspected pneumonia caused by COVID-19 infection.

There is already a similar AI algorithm used to detect signs of COVID-19 pneumonia from CT images, but our product is the first AI algorithm used to detect them from plain X-ray images. More than 10,000 medical facilities in Japan have CT equipment, representing more than ten percent of the total. On the other hand, some 50,000 to 60,000 have plain X-ray equipment, exceeding half of all medical facilities. As a result, the Company believes there is ample scope for an AI

algorithm that utilizes plain X-ray images to contribute more widely to preventing the spread of infection. In addition, compared to CT examination, plain X-ray examination is easier in terms of separating flow lines used by infected patients from those used by non-infected patients and the equipment is easier to disinfect after taking images. It can be said that plain X-ray equipment should be used preferentially in a situation where COVID-19 infection is spreading. Moreover, X-ray examination exposes patients to less radiation than CT examination, and can reduce burden on patients.

■ Features of "Chest X-ray Pneumonia Detection Engine DoctorNet JLK-CRP"[*2]

This AI algorithm has been developed using about 200,000 images for learning as well as the DenseNet algorithm and the Class Activation Map algorithm, which are neural network technologies, to incorporate deep learning. The AI algorithm automatically analyzes chest X-ray images and outputs, as a result of analysis, the degree of certainty of infectious pneumonia findings and the area of interest.

(1) Indication of the degree of certainty of findings for infectious pneumonia[*3]

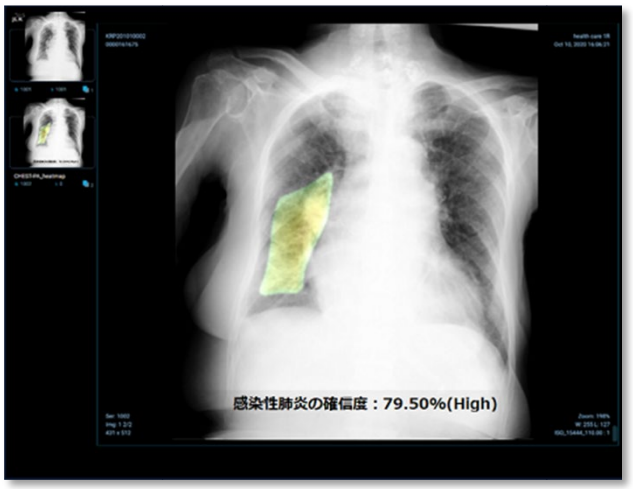
The AI algorithm indicates the degree of certainty of findings for infectious pneumonia detected from chest X-ray images and classifies it into the three types of certainty: Low (degree of certainty: < 30%), Medium (degree of certainty: ≥ 30% and < 65%), and High (degree of certainty: ≥ 65%).

(2) Indication and marking of an area of interest

When the degree of certainty of the findings for pneumonia is 50% or more, the product marks the area of interest on the chest X-ray image.

[Example of indicating analysis results on the system screen]

Images of analysis results can be displayed on a general-purpose viewer/report system.



[Example of indicating analysis results in the form of a report]

Analysis results may be output in the form of a report for easy linkage with reports from the hospital's internal system.

■ **Introduction and use of "Chest X-ray Pneumonia Detection Engine DoctorNet JLK-CRP"**

About 1,000 medical facilities already using the Company's service can use this AI algorithm via the existing remote request system. They do not need to introduce a new system.

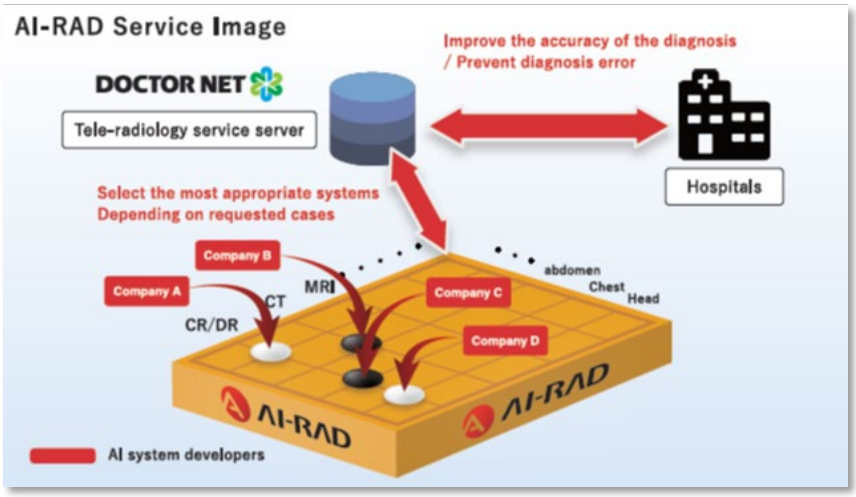
Medical facilities that are not currently using the Company's service do need to adopt the Company's remote request system. They can introduce it and link systems quickly and at low cost, regardless of their modality or PACS maker. Once a facility has introduced the system, it will be able to use AI algorithm services that the Company will develop in future as well as other services the Company provides, such as a remote diagnostic imaging service by doctors.

Users can operate the AI algorithm by themselves, and also request remote diagnostic imaging by doctors in addition to the analysis results that the AI algorithm provides. Fees for using the AI algorithm consist of a monthly usage charge and an analysis fee per case. (A separate reading fee applies when requesting a doctor to read an image.)

■ **The Company's future activities in the medical imaging AI algorithm business**

A medical imaging AI algorithm needs to be developed for each modality and disease/lesion, and it is impossible for a single company to develop algorithms for every field. As such, the Company aims to install, in the AI algorithm platform "AI-RAD" it has developed, AI algorithms developed by several other companies for various fields. This will take place after evaluating and selecting companies for each combination of modality and disease/lesion, using the two million cases per year of remote diagnostic imaging the Company performs. The Company will then provide those AI algorithm services to medical facilities that use its remote network.

The Company has already been promoting projects with AI algorithm development companies in the world. Through this project with JLK Inc. in South Korea, the Company has acquired knowleage on localization for the Japanese market as well as pharmaceutical approval in Japan, and this will give it more power to attract other AI algorithm developers worldwide.



*1: Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
*2: Program overview
- Date of approval: December 9, 2021
- Medical device approval number: 30300BZX00339000
- Type: Program (01): Disease diagnosis program
- Generic name: X-ray diagnostic imaging equipment workstation program
- Trade name: Chest X-ray Pneumonia Detection Engine DoctorNet JLK-CRP
- Classification: Class II

*3: The product does not judge whether the disease is infectious pneumonia or judge the presence/absence or severity (progress) of infectious pneumonia.

[Doctor-NET Inc.]

Doctor-NET Inc. is an industry leader, with Japan's largest share of the remote diagnostic imaging support market. The Company marked its 26th anniversary in 2021 under the corporate philosophy of "high-quality diagnostic imaging anytime, anywhere." At present, the Company's remote diagnostic imaging support service provides approximately 2 million cases of remote diagnostic imaging support per year (about 8,000 per day). It is also Japan's largest radiodiagnosis specialists' platform with which about 800 radiodiagnosis specialists, accounting for 13% of all radiodiagnosis specialists registered in Japan.

URL: https://dr-net.co.jp/

[JMDC Inc.]

JMDC Inc. was founded in 2002 as a pioneer in the medical big data industry, and owns unique anonymization technology as well as data analysis and calculation technology. It is developing a healthcare support service for insured persons based on receipt data on more than 650 million cases and medical checkup data on more than 28 million cases (as of March 2021), a drug safety evaluation service, a medical economy analysis service, and other information services. It also provides a Web service (Pep Up) for a single health index (health age) and for improving health, and is working to bring about a healthy society by applying its medical data and analytical skills.

URL: https://www.jmdc.co.jp/

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