CRO Success for World's First CT-LINAC by ChinaMed Device, LLC

ChinaMed Device, LLC has successfully got CFDA innovation pathway approval for United Imaging's world first integrated CT-LINAC without supplementary request .

NORTH ANDOVER, MA, USA, January 25, 2019 /EINPresswire.com/ -- ChinaMed Device, LLC(CMD), a leader in helping medtech/IVD companies with RA, QA and CRO in China, has successfully helped United Imaging to get NMPA (CFDA) innovation pathway approval within 12 months for its world's first integrated CT-LINAC without supplementary request . The technology of integrating LINAC and CT to bring high-resolution image guidance during cancer treatment is a breakthrough in China. The registration and clinial trial certainly encountered challenges. However, ChinaMed Device's team under the guidance of its clinical director, Jason Zhang, MD with the support of China CEO, Tony Liu, who obtained NMPA (CFDA) first domestic premium PET/CT system approval, understood United Imaging's CT-LINAC technology and clinical needs. The team completed the entire clinical trial process from design to final reporting at record time in less than 12 months for 70 patients with multiple types of cancers. ChinaMed Device proven approach of integrating technical, clinical and regulatory knowledge and experience has helped overcome the challenges along the way and expedited time to market for United Imaging in the NMPA (CFDA) innovation pathway approval.

Compared to the traditional CT (key players includes Philips, GE, Siemens, etc.)and linear accelarater (key players include Varian, Elekta, Siemens, etc.) in China market, United Imaging's CT-LINAC is the world's first integrated CT and linear accelerator which combines imaging diagnostic with radiotherapy together to achieve precise radiation.

United Imaging has overcom a major obstacle in radiotherapy: the precison of ionizing radiation given to patients. Because of the complexity of cancer, 'precision' has become the core of the development of radiotherapy equipment in this decade. Often times, while the radiation kills the cancer cells, it also damages the surrounding normal tissues. Equipped with diagnostic grade CT, CT-LINAC can display the details of organs and soft tissues in real time, and thus guide the precise implementation of radiotherapy. Moreover, it enables doctors to see the positional relationship between the lesion and the surrounding organs so that accidentally injuring surrounding normal tissue can be avoided.

Another breakthrough is the relocation of lesions. Doctors urgently hope to track the location of the lesion in real time. In the course of radiotherapy, patients cannot make any position change at the site where they need treatment! Even a few micrometers' changes may affect the overall radiotherapy effect. With several visual diagnostics spontaneously involved in the treatment of radiotherapy, CT-LINAC enables doctors to observe changes in the lesion.

"Changes in lesions can be seen before each radiotherapy treatment on the CT-LINAC. The physician can evaluate whether or not a correction plan is needed based on the images so that each stage of radiation therapy can be accurately implemented." According to Doctor Conghua Xie, Director of the Department of Tumor Radiotherapy and Chemotherapy at Zhongnan Hospital of Wuhan University, "Now it's like having a crystal ball in front of us that clearly tells us what will happen next and that's exactly what both patients and doctors needed."

With the help of ChinaMed Device, United Imaging's CT-LINAC received the NMPA (CFDA)

approval through Innovation pathway. What is more remarkable is that ChinaMed Device accomplished the complete clinical trial without having NMPA (CFDA) issuing any supplement requests or corrections! As a Class III innovative active device with approval from NMPA (CFDA) innovation pathway, United Imaging's CT-LINAC needs strong and robust clinical trial results in order to get the NMPA (CFDA) approval. ChinaMed Device, LLC conducted the entire clinical trial for United Imaging from clinical design, site selection, patient recruitment, Adverse Events Reporting (AER), follow-up monitoring, Efficacy Evaluation Report (AER), Safety Evaluation Report (SER), and the final Clinical Report.

Highlights from this clinical trial:
• 70 late-stage cancer patients in 3 sites
• The trial required different cancer patients, which increased the difficulty in patient recruitment
• Investigators from multiple therapeutic areas were required and coordinated, which increased the management and labor costs
• Significant efforts to advertise and work with PI to recruit enough patients
• We spent three months to help United Imaging to align the machines
• ChinaMed Device, LLC accomplished the complete clinical trial process in fewer than 12 months from patient recruitment to reporting

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