[SY13] Neuro Symposium lll

SY13-01

Drug development and Evaluation: Radiologist's perspectives

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Imaging use in drug development has seen tremendous growth over the past two decades. Especially, in the clinical trials, imaging endpoints has gained huge emphasis nowadays. Indeed, the US FDA issued a guidance to use imaging endpoints in the clinical trials in 2018 April. The addition of medical imaging in the clinical trials creates another layer of complexity for both imaging scientists and sponsors, as follows: (1) selection of appropriate qualified imaging biomarker, (2) standardization of imaging acquisition, archive, and analysis, and (3) complex workflow and new regulatory challenges. Radiologists should play an important role in such complex process of clinical trial imaging. When a well-prepared imaging team is incorporated in the clinical trials, the medical imaging can demonstrate more accurate and consistent results in the clinical trials.

Keywords : Drug development, Clinical trial, Regulation, FDA

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SY13-02

Imaging criteria for drug evaluation in Neuro-oncology

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The standard treatment for glioblastomas (GBM) comprises maximal tumor resection followed by concurrent chemoradiotherapy (CCRT) with temozolomide (TMZ) and six cycles of adjuvant TMZ. Despite the improved survival brought by TMZ, GBM remains a malignancy of dismal prognosis among various malignancies in the body.

Over the past few years, diverse drugs including anti-angiogenic drugs and immunotherapy have been under development to increase the progression-free and overall survivals in high-grade gliomas. However, the development of more effective drugs has been hindered by the lack of reliable criteria for the assessment of response and progression.

Traditionally, MacDonald criteria have been used in neuro-oncology clinical trials to determine drug responses since its introduction in 1990. However, they have shown to have limited use for the response assessment of recent therapies, because they do not take account of pseudoprogression, pseudoresponse, and nonenhancing tumor progression.

To overcome the shortcomings, updated criteria were developed by a multidisciplinary international group (Response Assessment in Neuro-Oncology [RANO] working group), consisting of neuro-oncologists, medical oncologists, neuroradiologists, neurosurgeons, radiation oncologists, and neuropsychologists, to improve clinical trial endpoints in neuro-oncology.

More recently, response assessment criteria refining the current RANO criteria for immunotherapy (iRANO) have been developed to address unique challenges such as delayed responses or therapy-induced inflammation following immunotherapy.

Keywords : MacDonald criteria, RANO, IRANO