Dr Yan Chang, National Shanghai Center for New Drug Safety Evaluation and Research, gave this presentation at the "Streamlining Drug Discovery" symposium held in Shanghai, China on 31 May 2018 .

**Abstract**

Genotoxicity tests are conducted to determine if a chemical or physical agent has the potential to cause mutations or chromosomal damage which, in turn, may lead to adverse health consequences, including cancer, reproductive impairment, developmental anomalies, or genetic diseases. The International Conference on Harmonisation (ICH) S2(R1) guideline (2011) recommends two standard regulatory test batteries, generally includes an assessment of genotoxicity in bacterial and/or mammalian cells *in vitro* together with rodent assays for chromosomal and/or DNA damage. Several test guidelines of the Organization for Economic Co-operation and Development (OECD) for evaluating the genotoxicity of chemicals and pharmaceuticals have been updated in 2016. The China FDA finalized the revision of the guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals this March.

In addition to the current test battery, it was also essential to focus on those technologies most likely to provide an adjunct to, or advantage over, current methods used to predict *in vivo* genotoxicity and/or carcinogenicity activity to improve human risk assessment.
*In vivo*
liver micronucleus test, Pig-a gene mutation assay and humanized in vitro genotoxicity test systems are being developed or in process of inter-lab validation.

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