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Scientific definitions and computerized algorithms for advancement of medical and pharmaceutical regulatory affairs

Disparity in basic scientific concept and theory lead to weakness in setting policy and regulatory affairs. At least three major areas in biomedical-research and pharmaceutical development exist confusion that need clarifications to improve research efficiency, developmental cost-effectiveness and rigorous regulatory affairs: (I) Loose in consensus on “synergy definition and its quantification” in drug combination synergy claims, especially in cancer and AIDS. (II) The terms PK/PD referred as Pharmacokinetics and Pharmacodynamics are used casually, where PD dose-effect dynamics for efficacy and toxicity algorithm for simulation is not yet defined clearly and with insufficient emphasis on PD comparing with PK. (III) The care and use of laboratory animals are good policy and regulation. However, the mass-action law-based conservation of animals to increase efficiency/cost-effectiveness and to minimize experimental size and data points, remain to be implemented and utilized. All the above important improvements can be implemented by employing the unified theory of the median-effect equation and the combination index theorem, based on the physico-chemical principle of mass-action law, using CompuSyn computer software for automatic simulation, that have, so far, been adopted by >10,000 scientists in over 5,000 papers worldwide as indicated by Thomson Reuters Web of Science core database.

Biography

Ting-Chao Chou received MS in Pharmacology from National Taiwan University, and PhD from Yale University, and Postdoctoral Fellowship at Johns Hopkins University, School of Medicine. He joined the Memorial Sloan-Kettering Cancer Center (MSKCC) and became a member in 1988, and was a Professor of Pharmacology at Cornell University, Graduate School of Medical Sciences during 1988-2000. He was the Director of Preclinical Pharmacology Core at MSKCC, where he retired on January 06, 2013. He is the Founder of PD Science, LLC., USA. He published 273 articles that have been cited by 16,421 papers in 620 biomedical journals worldwide including Thomson Reuters Web of Science and Google Scholar Citations with 22,336 citations, h-index 65 and 38 U.S. Patents. He introduced the “Unified Theory of the Median-Effect Equation of the Mass-Action Law” in 1976 for single drug, and with Prof. Paul Talalay (JHU) in 1984, created the “Combination Index Theorem” for multiple drug dynamics. His dynamics equations and software have been utilized to advance Econo-Green Bio-Research.

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