The 99¢ Clinical Trial: Accelerating Fast Failures in Clinical Trials Using Software that Models Weizmann BioNumbers on ErbB2 Activated Signaling Pathways and Lapatinib Drug Interaction for Advanced/Metastatic Breast Cancer

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6540 breast cancer clinical trials are performed in the world and drug life cycle takes an average of 14 years. The average pre-tax industry cost per new prescription drug approval (inclusive of failures and capital costs) is $2.55b. Accelerating fast failures can dramatically reduce drug approval costs and improve drug behavior predictability substantially. With this model/software, pharmaceutical scientists can predict drug behavior in 21 min (instead of 21 days) by simulating virtual trials which are predictive pharmacogenomic models of ErbB2 activated signaling pathways in conjunction with Lapatinib (CAS 388082-78-8). Accelerating the experiment (1440 times) involves modeling the Mechanism of Action of Lapatinib ditosylate in a cell region physiology exhibiting overexpression of ErbB2 (2-6 copies), a sub-cellular biomarker of advanced (Stage IV) metastatic breast cancer. By a user's single click, the clinical software: 1) begins test by activating H. sapiens cell for test clock O and biological clock ?? 2) waits for steady state to prepare case study sample based on parametric Weizmann BioNumbers 3) starts stochastic aggregator to scan active cell regions 4) invokes drug treatment daily oral lapatinib (1250mg/day) combined with capecitabine (2000mg/m2/day on days1-14 every 21 days) 5) takes ADMET/PDPK dose interval readings on tumor grade, mutation rate, substrate quantification and drug bioavailability. Validated with clinical data (at 5% significance level), there was a steady drop in tumor count on day 25 [0.49% tumor] for well-differentiated tumor grade. The computational scale can allow researchers to rapidly cycle through thousands of candidate molecules permutating over millions of patient biologies on a Spark cluster at low-cost with no patient intervention.

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