Abstract

The U.S. Food and Drug Administration (FDA) is in the process of developing a mechanism-based drug safety assessment and prediction program, and the application of systems biology is a cornerstone of this program. Regan-Udall Foundation is working with FDA and other stakeholders to launch a systems biology–based pilot project to examine the cardiac side effects of tyrosine kinase inhibitors (TKIs), a common and very useful class of cancer drugs — the Systems Toxicology Project (STP). This area was chosen because it is a growing problem; as treatments for cancer are improving and patients are living longer, the incidence of chronic adverse effects associated with treatment are increasing.

Mission

The goal of STP is to apply the tools of systems biology to better understand how TKIs lead to toxic effects on the heart and which patients are at increased risk for experiencing these effects. Systems biology can be used to model the activity of TKIs inside heart cells, which will inform understanding of how those activities and interactions lead to heart problems. Based on these models, STP will be able to generate hypotheses that can then be tested experimentally. An understanding of the mechanisms
of toxicity associated with TKIs can be used to develop models for assessing the safety of new and existing TKIs, informing the design of the multitude of new TKIs in development as well as the redesign of existing TKIs with predicted cardiotoxic potential, and in drug selection for a particular patient.

Financing

The Foundation received an initial $90,000 from Susan G. Komen for the Cure to convene the meeting and is working on obtaining additional funding.

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