of key molecules, and advanced imaging techniques such as computed tomography (CT) scanning, positron emission tomography (PET) techniques, and single-photon emission computed tomography (SPECT) imaging. To be clear, however, not all biomarkers are complex in nature. Blood pressure, heart rate, and even body temperature measurements would also be considered biomarkers based on the aforementioned definitions. These and other simple biomarkers have been available for a very long time. Most people can remember a time when their parents checked their temperature to determine whether or not a systemic infection was subsiding. However, the broad-based application of biomarker within the context of translational medicine to increase the efficiency of drug discovery and development dramatically increased at the beginning of the twenty-first century. Their primary purpose is to provide scientist with the data necessary to make more informed decision about whether or not a candidate compound (or hypothetical disease target) is worthy of further evaluation by providing data that can be used to predict performance in future studies. In theory, if scientists are better equipped to identify compounds with the desired properties using predictive assays and methods, then the compounds that move forward would be more likely to eventually reach the market. Similarly, the ability to predict which compounds possess undesirable properties (e.g., safety risks) would eliminate efficacious compound that would fail in clinical trials as a result of poor safety outcomes. In both cases, fewer compounds reach more advanced and more expensive assays, reducing the overall cost of the process.

In considering the use of biomarkers, it is important to understand that their use is not limited to clinical trials. Significant cost and time savings can be achieved by the judicious use of biomarker in the discovery/preclinical stage of the drug development process. Consider, for example, a program that has identified a set of 10 compounds with *in vitro* biochemical properties that suggest efficacy and the selectivity for the desired biochemical target. *In vivo* pharmacokinetic (PK) studies must be completed prior to launching *in vivo* efficacy studies. While it is certainly possible to run *in vivo* PK studies on all 10 compounds, there are several biomarker assays available that can be used to predict certain aspects of *in vivo* PK. *In vitro* microsomal stability studies[22] and permeability studies,[23] for example, can be used to identify compounds that are less likely to have the *in vivo* PK properties necessary to support efficacy. Compounds that are rapidly metabolized by microsomes are likely to be highly metabolized *in vivo*, while compounds that perform poorly in *in vitro* permeability assays are likely to have limited bioavailability. Although assay of this type are not perfect predictors of *in vivo* PK, they can be very effective in prioritizing compounds based on their likelihood having the desired PK properties. Ideally, this translates into fewer compounds moving into *in vivo* PK models, saving both time and money.