

METHODS AND SYSTEMS FOR ASSESSING CLINICAL OUTCOMES

CROSS-REFERENCE

This application is a Divisional Application of U.S. Ser. No. 12/412,334, filed on Mar. 26, 2009, which claims the benefit of U.S. Provisional Application No. 61/039,721, filed Mar. 26, 2008, which application is incorporated herein by reference.

BACKGROUND OF THE INVENTION

Conventional methods for assessing a patient's clinical outcome are primarily based on clinicians' judgment and past experience. The conventional methods generally involve laboratory tests, patient surveys and office visits at isolated time points, all of which are not scalable for a time series analysis, especially for one that tracks or predicts the trend of a patient's clinical outcome in real time. Intrinsic to the conventional methodologies is the profound drawback that a relatively small set of information such as a single clinician's personal preference is taken into consideration in reaching a clinical decision. As such, under the existing medical system, patient care becomes increasingly difficult when multiple variables are involved. In particular, there lacks a system and method to effect a multi-dimensional analysis in which a large set of biomarkers are used to aid in the diagnosis, prognosis, and treatment of a clinical outcome or the design and execution of a clinical trial.

Multivariate statistics are generally concerned with determining a statistical distribution of an outcome or a series of outcomes based on multiple variables. Inherently, most medical conditions and treatments are multivariate due to the complexities of the physiology. The discoveries of a vast number of disease biomarkers and the establishment of miniaturized analytic systems have made a new paradigm of patient care that makes multivariate analysis feasible. A desirable new paradigm would provide rapid access to information characterizing clinical outcome and then automatically linking that information through customized communication channels so that the desired medical actions (adaptive dose ranging, clinical decision making and so forth) can be performed. Also desirable is the ability to integrate information from an individual's blood tests with other physiologically relevant factors, and present that information in an actionable format. The technology described herein satisfies these needs and provides related advantages as well.

SUMMARY OF THE INVENTION

The present invention provides a medical information system for subject data analysis. In one aspect, a system of the present invention is particularly useful for advancing the future of blood testing and data analysis. For example, the system can be part of an integrated infrastructure built around real-time, point-of-care consumer blood monitoring devices which analyze a small blood sample (e.g., 500 ul, 50 ul, 25 ul, 10 ul or even less) and wirelessly transmit that information to a database which integrates real-time data with stored data from disparate databases (patient record, genetic/genomic information, data from pivotal trials) into one central repository. The system then allows for the automatic application of multivariate, multidimensional mathematics to the data repository to perform specific commands or tasks, e.g., mapping real-time PK/PD dynamically in the context of the pathophysiology of a given medical condition.

In another aspect, a system of the present invention can be used to improve the label of key drugs through adaptive clinical studies which generate publications for label expansions for new indications, patient subpopulations, and for ameliorating safety concerns. The development of such a system for home, real-time blood monitoring has significant implications which allow one to collect information which is otherwise not available through the use of the conventional laboratory testing.

The medical information system typically comprises (a) an input device for receiving subject data and in communication with a processor; (b) storage unit in communication with the processor having a database for: (i) storing data corresponding to a probability space defined by a set of discrete clinical outcomes, each of which is characterized by statistical distribution of at least one biological marker; and (ii) storing subject data corresponding to the at least one biological marker; (c) a processor that calculates the position of said subject data in said probability space as a way of assessing the probability of a discrete clinical outcome of said subject; and (d) an output device that transmits information relating to the discrete clinical outcome of c) to an end user.

Non-limiting clinical outcome that the system is adapted to predict can be selected from the group consisting of but not limited to: complete response (CR), partial response (PR), stable disease (SR), non-response (NR), adverse drug effect (ADR), and drug toxicity. In using the medical information system, the end user can be a medical personnel or the subject himself or herself. In some instances, the end user is from a pharmaceutical company.

In one aspect, the processor of the system calculates the position of said subject data in said probability space as a way of assessing the probability of a discrete clinical outcome of said subject.

In another aspect, the input device of the system comprises a touch screen. Where desired, the input system can comprise a data entry portal or a keyboard. The subject data to be input into, processed by, or transmitted as an output by the system can be textual, numeric or a category. Where desired, the textual or numeric information is solicited from the end user.

In some instances, the subject data represent measurements of the at least one biological marker present in a bodily fluid. In some instances, the measurements are obtained by a point-of-care device that is operated by the subject. The measurements can be taken at various time points to yield a trajectory within the probability space, wherein said trajectory represents a time series of the assessed clinical outcome. The various time points can cover a period of less than or about 24 hours

In another aspect, the medical information system comprises an output device having an automatic alert system. The automatic alert system can be programmable by the end user. Where desired, the automatic alert system is programmable based on a predefined protocol for a clinical trial. In another aspect, the output device of the system transmits selected portions of the subject data and the probability space in response to instructions from the end user. In yet another aspect, the information transmitted by the output device is encrypted. In still another aspect, the information transmitted by the output device represents an assessment of the clinical outcome of said subject at a single time point. The information transmitted by the output device can represent a time series of the assessed clinical outcome.

In still another aspect, the input device and/or the output device of the system comprises a user interface that can remotely access the network.