

CLAIMS

WHAT IS CLAIMED IS:

1. A method for characterizing a clinical or medical condition of a subject, comprising:
 - a. obtaining a first set of subject data from a sample obtained from and/or from observation of said subject, said subject data comprising at least one biological marker and at least one physiological parameter from the subject;
 - b. determining the probability of a medical condition of the subject using the first set of subject data obtained by constructing a probability space defined by a plurality of discrete clinical outcomes, wherein each discrete clinical outcome of said plurality is characterized by a statistical distribution of a set of markers, comprising at least one biological marker, and wherein said probability space is reflective of a medical condition, medical procedure, therapy, clinical trial, drug discovery, or drug development;
 - c. selecting a second set of subject data from the probability of the medical condition;
 - d. obtaining the second set of subject data from a sample obtained from and/or from observation of the subject, thereby characterizing the clinical or medical condition of the subject; and
 - e. calculating a trajectory in said probability space based on said first set of subject data and said second set of subject data, when said trajectory in said probability space being calculated based on positions of said subject data within each statistical distribution of said set of markers characterizing each of said discrete clinical outcomes, wherein said trajectory is indicative of the likelihood of progression of the medical condition of said subject.
2. ~~A~~ The method of claim 1 for characterizing periodicity of a clinical or medical condition of a subject, said clinical or medical condition comprising periodicity, the method further comprising:
 - a. identifying a set of biomarkers for a clinically relevant condition;
 - b. obtaining longitudinal subject data corresponding to at least one biomarker in said set to obtain a trend of the subject data;
 - c. analyzing said trend to identify periodic changes in the at least one biomarker;
 - d. measuring values of peak measurements of the periodic changes of the trend; and
 - e. characterizing the values of the peaks thereby characterizing the periodicity of the clinically relevant condition.

3. The method of claim 2, wherein the analyzing step comprises developing an ARIMA model to determine a differencing lag in the underlying model.
4. The method of claim 3, wherein the differencing lag is used to de-trend the trend and establish a stationary trend.
5. The method of claim 2, wherein the analyzing step comprises calculating an autocorrelation function.
6. The method of claim 5, wherein the measuring step comprises identifying the statistically significant peaks in the autocorrelation function.
7. The method of claim 2, wherein the analyzing step comprises calculating spectral density.
8. The method of claim 7, wherein the calculating spectral density is performed using a Fast Fourier Transform.
9. The method of claim 2, wherein the measuring step comprises identifying the power spectrum of the maximum spectral density frequency.
10. A-The method of claim 1 for characterizing a clinical or medical condition of a subject, further comprising monitoring subject response to therapy, the method further comprising:
 - a. obtaining longitudinal subject data corresponding to at least one biomarker in a set of biomarkers for a clinically relevant condition to obtain a trend of the subject data, wherein the subject data is obtained from a subject receiving a therapy;
 - b. monitoring periodicity of the trend; and
 - c. corresponding the periodicity to a response to the therapy received by the subject.
11. The method of claim 10, wherein the therapy is a periodic dosing regimen.
12. The method of claim 10, wherein the response to the therapy is characterized by a time-dependent behavior of peak levels of the trend.
13. The method of claim 12, wherein the time-dependent behavior is substantially constant.
14. The method of claim 12, wherein the time-dependent behavior is changing linearly.
15. The method of claim 12, wherein the time-dependent behavior is changing exponentially.