CLAIMS

WHAT IS CLAIMED IS:

1. A method for clinical trial design by characterizing the emergence of clinically relevant subpopulations of patients exposed to a therapeutic agent, the method comprising:

a. identifying a set of biomarkers in a blood sample that act as surrogate markers for the therapeutic agent;

b. receiving subject data regarding the set of biomarkers measured longitudinally from a group of patients exposed to the therapeutic agent;

c. identifying distinct clusters in a multivariate clustering space of the measured values of the set of biomarkers from the group of patients;

d. determining the rate of separation of the distinct clusters and measuring the distance between the distinct clusters in a statistical manner;