

CLAIMS

1. A system for determining a personalized dose of a pharmaceutical for an individual, the system comprising:
 - an input port configured to receive:
 - first data representative of one or more characteristics of the individual prior to administration of the pharmaceutical; and
 - second data representative of a measurement of a physiological parameter of the individual after administration of the pharmaceutical; and
 - a computer processor in communication with the input port and an electronic database having information that represents a computational model to predict an effect of the pharmaceutical on the individual's body, the computational model including a pharmacokinetic component and a pharmacodynamic component, and the computer processor being configured to:
 - generate, based on the first data and the computational model, a first target concentration and one or more first doses determined to likely achieve the first target concentration for the pharmaceutical in the individual's body;
 - compute, based on the second data, an update to the pharmacokinetic component and the pharmacodynamic component of the computational model to obtain an updated computational model that reflects the measurement of the physiological parameter; and
 - generate, based on the updated computational model, a second target concentration and one or more second doses determined to likely achieve the second target concentration for the pharmaceutical in the individual's body, wherein the update to the pharmacodynamic component of the computational model is used to predict that the second target concentration will have a therapeutic effect on the individual.

2. The system of claim 1, wherein the pharmacokinetic component of the computational model includes a compartmental model, and the computer processor is configured to use the pharmacokinetic component to predict a concentration time profile of the pharmaceutical in at least one compartment in the compartmental model.
3. The system of claim 2, wherein the predicted concentration time profile is predicted by using a first differential equation that describes a flow rate of the pharmaceutical into and out of the at least one compartment in the compartmental model.
4. The system of any of the above claims, wherein:
the pharmacodynamic component of the computational model includes a synthesis rate parameter representative of a synthesis flow rate of a pharmacodynamic marker and a degradation rate parameter representative of a degradation flow rate of the pharmacodynamic marker; and
the synthesis rate parameter and the degradation rate parameter are used in a second differential equation that predicts the individual's response to the pharmaceutical.
5. The system of any of the above claims, wherein the physiological parameter is a measured concentration time profile of the pharmaceutical in the individual's blood, tissue, or cells, and the computer processor generates the second target concentration and the one or more second doses by comparing the measured concentration time profile to the predicted concentration time profile.
6. The system of any of the above claims, wherein the computer processor generates the second target concentration and the one or more second doses by performing an optimization technique to minimize a difference between the measured concentration time profile and the predicted concentration.

7. The system of any of the above claims, wherein the pharmaceutical is infliximab, and the pharmacodynamic component of the computational model reflects an effect of infliximab on the individual's body.
8. The system of claims 3 and 7, wherein the flow rate is modified to account for the individual's predicted response to the infliximab as the individual heals.
9. The system of any of the above claims, wherein the first target concentration and the second target concentration each corresponds to a concentration that is predicted to cause an effect in the individual's body that is at least half of a predicted maximal effect.
10. The system of any of the above claims, wherein:
the first target concentration and the one or more first doses are portions of a first dosing regimen that includes recommended times and doses to administer to the individual;
the input port is further configured to receive third data indicative of one or more dosing requirements set by a manufacturer of the pharmaceutical, wherein the dosing requirements are based on approved dosing information contained in a package insert for the pharmaceutical; and
the computer processor is further configured to modify the first dosing regimen to comply with the one or more requirements while simultaneously using the computational model to reduce an adverse effect of modifying the first dosing regimen.
11. The system of any of the above claims, wherein the first data and the second data each include an anonymized identifier for the individual.

12. A method for determining a personalized dose of a pharmaceutical for an individual, the method comprising:

receiving, at an input port, first data representative of one or more characteristics of the individual prior to administration of the pharmaceutical;

generate, at a computer processor, based on the first data and a computational model, a first target concentration and one or more first doses determined to likely achieve the first target concentration for the pharmaceutical in the individual's body, wherein the computer processor is in communication with the input port and an electronic database having information that represents the computational model to predict an effect of the pharmaceutical on the individual's body, the computational model including a pharmacokinetic component and a pharmacodynamic component;

receiving, at the input port, second data representative of a measurement of a physiological parameter of the individual after administration of the pharmaceutical;

computing, based on the second data, an update to the pharmacokinetic component and the pharmacodynamic component of the computational model to obtain an updated computational model that reflects the measurement of the physiological parameter; and

generating, based on the updated computational model, a second target concentration and one or more second doses determined to likely achieve the second target concentration for the pharmaceutical in the individual's body, wherein the update to the pharmacodynamic component of the computational model is used to predict that the second target concentration will have a therapeutic effect on the individual.

13. The method of claim 12, wherein the pharmacokinetic component of the computational model includes a compartmental model, and the method further comprises using the pharmacokinetic component to predict a concentration time profile of the pharmaceutical in at least one compartment in the compartmental model.

14. The method of any of claims 12-13, further comprising predicting the predicted concentration time profile by using a first differential equation that describes a flow rate of the pharmaceutical into and out of the at least one compartment in the compartmental model.
15. The method of any of claims 12-14, wherein:
- the pharmacodynamic component of the computational model includes a synthesis rate parameter representative of a synthesis flow rate of a pharmacodynamic marker and a degradation flow rate parameter representative of a degradation rate of the pharmacodynamic marker; and
- the synthesis rate parameter and the degradation rate parameter are used in a second differential equation that predicts the individual's response to the pharmaceutical.
16. The method of any of claims 12-15, wherein the physiological parameter is a measured concentration time profile of the pharmaceutical in the individual's blood, tissue, or cells, and the second target concentration and the one or more second doses are generated by comparing the measured concentration time profile to the predicted concentration time profile.
17. The method of any of claims 12-16, the second target concentration and the one or more second doses are generated by performing an optimization technique to minimize a difference between the measured concentration time profile and the predicted concentration.
18. The method of any of claims 12-17, wherein the pharmaceutical is infliximab, and the pharmacodynamic component of the computational model reflects an effect of infliximab on the individual's body.

19. The method of claims 14 and 18, wherein the flow rate is modified to account for the individual's predicted response to the infliximab as the individual heals.

20. The method of any of claims 12-19, wherein the first target concentration and the second target concentration each corresponds to a concentration that is predicted to cause an effect in the individual's body that is at least half of a predicted maximal effect.

21. The method of any of claims 12-20, wherein the first target concentration and the one or more first doses are portions of a first dosing regimen that includes recommended times and doses to administer to the individual, and the method further comprises:

receiving, at the input port, third data indicative of one or more requirements set by a manufacturer of the pharmaceutical, and

modifying the first dosing regimen to comply with the one or more requirements while simultaneously using the computational model to reduce an adverse effect of modifying the first dosing regimen.

22. The method of any of claims 12-21, wherein the first data and the second data each include an anonymized identifier for the individual.

23. The method of any of claims 12-22, wherein the computational model is a function of response profiles for a population of patients and patient factor covariates corresponding to the characteristics of the individual.