

Claims:

1. A method for generating a patient-specific medication dosing regimen for a drug class, wherein the drug class comprises a plurality of drugs that exhibit similar pharmacokinetic (PK) behavior, similar pharmacodynamic (PD) behavior, or both, the method using a computerized medication dosing regimen recommendation system comprising a processor and a memory, the method comprising:

(a) receiving inputs into the processor of the system, the inputs including:

(i) drug data indicative of drugs in the drug class and associated routes of administration,

(ii) concentration or response data indicative of a concentration or response level of a first specific drug within the drug class in a sample obtained from the patient after administration of that drug to the patient, and

(iii) a target drug exposure or response level for the patient;

(b) selecting a mathematical model from a database stored in the memory, the database being accessible by the processor and storing a plurality of mathematical models, wherein the selected mathematical model is representative of responses by a plurality of patients to one or more drugs in the drug class, wherein each response is indicative of a patient response to at least one drug of the drug class, and wherein the mathematical model is configured to generate dosing regimens that are applicable to all drugs in the drug class;

(c) forecasting, using the selected mathematical model and based on the concentration data and the associated route of administration, a plurality of predicted concentration time profiles indicative of a predicted response of the patient to any drug within the drug class via the associated route of administration, wherein each predicted concentration time profile corresponds to a dosing regimen of a plurality of dosing regimens, each dosing regimen of the plurality of dosing regimens comprising (i) at least one dose amount, and (ii) a recommended schedule for administering the at least one dose amount to the patient;

(d) selecting from the plurality of dosing regimens a first dosing regimen having predicted concentration time profiles forecasted to achieve a treatment objective based on the target drug exposure or response level, the first dosing regimen structured so as to be applicable for administration of any drug selected from the drug class;

(e) selecting a second specific drug from the drug class for administration to the patient; and

(f) outputting the first dosing regimen for administering the selected second specific drug to the patient.

2. The method of claim 1, wherein the drug data excludes information identifying any specific drug belonging in the drug class.

3. The method of claim 1, the method further comprising:

receiving additional drug data indicative of an updated route of administration for the first specific drug;

updating the mathematical model, based on the updated route of administration for the first specific drug;

calculating, based on the updated mathematical model, at least one updated dosing regimen to reach the treatment objective for the patient; and

outputting the at least one updated dosing regimen for the patient.

4. The method of claim 3, wherein the drug data further comprises at least one of: one or more available dosage units corresponding to one or more drugs in the drug class, one or more available dosing strengths corresponding to one or more drugs in the drug class, or one or more indicators representative of whether one or more drugs in the drug class are fully human, and wherein the dose amount is a multiple of the available dosage unit.

5. The method of claim 4, the method further comprising:

receiving additional patient data indicative of a response of the patient to administration of the second specific drug in the drug class according to the first dosing regimen or a modified version of the first dosing regimen, the additional patient data comprising additional concentration data indicative of one or more concentration levels of the second specific drug in one or more samples obtained from the patient;

updating the mathematical model, based on the response of the patient to administration of the second specific drug according to the first dosing regimen or the modified version of the first dosing regimen;

calculating, based on the updated mathematical model, at least one updated dosing regimen to reach the treatment objective for the patient; and

outputting the at least one updated dosing regimen for the patient.

6. The method of claim 5, wherein the route of administration is at least one of: subcutaneous, intravenous, oral, intramuscular, intrathecal, sublingual, buccal, rectal, vaginal, ocular, nasal, inhalation, nebulization, cutaneous, and transdermal, and wherein the drug class is one of: monoclonal antibodies and antibody constructs, cytokines, drugs

used for enzyme replacement therapy, aminoglycoside antibiotics, and chemotherapeutic agents that cause white cell decreases.

7. The method of claim 5, wherein all drugs in the drug class share at least one of a similar chemical structure or a similar mechanism of action.

8. The method of claim 5, wherein the drugs in the drug class are indicated for use to treat at least one of: an inflammatory disease, inflammatory bowel disease (IBD), rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, asthma, and multiple sclerosis.

9. The method of claim 1, wherein the received inputs include at least one of: patient data indicative of a patient disease to treat or physiological data indicative of one or more measurements of at least one physiological parameter of the patient.

10. The method of claim 9, wherein the at least one physiological parameter of the patient includes at least one of: markers of inflammation, an albumin measurement, an indicator of drug clearance, a measure of C-reactive protein (CRP), a measure of anti-drug antibodies, a hematocrit level, a biomarker of drug activity, weight, body size, gender, race, disease stage, disease status, prior therapy, prior laboratory test result information, concomitantly administered drugs, concomitant diseases, a Mayo score, a partial Mayo score, a Harvey-Bradshaw index, a blood pressure reading, a psoriasis area, a severity index (PASI) score, a disease activity score (DAS), a Sharp score, and demographic information.

11. The method of claim 10, the method further comprising selecting the mathematical model from a set of mathematical models to best fit the received physiological data.

12. The method of claim 11, further comprising generating for display at least one of: (i) a patient-specific predicted concentration time profile indicative of the patient response to the first or second specific drug in response to the first dosing regimen, (ii) an indication of at least some of the concentration data and the additional concentration data, and (iii) an indication of the target drug exposure or response level.

13. The method of claim 12, wherein the model comprises a pharmacokinetic or pharmacodynamic component indicative of a concentration or response time profile of the drugs in the drug class, or based on synthesis and degradation rates of a pharmacodynamic marker, indicative of an individual response of the patient to the first or second specific drug.

14. The method of claim 1, further comprising receiving historical data indicative of a response of the patient to the second specific drug, wherein the computational model

accounts for the historical data in order to generate updated predictions of concentration time profiles for all the drugs in the drug class.

15. A system for generating a patient-specific medication dosing regimen for a drug class, wherein the drug class comprises a plurality of drugs that exhibit similar pharmacokinetic (PK) behavior, similar pharmacodynamic (PD) behavior, or both, the system comprising:

a memory, and

at least one processor configured to:

(a) receive inputs into the processor of the system, the inputs including:

(i) drug data indicative of drugs in the drug class and associated routes of administration,

(ii) concentration or response data indicative of a concentration or response level of a first specific drug within the drug class in a sample obtained from the patient after administration of that drug to the patient, and

(iii) a target drug exposure or response level for the patient;

(b) select a mathematical model from a database stored in the memory, the database being accessible by the at least one processor and storing a plurality of mathematical models, wherein the selected mathematical model is representative of responses by a plurality of patients to one or more drugs in the drug class, wherein each response is indicative of a patient response to at least one drug in the drug class, and wherein the mathematical model is configured to generate dosing regimens that are applicable all drugs in the first drug class;

(c) forecast, using the selected mathematical model and based on the concentration data and the associated route of administration, a plurality of predicted concentration time profiles indicative of a predicted response of the patient to any drug within the drug class via the associated route of administration, wherein each predicted concentration time profile corresponds to a dosing regimen of a plurality of dosing regimens, each dosing regimen of the plurality of dosing regimens comprising (i) at least one dose amount, and (ii) a recommended schedule for administering the at least one dose amount to the patient;

(d) select from the plurality of dosing regimens, a first dosing having predicted concentration time profiles forecasted to achieve a treatment objective based on the target drug exposure or response level, the first dosing regimen structured so as to be applicable for administration of any drug selected from the drug class;

(e) select a second specific drug from the drug class for administration to the patient; and

(f) output the first dosing regimen for administering the selected second specific drug to the patient.

16. The system of claim 15, wherein the drug data excludes information identifying any specific drug belonging in the drug class.

17. The system of claim 15, the at least one processor being further configured to:
receive additional drug data indicative of an updated route of administration for the first specific drug;

update the mathematical model, based on the updated route of administration for the first specific drug;

calculate, based on the updated mathematical model, at least one updated dosing regimen to reach the treatment objective for the patient; and

output the at least one updated dosing regimen for the patient.

18. The system of claim 17, wherein the drug data further comprises at least one of: one or more available dosage units corresponding to one or more drugs in the drug class, one or more available dosing strengths corresponding to one or more drugs in the drug class, or one or more indicators representative of whether one or more drugs in the drug class are fully human, and wherein the dose amount is a multiple of the available dosage unit.

19. The system of claim 17, the at least one processor being further configured to:

receive additional patient data indicative of a response of the patient to administration of the second specific drug or another drug in the drug class according to the first dosing regimen or a modified version of the first dosing regimen, the additional patient data comprising additional concentration data indicative of one or more concentration levels of the second specific drug in one or more samples obtained from the patient;

update the mathematical model, based on the response of the patient to administration of the second specific drug or another drug in the drug class according to the first dosing regimen or the modified version of the first dosing regimen;

calculate, based on the updated mathematical model, at least one updated dosing regimen to reach the treatment objective for the patient; and

output the at least one updated dosing regimen for the patient.

20. The system of claim 19, wherein the route of administration is least one of: subcutaneous, intravenous, oral, intramuscular, intrathecal, sublingual, buccal, rectal, vaginal, ocular, nasal, inhalation, nebulization, cutaneous, and transdermal, and wherein

the drug class is one of: monoclonal antibodies and antibody constructs, cytokines, drugs used for enzyme replacement therapy, aminoglycoside antibiotics, and chemotherapeutic agents that cause white cell decreases.

21. The system of claim 20, wherein all drugs in the drug class share at least one of: a similar mechanism of action or a similar chemical structure.

22. The system of claim 21, wherein the drugs in the drug class are indicated for use to treat at least one of: an inflammatory disease, inflammatory bowel disease (IBD), rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, asthma, and multiple sclerosis.

23. The system of claim 15, wherein the received inputs include at least one of: patient data indicative of a patient disease to treat or physiological data indicative of one or more measurements of at least one physiological parameter of the patient.

24. The system of claim 23, wherein the at least one physiological parameter of the patient includes at least one of: markers of inflammation, an albumin measurement, an indicator of drug clearance, a measure of C-reactive protein (CRP), a measure of anti-drug antibodies, a hematocrit level, a biomarker of drug activity, weight, body size, gender, race, disease stage, disease status, prior therapy, prior laboratory test result information, concomitantly administered drugs, concomitant diseases, a Mayo score, a partial Mayo score, a Harvey-Bradshaw index, a blood pressure reading, a psoriasis area, a severity index (PASI) score, a disease activity score (DAS), a Sharp score, and demographic information.

25. The system of claim 24, the method further comprising selecting the mathematical model from a set of mathematical models to best fit the received physiological data.

26. The system of claim 25, wherein the at least one processor is further configured to generate for display at least one of: (i) a patient-specific predicted concentration time profile indicative of the patient response to the first or second specific drug in response to the first dosing regimen, (ii) an indication of at least some of the concentration data and the additional concentration data, and (iii) an indication of the target drug exposure or response level.

27. The system of claim 26, wherein the model comprises a pharmacokinetic or pharmacodynamic component indicative of a concentration time profile of the drugs in the drug class or based on synthesis and degradation rates of a pharmacodynamic marker indicative of an individual response of the patient to the first or second specific drug.

28. The system of claim 15, the at least one processor is further configured to receive historical data indicative of a response of the patient to the second specific drug, wherein

the computational model accounts for the historical data in order to generate updated predictions of concentration time profiles for all the drugs in the drug class.

29. The system of claim 15, wherein the system is a cloud-based computing system operated by the at least one processor.

30. The system of claim 29, wherein the cloud-based computing system comprises a network and at least one server, the network configured to link at least two selected from the group of: the at least one processor, the memory, the at least one server, and at least one user device.

31. The system of claim 29, further comprising an interface connection to an electronic medical record database, interface connection being operable by software or firmware configured to retrieve one or more indicators of patient information for a patient via the interface connection.