

CLAIMS

What is claimed is:

1. A method comprising:

codifying, by a server, a pre-existing informed consent document into a machine actionable set of rules using machine-learning, natural language processing, and expert assessment, wherein the machine actionable set of rules defines what a patient has consented to be done with a specimen and data derived from the specimen in at least one of a plurality of locations;

storing within non-transitory memory in the server, the machine actionable set of rules;

tracking, by the server, changes to the machine actionable set of rules;

automatically generating, by the server, a new consent document based at least in part on global regulations data derived from proprietary and public sources, by using the machine actionable set of rules with any changes and a machine learning regulatory intelligence knowledgebase (RIK), wherein the machine learning RIK includes the global regulations data and learns behaviors of bodies involved in consent approval in the at least one of a plurality of locations; and

displaying visual risk indicators for collection of the specimen as visually corresponding the plurality of locations on a map, wherein the visual risk indicators are indicative of risk for at least one of performing trials, collecting specimens, or enrolling patients.

2. The method of claim 1, wherein codifying, by a server, a pre-existing informed consent document is linked to and performed based upon prevailing global, country, regional, and local regulations in force at a time of codification in the at least one of the plurality of locations.

3. The method of claim 1, further comprising creating, for the patient, a consent profile indicating what the patient has consented to be done with the specimen and data derived from the specimen.

4. The method of claim 1, wherein storing within non-transitory memory in the server, the machine actionable set of rules is performed on a patient, collection site, sample type, country, and regional basis.

5. The method of claim 1, wherein tracking, by the server, changes to the machine actionable set of rules includes dynamically tracking changes in restrictions regarding what can be done to the specimen and/or whether the patient withdraws consent.
6. The method of claim 1, wherein the machine-learning RIK is used to create risk-based models for specimen and data collection.
7. The method of claim 6, wherein the machine-learning RIK further informs the risk-based models by learning behaviors of internal review boards (IRBs), ethics committees, health authorities, and other bodies involved in consent approval in the at least one of the plurality of locations.
8. The method of claim 7, wherein the behaviors include one or more of: performance, speed of approval, interpretation of local and global regulations, level of cautiousness, and trends over time.
9. The method of claim 1, wherein automatically generating, by the server, a new consent document includes generating the new consent document based on an outline of desired consent, categories of consent needed, and regulations in at least one of the plurality of locations.
10. The method of claim 1, wherein the map includes filters operable to provide interactive visualization of different risk categories.
11. A system comprising:
 - a machine-learning regulatory intelligence knowledgebase (RIK), wherein the RIK includes global regulations data derived from proprietary and public sources and learns behaviors of bodies involved in consent approval in at least one of a plurality of locations; and
 - a server with a processor and a non-transitory memory configured to:
 - codify a pre-existing informed consent document using machine-learning, natural language processing, and expert assessment to a machine actionable set of rules, wherein the machine actionable set of rules defines

what a patient has consented to be done with a specimen and data derived from the specimen in the at least one of a plurality of locations;

store within the non-transitory memory, the machine actionable set of rules;

track any changes to the machine actionable set of rules;

automatically generate a new consent document based on the machine actionable set of rules with any changes and the machine-learning RIK; and

displaying visual risk indicators that are indicative of risk for at least one of performing trials, collecting specimens, or enrolling patients as visually corresponding the plurality of locations on a map.

12. A computer program product, said computer program product comprising:

computer code for codifying a pre-existing informed consent document using machine-learning, natural language processing, and expert assessment to a machine actionable set of rules, wherein the machine actionable set of rules defines what a patient has consented to be done with a specimen and data derived from the specimen in at least one of a plurality of locations;

computer code for storing the machine actionable set of rules;

computer code for tracking any changes to the machine actionable set of rules;

computer code for automatically generating a new consent document using the machine actionable set of rules with any changes and a machine-learning regulatory intelligence knowledgebase (RIK), wherein the machine-learning RIK includes global regulations data derived from proprietary and public sources and learns behaviors of bodies involved in consent approval in the at least one of the plurality of locations; and

computer code for displaying visual risk indicators indicative of risk for at least one of performing trials, collecting specimens, or enrolling patients as visually corresponding the plurality of locations on a map.