SYSTEM AND METHOD FOR LABELING TRIAL STUDY MATERIALS

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ABSTRACT
The present disclosure relates to methods and systems for labeling trial study materials. The method, in some embodiments comprises the steps of providing bulk supplies to one or more study supply depots, receiving one or more requests for at least one study test kit at the one or more study supply depots, packaging the bulk supplies into one or more study test kit components, printing at least two different study supply label types on a single label sheet, affixing the at least two different study supply label types to the study test kit components, packaging the study test kit components into at least one study test kit; and shipping the at least one study test kit to a trial site.
SYSTEM AND METHOD FOR LABELING TRIAL STUDY MATERIALS

FIELD OF THE INVENTION

[0001] The present disclosure generally relates to systems and methods for labeling clinical trial materials on an as-needed or on-demand basis. Embodiments of the present disclosure may provide significant cost and time savings over traditional methods used for labeling study materials.

BACKGROUND

[0002] A clinical trial may include testing a medicament or device intended to benefit a human or animal, to determine its efficacy and safety. Most clinical trials require that the drug be administered to patients or volunteers (collectively commonly referred to as “subjects”). Typically trials require that a test drug be compared to both a placebo, and a known “standard” or “comparator” drug. Thus, study subjects may be treated with the study drug(s), a placebo, and/or a comparator drug in any combination depending upon the design of the study.

[0003] Clinical trials and the coordination thereof are complex, with the degree of complexity depending in part upon the study phase. Generally, trials can be divided into four phases, as described below:

[0004] Phase I: these studies typically involve a relatively small number of subjects. Some or all of the subjects may not know exactly what treatment they are getting (i.e. an “open study”). Or alternatively, some or all of the subjects may not know what treatment they will receive (i.e. a “blinded study”).

[0005] Phase II: these are larger studies involving up to several hundred patients or subjects, and are typically used to determine the optimum dose for a new drug. The study may incorporate the use of placebo and comparator treatments and may be ‘open’ or ‘blinded’. The number of bottles of drug involved in such studies may be in the region of dozens to several hundred.

[0006] Phase III: these are typically even larger studies than Phase II studies, involving hundreds to thousands of subjects in most cases. These studies are used to demonstrate the safety and efficacy of the new drug. These studies may include placebo and/or comparator treatments and will usually be blinded. The duration of the study may vary from a few days to several years, involving from several hundred to hundreds of thousands of drug containers.

[0007] Phase IV: these are typically post approval marketing-studies that may vary in size and complexity. They may be open or blinded and may or may not include comparators. The size and complexity of these studies may be similar to those for a Phase III study.

[0008] The clinical trial process encompasses a range of different and complex operations. For example, a trial may involve the production of the investigational or candidate drug (i.e. synthesis and formulation of the active ingredient or clinical entity and the manufacture of the final drug product), packaging, labeling and dispatch to investigator sites, administration to subjects, physician assessments and return of biological samples (e.g. blood, urine samples) for analysis and the return and accountability of the unused drug.

[0009] The manufacture, packaging and administration use of drugs is subject to regulatory control. Thus, for example, the packaging of drugs or “investigational products” used in clinical trials is subject to the same regulatory control as is the packaging of any other pharmaceutical product. For example, currently in Europe, the ECG guide to Good Manufacturing Practice must be followed. In the United States, various parts of the US Code of Federal Regulations must be followed, including, but not necessarily limited to—Title 21—Food and Drugs (Part 11—Electronic Records; Part 210—Labeling; Part 312—Investigational New Drug Application; Part 210—Current Good Manufacturing Practice in Manufacturing, Processing, Packaging or Holding Drugs; General; Part 211—Current Good Manufacturing Practice for Finished Pharmaceuticals; Part 600—Biologics Products; General; Part 800 General—Medical Devices and Part 1300—Controlled Substances). Each country typically has its own complex set of regulations and procedures that apply to drug labeling for clinical trials that must be followed.

[0010] Generally, clinical trial drug labels may be used to provide doctors, subjects, and trial sponsors with critical data such as: batch numbers, directions for use, drug strength or potency, expiration dates, package numbers, storage requirements, and unique subject identifiers, for example. In many cases, each clinical trial label identifies the packaged drug, the study, and the subject. Each label is unique to the individual subject, in addition to being trail and country specific. In some cases, labels may be affixed to a primary container (e.g. the pill bottle, tube, etc. itself) and one or more secondary containers (e.g. a cardboard box containing multiple pill bottles, or a kit box containing all of a subject’s individual drug containers for an entire trial or portion of a trial, or any other secondary container, such as shipping containers, for example). The FDA and other regulatory authorities require that every drug be correctly labeled and if possible permanently adhered to the container. Each country’s labeling laws must also be complied with for each country participating in the trial. To this end, drug companies typically submit proposed labels (including labels for drugs to be used with U.S. subjects as well as labels for drugs to be used with subjects from one or more other countries, which may need to be provided in one or more foreign languages) to obtain approvals from quality assurance and regulatory reviewers in each country.

[0011] Traditional trial study supply packaging and labeling methods typically include anywhere from dozens to tens of thousands of trial study supply units being prepared for a given study protocol or protocols. In a traditional model, all of the labels for a trial or a significant portion of the trial will be created, approved, and sometimes printed before the trial even begins. As previously explained, many trials include the administration of multiple different treatments, at multiple doses, at multiple sites in potentially multiple countries to potentially many thousands of subjects. Accordingly, the regulatory agencies of each country must approve all of the labels for a given study before a trial begins. If multiple labels are required for a given unit, for example, a bottle label and a kit label, each label is batched, printed, and released separately. Additionally, if a trial study is blinded, for example, there may be multiple types of labels of different sizes and information for each blinded dosage strength with each label group printed and released separately, even though many of the labels are of the same size and look identical except for a randomization or identifying number or barcode. In many cases, trial administrators will keep a study label book that contains all of the approved labels for all of the study sites and countries participating in the trial. The study drugs are not
typically packaged until all of the labels for all of the expected primary and secondary containers have been created, approved and sometimes printed (which may include filling and storing all of the labeled containers and kits). As can be imagined, this model results in delay, waste, and inefficiencies. This portion of a clinical trial (not including drug development) may be the portion of the study contributing most significantly to study start delays.

By way of example, if a trial study protocol for a pharmaceutical product calls for 1,200 patients with each patient receiving one of two drug dosage strengths or a placebo (i.e., 1:1:1 or 400 patients on each regimen) and requires each patient to receive two bottles that are to be placed in a single dispensing kit, wherein each bottle and each kit is to be labeled with a clinical label, then the following quantity and label types would need to be prepared and printed separately according to the traditional model:

<table>
<thead>
<tr>
<th>Label Qty</th>
<th>Designation</th>
<th>Label type</th>
<th>Label dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>800</td>
<td>Active A</td>
<td>Bottle labels</td>
<td>1&quot; x 2&quot;</td>
</tr>
<tr>
<td>800</td>
<td>Active B</td>
<td>Bottle labels</td>
<td>1&quot; x 2&quot;</td>
</tr>
<tr>
<td>800</td>
<td>Placebo</td>
<td>Bottle labels</td>
<td>1&quot; x 2&quot;</td>
</tr>
<tr>
<td>400</td>
<td>Active A</td>
<td>Kit labels</td>
<td>3&quot; x 4&quot;</td>
</tr>
<tr>
<td>400</td>
<td>Active B</td>
<td>Kit labels</td>
<td>3&quot; x 4&quot;</td>
</tr>
<tr>
<td>400</td>
<td>Placebo</td>
<td>Kit labels</td>
<td>3&quot; x 4&quot;</td>
</tr>
</tbody>
</table>

All of these labels would be printed in advance based upon an approved randomization schedule and released prior to any labeling operations or production being undertaken. Additionally, if this study was a multi-national study, a separate printing would occur for each country. Thus in the example described, if the study was planned for ten different countries, then a total of sixty different label types would need to be printed. Numerous difficulties arise on top of the relatively straightforward logistics of planning and executing a supply plan for a clinical trial study, especially in the medical and pharmaceutical fields. First, in many multi-national studies, where labels must be printed in different languages, it is a common practice to create booklets of labels. Study labels are almost always subject to regulatory approval in every country, territory, or jurisdiction in which the label is used. This requirement can cause significant delays, particularly in multi-national studies, as booklet labels cannot be released for labeling until they are approved in every jurisdiction. Thus, if booklet labels are used, the entire study may be delayed due to delays in a single jurisdiction. Additionally, it is not uncommon to have languages in a booklet label that are never used due to inaccurate forecasts of countries participating in a clinical trial.

Test kits are generally not transferable between test sites and clinics participating in clinical trials. Accordingly, if a site is unable to enroll as many subjects as anticipated, a number of test kits, and in some cases a significant number of test kits may be wasted, resulting in both loss of time and loss of money. It is not uncommon for studies to have overages of treatment supplies ranging from 100 to 300 percent, or more. In an effort to reduce such waste, some studies are broken into two or more campaigns. However, studies conducted in campaigns can be more expensive, because costly steps such as packaging and labeling must be repeated for each campaign.

Some medical and pharmaceutical products are subject to expiration or retesting requirements. Where enrollment is slow, for example where a study initially intended to take two years extends to four years; the products in test kits may expire or need to be retested. If this occurs, the packaged and labeled study drug in inventory which was never used must be reworked and relabeled.

Accordingly, a need exists for a labeling method that may reduce the overall time a trial takes to start and/or complete; is more efficient; reduces the amount of materials that may be wasted; is more cost-effective; and/or can relatively easily accommodate changes that may occur during the planning and execution of a trial.

**BRIEF SUMMARY OF THE INVENTION**

The present method for labeling trial study materials is a method for preparing materials for blinded studies comprising the steps of providing bulk supplies to one or more study supply depots, receiving one or more requests for at least one study test kit at the one or more study supply depots, packaging the bulk supplies into one or more study test kit components, printing at least two different study supply label types on a single label sheet, affixing the at least two different study supply label types to the study test kit components, packaging the study test kit components into at least one study test kit; and shipping the at least one study test kit to a trial site. The method may further comprise receiving the one or more requests for at least one study test kit through a computer network, and the method may further provide a centralized database electronically accessible by the one or more study supply depots through the computer network. In addition, the centralized database may contain a randomization schedule, and the at least two different study supply label types may be printed according to the randomization schedule. Further, a first study test kit may contain labels in a first language and a second study test kit may contain labels in a second language, and the at least two different study supply label types may include a first component label, a second component label, and a kit label.

In another embodiment, the present method for labeling trial study materials is a method for preparing materials for clinical medical trials comprising the steps of providing bulk supplies to one or more clinical supply depots; receiving one or more requests for at least one clinical test kit at the one or more clinical supply depots; packaging the bulk supplies into one or more clinical test kit components; printing at least two different clinical supply label types at the time of packaging; affixing the at least two different clinical supply label types to the clinical test kit components; packaging the clinical test kit components into at least one clinical test kit; and shipping the at least one clinical test kit to a trial site. The one or more requests for at least one clinical test kit may be received through a computer network, and the method may further comprise providing a centralized database electronically accessible by the one or more clinical supply depots through the computer network. The centralized database may contain a randomization schedule, and the at least two different clinical supply label types may be printed according to the randomization schedule. Further, a first study test kit may contain labels in a first language and a second study test kit may contain labels in a second language. In addition, the at least two different clinical supply label types may include a first component label, a second component label, and a kit label. Finally, in some embodiments, the method may comply with good manufacturing practices for finished pharmaceuticals.
[0019] In yet another embodiment, the present method for labeling trial study materials is a method for preparing materials for clinical medical trials comprising the steps of providing clinical trial label data to a central database, creating label text for at least two different clinical supply label types from the clinical trial label data, obtaining regulatory approval for the label text, printing the at least two different clinical supply label types on a single label sheet, verifying the accuracy of the at least two different clinical supply label types, and affixing the at least two different clinical supply label types to clinical test kit components. The central database may be connected to a computer network, and the centralized database may contain a randomization schedule. The at least two different clinical supply label types may be printed according to the randomization schedule. Further, a first study test kit may contain labels in a first language and a second study test kit may contain labels in a second language. In some embodiments, the at least two different clinical supply label types includes a first component label, a second component label, and a kit label. In addition, the method complies with good manufacturing practices for finished pharmaceuticals.

DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 shows a label sheet or continuous feed for use with the some embodiments of the present disclosure.

[0021] FIG. 2 shows a kit of trial study materials for use with the some embodiments of the present method for labeling trial study materials.

[0022] FIG. 3 is a flow chart showing the steps of a method for labeling trial study materials, according to embodiments of the present disclosure.

[0023] FIG. 4 is a schematic diagram of a system for implementing methods the present disclosure in accordance with embodiments of the present disclosure.

DETAILED DESCRIPTION

[0024] The present disclosure is generally related to efficient, relatively cost-effective methods and systems for providing labels for clinical trials on an “as-needed” or “on-demand” basis, while still complying with applicable regulations and meeting quality assurance standards. In some embodiments, instead of having all labels for a study approved and printed prior to the commencement of the study, labels may be approved and/or printed on an on-demand, or as-needed basis. Accordingly, in some embodiments, labels may not be printed and study prescriptions may not be filled until a specific order is received. As used herein, unless otherwise specified, the reference to the printing and/or approval of labels in the clinical trial setting may include labels for use on drug, or other container that houses a treatment (e.g. a drug, ointment, drop, injectable device, etc.); labels for use on a test kit that comprises an individual subject’s plurality of containers of treatments for use by the subject over the entire course of the clinical trial or some portion of the trial; labels for the shipment of multiple drug containers and/or multiple drug kits; and/or labels for use with ancillary supplies related to a trial.

[0025] As explained herein, multiple embodiments of the present disclosure are possible that allow for a tailored approach to label approval and printing for use in a complex and potentially changing environment such as that of clinical trials.

[0026] FIG. 1 shows one embodiment of a label sheet 30 for use in connection with embodiments of the present disclosure. The label sheet 30 may be of any suitable or desired size. In some embodiments, the label sheet 30 may be of a conventional and widely-available size, such as U.S. letter size or A4 size. In other embodiments, the label sheet 30 may be of an unconventional or custom proprietary size and may be cut from a continuous label stock feed. The label sheet 30 may be made of any material suitable for machine printing, such as by a laser printer, ink jet printer, thermal printer or any other printing technology. The label sheet 30 in some embodiments may be comprised of two or more layers, including a printable layer 32 and a backing layer 34. In such embodiments, the printable layer 32 may include an adhesive material for contacting the backing layer 34, and the surface of the backing layer 34 contacting the printable layer 32 may be coated with silicone or other material suitable for easily releasing the adhesive. In some embodiments, the back surface of the backing layer 34 may also be suitable for printing. In other embodiments, the label sheet 30 may comprise a single layer, and in such embodiments, it may be desirable for the back surface of the label sheet 30 to include an adhesive that can be activated by water or other solvent.

[0027] The label sheet 30 may include any number of sections dedicated or designated for labeling components of a test kit. For example, the label sheet 30 shown in FIG. 1 may be used in a clinical pharmaceutical trial study. The label sheet 30 may include drug package labels 36, each of which may include a first panel 36a and a second panel 36b. In this embodiment, the label sheet 30 also includes a kit label 38, a container label 40, an instruction panel 42, and a label information panel 44. In some embodiments, the label portions 36, 38, and 40 of the label sheet 30 may be defined by die cut or perforated edges 46, for example, for facilitating removal of each label 36, 38, or 40 from the label sheet 30. The instructions 48 and label information 50 in some embodiments may include text, diagrams, and machine-readable codes, such as bar codes 52, necessary for containing and communicating information to individuals and machines executing the labeling process. One or both of these sections 48, 50 may also include, without limitation, information regarding the particular testing regimen for the subject, safety information, and binding information, including a binding key, for example. Similarly, each of the drug package labels 36, kit label 38, and container label 40 may contain relevant information. For instance, drug package labels 36 may contain dosing information, drug expiration information, and emergency information, for example for use in the event that emergency un-blinding of the study drug is required. Kit label 38 and container label 40 may contain similar information. Each of labels 36, 38, and 40 may also contain machine-readable codes, such as bar codes 52, for use by the supply depot or location that may fill the order and/or study manager(s) for tracking the shipment or movement of study items, verifying the contents of labeled containers or kits, and/or any other suitable purpose. Labels or label sheets may include any combination of the aforementioned features and/or any other desired feature or information.

[0028] As shown in FIG. 2, a kit 60 may include a plurality of individual packages or containers 62. In some embodiments the kit may comprise a particular subject’s entire drug regimen for a trial, or some portion thereof. The particular type of package or container 62 included in a kit may vary according to the material it contains. For instance, containers
62 could be vials, tubes, bundles or other devices for packaging study materials. The kit 60 may also include a packaging instruction sheet, and/or batch record sheet, and/or an accountability sheet for reconciliation, and/or a packing list, and/or dispensing instructions for the site 64 that may accompany the containers 62 that are collectively packaged in a kit container 66, for example. Individual containers 62 may be filled according to the instruction panel 42, either before or after the package label 36 is affixed to the container 62. Similarly, a kit label 38 and container label 40 may be attached to the kit container 66. Other kit configurations are also possible. For example, a site kit may also be used in accordance with some embodiments, whereby a site kit may be filled with individual containers of study drugs, for example, or with subject kits for a plurality of subjects at a particular site.

[0029] A method 100 for labeling trial study materials in accordance with some embodiments of the present disclosure is now provided with reference to FIG. 3. The method 100 comprises several steps, for example, including, but not limited to a planning step 102, an order step 104, and a fulfillment step 106. In other embodiments additional or different steps may be included in the method. The planning step 102 may include collecting the information 102a required for the labeling process 100, including, for example: information related to the clinical trial design, goals, and/or any other relevant information; information related to the study medication or drug(s) to be administered, including doses, administration information, type of drug, etc.; drug study type (i.e. placebo, active test drug, comparator drug, etc.); regulatory information; country specific information; and/or any other necessary or desired information. The collected information may be stored in a database, as shown in FIG. 4 and described further below. In some cases, some or all of the information may, or may also be stored in hardcopy form. The information may be securely stored in some cases by any suitable means, for example, data stored electronically may be encrypted and/or password protected, and data stored in hard copy may be housed in a locked file cabinet or access-card protected room, for example. The planning step 102a may also include ordering bulk supplies or other supplies or materials that may be necessary for the labeling process.

[0030] The planning step 102 of the labeling process 100 may also include creating and/or receiving label text 102b for each of the labels to be printed. In some embodiments, the label text may be drafted, submitted for regulatory approval to the appropriate authorities or review agencies, and revised as necessary to obtain approval. In other embodiments, already approved label text may be received from other entities that have obtained approval for the labels. In other embodiments, a portion of the approval process may be performed by outside entities and some portion may be performed “in-house.” Label text may include such relevant information as dosing and safety information, protocol number, and/or randomization or serial number, for example. In some cases, depending on the design of the study and the label at issue, if the container is to house a blinded drug, the label would not include any information that would identify the drug to the subject and/or site and/or principal investigator or trial team (depending on the study design). The step of creating/receiving label text 102b may also include creating/receiving label text for each supply kit and the supply kit component that require a label.

[0031] Labels for supply kits may also need to be reviewed and approved by one or more agency for compliance with applicable regulations. Once finalized or approved, label text information may be stored in the system database and/or hard copy form (in some cases securely stored). The label text may be associated in the system with other relevant information for a particular trial study.

[0032] Finally, the planning step 102 of the labeling process 100 may include planning the label layout 102c. Planning label layout may include determining the appropriate size for a label sheet, such that all labels needed for all components of a test kit can be arranged on a single label sheet (from a single printing), along with any label sheet information or instructions. In other embodiments, however, a label sheet may be designed in any desired manner. Once the label sheet is planned, label stock may be ordered for use with the printing of the label sheet. In some cases, label stock may be ordered at other points in the label process 100. All or any suitable information relevant to the label layout and stock ordering, including information related to die-cutting dimensions on a continuous feed, if applicable, may be added to a secure system database and saved therein (discussed further below).

[0033] The label process 100 may also include the order step 104. Testing sites or individuals participating in a trial study may order one or more test kits for use in a particular study, for example. Accordingly, order information 104a may be received by the system 10 in any number of ways, including online through a website or other interactive website response mechanism or via telephone, or an interactive voice recognition mechanism, or any other suitable manner. Received order information 104a may be entered into the system of the present disclosure and associated with information already stored in the database for the particular study for which kits have been ordered.

[0034] In some embodiments, the final phase of the method for labeling trial study materials 100 is the fulfillment step 106. The fulfillment step 106 may include printing the appropriate labels 106a for the received order (i.e. printing the labels associated in the system for the test kits that were ordered as per the order step), verifying that the printed labels 106b are correct (by any suitable means, including but not limited to visual inspection, or scanning the labels for comparison against saved data stored in the system), packaging and labeling 106c: the test kits and test kit components, and shipping 106d the ordered test kits to the proper location. In some embodiments, additional, fewer, or different steps may be included in the fulfillment step.

[0035] In some embodiments, the order may be filled by a third party (i.e. a third party may actually fill the containers with medications as per the instructions for the order and requirements of the study). In such cases, the order information 104a may be forwarded to a supply depot/limited that is capable of filling the order. The supply depot may be selected based upon one or more factors, including, without limitation, language, proximity to the ordering test site or location, regulatory requirements, and/or ability to fill the order (i.e. the supply depot having the relevant bulk supplies).

[0036] Once a supply depot is selected to fill the order, the appropriate labels may be printed at step 106a on appropriate label stock. As discussed above, in some embodiments, the labels may be printed in the form of label sheets that are specifically designed to include, for example, all of the labels necessary for an individual kit. As previously explained, the particular labels to be printed are determined by the shipment/
dispensing request authorization and a randomization sched-
ule (when applicable) applied to the particular study being
conducted. The randomization schedule and attendant labels
for an order determine the particular supplies to be packed in
the kits that will fulfill the order, and the label instructions
may contain filling and packaging instructions for the person
or persons who fill the order. In some embodiments, such as
those dealing with medical or pharmaceutical studies, it may
be desirable or necessary to separate the different labels
according to the particular drug, dose, or placebo to be con-
tained in particular kits in order to comply with relevant
regulations pertaining to good manufacturing practices for
relevant goods, such as pharmaceutical products.

[0037] After each label sheet is printed, it may be scanned
at step 106b into the system to confirm, and in some cases
nearly instantaneously confirm, that each label on the label
sheet has been printed without any errors. If errors are
present, a feedback loop may be employed to reprint the label
at issue or otherwise troubleshoot an erroneous label. The
image of each label may also be stored in the system database
in connection with the particular study information, in order
to maintain an electronic record of labeling events for future
use or reference, for example.

[0038] Once the labels have been verified at step 106b,
the relevant kit components may be dispensed and the kits pack-
aged and labeled at step 106c. At this packaging and labeling
step 106c, a scanner, for example a hand-held scanner in some
embodiments, may be used to scan the bar codes 52 on each
label 36, 38, 40, and 44 to insure that each kit contains the
proper materials. Additionally the containers, drums and/or
bags holding the bulk drug, bulk components and/or devices,
etc. used during the packaging operation may also have a bar
code that is associated with each of the bar codes on each of
the components contained in a given kit, to further ensure
that the correct labels are applied to the correct container, and
that the correct drug is contained in the correct container. In
such embodiments, the scanner may be in electronic communica-
tion with the system and verifications may be recorded in the
system database. Once packaging, labeling, and verification
are complete at step 106c, one or more kits 66 prepared to
fulfill a particular order may be shipped to the ordering indi-
vidual or test site at step 106d. In embodiments in which the
method 100 is used in connection with clinical studies for
pharmaceuticals, it is preferred, and in some jurisdictions it
may be required, that steps 106a through 106c or 106d are
performed in close temporal proximity with each other.

[0039] Accordingly, embodiments of methods of the
present disclosure may advantageously allow for on-demand
label printing and thus supply shipping to sites or subjects as
needed. This method may allow for a significant time savings
over traditional methods of label printing and supply ship-
ment, which generally requires all of the labels to be created,
approved, and printed prior to any study containers or kits
being shipped, or study commencement. Further, because
containers or kits are not filled and labels are not printed until
a specific order is placed for the container or kit, a potentially
enormous reduction in wasted study materials may result
from the use of embodiments of the present disclosure.

[0040] While embodiments disclosed herein are described
with reference to use in the clinical trial environment, it will
be understood that other embodiments that are within the
spirit and scope of the present disclosure may be used in any
other suitable environments, such as the general pharmaceu-
ticals and device industry, for example, studies involving
animals, labeling of clinical lab kits or any other suitable field.

[0041] The methods of the present disclosure in some
embodiments may be used in conjunction with a computer-
based system. FIG. 4 shows a system 10 for implementing
some embodiments of the present disclosure for labeling trial
study materials. The system 10 may include a computer pro-
gram, for example, software including computer executable
instructions, hosted on one or more computer servers 12 or
other computer processing device. The server 12 may also
host or be in communication with one or more databases 14.
In some embodiments, the program and server 12 may be
centralized and be in electronic communication with one or
more supply locations/deposits, which deposits may be located
anywhere in the world. Each supply depot may include a printer 16, a scanner 18, and in some embodiments a machine
for performing die-cuts on-line for example, each of which
may be in electronic communication with the program and
server 12 via a router or modem 19 or other device for elec-
tronically connecting computer network components. In
addition, each supply depot may have a computer terminal 20
or other computing or input/output device that may also be in
electronic communication with the program and server 12. In
some embodiments, the system 10 may be configured such
that the terminal 20 hosts a local program or otherwise medi-
ates the interaction between the program and server 12 and
the printer 16 and scanner 18 located at a particular supply
depot. In some embodiments, printer 16 and scanner 18 may
be in direct communication with the program and server 12
without a local terminal 20. Each supply depot may be set up
differently in this regard. In some embodiments, the program
and server 12 are configured to receive input from one or more
interactive website response mechanisms (not shown) or
interactive voice recognition mechanisms (not shown), either
of which allow for system users to provide inputs (not shown)
to the program and server 12, such as placing orders for trial
study kits.

[0042] The database 14 may be any database or set of linked
or relational databases. The database 14 may contain any
information relevant to the trial study, including, without
limitation, a randomization schedule; information about the
trial study materials, including bulk supplies, inventory, and
ordering information; kit information, including composition
and specifications; safety and regulatory information; order
information, including purchaser information, order status
information, and shipping information, information for cre-
ating labels, including label content and label text, label
stock, label proofs, label approvals, etc., as well as any
desired or useful software, for example project management
software. In some embodiments a single database 14 may be
used in connection with a single system 10 and program and
server 12. In some embodiments, a particular trial study may
use a separate, segregated, or dedicated database 14.

[0043] While the system 100 has been described in refer-
ence to some exemplary embodiments, these embodiments
are not limiting and are not necessarily exclusive of each
other, and it is contemplated that particular features of various
embodiments may be omitted or combined for use with fea-
tures of other embodiments while remaining within the scope
of the invention.

What is claimed is:

1. A method for preparing materials for blinded studies
comprising the steps of:
providing bulk supplies to one or more study supply depots;
receiving one or more requests for at least one study test kit at the one or more study supply depots;
packaging the bulk supplies into one or more study test kit components;
printing at least two different study supply label types on a single label sheet;
affixing the at least two different study supply label types to the study test kit components;
packaging the study test kit components into at least one study test kit; and
shipping the at least one study test kit to a trial site.
2. The method of claim 1, further comprising:
wherein the one or more requests for at least one study test kit are received through a computer network.
3. The method of claim 2, further comprising:
providing a centralized database electronically accessible by the one or more study supply depots through the computer network.
4. The method of claim 3, further comprising:
wherein the centralized database contains a randomization schedule.
5. The method of claim 4, further comprising:
wherein the at least two different study supply label types are printed according to the randomization schedule.
6. The method of claim 1, further comprising:
wherein a first study test kit contains labels in a first language and a second study test kit contains labels in a second language.
7. The method of claim 1, further comprising:
wherein the at least two different study supply label types includes a first component label, a second component label, and a kit label.
8. A method for preparing materials for clinical medical trials comprising the steps of:
providing bulk supplies to one or more clinical supply depots;
receiving one or more requests for at least one clinical test kit at the one or more clinical supply depots;
packaging the bulk supplies into one or more clinical test kit components;
printing at least two different clinical supply label types at the time of packaging;
affixing the at least two different clinical supply label types to the clinical test kit components;
packaging the clinical test kit components into at least one clinical test kit; and
shipping the at least one clinical test kit to a trial site.
9. The method of claim 8, further comprising:
wherein the one or more requests for at least one clinical test kit are received through a computer network.
10. The method of claim 9, further comprising:
providing a centralized database electronically accessible by the one or more clinical supply depots through the computer network.
11. The method of claim 10, further comprising:
wherein the centralized database contains a randomization schedule.
12. The method of claim 11, further comprising:
wherein the at least two different clinical supply label types are printed according to the randomization schedule.
13. The method of claim 8, further comprising:
wherein a first study test kit contains labels in a first language and a second study test kit contains labels in a second language.
14. The method of claim 13, further comprising:
wherein the at least two different clinical supply label types includes a first component label, a second component label, and a kit label.
15. The method of claim 8, further comprising:
wherein the method complies with good manufacturing practices for finished pharmaceuticals.
16. A method for preparing materials for clinical medical trials comprising the steps of:
providing clinical trial label data to a central database;
creating label text for at least two different clinical supply label types from the clinical trial label data;
obtaining regulatory approval for the label text;
printing the at least two different clinical supply label types on a single label sheet;
verifying the accuracy of the at least two different clinical supply label types; and
affixing the at least two different clinical supply label types to clinical test kit components.
17. The method of claim 16, further comprising:
wherein the central database is connected to a computer network.
18. The method of claim 16, further comprising:
wherein the centralized database contains a randomization schedule.
19. The method of claim 18, further comprising:
wherein the at least two different clinical supply label types are printed according to the randomization schedule.
20. The method of claim 16, further comprising:
wherein a first study test kit contains labels in a first language and a second study test kit contains labels in a second language.
21. The method of claim 16, further comprising:
wherein the at least two different clinical supply label types include a first component label, a second component label, and a kit label.
22. The method of claim 16, further comprising:
wherein the method complies with good manufacturing practices for finished pharmaceuticals.