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(54) **SYSTEMS AND METHODS FOR DATA DRIVEN DOCUMENT CREATION AND MODIFICATION**

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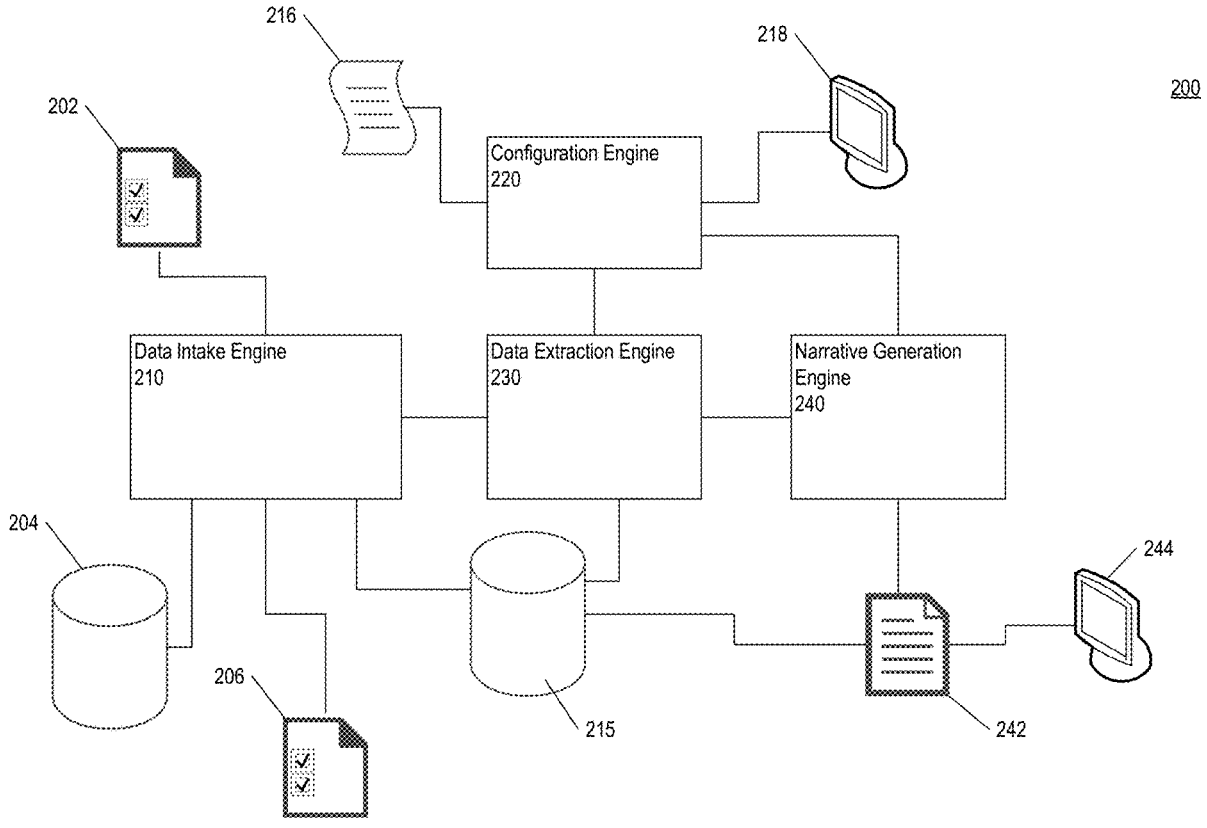
G06F 40/14	(2006.01)

(52) **U.S. Cl.**

CPC ***G06F 40/166*** (2020.01); ***G06F 40/14*** (2020.01); ***G16H 15/00*** (2018.01)

(57) **ABSTRACT**

Systems and methods are disclosed for data driven document creation and modification. The systems and methods include obtaining a first dataset having data records associated with entities, obtaining a list of entities associated with a first subset of data records in the first dataset, and obtaining configuration information, wherein the configuration information includes rules for identifying logical relationships in the data records and wherein the configuration information is specified using a vector-oriented language. The systems and methods further include extracting, for each entity in the list of entities, based on the rules, data records from the first subset of data records associated with the entity and generating a document for each entity in the list of entities using the extracted data records and the configuration information.



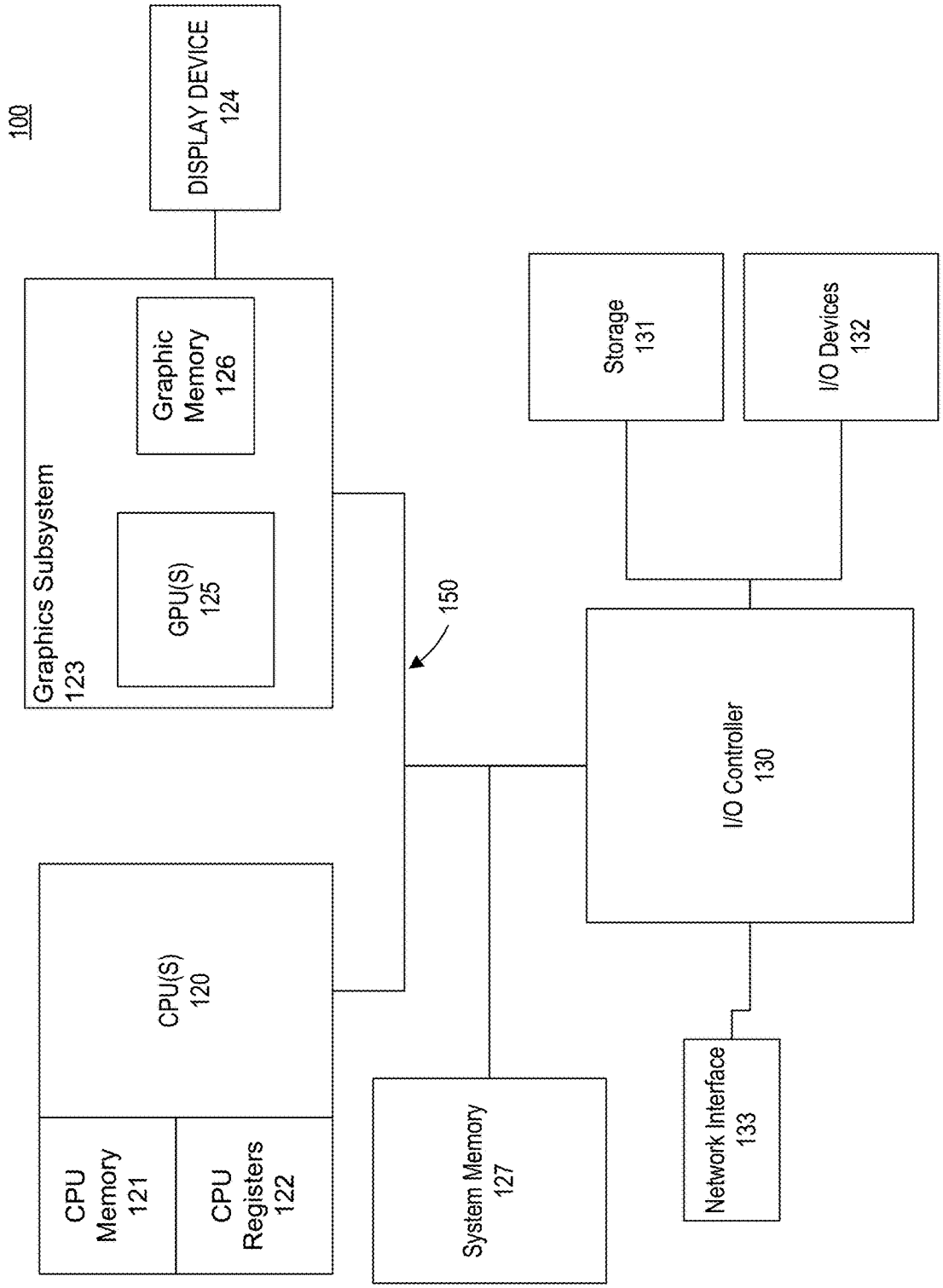

100
DISPLAY DEVICE
124
Graphics Subsystem
123
Graphic
Memory
126
GPU(S)
125
150
Storage
131
I/O Devices
132
I/O Controller
130
CPU(S)
120
CPU
Memory
121
CPU
Registers
122
System Memory
127
Network Interface
133

FIG. 1

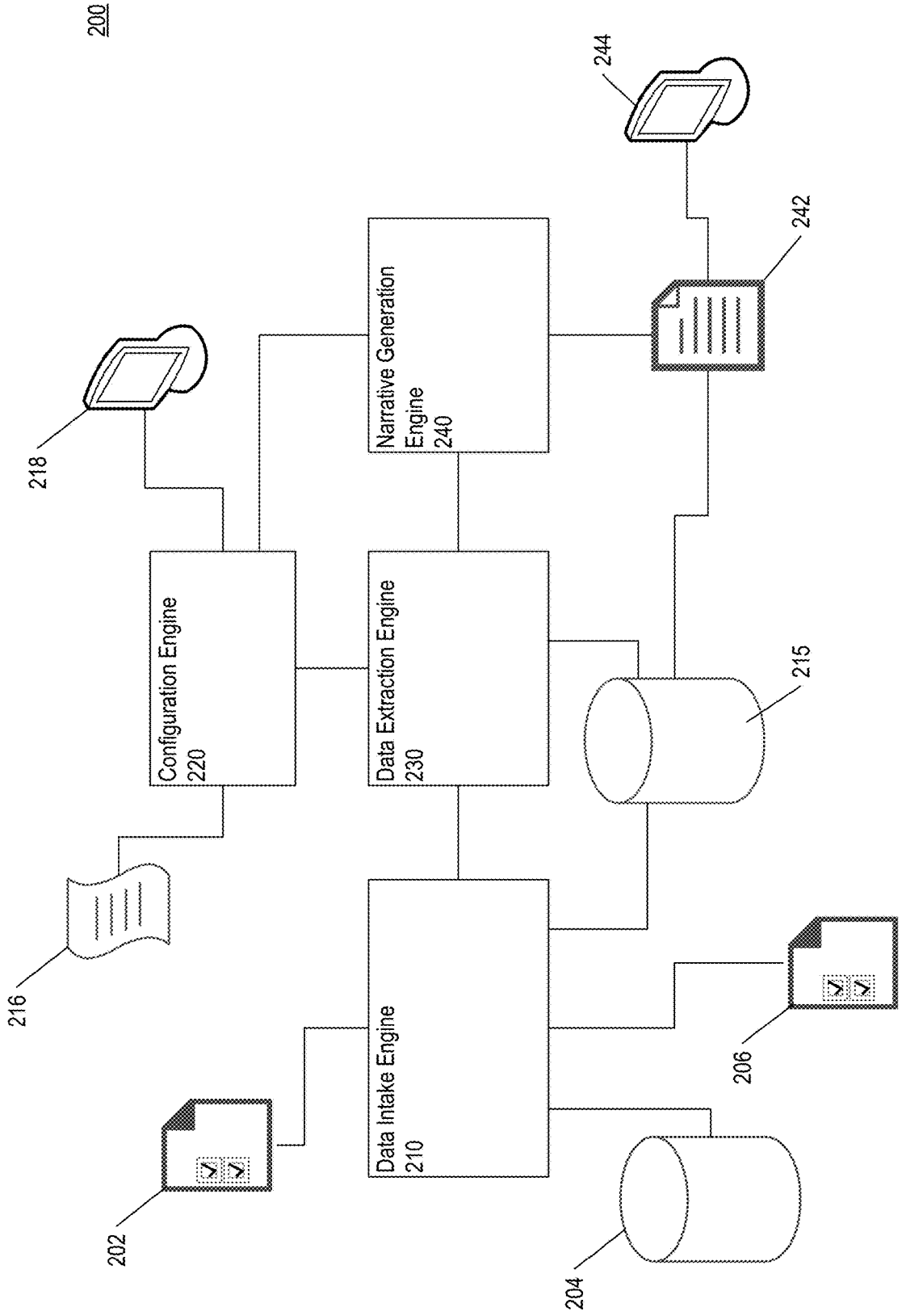

200
244
242
218
Narrative Generation Engine 240
Configuration Engine 220
Data Extraction Engine 230
215
216
Data Intake Engine 210
206
202
204

FIG. 2

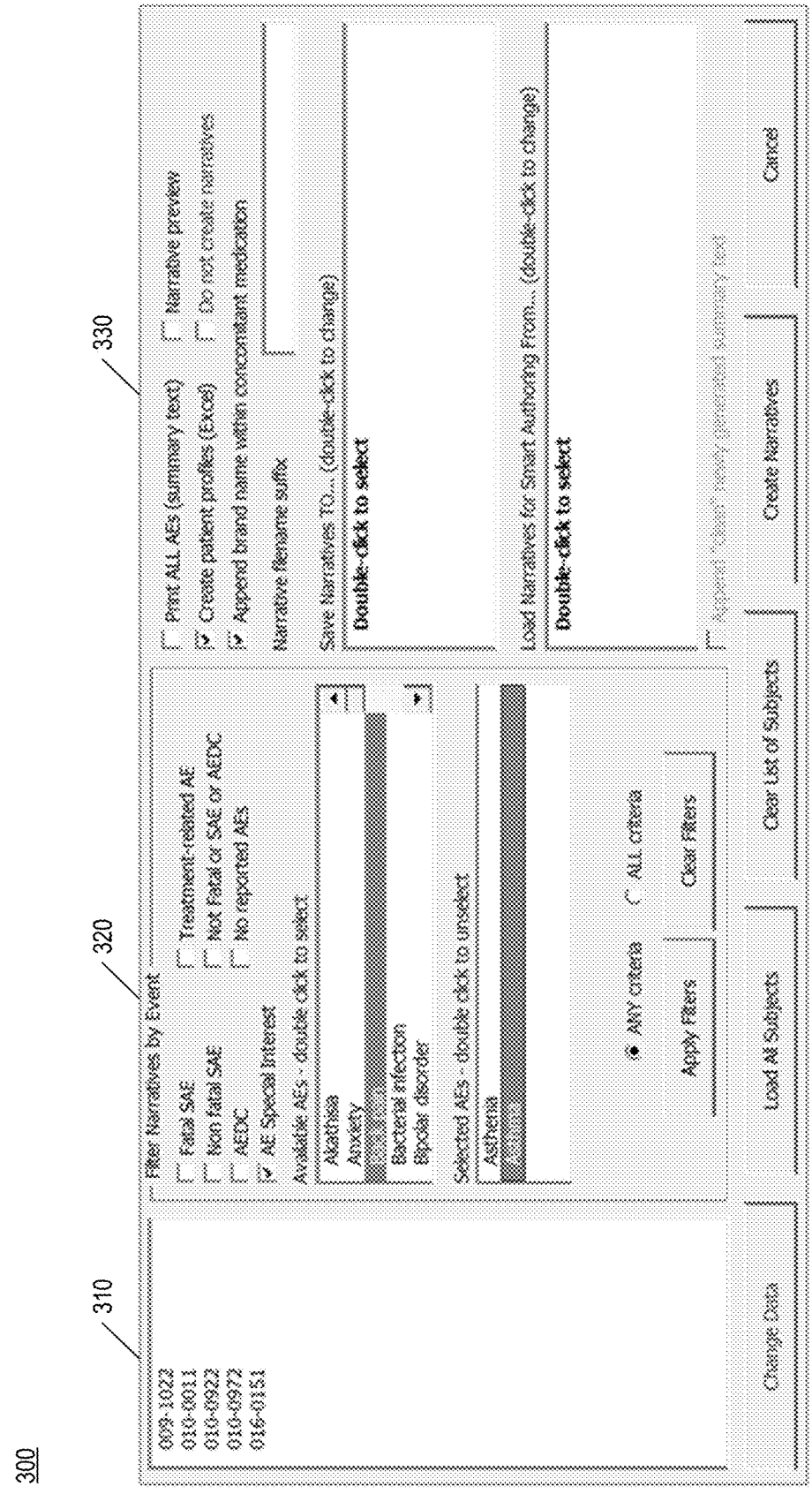

300
310
320
330
099-1022
010-0011
010-0922
010-0972
016-0151
Change Data
Filter Narratives by Event
Fatal SAE
Non fatal SAE
AEDC
AE Special Interest
Treatment-related AE
Not Fatal or SAE or AEDC
No reported AEs
Available AEs - double click to select
Akathisia
Anxiety
Bacterial infection
Bipolar disorder
Selected AEs - double click to unselect
Asthenia
ANY criteria
ALL criteria
Apply Filters
Clear Filters
Load All Subjects
Clear List of Subjects
Print ALL AEs (summary text)
Create patient profiles (Excel)
Append brand name when concomitant medication
Narrative filename suffix
Narrative preview
Do not create narratives
Save Narratives TO... (double-click to change)
Double-click to select
Load Narratives for Smart Authoring From... (double-click to change)
Double-click to select
Create Narratives
Cancel

FIG. 3

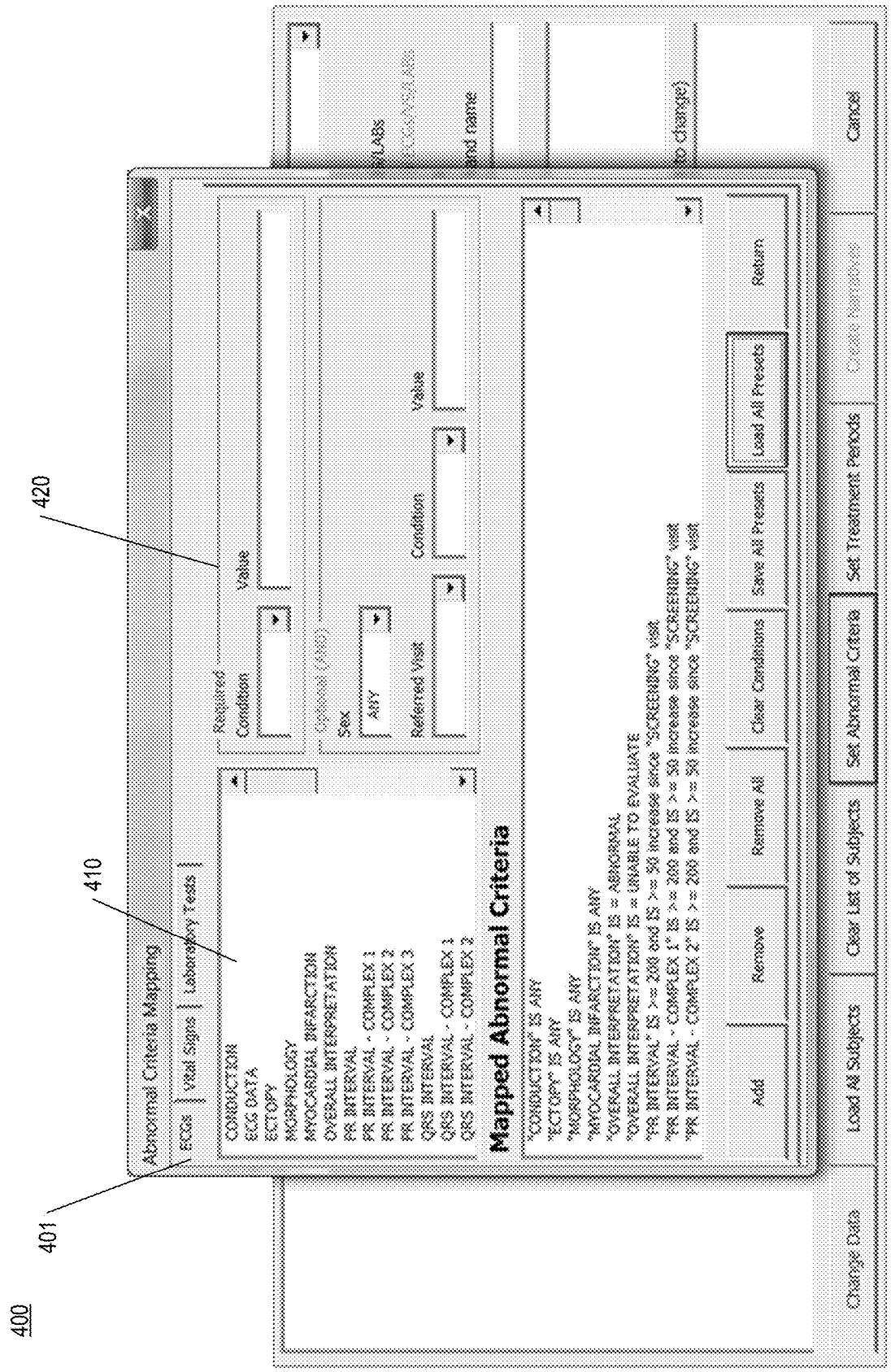

400
401
410
420
Abnormal Criteria Mapping
ECGs
Vital Signs
Laboratory Tests
CONDUCTION
ECG DATA
ECTOPY
MORPHOLOGY
MYOCARDIAL INFARCTION
OVERALL INTERPRETATION
PR INTERVAL
PR INTERVAL - COMPLEX 1
PR INTERVAL - COMPLEX 2
PR INTERVAL - COMPLEX 3
QRS INTERVAL
QRS INTERVAL - COMPLEX 1
QRS INTERVAL - COMPLEX 2
Required
Condition
Value
Optional (AND)
Sex
ANY
Referred Visit
Condition
Value
Mapped Abnormal Criteria
"CONDUCTION" IS ANY
"ECTOPY" IS ANY
"MORPHOLOGY" IS ANY
"MYOCARDIAL INFARCTION" IS ANY
"OVERALL INTERPRETATION" IS = ABNORMAL
"OVERALL INTERPRETATION" IS = UNABLE TO EVALUATE
"PR INTERVAL" IS >= 200 and IS > = 50 increase since "SCREENING" visit
"PR INTERVAL - COMPLEX 1" IS >= 200 and IS > = 50 increase since "SCREENING" visit
"PR INTERVAL - COMPLEX 2" IS >= 200 and IS > = 50 increase since "SCREENING" visit
Add
Remove
Remove All
Clear Conditions
Save All Presets
Load All Presets
Return
Change Data
Load All Subjects
Clear List of Subjects
Set Abnormal Criteria
Set Treatment Periods
Cancel
LABs
Test name
to change)

FIG. 4A

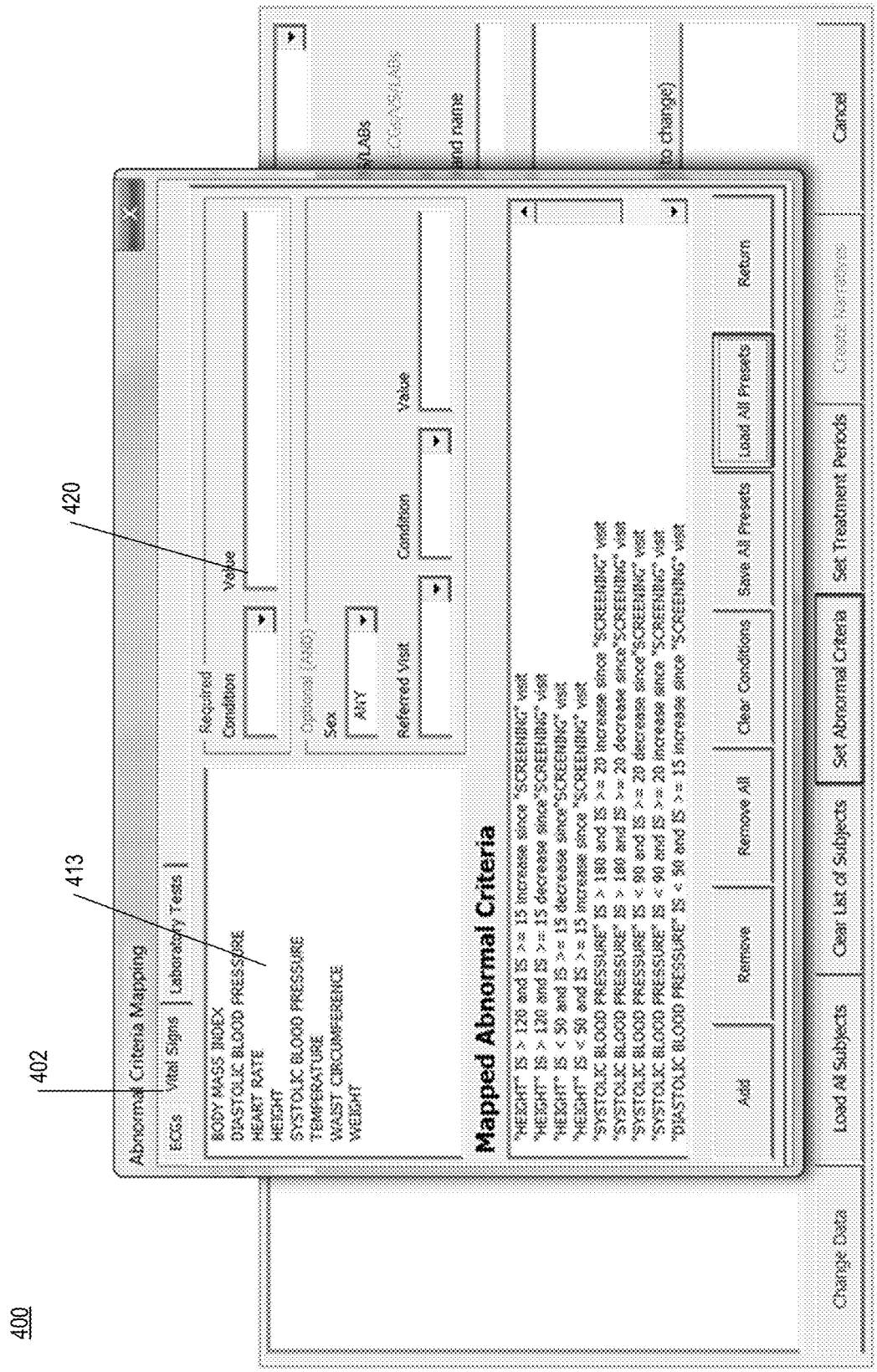

400
402
413
420
Abnormal Criteria Mapping
ECGs
Vital Signs
Laboratory Tests
BODY MASS INDEX
DIASTOLIC BLOOD PRESSURE
HEART RATE
HEIGHT
SYSTOLIC BLOOD PRESSURE
TEMPERATURE
WAIST CIRCUMFERENCE
WEIGHT
Required
Condition
Value
Optional (AND)
Sex
ANY
Referred Visit
Condition
Value
Mapped Abnormal Criteria
"HEIGHT" IS > 120 and IS > = 15 increase since "SCREENING" visit
"HEIGHT" IS > 120 and IS > = 15 decrease since "SCREENING" visit
"HEIGHT" IS < 90 and IS > = 15 decrease since "SCREENING" visit
"HEIGHT" IS < 90 and IS > = 15 increase since "SCREENING" visit
"SYSTOLIC BLOOD PRESSURE" IS > 180 and IS > = 20 increase since "SCREENING" visit
"SYSTOLIC BLOOD PRESSURE" IS > 180 and IS > = 20 decrease since "SCREENING" visit
"SYSTOLIC BLOOD PRESSURE" IS < 90 and IS > = 20 decrease since "SCREENING" visit
"SYSTOLIC BLOOD PRESSURE" IS < 90 and IS > = 20 increase since "SCREENING" visit
"DIASTOLIC BLOOD PRESSURE" IS > 90 and IS > = 15 increase since "SCREENING" visit
Add
Remove
Remove All
Clear Conditions
Save All Presets
Load All Presets
Return
Change Data
Load All Subjects
Clear List of Subjects
Set Abnormal Criteria
Set Treatment Periods
Cancel

FIG. 4B

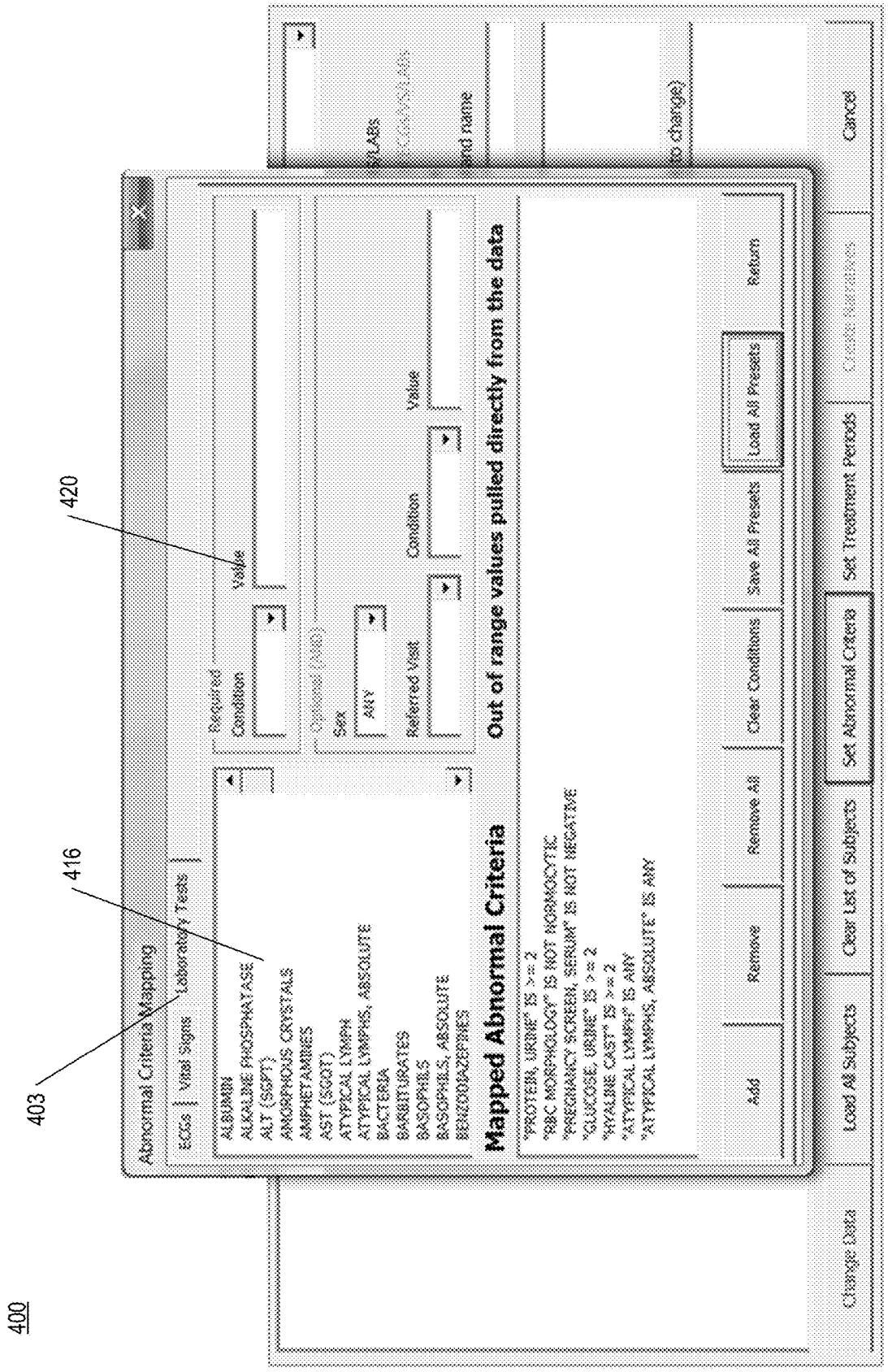

400
403
416
420
Abnormal Criteria Mapping
ECGs
Vital Signs
Laboratory Tests
ALBUMIN
ALKALINE PHOSPHATASE
ALT (SGPT)
AMORPHOUS CRYSTALS
AMPHETAMINES
AST (SGOT)
ATYPICAL LYMPH
ATYPICAL LYMPHS, ABSOLUTE
BACTERIA
BARBITURATES
BASOPHILS
BASOPHILS, ABSOLUTE
BENZODIAZEPINES
Required
Condition
Value
Optional (AND)
Sex
ANY
Referred Visit
Condition
Value
Out of range values pulled directly from the data
Mapped Abnormal Criteria
"PROTEIN, URINE" IS >= 2
"RBC MORPHOLOGY" IS NOT NORMOCYTIC
"PREGNANCY SCREEN, SERUM" IS NOT NEGATIVE
"GLUCOSE, URINE" IS >= 2
"HYALINE CAST" IS >= 2
"ATYPICAL LYMPH" IS ANY
"ATYPICAL LYMPHS, ABSOLUTE" IS ANY
Add
Remove
Remove All
Clear Conditions
Save All Presets
Load All Presets
Reform
Change Data
Load All Subjects
Clear List of Subjects
Set Abnormal Criteria
Set Treatment Periods
Cancel
LABs
Lab name
change)

FIG. 4C

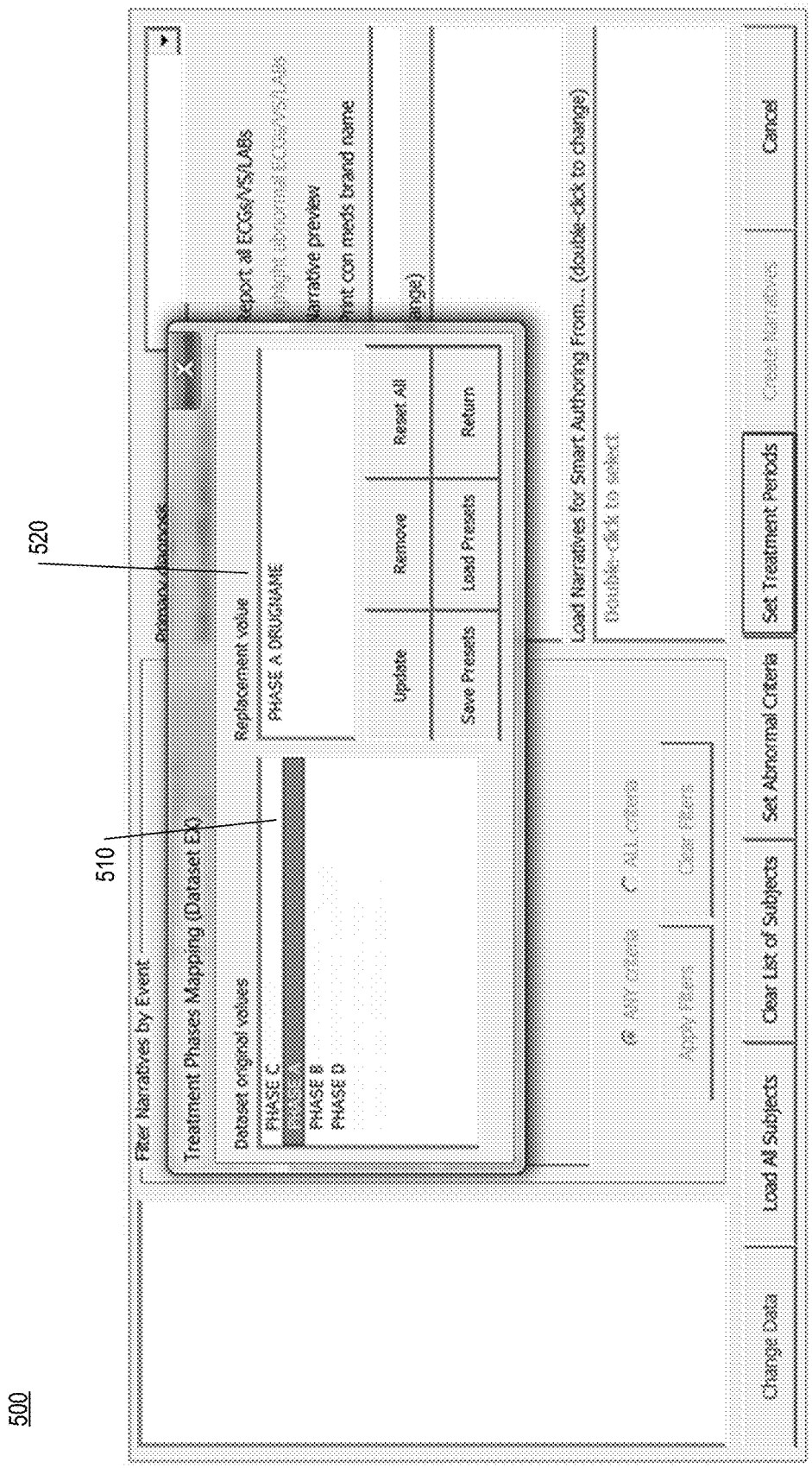

500
510
520
Filter Narratives by Event
Treatment Phases Mapping (Dataset EX)
Dataset original values
PHASE C
PHASE B
PHASE D
Replacement value
PHASE A DRUGNAME
Update
Remove
Reset All
Save Presets
Load Presets
Return
Report all ECGs/VS/LABs
Narrative preview
Pint con meds brand name
Load Narratives for Smart Authoring From... (double-click to change)
Double-click to select
Change Data
Load All Subjects
Clear List of Subjects
Set Abnormal Criteria
Set Treatment Periods
Cancel

FIG. 5

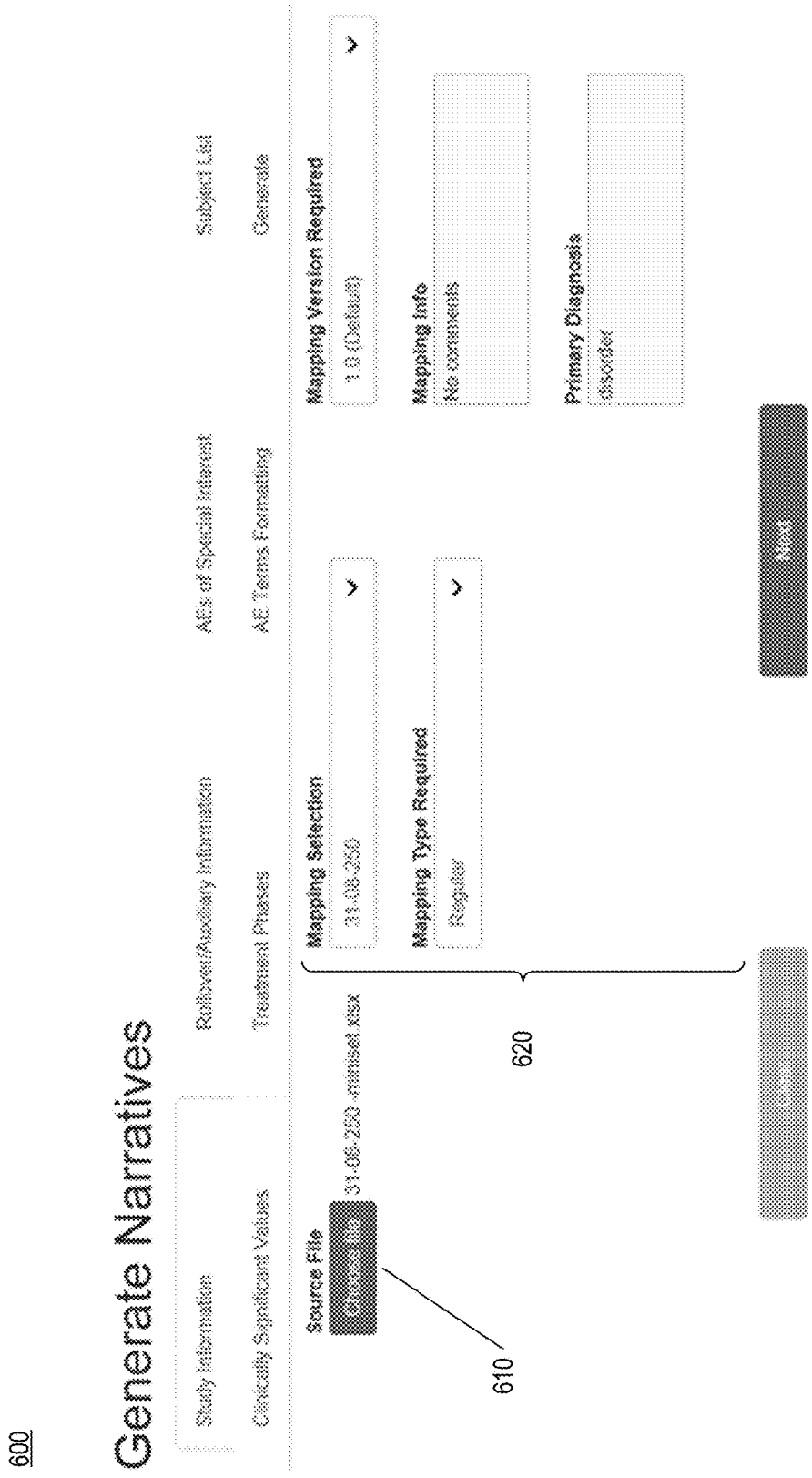

600
Generate Narratives
Study Information
Related/Auxiliary Information
AEs of Special Interest
Subject List
Clinically Significant Values
Treatment Phases
AE Terms Formatting
Generate
610
Source File
Choose File
31-08-250 -mimed.xlsx
620
Mapping Selection
31-08-250
Mapping Type Required
Register
Mapping Version Required
1.0 (Default)
Mapping Info
No comments
Primary Diagnosis
Disorder
Next

FIG. 6A

650

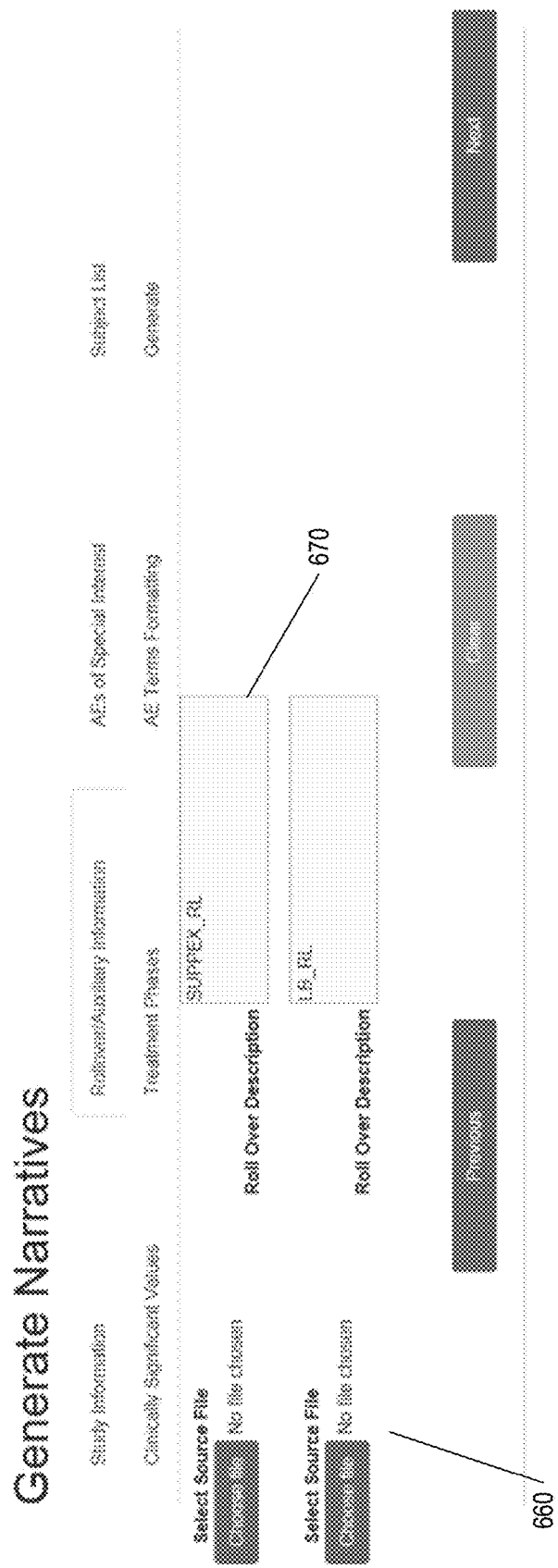

Generate Narratives
Study Information
Clinically Significant Values
Rollover/Auxiliary Information
Treatment Phases
AEs of Special Interest
AE Terms Formatting
Subject List
Generate
Select Source File
Choose file
No file chosen
Select Source File
Choose file
No file chosen
Roll Over Description
Roll Over Description
SUPPEX_RL
LB_RL
670
660

FIG. 6B

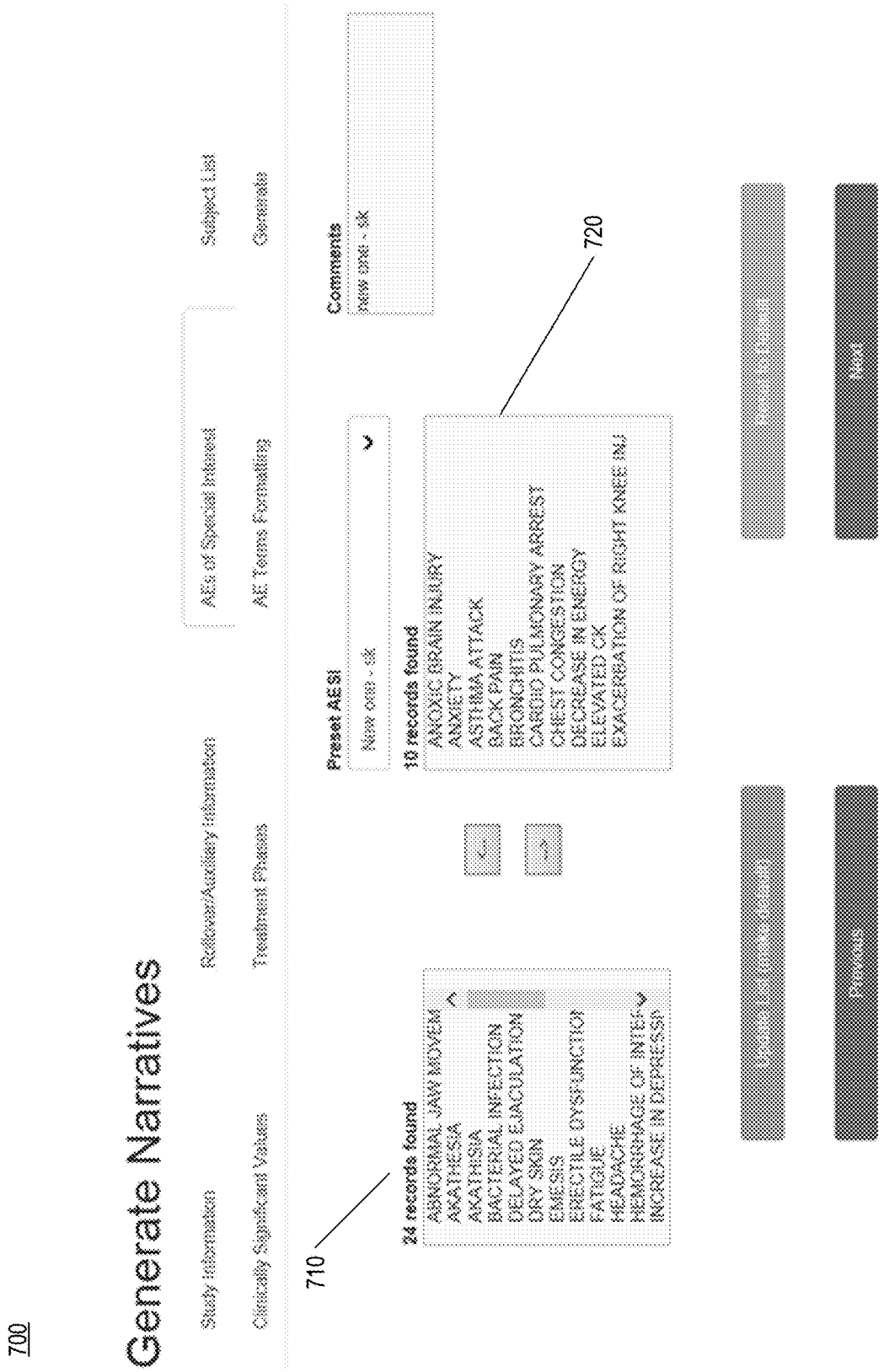

700
Generate Narratives
Study Information
Relevant/Auxiliary Information
AEs of Special Interest
Subject List
Clinically Significant Values
Treatment Phases
AE Terms Formatting
Generate
710
24 records found
ABNORMAL JAW MOVEM
AKATHESIA
AKATHISIA
BACTERIAL INFECTION
DELAYED EJACULATION
DRY SKIN
EMESIS
ERECTILE DYSFUNCTIO
FATIGUE
HEADACHE
HEMORRHAGE OF INTES
INCREASE IN DEPRESSI
Preset AESI
New ones - sk
10 records found
ANOXIC BRAIN INJURY
ANXIETY
ASTHMA ATTACK
BACK PAIN
BRONCHITIS
CARDIO PULMONARY ARREST
CHEST CONGESTION
DECREASE IN ENERGY
ELEVATED CK
EXACERBATION OF RIGHT KNEE INJ
720
Comments
New ones - sk
Preview
Done

FIG. 7

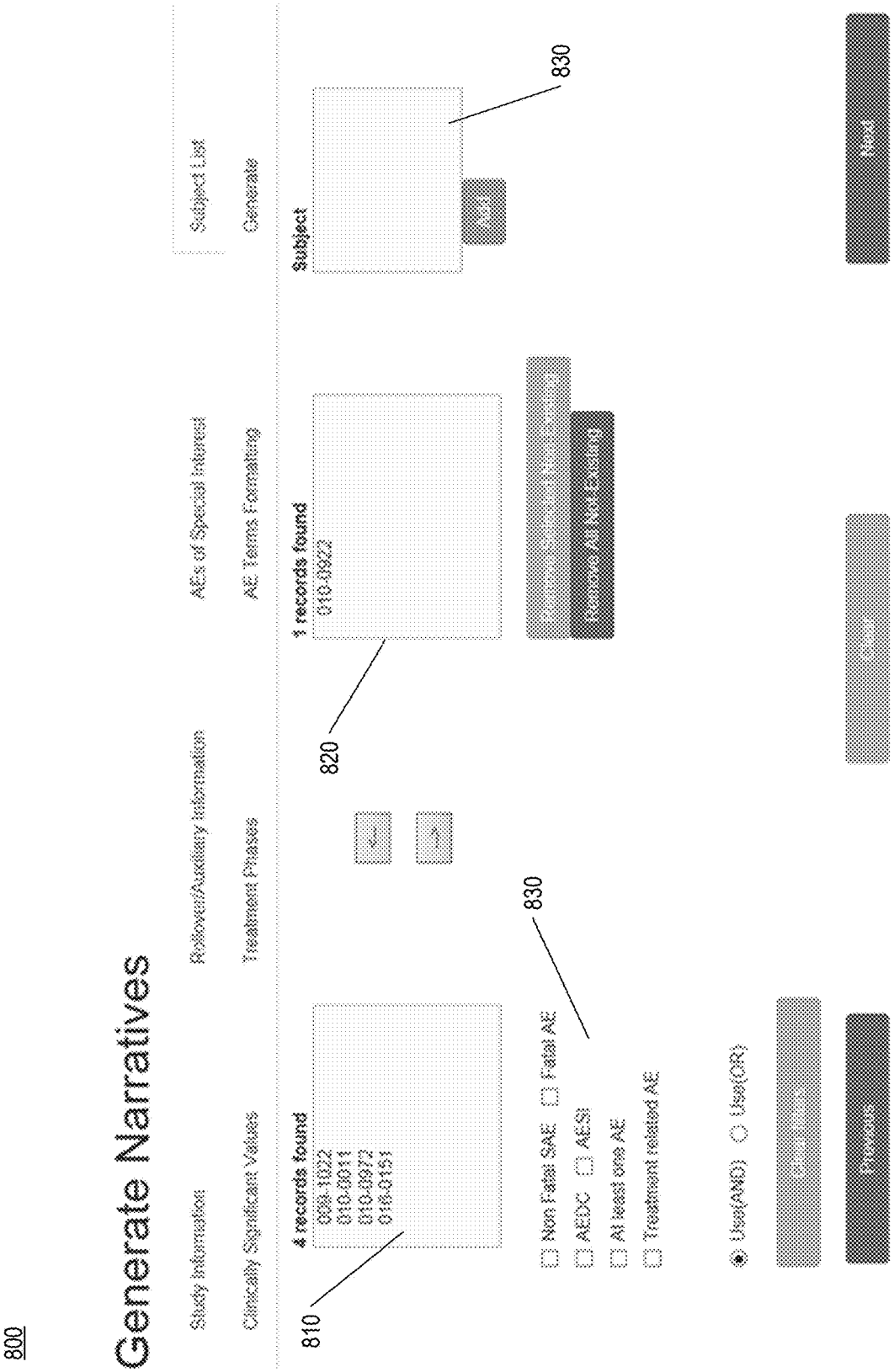

800
Generate Narratives
Study Information
Retrieved/Auxiliary Information
AEs of Special Interest
Subject List
Clinically Significant Values
Treatment Phases
AE Terms Formatting
Generate
4 records found
008-1022
010-0011
010-0977
016-0151
810
820
1 records found
010-0922
830
Subject
Non Fatal SAE
Fatal AE
AEDC
AESI
At least one AE
Treatment related AE
830
Use(AND)
Use(OR)

FIG. 8

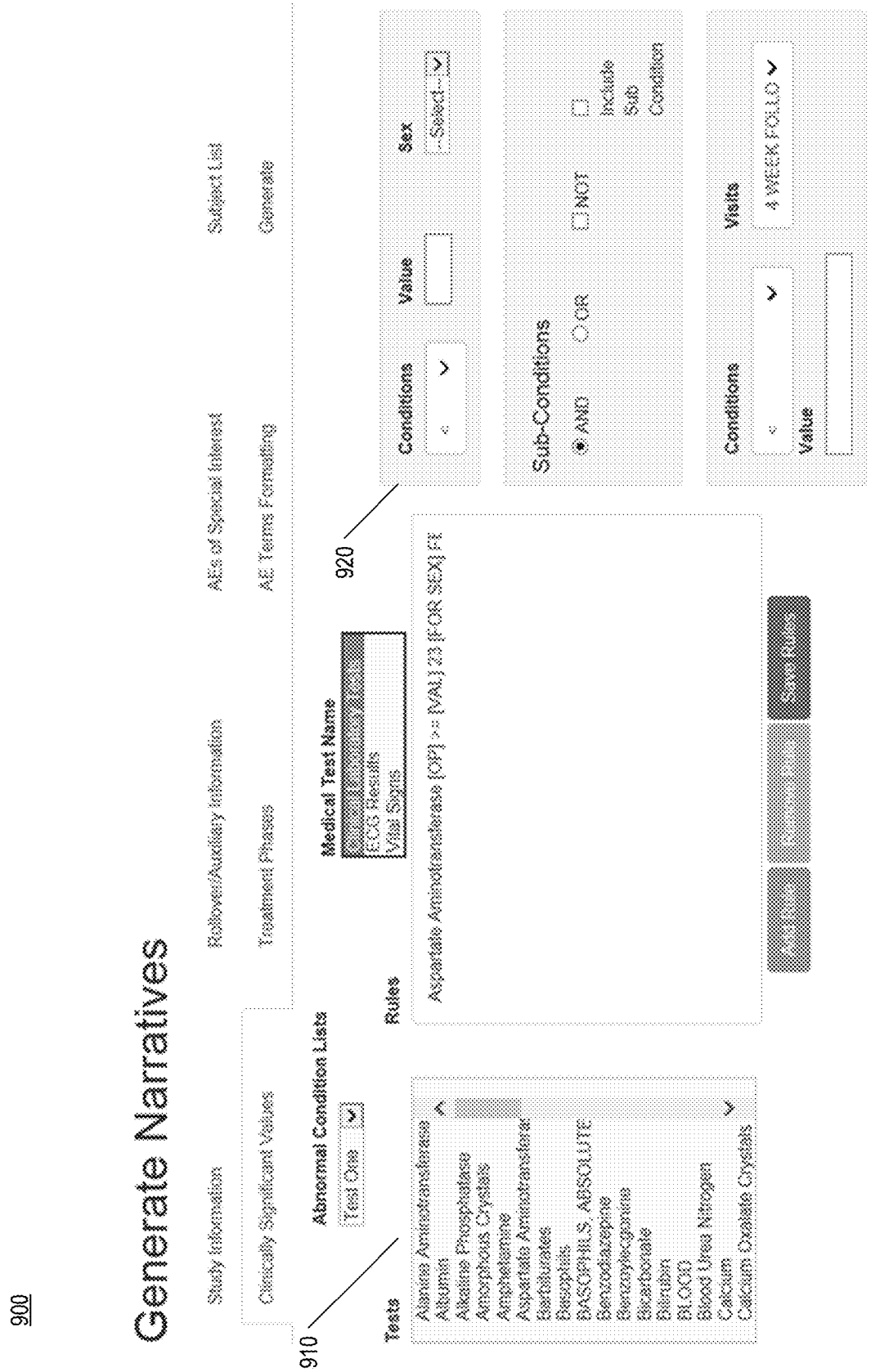

900
Generate Narratives
Study Information
Rollover/Auxiliary Information
AEs of Special Interest
Subject List
Clinically Significant Values
Treatment Phases
AE Terms Formatting
Generate
910
Tests
Abnormal Condition Lists
Test One
Alanine Aminotransferase
Albumin
Alkaline Phosphatase
Amorphous Crystals
Amphetamine
Aspartate Aminotransferase
Barbiturates
Basophils
BASOPHILS, ABSOLUTE
Benzodiazepine
Benzoylecgonine
Bicarbonate
Bilirubin
BLOOD
Blood Urea Nitrogen
Calcium
Calcium Oxalate Crystals
Rules
Medical Test Name
Clinical Laboratory Tests
ECG Results
Vital Signs
Aspartate Aminotransferase (OP) >= (VAL) 23 (FOR SEX) FE
920
Conditions
Value
Sex
-Select-
Sub-Conditions
AND
OR
NOT
Include Sub Condition
Conditions
Visits
4 WEEK FOLLO
Value

FIG. 9

1000
Generate Narratives
Study Information
Clinically Significant Values
Treatment Phase List
12
Rollover/Auxiliary Information
Treatment Phases
Source List
TREATMENT PHASE A
TREATMENT PHASE B
TREATMENT PHASE C
TREATMENT PHASE D
TREATMENT PHASE M
PHASE A
TREATMENT PHASE Q
1010
AEs of Special Interest
AE Terms Formatting
Replacement List
Phase A
Ba
TREATMENT PHASE C
TREATMENT PHASE D
TREATMENT PHASE M
Phase A
TREATMENT PHASE Q
1020
Subject List
Generate

FIG. 10

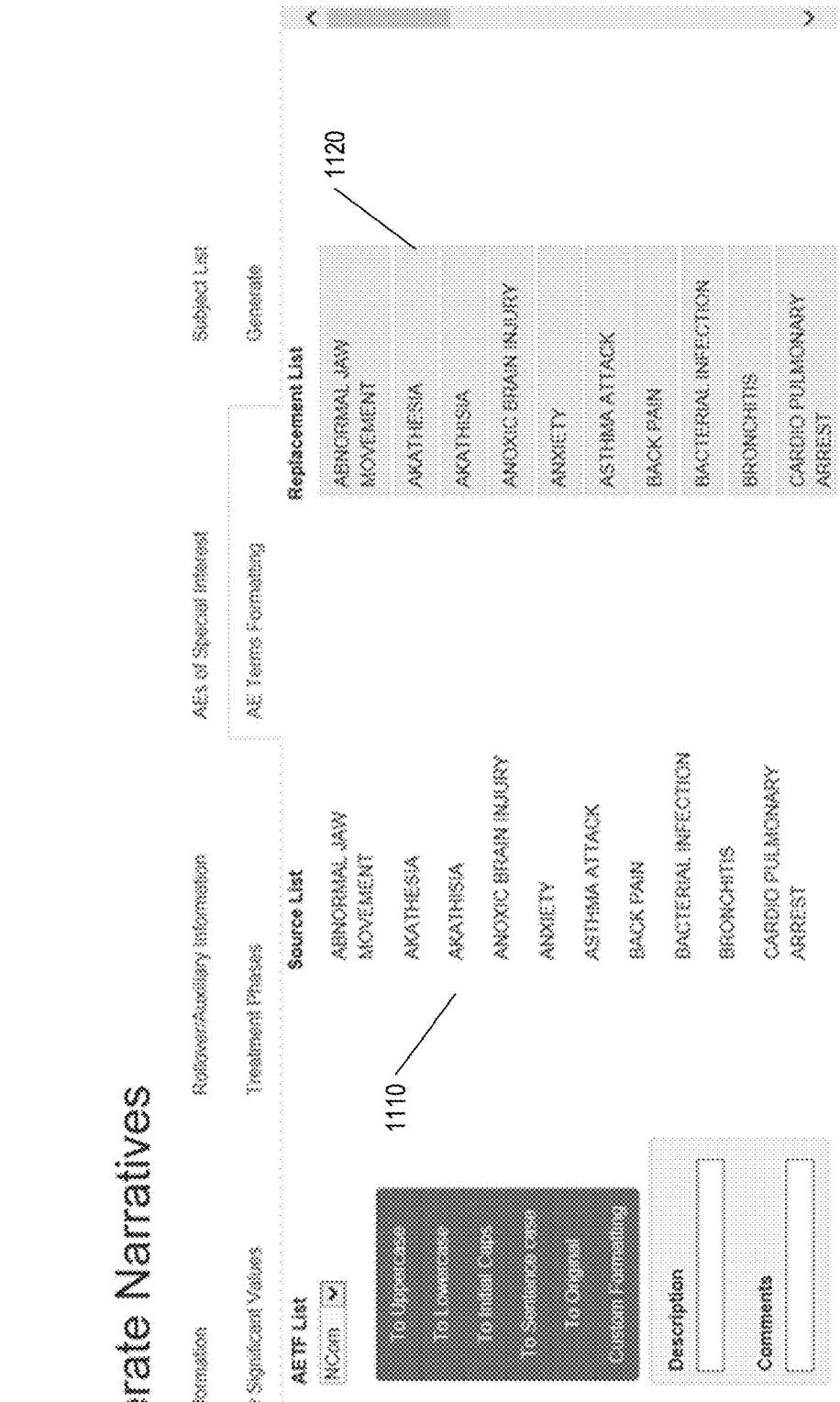

1100
Generate Narratives
Study Information
Related/Auxiliary Information
AEs of Special Interest
Subject List
Clinically Significant Values
Treatment Phases
AE Terms Formatting
Generate
AETF List
NCan
Source List
ABNORMAL JAW MOVEMENT
AKATHESIA
AKATHISIA
ANOXIC BRAIN INJURY
ANXIETY
ASTHMA ATTACK
BACK PAIN
BACTERIAL INFECTION
BRONCHITIS
CARDIO PULMONARY ARREST
1110
Description
Comments
Replacement List
ABNORMAL JAW MOVEMENT
AKATHESIA
AKATHISIA
ANOXIC BRAIN INJURY
ANXIETY
ASTHMA ATTACK
BACK PAIN
BACTERIAL INFECTION
BRONCHITIS
CARDIO PULMONARY ARREST
1120

FIG. 11

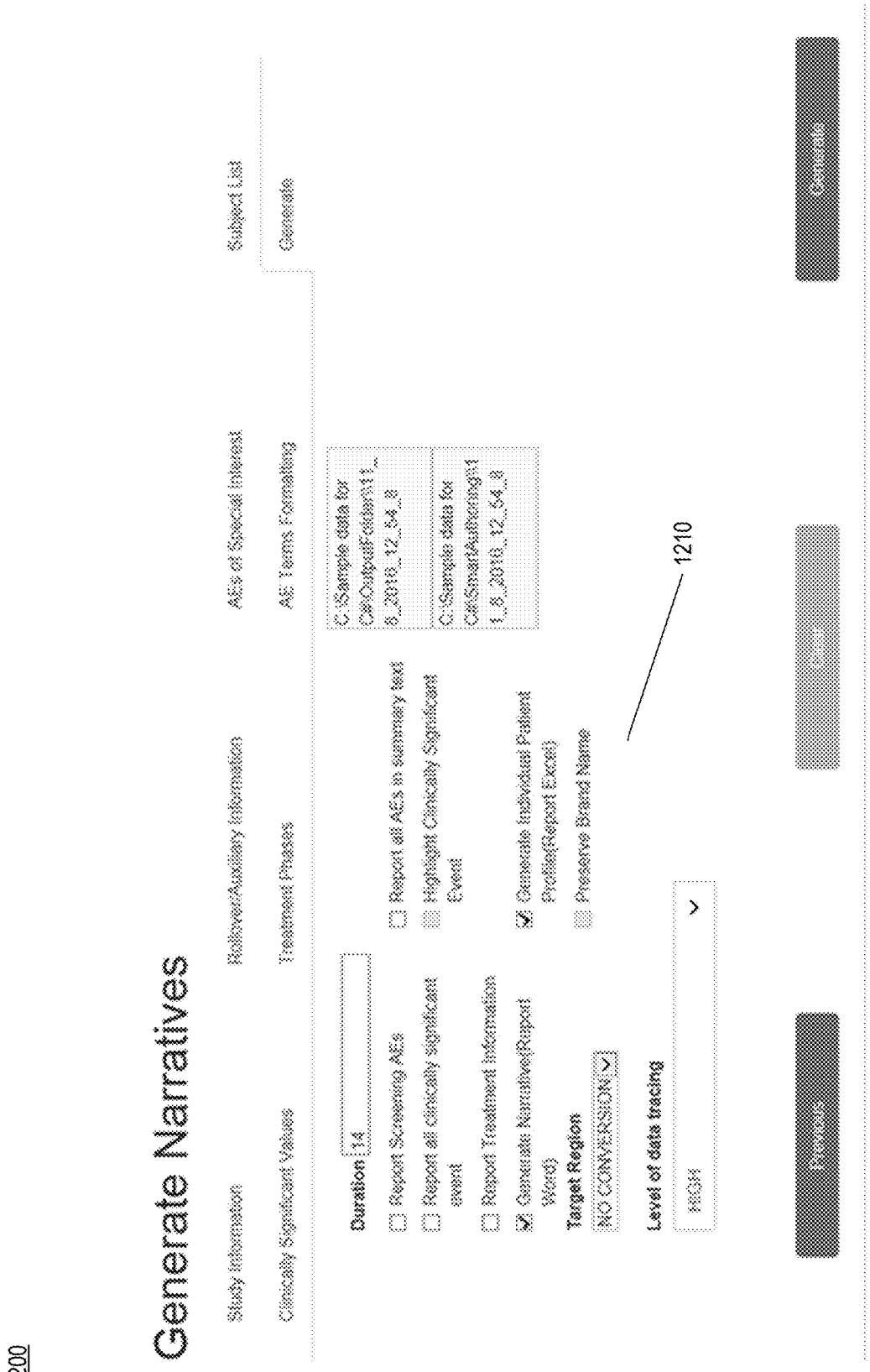

1200
Generate Narratives
Study Information
Related/Auxiliary Information
AEs of Special Interest
Subject List
Clinically Significant Values
Treatment Phases
AE Terms Formatting
Generate
Duration 14
Report Screening AEs
Report all clinically significant event
Report Treatment Information
Generate Narrative(Report Word)
Target Region
RO CONVERSION
Level of data tracing
HIGH
Report all AEs in summary text
Highlight Clinically Significant Event
Generate Individual Patient Profile(Report Excel)
Preserve Brand Name
C:\Sample data for Cis\Output\Patient1\1_8_2018_12_54_8
C:\Sample data for Cis\SmartAuthoring\1\1_8_2018_12_54_8
1210
Previous
Next
Generate

FIG. 12

1300

Akathisia	N	N	25 Sep 2014	151	Unknown	Moderate	Related	Dose not changed	Not recovered/not resolved
Nausea	N	N	07 Oct 2014	163	22 Oct 2014	Mild	Not related	Dose not changed	Recovered/resolved
Vomiting	N	N	13 Oct 2014	169	13 Oct 2014	Moderate	Not related	Dose not changed	Recovered/resolved
Back pain	N	N	23 Oct 2014	179	Unknown	Mild	Not related	Dose not changed	Not recovered/not resolved
Suicidal ideation	Y	Y	30 Nov 2014	217	03 Dec 2014	Moderate	Not related	Drug withdrawn	Recovered/resolved
Depression	Y	Y	30 Nov 2014	217	05 Jan 2015	Moderate	Not related	Drug withdrawn	Recovered/resolved

Medical History

Condition	Onset Date	Ongoing
Congenital scoliosis	Mar 2014	Yes
Eczema	2009	Yes
Ligament rupture	13 Mar 2013	Yes
Meniscus injury	13 Mar 2013	Yes
Psoriasis	Aug 2013	Yes

Narrative Summary

Subject 08250-009-S1022

Subject 08250-009-S10022, a [DESCRIPTION OF SUBJECT], was diagnosed with disorder in 2010. The subject was enrolled in a "Study Trial". She entered the study in Phase A: Conversion Phase and began receiving oral [DRUGNAME / DOSAGE] on [DATE]. The subject's medical history is provided above. The subject received the first [DRUGNAME / DOSAGE] on [DATE]. The subject was not randomized into Phase D: Double-blind IM Depot Maintenance Phase.

On [DATE] (Day 217), the subject experienced the serious adverse event of [DESCRIPTION OF ADVERSE EVENT] and was withdrawn from treatment. No corrective medications were administered. [ENTER CIOMS DETAILS HERE]. The event was considered resolved on [the was discharged from hospital on /check CIOMS] [DATE]. The investigator concluded the [DESCRIPTION OF ADVERSE EVENT] was not related to the study medication. The sponsor concluded the [DESCRIPTION OF ADVERSE EVENT] was [relationship from CIOMS] to the study medication. Concomitant medications taken within 14 days prior to the onset date of the event included citalopram hydrobromide, oxcarbazepine, ibuprofen, propranolol hydrochloride, and clonazepam.

On [DATE] (Day 217), the subject experienced the serious adverse event of [DESCRIPTION OF ADVERSE EVENT] and was withdrawn from treatment. No corrective medications were administered. [ENTER CIOMS DETAILS HERE]. The event was considered resolved on [the was discharged from hospital on /check CIOMS] [DATE]. The...

FIG. 13

1400

Akathisia	N	N	25 Sep 2014	151	Unknown	Moderate	Related	Dose not changed	Not recovered/not resolved
Nausea	N	N	07 Oct 2014	163	22 Oct 2014	Mild	Not related	Dose not changed	Recovered/resolved
Vomiting	N	N	13 Oct 2014	169	13 Oct 2014	Moderate	Not related	Dose not changed	Recovered/resolved
Back pain	N	N	23 Oct 2014	179	Unknown	Mild	Not related	Dose not changed	Not recovered/not resolved
Suicidal ideation	Y	[illegible]	[illegible] Nov 2014	217	03 Dec 2014	Moderate	Not related	[illegible] not changed	Recovered/resolved
Depression	Y	Y	30 Nov 2014	217	05 Jan 2015	Moderate	Not related	Drug withdrawn	Recovered/resolved

Medical History

Condition	Onset Date	Ongoing
Congenital scoliosis	Mar 2014	Yes
Eczema	2009	Yes
Ligament rupture	13 Mar 2013	Yes
Meniscus injury	13 Mar 2013	Yes
Psoriasis	Aug 2013	Yes

Narrative Summary

Subject 08250-009-S1022

Subject 08250-009-S10022, a [DESCRIPTION OF SUBJECT], was diagnosed with disorder in 2010. The subject was enrolled in a "Study Trial". She entered the study in Phase A: Conversion Phase and began receiving oral [DRUGNAME / DOSAGE] on [DATE]. The subject's medical history is provided above. The subject received the first [DRUGNAME / DOSAGE] on [DATE]. The subject was not randomized into Phase D: Double-blind IM Depot Maintenance Phase. [illegible]

1410

On [DATE] (Day 217), the subject experienced the serious adverse event of [DESCRIPTION OF ADVERSE EVENT] [illegible]. No corrective medications were administered. [illegible]. The event was considered resolved on [illegible] [DATE]. The investigator concluded the [DESCRIPTION OF ADVERSE EVENT] was not related to the study medication. The sponsor concluded the [DESCRIPTION OF ADVERSE EVENT] was [illegible] to the study medication. Concomitant medications taken within 14 days prior to the onset date of the event included citalopram hydrobromide, [illegible], ibuprofen, propranolol hydrochloride, and clonazepam.

1430

On [DATE] (Day 217), the subject experienced the serious adverse event of [DESCRIPTION OF ADVERSE EVENT] and was withdrawn from treatment. No corrective medications were administered. [illegible]. The event was considered resolved on [illegible] [DATE]. The...

Comment [RB1]: Incorrect action

1420

Comment [RB2]: Check the date

1420

FIG. 14

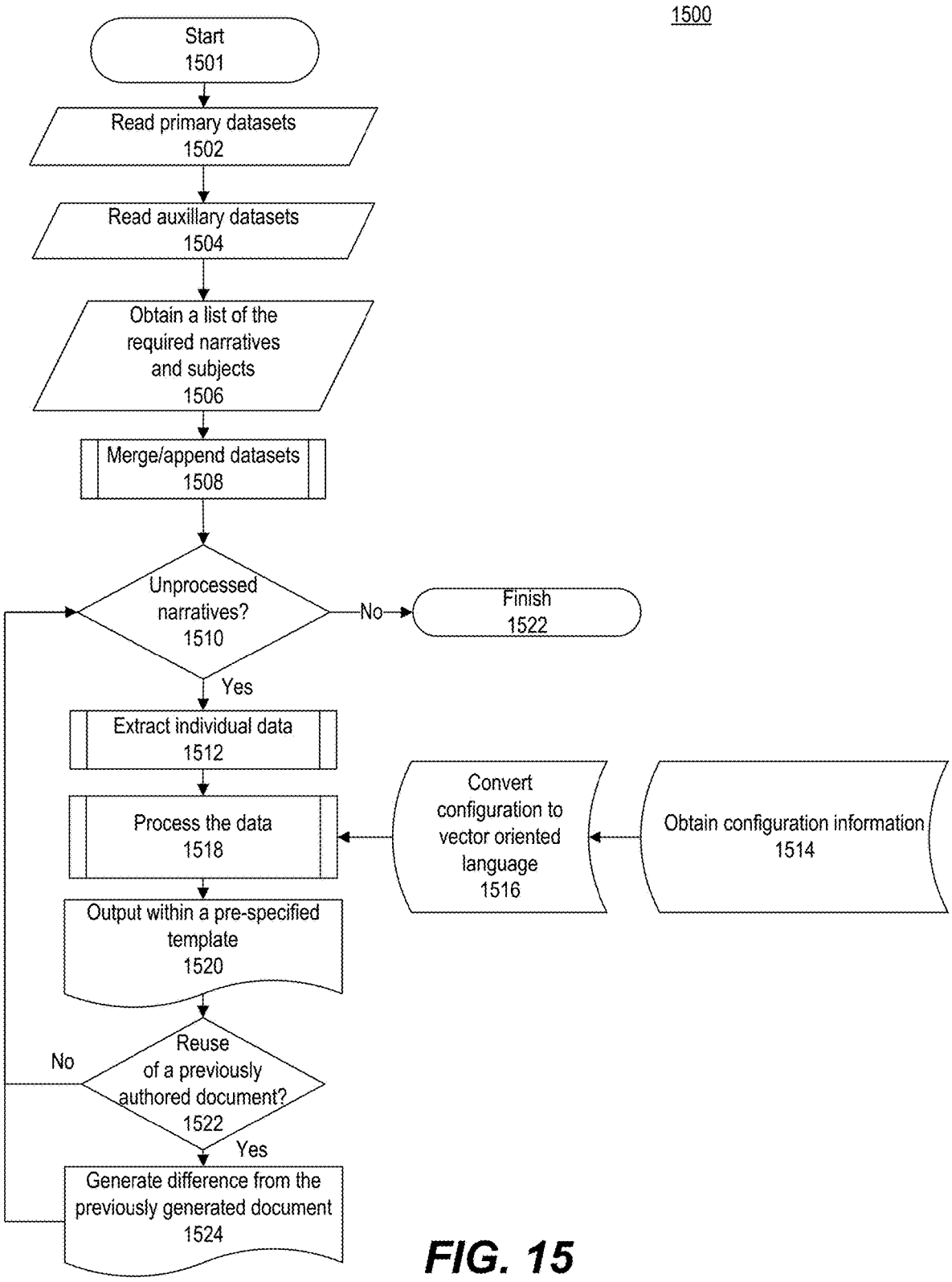

1500
Start
1501
Read primary datasets
1502
Read auxillary datasets
1504
Obtain a list of the required narratives and subjects
1506
Merge/append datasets
1508
Unprocessed narratives?
1510
No
Finish
1522
Yes
Extract individual data
1512
Process the data
1518
Convert configuration to vector oriented language
1516
Obtain configuration information
1514
Output within a pre-specified template
1520
Reuse of a previously authored document?
1522
No
Yes
Generate difference from the previously generated document
1524

FIG. 15

SYSTEMS AND METHODS FOR DATA DRIVEN DOCUMENT CREATION AND MODIFICATION

REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation of U.S. Provisional Patent Application No. 62/482,526, filed on Apr. 6, 2017, the contents of which are expressly incorporated herein by reference in their entireties.

BACKGROUND

[0002] Scientific research and study can result in the generation of many data sets over many intervals of time. Researchers must process the relevant data and generate descriptive narratives, documents, or reports about specific events and outcomes for individuals or subjects participating in the research or studies. These narratives, documents, or reports can also often include in-text tables and summary text or other specifically-formatted content that requires close attention when creating or updating. Additionally, regulations or other administrative policies can require that narratives be produced in particular formats and contain particular information. Because of the vast amount of data generated during a research study, preparing narratives for the various subjects can be an extremely tedious, time consuming, and error prone task. Moreover, as the source data is updated, the existing documents must be reprocessed to reflect the new information. Current manual systems and methods for reprocessing such documents typically involve a complete redo of the document generation. There exists a need to efficiently and effectively automate document generation, including narrative and report generation, in a manner that not only allows for accuracy in the creation of the documents, but that also provides an efficient way to quickly generate documents that satisfy the requirements associated with modern scientific research, which often include strict requirements on data storage, transformation, reproducibility, and presentation of information. Moreover, there exists a need to effectively and efficiently update those documents.

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] Reference will now be made to the accompanying drawings showing example embodiments of this disclosure. In the drawings:

[0004] FIG. **1** is a block diagram of an exemplary computing device, consistent with embodiments of the present disclosure.

[0005] FIG. **2** is a block diagram of an exemplary system, consistent with embodiments of the present disclosure.

[0006] FIG. **3** is a diagram of an exemplary user interface, consistent with embodiments of the present disclosure.

[0007] FIGS. **4**A-**4**C are diagrams of exemplary user interfaces, consistent with embodiments of the present disclosure.

[0008] FIG. **5** is a diagram of an exemplary user interface, consistent with embodiments of the present disclosure.

[0009] FIG. **6**A is a diagram of an exemplary user interface, consistent with embodiments of the present disclosure.

[0010] FIG. **6**B is a diagram of an exemplary user interface, consistent with embodiments of the present disclosure.

[0011] FIG. **7** is a diagram of an exemplary user interface, consistent with embodiments of the present disclosure.

[0012] FIG. **8** is a diagram of an exemplary user interface, consistent with embodiments of the present disclosure.

[0013] FIG. **9** is a diagram of an exemplary user interface, consistent with embodiments of the present disclosure.

[0014] FIG. **10** is a diagram of an exemplary user interface, consistent with embodiments of the present disclosure.

[0015] FIG. **11** is a diagram of an exemplary user interface, consistent with embodiments of the present disclosure.

[0016] FIG. **12** is a diagram of an exemplary user interface, consistent with embodiments of the present disclosure.

[0017] FIG. **13** is an exemplary narrative, consistent with embodiments of the present disclosure.

[0018] FIG. **14** is an exemplary narrative, consistent with embodiments of the present disclosure.

[0019] FIG. **15** is a flowchart of an exemplary method for data driven document creation and modification, consistent with embodiments of the present disclosure.

DETAILED DESCRIPTION

[0020] Reference will now be made in detail to the exemplary embodiments implemented according to the present disclosure, the examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[0021] Embodiments consistent with the present disclosure provide systems and methods for data driven document creation and modification. The disclosed technologies provide a mechanism to efficiently and accurately generate documents such as narratives or reports associated with scientific research. Systems and methods consistent with the present disclosure can automate the task of creating scientific narratives. Previous methods relied on tedious creation of individual narratives that resulted in error prone and time consuming results. Automated systems consistent with embodiments of the present disclosure allow for both consistency and accuracy in produced narratives by allowing for configuration of the individuals and types of information for which narratives are needed and using data driven analysis and processing to automatically generate those narratives. Moreover, the disclosed technologies provide systems and methods for using previously generated narratives that can contain researcher comments and annotations as a basis for generating a new narrative. The newly generated narratives can show differences between past narratives and retain manually created comments or annotations. Because systems and methods consistent with the present disclosure can update previously generated narratives, researchers can begin generating narratives before all of the data is collected or available. This provides a significant advantage in that researchers can begin the process of generating narratives much earlier in a research cycle. This can further allow researchers to identify potential problems or preliminary results much earlier. As new data is gathered, the disclosed systems and methods can incorporate that new data into updated narratives. The efficiency gains of the present disclosure can provide significant advantages over the previous techniques of document and narrative generation and greatly reduce the time needed to compile regulatory applications that can depend on those documents and narratives. Although the generation of narratives are described throughout the present disclosure, the use of this term is not intended to be limiting. Embodiments consistent with the present disclosure can be used to generate various types of output or

reports based on an analysis of scientific data. The specific type of output can be dependent on the particular domain in which embodiments consistent with the present disclosure are being used.

[0022] FIG. **1** is a block diagram of an exemplary computing device **100**, consistent with embodiments of the present disclosure. Computing device **100** can include one or more central processing units (CPUs) **120**, a graphics subsystem **123** with one or more GPUs **125** and graphic memory **126**, a display device **124**, system memory **127**, I/O controller **130**, storage **131**, I/O devices **132**, and network interface **133**. The components of computing device **100** can be connected through a system bus **150**. It is appreciated computing device **100** can use more or fewer components and organizations of components.

[0023] CPUs **120** can be any logic circuitry that responds to and processes instructions retrieved from the system memory **127**, CPU cache **121**, or CPU registers **122**. CPUs **120** can be a single or multiple microprocessors, field-programmable gate arrays (FPGAs), or digital signal processors (DSPs) capable of executing particular sets of instructions stored in a memory (e.g., system memory **127**), a cache (e.g., CPU cache **121**), or registers (e.g., CPU registers **122**). CPU registers **122** can store variable types of data. For example, these registers can store data, instructions, floating point values, conditional values, and/or addresses for locations in system memory **127**. CPU registers **122** can include special purpose registers used to store data associated with the running process. The system memory **127** can include a tangible and/or non-transitory computer-readable medium, such as a flexible disk, a hard disk, a CD-ROM (compact disk read-only memory), MO (magneto-optical) drive, a DVD-ROM (digital versatile disk read-only memory), a DVD-RAM (digital versatile disk random-access memory), a flash drive and/or flash memory, processor cache, memory register, or a semiconductor memory. System memory **127** can be one or more memory chips capable of storing data and allowing any storage location to be directly accessed by CPUs **120**. System memory **127** can be any type of random access memory (RAM), or any other available memory chip capable of operating as described herein. CPUs **120** can communicate with system memory **127** and other components via system bus **150**. System bus **150** can bridge communication between components in computing device **100** including CPUs **120** and graphics subsystem **123**. In some embodiments, CPUs **120**, GPUs **125**, system bus **150**, or any combination thereof, can be integrated into a single processing unit. In some embodiments, additional components of computing device **100**, such as I/O controller **130**, network interface **133**, storage **131**, and I/O device **132**, or any combination thereof, can further be integrated with CPUs **120** and graphics subsystem **123** in a single processing unit.

[0024] Graphics subsystem **123** can include one or more components for providing a graphics display (e.g., on display device **124**). Graphics subsystem **123** can include GPUs **125**. GPUs **125** can have a highly parallel structure making them more effective than general-purpose CPUs **120** for algorithms where processing of large blocks of graphical data can be performed in parallel. GPUs **125** can be any type of specialized circuitry that can manipulate and alter memory (e.g., graphic memory **126**) to provide and/or accelerate the creation or manipulation of images for output to a display device (e.g., display device **124**).

[0025] GPUs **125** can be capable of executing particular sets of instructions stored in system memory **127** or graphic memory **126** to manipulate graphical data stored in system memory **127** or graphic memory **126**. For example, GPUs **125** can receive instructions transmitted by the CPUs **120** and processes the instructions in order to render graphics data stored in the graphic memory **126**. Graphic memory **126** can be any memory space accessible by GPUs **125**, including local memory, system memory, on-chip memories, and hard disk. GPUs **125** can enable displaying of graphical data stored in graphic memory **126** on display device **124**.

[0026] Computing device **100** can also include input/output (I/O) controller **130**. I/O controller **130** can provide an interface to input/output (I/O) devices **132** (e.g., a keyboard, mouse, or pointing device) connected through an I/O controller **130**, which can communicate via system bus **150**. I/O controller can communicate with various types of components through various types of connections (e.g., using, among others, serial and parallel port connections, SATA, IDE, PCI, USB, Thunderbolt, or Firewire).

[0027] I/O controller **130** can also communicate with a network interface **133**. Network interface **133** can allow computing device **100** and the components of computing device **100** (e.g., CPUs **120**) to connect to a network such as a LAN, WAN, MAN, or the Internet, through a variety of connections including, but not limited to, standard telephone lines, LAN or WAN links (e.g., 802.11, T1, T3, 56 kb, X.25), broadband connections (e.g., ISDN, Frame Relay, ATM), wireless connections, or some combination of any or all of the above. Network interface **133** can comprise a built-in network adapter, network interface card, PCMCIA network card, card bus network adapter, wireless network adapter, USB network adapter, modem or any other device suitable for interfacing computing device **100** to any type of network capable of communication and performing the operations described herein.

[0028] I/O controller **130** can also provide access to storage **131** which can be one or more mass storage devices such as a floppy disk drive for receiving floppy disks such as 3.5-inch, 5.25-inch disks or ZIP disks, a CD-ROM drive, a CD-R/RW drive, a DVD-ROM drive, a Blu-Ray drive, tape drives of various formats, a USB device, a hard-drive, a flash drive, redundant arrays of independent disks, or any other device suitable for storage.

[0029] FIG. **2** is an exemplary system **200** for data driven document creation and modification consistent with embodiments of the present disclosure. In some embodiments, system **200** can be used to generate and update clinical narratives based on clinical and other data, including collected data or user specified data such as safety data. System **200** can include data intake engine **210**, configuration engine **220**, data extraction engine **230**, and narrative generation engine **240**. Data intake engine **210** can process data from data sources **202**, **204**, **206** and information or data stored in data storage **215**. Data configuration engine **220** can receive input from and provide output to device **218**. Device **218** can provide output from system **200** to a user and can receive input from a user using device **218**. Moreover, configuration engine **220** can process data from configuration files **216** to configure system **200**. Narrative generation engine can output narratives **242**. Narratives **242** can be stored in data storage **215** and, in some embodiments, narratives and/or audit trail of the narrative generation can be displayed on device **244**. System **200**, data intake engine **210**, data

configuration engine **220**, data extraction engine **230**, and narrative generation engine **240** can be implemented using a computing device such as computing device **100** described in FIG. **1**.

[0030] The components of system **200** can be implemented on a single computing device (e.g., computing device **100**), each component of system **200** can be implemented on a separate computing device (e.g., a plurality of computing devices such as computing device **100**), or some combination thereof, can utilize storage **131** and/or system memory **127** for storing data, and can utilize I/O devices **132** or network interface **133** for transmitting and/or receiving data. Moreover, each of device **218** and device **244** can be implemented using a separate computing device (e.g., computing device **100**) or can be implemented on the same computing device (e.g., computing device **100**) and can be used to provide output to a user and to receive input from a user. Each of data intake engine **210**, configuration engine **220**, data extraction engine **230**, and narrative generation engine **240** can be a module, which is a packaged functional hardware unit designed for use with other components (e.g., portions of an integrated circuit) or a part of a program (stored on a computer readable medium) that performs a particular function or related functions. Each of these components is described in more detail below.

[0031] Data intake engine **210** is a module that can retrieve data from a variety of data sources. Each of these data sources can represent different types of data. For example, data source **202** and data source **206** can represent clinical data from clinical trials. Data source **202** can include data from an ongoing clinical study. Data source **206** can include data from past or related clinical studies. This data can be in various formats depending on the manner in which the data was produced or collected. Data intake engine can further utilize data stored in data source **204**. Data source **204** can include, among other things, demographic or other information related to the individuals participating in a study. It is appreciated that the descriptions of data source **202**, data source **206**, and data source **204** as storing clinical and/or safety data associated with clinical trials is exemplary. In some embodiments for different domains and applications of system **200**, data source **202**, data source **206**, and data source **204** may contain alternative types and formats of data.

[0032] Data intake engine **210** can retrieve data from the various data source. Because the data in different data sources can represent information occurring over different intervals of time and can have different data formats, data intake engine can process data from the data sources (e.g., data source **202**, data source **206**, and data source **204**) and normalize the data into a consistent or common format. Data intake engine **210** can further append the raw or normalized data sets together in order to create a unified data set. The unified data set can be stored in, for example, data storage **215** and can be provided to data extraction engine **230** and the other components of system **200**. In some embodiments, the unified data set can be provided to data extraction engine **230** and other components of system **200** without being permanently stored. The data sets shown in FIG. **2** are exemplary. It is appreciated that in some embodiments the number and type of data sets are unlimited.

[0033] Configuration Engine **220** is a module that can configure the format, content, and scope of narratives or documents generated by system **200** as well as configure automatic content updates to the narratives or documents. Configuration engine can utilize configuration scripts **216** or other configuration files to establish the configuration of system **200**. Additionally, configuration engine **220** can receive direct input from a user via computing device **218**.

[0034] Configuration engine **220** can utilize the provided configuration information to determine what information is used for the creation of a narrative. For example, Configuration engine **220** can specify the patients in a clinical study for which a narrative will be generated by system **200**. Patients for inclusion in the narrative generation can be chosen directly or selected using a specified criteria provided to configuration engine **220**. For example, configuration engine **220** can be instructed to include every patient sharing a certain demographic characteristic such as age or every patient experiencing a certain adverse event and adverse event category such as becoming pregnant, or testing positive for pregnancy, or every patient experiencing a certain response to the study. In this way, a user of system **200** can use configuration engine **220** to control the number and type of narratives generated by the system.

[0035] Configuration engine **220** can further be used to specify the logic and handling associated with certain adverse events. For example, during a clinical study, patients can experience a death serious adverse event, non-fatal serious adverse event, or an adverse event requiring a patient's discontinuation. Additional triggering of adverse events (e.g., adverse events of special interest) or positive pregnancy tests/pregnancy can also be utilized as part of the conditional logic within engine **220**. Using configuration engine **220**, a user of system **200** can specify the specific way these adverse events should be handled including how the adverse events should be processed by narrative generation engine **240** and which data structures in data sources **202**, **204**, and **206** can contain information associated with the adverse events. For example, configuration engine **220** can be configured to determine that a certain lab result values are of interest, perhaps based on regulatory, administrative, or other requirements, and should qualify as a specific event that is processed using a particular formatting or logic. Although the lab results can otherwise be interpreted as normal, configuration engine **220** can be instructed to identify specific criteria that cause those results to trigger an adverse event in the context of the clinical trials or study. In this way, configuration engine **220** can be used to customize system **200** to generate documents or narratives that specifically meet the needs of a study or data set

[0036] Moreover, configuration engine **200** can provide an intuitive interface and language for selecting the criteria used for narrative generation. The interface can be provided, for example, using display device **218**. Further examples of the user interface are provided in more detail below in reference to FIGS. **3-12**. The input entered through the user interface via computing device **218** or via configuration script **216**, can be entered using non-technical input and translated into a vector-oriented language for application to the prepared data sets. By doing this conversion, configuration engine can provide a user with easily understandable options and criteria without requiring complex technical knowledge from the user. Configuration engine **220**, can map the human readable language used for input and configuration into the vector-oriented language used to process the datasets. By using a vector-oriented language or script, system **200** can efficiently apply the specified configuration

to vectors of data set that contain the study information. In this way, a rule or condition specified by the user can be applied to all elements in the data set in an efficient manner to effectively determine what data should be used for the generated narrative.

[0037] Moreover, configuration engine **220** can allow for the user to create dynamic conjunctions or combinations of criteria or keywords. Configuration engine **220** can process this input into a computer readable instructions that can be applied to all of the elements of the available data sets. For example, a user can specify abnormal criteria that includes that the overall interpretation of the results is "abnormal" or that the overall interpretation of the results is "undetermined." Configuration engine **220** can map "overall interpretation" to a specific keyword containing that value in the data set and specify that if the value for the keyword is "undetermined" or "abnormal" for a given element of data, than that data should be included in the narrative. Additional examples of criteria that can be entered are demonstrated in relation to FIGS. **3** and **12**, described in more detail below. Configuration engine **220**, can map the input criteria to a vector-oriented language that is applied to the data sets. Vector-oriented languages, or array programming, can refer to a programming language optimized to generalize scalar operations to apply to vectors, matrices, or other high level or specialized data structures. Moreover, the vector-oriented language can utilize aliases to abstract the language from the data and can allow the script to be portable and applied to varied data sets in varied domains. The configuration generated by configuration engine **220** can be provided to data extraction engine **230** and narrative generation engine **240**.

[0038] Moreover, configuration engine **220** can specify formatting or similar characteristics to use in the generated document or narrative. Using the above example, configuration engine **220** can specify that information related to the overall interpretation should be bolded for a value of "undetermined" and should be bold red text for a value of "abnormal." In this way, a user can use computing device **218** or configuration script **216** to instruct configuration engine **220** how to format the specified criteria. Configuration engine **220** can provide those formatting directives, along with the other instructions, to narrative generation engine **240** for use in generating the resulting narrative or document.

[0039] Data extraction engine **230** is a module that can utilize configuration information from configuration engine **220** and can retrieve a subset of data from the provided data sets for additional processing. For example, configuration engine **220** can specify a particular group of patients in a clinical study or a certain criteria that identifies a specific group of patients. Data extraction engine **230** can, using that list of patients or criteria, extract all relevant data records from the data sets that correspond to the determined group of patients. By extracting such data, data extraction engine **230** can reduce the overall size of the data set and ensure that only the data that will be relevant to the current patient is processed. Extracting relevant data is important because, in some embodiments, a document or narrative associated with every patient in a study is not necessary. Accordingly, the ability to extract data related to only those patients for whom a narrative is being generated reduces the computational overhead necessary to generate the narratives. This is particularly important, as each patient being processed may require multiple narratives or documents to be generated. Accordingly, reducing the amount of information that must be processed prior to analysis can greatly increase the computational efficiency of system **200**. After extracting the relevant data records from the data set, data extraction engine **230** can provide the data records to narrative generation engine **240**.

[0040] Narrative generation engine **240** is a module that can process multiple data elements using criteria and input from configuration engine **220** in order to generate a document or narrative **242** associated with the data. Narrative generation engine **240** gather the data for a patient specified by data extraction engine **220**, and apply the vector-oriented instructions provided by configuration engine **220** to each record in the data set. Because configuration engine **220** already defines relevant criteria, narrative generation engine **240** can determine what data records, if any, in the relevant data set include values matching the defined criteria. In the example described above, narrative generation engine **240** can apply the vector-oriented instructions from configuration engine **220** to determine all records for a particular patient that show an "overall interpretation" of "undetermined" or "abnormal."

[0041] After determining data that matches the relevant criteria specified through configuration engine **220**, narrative generation engine can use pre-existing document or narrative templates or narratives (e.g., narrative templates stored in data storage **215**) for the relevant domain. Narrative generation engine **240** can populate the template using the data in the various data records for a particular patient. Additionally, narrative generation engine can use its determination of the data records matching the previously specified relevant criteria to populate portions of the clinical narrative associated with that data. For example, narrative generation engine **240** can generate a narrative that includes separate paragraphs or other notations indicating that the overall interpretation is either "undetermined" or "abnormal." Moreover, narrative generation engine **240** can utilize any formatting information provided by configuration engine **220** to properly format the relevant data. For example, the generated document can include in-text tables, summary text, charts, and graphs.

[0042] The narrative can be provided to a user on, for example, computing device **244**. Additionally, the narratives can be stored in data storage **215** for later review or use. In some embodiments, narrative generation engine **240** can utilize previously generated narratives for the same patient. When generating a new narrative for that particular patient, narrative generation engine can make use of new data that has been gathered since the previous report was generated. Narrative generation engine **240** can compare the newly generated report with the previously generated report and provide differences that show what information changed between the two narratives. In some embodiments, differences can be shown using highlighting. In some embodiments, differences can be shown with comments or other annotations. For example, deleted items can be shown with strikethrough text. Moreover, if the previously generated report has been updated or annotated by a user, those annotations can be incorporated and displayed as part of the newly generated narrative.

[0043] FIGS. **3-12** are exemplary user interfaces for interacting with system **200**. It is appreciated that these various user interfaces are exemplary, and are not intended to be an exhaustive list or diagram of the available user interface

elements for interacting with and configuring system **200**. Accordingly, many additional user interfaces, layouts, and control mechanisms are consistent with the disclosed embodiments.

[0044] FIG. **3** is an exemplary user interface **300** for system **200** consistent with embodiments of the present disclosure. User interface **300** can be provided on, for example, computing device **218** or computing device **244**. User interface **300** can provide a list of patient identifiers **310** for which a document or narrative will be generated by system **200**. System **200** can receive the list of patient identifiers **310** through, for example configuration engine **220**. In some embodiments, user interface **300** can represent an application executing natively on a computing device such as computing device **218** or computing device **244**. In some embodiments, user interface **300** can represent a user interface executing natively but connecting to a data storage executing in a remote computing environment (e.g., a cloud storage or Electronic Document Management System).

[0045] User interface **300** can further include filters **320**. Filters **320** can provide a mechanism further tailoring documents and narratives generated by system **200**. As shown in FIG. **3**, filters **320** can include checkboxes to select categories of adverse events that should be included in the narrative generation. Moreover, filters **320** can provide list boxes showing all available adverse events and selected adverse events. Using the controls in filters **320**, a user using user interface **300** can select which adverse events are of interest, which can filter the set of patients for which narratives can be generated.

[0046] User interface **300** can also include narrative options **330**. Narrative options **330** can provide controls to allow for additional configuration of the narrative output. For example, controls under narrative options **330** can allow the user to specify where narratives should be save (e.g., in storage **215**), what narratives should be loaded for comparison with newly generated narratives (e.g., the existing narratives can be stored in storage **215**), as well as other options for specifying narrative output on, for example, computing device **218** or computing device **244**.

[0047] FIGS. **4**A-**4**C are exemplary embodiments of a user interface dialog box **400** for use with a user interface (e.g., user interface **300** of FIG. **3**), consistent with embodiments of the present disclosure. User interface dialog box **400** and the various depicted embodiments are exemplary and are not intended to be an exhaustive representation of the options and dialogs provided to configure or interact with system **200**. User interface dialog box **400** can be provided on, for example, computing device **218** or computing device **244**.

[0048] FIG. **4**A is an exemplary tab **401** of user interface dialog box **400** for system **200** consistent with embodiments of the present disclosure. Tab **401** can be used to select abnormal criteria for generation of documents or narratives. The abnormal criteria can be used by configuration engine **220** and applied to clinical data by narrative generation engine **240**. Tab **401** can include condition list **410**. As shown, condition list **410** can include specific conditions or categories associated with a particular treatment or test or a test name itself (e.g., an electrocardiogram ("ECG")). A user can select a specific condition, keyword or category from condition list **410** and can use the controls provided in abnormal condition options **420** to choose values and tests to apply to the data. By choosing condition criteria using condition list **410** and condition options **420**, a user can configure system **200** (e.g., through configuration engine **220**) to find data that matches the specified condition variables. Matching data can then be included or emphasized in the generated narratives (e.g., by narrative generation engine **240**).

[0049] FIG. **4**B is an exemplary tab **402** of user interface dialog box **400** for system **200** consistent with embodiments of the present disclosure. Tab **402** can, similar to tab **401** in FIG. **4**A, be used to select abnormal criteria for generation of documents or narratives. The abnormal criteria can be used by configuration engine **220** and applied to clinical data by narrative generation engine **240**. Similar to tab **401** of FIG. **4**A, tab **402** can include condition list **413** and condition options **420**. Condition list **413**, however, can provide different categories of conditions than condition list **410** of FIG. **4**A. As shown in FIG. **4**B, condition list **413** can be associated with vital signs of a patient. As described above in relation to FIG. **4**A, a user can use tab **402** to configure criteria for narrative generation using condition list **413** and condition options **420**.

[0050] FIG. **4**C is an exemplary tab **403** of user interface dialog box **400** for system **200** consistent with embodiments of the present disclosure. Tab **403** can, similar to tab **401** in FIG. **4**A and tab **402** in FIG. **4**B, be used to select abnormal criteria for generation of documents or narratives. The abnormal criteria can be used by configuration engine **220** and applied to clinical data by narrative generation engine **240**. Similar to tab **401** and tab **402** described above, tab **403** can include condition list **416** and condition options **420**. Condition list **416** can provide different categories of conditions than condition list **410** of tab **401** and condition list **413** or tab **402**. As shown in FIG. **4**C, condition list **416** can be associated with laboratory test results. As described above in relation to FIGS. **4**A and **4**B, a user can use tab **403** to configure criteria for narrative generation using condition list **416** and condition options **420**.

[0051] FIG. **5** is an exemplary embodiments of a user interface dialog box **500** for use with a user interface (e.g., user interface **300** of FIG. **3**), consistent with embodiments of the present disclosure. User interface dialog box **500** is exemplary and is not intended to be an exhaustive representation of the options and dialogs provided to configure or interact with system **200**. User interface dialog box **500** can be provided on, for example, computing device **218** or computing device **244**. User interface dialog box **500** can allow a user to map particular values or keywords associated with the data set being processed with names to be used in the document or narrative creation. For example, as shown in FIG. **5**, user interface dialog box **500** can include dataset original values **510** showing keywords or values found in the data set being processed. User interface dialog box **500** can include replacement value box **520**. In some embodiments, when a value or keyword is selected in dataset original values **510**, the corresponding replacement value used in the narrative can be shown in replacement value box **520**. Moreover, user interface dialog box **500** can be used to update, modify, delete, create, load or save one or more replacement values for a selected value or multiple values in dataset original values **510**.

[0052] FIGS. **6-12** are exemplary user interfaces (e.g., user interfaces **600**, **700**, **800**, **900**, **1000**, **1100**, and **1200**) for interacting with system **200** consistent with embodiments of the present disclosure. These user interfaces can be provided on, for example, computing device **218** or computing device

244. In some embodiments, user interfaces **600-1200** can be part of a web service or web application executing on a web server and displayed through a desktop or mobile web browser (e.g., Mozilla Firefox, Apple Safari, Microsoft Internet Explorer, Microsoft Edge, Google Chrome, or similar). Computing device **218** or computing device **244** can provide system **200**, a web server with access to system **200**, and the web browser connecting to the web server and providing user interfaces **600-1200**, or some combination thereof. In some embodiments, system **200** can execute on computing devices separate from the computing devices providing the web server and/or web browser that provides user interfaces **600-1200**. In these embodiments, the web server and/or web browser can connect remotely to the computing device executing system **200**.

[0053] FIG. **6**A is an exemplary user interface **600** for system **200** consistent with embodiments of the present disclosure. User interface **600** can provide source file selector **610** that can be used to select a source dataset for document or narrative generation. Additionally, user interface **600** can provide study information options **620** that can allow a user to provide general parameters or information about the study and/or documents or narratives that will be generated.

[0054] FIG. **6**B is an exemplary user interface **650** for system **200** consistent with embodiments of the present disclosure. User interface **600** can provide additional source file selector **660** that can be used to select a source dataset for rollover data. Rollover data can be data related to patients who participated in a previous study. User interface **650** can include multiple source file selectors **660** for selecting multiple source files with rollover data. Additionally, user interface **650** can provide rollover description box **670** that can be used to describe the rollover data when it is included in the current set of data. Using user interface **650**, system **200** can utilize additional source files for rollover data. Additionally, user interface **650** can support raw data which was provided as a physically separate file(s) from source file selector **610**.

[0055] FIG. **7** is an exemplary user interface **700** for system **200** consistent with embodiments of the present disclosure. User interface **700** can provide adverse events that can be selected to trigger the document or narrative generation. User interface **700** can provide adverse event records **720** that categorized as adverse events of special interest. Additionally, user interface **700** can provide adverse event records **710** that show additional adverse event records that have been found but are not selected to trigger the document or narrative generation. Using user interface **700**, a user can moved selections from one list to the other to control which adverse events are included in the generated documents or narratives.

[0056] FIG. **8** is an exemplary user interface **800** for system **200** consistent with embodiments of the present disclosure. User interface **800** can provide patient or individual identifiers that are in the data set being processed. Similar to user interface **700** described above, user interface **800** can provide selected patient identifiers **820** and can provide unselected patient identifiers **810** in the dataset. Using user interface **800**, a user can moved selections from one list to the other to control which patient data is processed for the generated documents or narratives. User interface **800** can further provide filters **830** that can be used to dynamically filter selected individuals based on the types of adverse events associated with the individuals represented in the dataset. After selecting an adverse event or combination of adverse events from filters **830**, individuals not matching the selected criteria can be excluded from the document or narrative generation. Additionally, user interface **800** can provide subject input **830** which can be used to add additional subjects or patient identifiers. Using subject input **830**, a user can specify additional patients for which narratives should be generated.

[0057] FIG. **9** is an exemplary user interface **900** for system **200** consistent with embodiments of the present disclosure. User interface **900** can provide an interface for selecting conditions, criteria, or pre-populated flags provided within the data for inclusion in the generated documents or narratives. User interface **900** can provide selection box **910** for selecting specific types of medical tests or categories. As shown in FIG. **9**, selection box **910** can allow for the selection of "Clinical Laboratory Tests," "ECG Results," and "Vital Signs." The count, order, and/or naming shown in selection box **910** can be dynamically controlled within configuration engine **220**. Each of these medical test names can include multiple tests or keywords that can be displayed in tests list **920**. It is appreciated that the three categories listed are only exemplary, and that other categories or test names may be available in the data set being processed and presented through medical test names **910**. After selecting a medical test name from medical test names **910**, a user can select specific tests from tests list **920**, and specific criteria and conditions **930**. Using the elements of user interface **900**, a user can specify a plurality of criteria that can be used during the processing of the datasets. The rules or criteria created can be provided to system **200** (e.g., through configuration engine **220**) to determine the information that is included in the generated documents or narratives.

[0058] FIG. **10** is an exemplary user interface **1000** for system **200** consistent with embodiments of the present disclosure. User interface **1000** can provide an interface for substituting text labels for treatment phases of clinical trials. User interface **1000** can provide source list **1010**. Source list **1010** can represent the clinical phases in the dataset. Replacement list **1020** can represent the names or labels of the clinical phases to be used in the generation of documents or narratives. Through user interface **1000**, system **200** can be directed to rename treatment phases appearing in the source data in order to provide consistent output in the generated documents or narratives.

[0059] FIG. **11** is an exemplary user interface **1100** for system **200** consistent with embodiments of the present disclosure. User interface **1100** can provide an interface for mapping the labels of adverse events used in the document or narrative creation. User interface **1100** can provide source list **1110**. Source list **1110** can represent the adverse event names found in the dataset. Replacement list **1120** can represent the names or labels of the adverse events to be used in the generation of documents or narratives. Through user interface **1100**, system **200** can be directed to rename adverse events appearing in the source data in order to provide consistent output in the generated documents or narratives.

[0060] FIG. **12** is an exemplary user interface **1200** for system **200** consistent with embodiments of the present disclosure. User interface **1200** can provide an interface for configuring options for the document or narrative creation.

User interface **1200** can provide output options **1210**. These output options can be used to control the level of detail and type of events that are reported in the generated documents or narratives.

[0061] FIG. **13** is an exemplary narrative **1300** consistent with embodiments of the present disclosure. Narrative **1300** can represent a narrative generated by system **200**. As shown in FIG. **13**, narrative **1300** can include tabular data representing the adverse events experienced by a particular individual. Additionally, narrative **1300** can include medical history showing past conditions, the onset date, and if the conditions are still ongoing. Moreover, using data from the datasets, system **200** can include textual descriptions of the relevant clinical study and adverse events experienced by the individual. As shown in FIG. **13**, narrative **1300** can include placeholders where additional information can be entered by those running the study. Narrative **1300** can be based on a template that includes specified areas of text that are generated by system **200** (e.g., by narrative generation engine **240**).

[0062] FIG. **14** is an exemplary narrative **1400** consistent with embodiments of the present disclosure. Narrative **1400** can represent an updated narrative generated by system **200** (e.g., through narrative generation engine **240**). Narrative **1400** can be an updated version of the narrative represented in FIG. **13**. Narrative **1400** can display differences between the previously generated narrative (e.g., narrative **1300** in FIG. **13**) and the current narrative. For example, narrative **1400** can show data that has been updated using strike-through text **1410** for the previous data and underlined text for the new data. Additionally, comments **1420** or other custom annotations added manually can be retained in the updated narrative **1400**. Moreover, new data can be represented with underlined text **1430** and inserted into narrative **1400** where appropriate. Using these annotations, system **200** can generate updated narratives **1400** that clearly indicate portions of narrative **1400** that have changed based on newly available data.

[0063] FIG. **15** is flowchart of an exemplary method **1500** for data driven document creation and modification. After initial step **1501**, the system (e.g., system **200** of FIG. **2**) can read (step **1502**) primary datasets (e.g., using data intake engine **210** of FIG. **2**). The primary datasets can include clinical trial information associated with patients or individuals taking part in a particular study or set of clinical trials. The system can further read (step **1504**) auxiliary data sets (e.g., using data intake engine **210**). Auxiliary data sets can include additional information about a clinical study or participants in a clinical study. The Auxiliary data sets can include past clinical trials associated with individuals in the current study. In some embodiments, auxiliary data sets can include demographic information or other ancillary data associated with the current study.

[0064] The system can further obtain (step **1506**) a list of required narratives and subjects (e.g., using configuration engine **220** of FIG. **2**, user interface **300** of FIG. **2**, or user interface **800** of FIG. **8**). The list of subjects can include all subjects participating in a study or a subset of the subjects participating in a study. Moreover, the list of subjects can be further filtered based on the types of adverse events experienced by the participants in the study.

[0065] The system can merge or append (step **1508**) datasets that contain information relevant to the narratives and documents being generated. The system can utilize the various data sources and create a unified data set that can be processed be the system. Data sets having different formats or structures can be normalized into a consistent format for further processing.

[0066] If no narratives need to be processed (step **1510**) then method **1500** can end (step **1522**.) Otherwise, the system can extract (step **1512**) individual data from the unified data set that is associated with the particular subject or narrative currently being generated. The data relevant data can be retrieved from the unified data set.

[0067] The system can obtain (step **1514**) configuration information from users (e.g., using user interfaces **300**-**1200** of FIGS. **3**-**12**). As described above the configuration information can include the types of adverse events to include specific criteria to be matched in the data sets, and specific values that may represent important attributes for the study. The configuration information can be provided, for example, through configuration engine **220**. The system can further convert (step **1516**) the configuration provided to the system into a vector oriented language or instructions (e.g., using configuration engine **220**) that can be efficiently applied to the datasets being processed. The system can process (step **1518**) the datasets using the generated vector oriented language or instructions. The intermediate results from processing the datasets can be presented using, for example, device **244**. After processing the datasets based on the specific configuration information provided, the system can output (step **1520**) information associated with a particular subject or narrative using a pre-specified template. The output narrative (e.g., narrative **1300** of FIG. **13**) can represent the dataset in a consistent format for use in analyzing the study. The system can determine (step **1522**) if a previously authored document or narrative is being reused. If not, the system can return to step **1510** and determine if additional narratives are needed. If a previously authored document is being reused, the system can generate (step **1524**) a difference file (e.g., narrative **1400**) that shows the various changes between the original narrative (e.g., narrative **1300**) and the new data. The system can then return to step **1510** to determine if additional narratives need processed.

[0068] In the foregoing specification, embodiments have been described with reference to numerous specific details that can vary from implementation to implementation. Certain adaptations and modifications of the described embodiments can be made. For example, some embodiments consistent with the present disclosure include support for rollover patients that participated in previous studies. Other embodiments can be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only. It is also intended that the sequence of steps shown in figures are only for illustrative purposes and are not intended to be limited to any particular sequence of steps. As such, those skilled in the art can appreciate that these steps can be performed in a different order while implementing the same method.

1. (canceled)

2. A method for generating a document comprising:

obtaining, using one or more computers, data that indicates criteria including one or more limiting conditions that identify a portion of a data set, the one or more limiting conditions including entity identifying criteria,

the entity identifying criteria defining a cross-section of a population that have experienced the same adverse event;

generating, using one or more computers and using a vector-oriented language, a data filter that includes one or more filtering parameters that can be applied to a superset of entities, wherein the one or more filtering parameters are determined using the obtained data;

filtering, using one or more computers, the superset of entities using the generated data filter to identify a filtered subset of entities that satisfy the entity identifying criteria;

for each particular entity in the filtered subset of entities:

accessing, using one or more computers, data records associated with the particular entity;

detecting, using one or more computers, each record of the accessed records that is indicative of an abnormal entity state;

selecting, using one or more computers, a pre-existing template based on a domain of the accessed data records;

populating, using one or more computers, the selected template using at least some of the data in the detected records indicative of an abnormal entity state;

determining, using one or more computers, whether a document exists in a database for the particular entity; and

based on a determination that a document does not already exist in the database for the particular entity, generating, using one or more computers, a document for storage in the database, wherein the document includes the populated template.

3. The method of claim **2**, wherein the cross-section of the population includes each entity that participated in a particular clinical study.

4. The method of claim **2**, wherein the entity identifying criteria include data that indicates one or more demographic characteristics associated with the entity.

5. The method of claim **2**, the method further comprising:

based on a determination that a document already exists in the database for the particular entity, updating, using one or more computers, the existing document in the database to include the populated template.

6. The method of claim **5**, updating the existing document comprises:

annotating, using one or more computers, the updated portions of the document.

7. The method of claim **2**, wherein generating, using a vector-oriented language, a data filter that includes one or more filtering parameters that can be applied to a superset of entities comprises:

translating, using one or more computers, the obtained data into one or more abstract filtering parameters that are data source independent.

8. A system for generating a document, the system comprising:

one or more computers; and

one or more computer-readable media storing instructions that, when executed by the one or more computers, cause the one or more computers to perform operations, the operations comprising:

obtaining, using the one or more computers, data that indicates criteria including one or more limiting conditions that identify a portion of a data set, the one or more limiting conditions including entity identifying criteria, the entity identifying criteria defining a cross-section of a population that have experienced the same adverse event;

generating, using the one or more computers and using a vector-oriented language, a data filter that includes one or more filtering parameters that can be applied to a superset of entities, wherein the one or more filtering parameters are determined using the obtained data;

filtering, using the one or more computers, the superset of entities using the generated data filter to identify a filtered subset of entities that satisfy the entity identifying criteria;

for each particular entity in the filtered subset of entities:

accessing, using the one or more computers, data records associated with the particular entity;

detecting, using the one or more computers, each record of the accessed records that is indicative of an abnormal entity state;

selecting, using the one or more computers, a pre-existing template based on a domain of the accessed data records;

populating, using the one or more computers, the selected template using at least some of the data in the detected records indicative of an abnormal entity state;

determining, using the one or more computers, whether a document exists in a database for the particular entity; and

based on a determination that a document does not already exist in the database for the particular entity, generating, using the one or more computers, a document for storage in the database, wherein the document includes the populated template.

9. The system of claim **8**, wherein the cross-section of the population includes each entity that participated in a particular clinical study.

10. The system of claim **8**, wherein the entity identifying criteria include data that indicates one or more demographic characteristics associated with the entity.

11. The system of claim **8**, the operations further comprising:

based on a determination that a document already exists in the database for the particular entity, updating, using the one or more computers, the existing document in the database to include the populated template.

12. The system of claim **11**, wherein updating the existing document comprises:

annotating, using the one or more computers, the updated portions of the document.

13. The system of claim **8**, wherein generating, using a vector-oriented language, a data filter that includes one or more filtering parameters that can be applied to a superset of entities comprises:

translating, using the one or more computers, the obtained data into one or more abstract filtering parameters that are data source independent.

14. One or more computer-readable storage media storing instructions, that when executed by one or more computers, cause the one or computers to perform operations, the operations comprising:

obtaining data that indicates criteria including one or more limiting conditions that identify a portion of a data set, the one or more limiting conditions including entity identifying criteria, the entity identifying criteria defining a cross-section of a population that have experienced the same adverse event;

generating, using a vector-oriented language, a data filter that includes one or more filtering parameters that can be applied to a superset of entities, wherein the one or more filtering parameters are determined using the obtained data;

filtering the superset of entities using the generated data filter to identify a filtered subset of entities that satisfy the entity identifying criteria;

for each particular entity in the filtered subset of entities:

accessing data records associated with the particular entity;

detecting each record of the accessed records that is indicative of an abnormal entity state;

selecting a pre-existing template based on a domain of the accessed data records;

populating the selected template using at least some of the data in the detected records indicative of an abnormal entity state;

determining whether a document exists in a database for the particular entity; and

based on a determination that a document does not already exist in the database for the particular entity, generating a document for storage in the database, wherein the document includes the populated template.

15. The computer-readable medium of claim **14**, wherein the cross-section of the population includes each entity that participated in a particular clinical study.

16. The computer-readable medium of claim **14**, wherein the entity identifying criteria include data that indicates one or more demographic characteristics associated with the entity.

17. The computer-readable medium of claim **14**, the operations further comprising:

based on a determination that a document already exists in the database for the particular entity, updating the existing document in the database to include the populated template.

18. The computer-readable medium of claim **17**, updating the existing document comprises:

annotating the updated portions of the document.

19. The computer-readable medium of claim **14**, wherein generating, using a vector-oriented language, a data filter that includes one or more filtering parameters that can be applied to a superset of entities comprises:

translating the obtained data into one or more abstract filtering parameters that are data source independent.

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