US 20090138289A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2009/0138289 A1**

(43) **Pub. Date: May 28, 2009**

Klass et al.

(54) **METHOD AND SYSTEM FOR IDENTIFYING AND ANTICIPATING ADVERSE DRUG EVENTS**

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Minneapolis, MN 55402-1498 (US)

(21) Appl. No.: **12/351,327**

(22) Filed: **Jan. 9, 2009**

Related U.S. Application Data

(63) Continuation of application No. 11/206,261, filed on Aug. 16, 2005, now abandoned, which is a continuation of application No. 09/970,320, filed on Oct. 3, 2001, now Pat. No. 6,993,402.

(60) Provisional application No. 60/272,019, filed on Feb. 28, 2001.

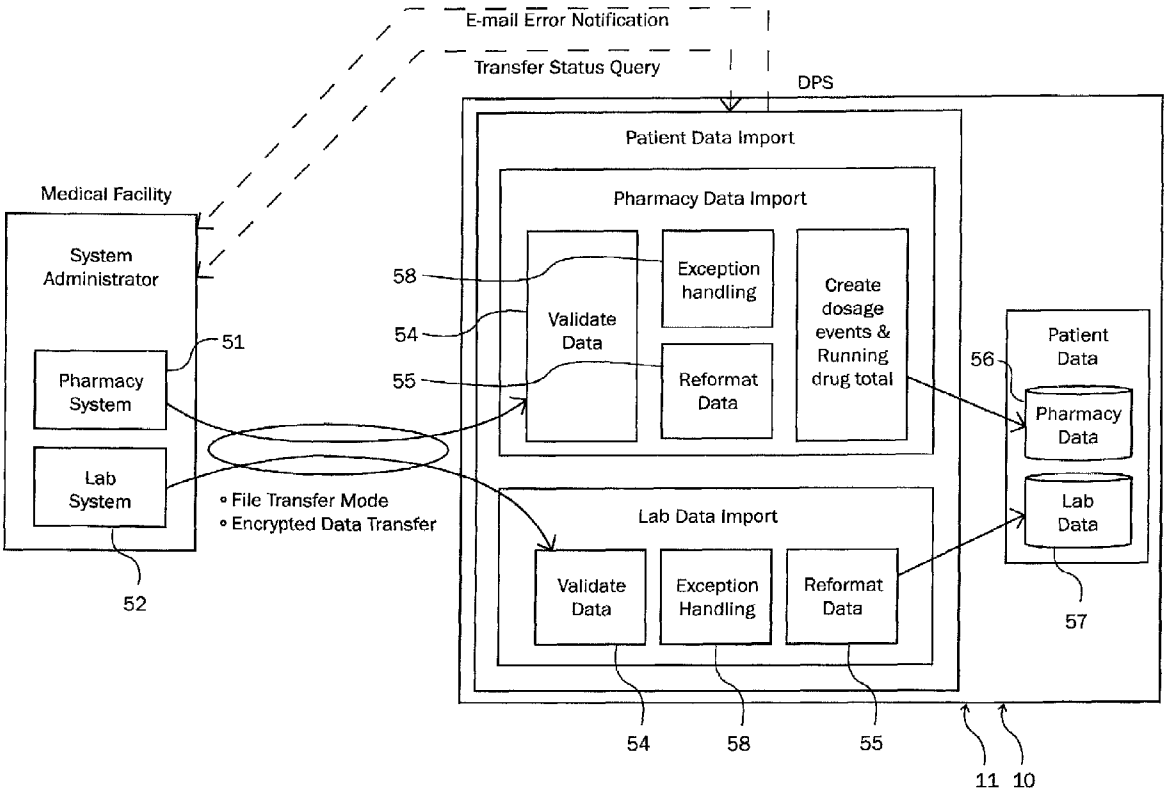
Publication Classification

(51) **Int. Cl.**
G06Q 50/00 (2006.01)
G06F 17/30 (2006.01)

(52) **U.S. Cl.** **705/3**; 707/3; 707/104.1; 707/E17.108

(57) **ABSTRACT**

The present invention is a system and method for anticipating potential Adverse Drug Events (ADE) in a patient's medication regimen by integrating data typically located in laboratory and pharmacy information systems and filtering the data using predefined criteria. The present invention includes a system for anticipating a possible ADE through the use of a search engine that compares integrated data from laboratory and pharmacy information systems and compares it to predefined ADE rules defining normal ranges for a particular laboratory test. If an abnormal test value is received and a drug in the patient's medication regimen satisfies a drug included in an ADE rule then an alert procedure is triggered which allows for a period of time wherein the patient's lab and pharmacy data is monitored in order to determine if a proper corrective action is undertaken, and if no corrective action or an improper corrective action is taken within that period of time, the healthcare provider is warned of a potential ADE.



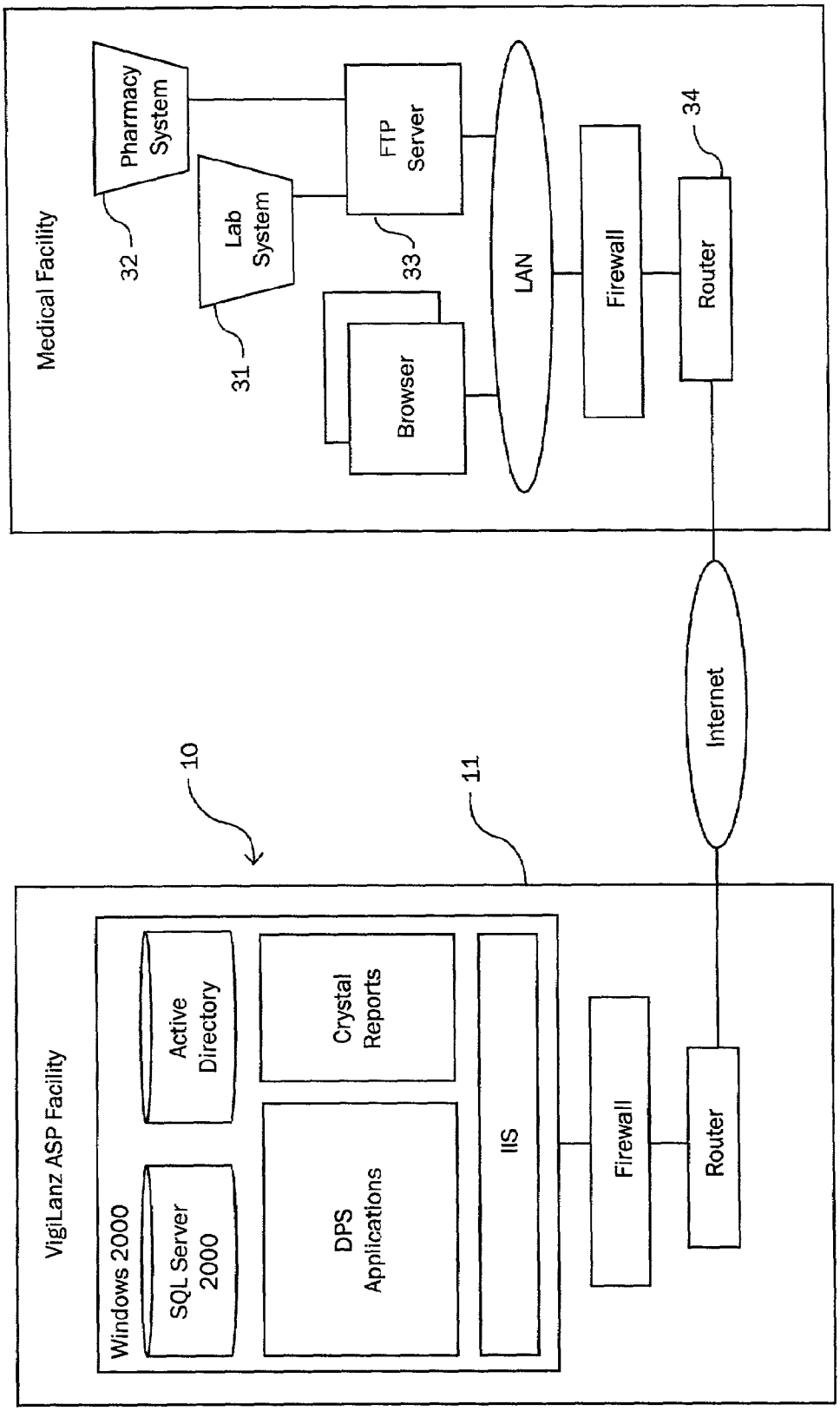

Medical Facility
Pharmacy System
Lab System
FTP Server
Browser
LAN
Firewall
Router
34
32
33
31
Internet
10
11
VigiLanz ASP Facility
Windows 2000
SQL Server 2000
Active Directory
DPS Applications
Crystal Reports
IIS
Firewall
Router

Fig 1

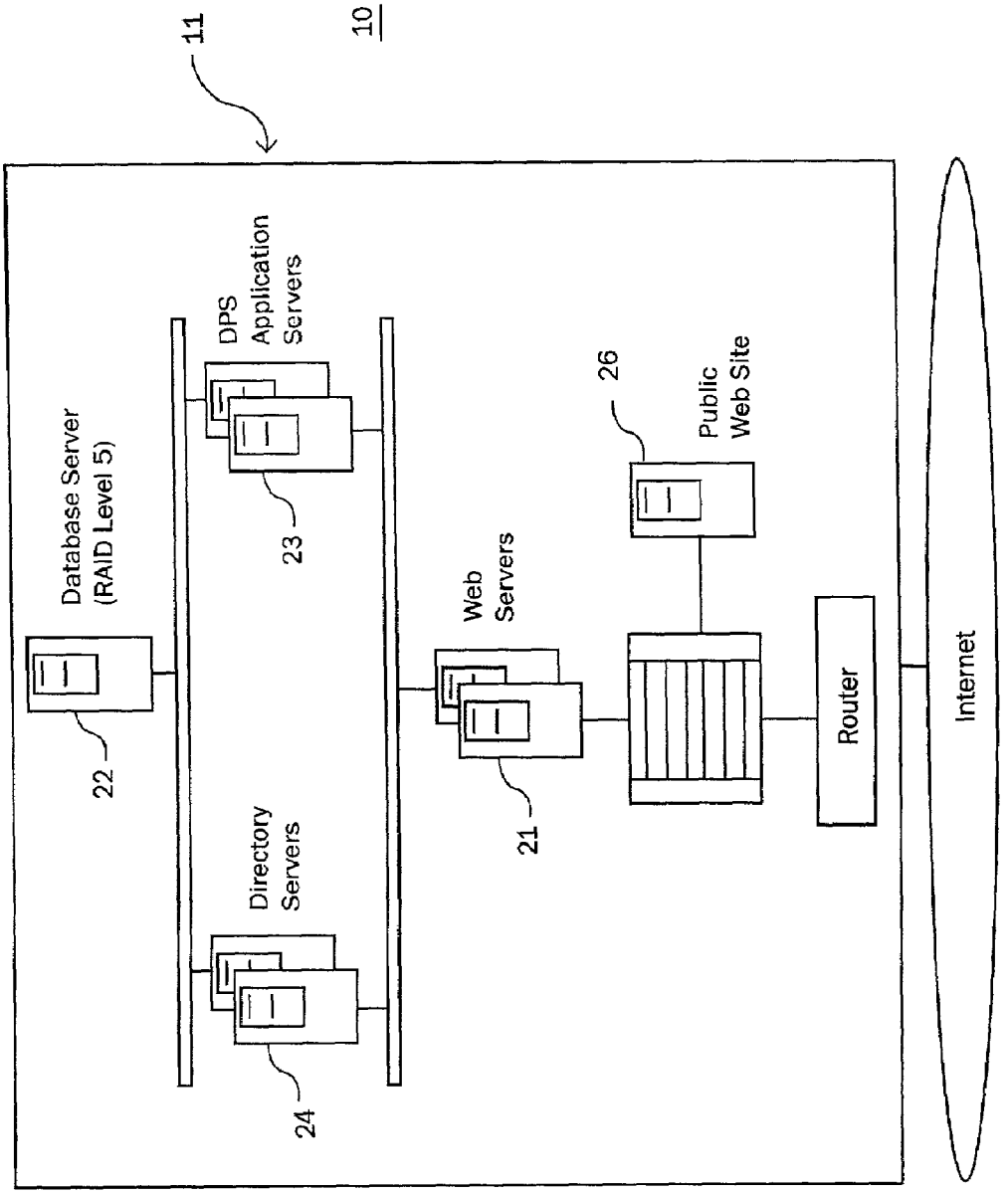

10
11
Database Server
(RAID Level 5)
22
DPS
Application
Servers
23
Directory
Servers
24
Web
Servers
21
26
Public
Web Site
Router
Internet

Fig 2

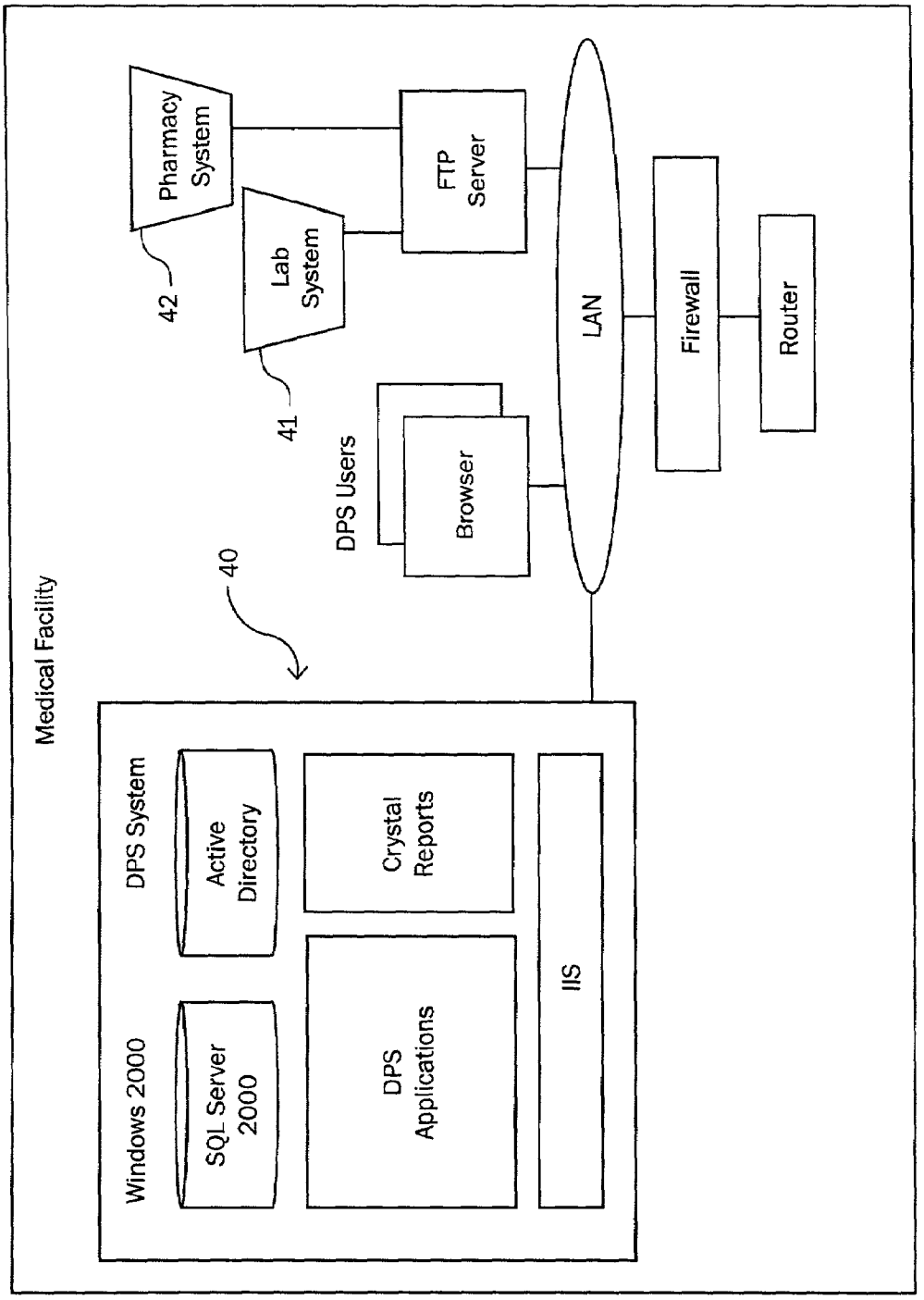

Medical Facility
40
DPS System
Windows 2000
Active Directory
SQL Server 2000
Crystal Reports
DPS Applications
IIS
DPS Users
Browser
LAN
Firewall
Router
FTP Server
Pharmacy System
Lab System
42
41

Fig 3

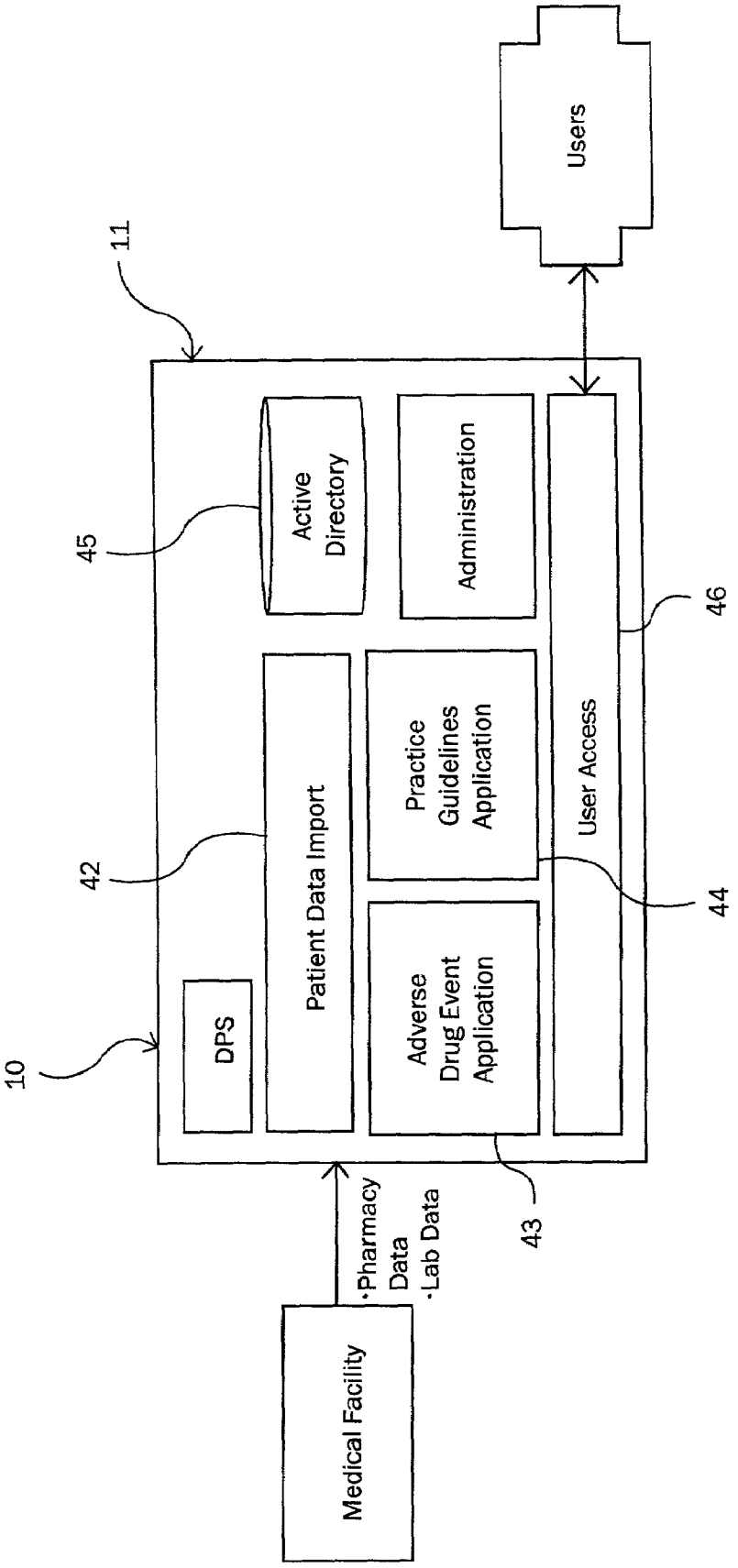

Users
11
Active Directory
Administration
45
46
Practice Guidelines Application
User Access
Patient Data Import
42
44
DPS
Adverse Drug Event Application
10
43
·Pharmacy Data
·Lab Data
Medical Facility

Fig 4

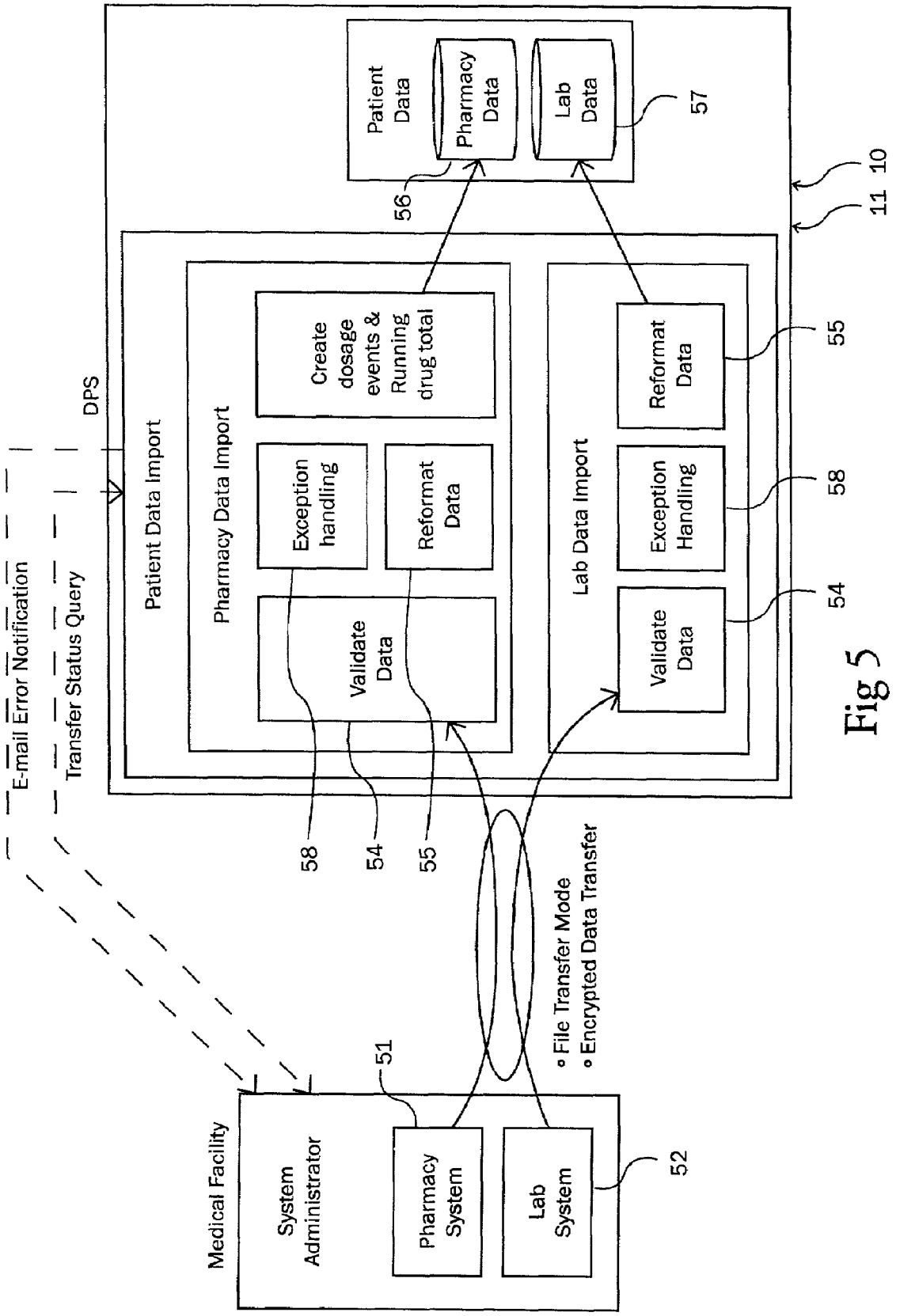

Medical Facility
System Administrator
Pharmacy System
Lab System
51
52
File Transfer Mode
Encrypted Data Transfer
E-mail Error Notification
Transfer Status Query
DPS
Patient Data Import
Pharmacy Data Import
Validate Data
Exception handling
Reformat Data
Create dosage events & Running drug total
Lab Data Import
Validate Data
Exception Handling
Reformat Data
Patient Data
Pharmacy Data
Lab Data
10
11
54
55
56
57
58

Fig 5

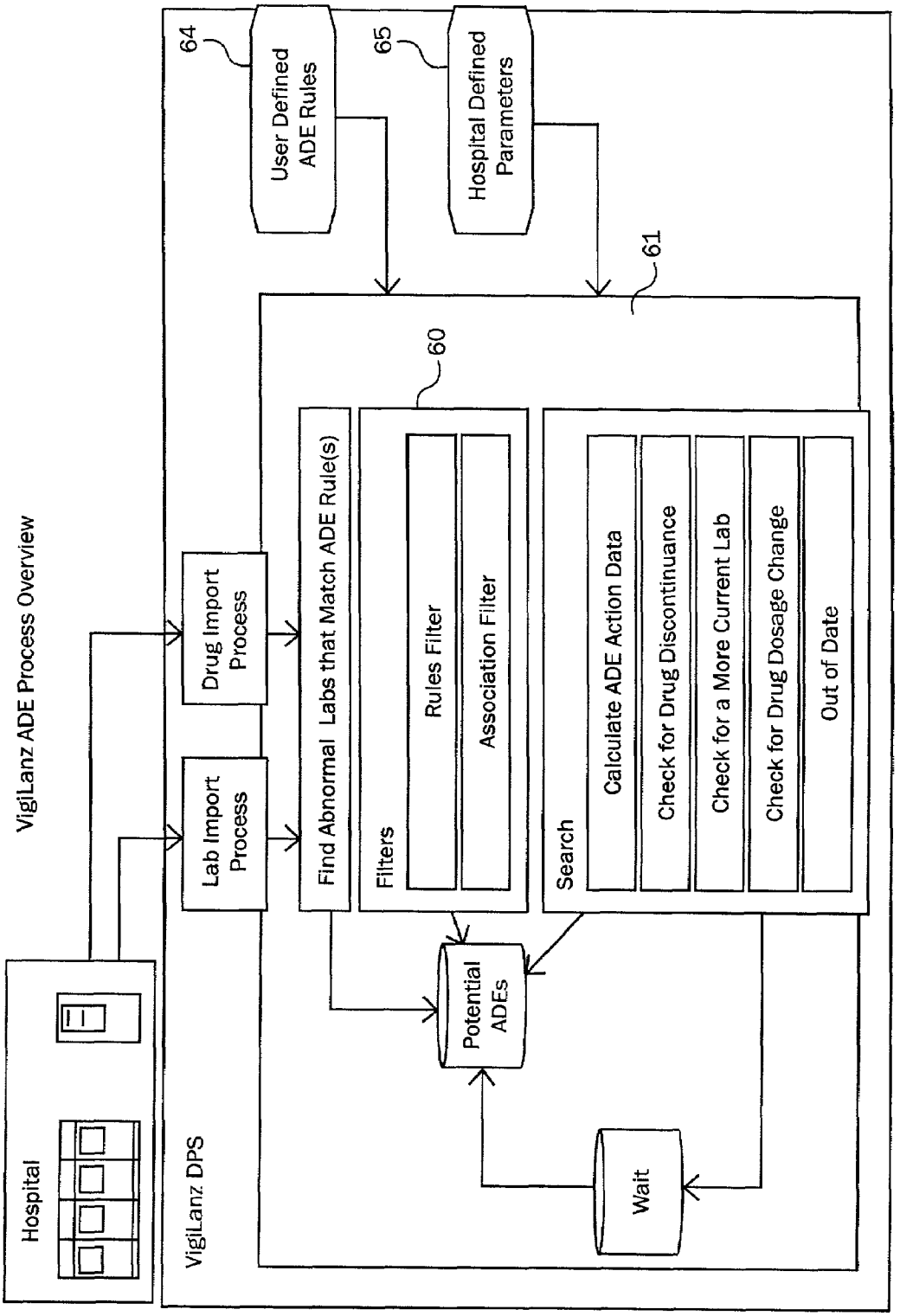

VigiLanz ADE Process Overview
Hospital
VigiLanz DPS
Drug Import Process
Lab Import Process
Find Abnormal Labs that Match ADE Rule(s)
Filters
Rules Filter
Association Filter
Search
Calculate ADE Action Data
Check for Drug Discontinuance
Check for a More Current Lab
Check for Drug Dosage Change
Out of Date
Potential ADEs
Wait
User Defined ADE Rules
Hospital Defined Parameters
64
65
60
61

Fig 6

Fig. 7

	Parameter	Description
71	Search Status	Status of Drug/Lab Search: Enabled/Disabled. Search is performed only if it is "Enabled"
72	Search Type	Type of Drug/Lab Search: Alert or Research. "Alert" type WILL generate alerts; "Research" type will Not generate an alert.
73	Target Drug	Name of "Target" Drug. Note: All drug names are automatically extracted from the pharmacy import data file.
74	Target Lab	Name of the lab test. Note: All lab names are automatically extracted from the lab import data file.
75	Drug/Lab Search Name	Unique identifier of this drug/lab pair search
76	Severity	Severity of the ADE.
77	Lab Code	Abbreviation or acronym for the lab test.
78	Pattern	Pattern specifies two things: First, if this Drug/Lab Search looking for a "high" lab test or a "low" lab test? Second, what is the "normal" drug response to lab test (i.e. To "raise" the drug dosage, or to "lower" the drug dosage.
79	Type	High or low type of lab test. "High" -Drug/Lab Search set to look for a "high" lab test result; "Low" -lab test set to look for a "low" lab test result.
80	Baseline	The lab test value at which point the lab test is considered "abnormal".
81	Absolute	The lab test value at which point the lab test is considered a "medical emergency".
82	Interval	The amount of time that would typically be allowed to respond, based upon an abnormal lab test.
83	Danger Multiplier	A value is entered which shortens the "interval" as the lab test result value gets closer to the "Absolute" level.
84	Momentum Multiplier	A value is entered which shortens or lengthens the "interval" based upon the previous lab test result value.
85	Allergy	Allergy test indicator.
86	Hospital Unit(s)	A set of "Hospital Units" to which this Drug/Lab Search applies.
87	Doctor(s)	A set of "Doctor(s)" to which this Drug/Lab Search applies.
88	Diagnosis(s)	A set of "Diagnoses" to which this Drug/Lab Search applies.
89	Gender	Identifies whether one, or both sexes are applied to this Drug/Lab Search.
90	Age Range	Identifies if the age range to which this Drug/Lab Search applies.
91	Concurrent Drug	Name of "Drug(s)" that must currently be prescribed to the patient. Up to three other Drugs may be specified.
92	Concurrent Lab	Name of "Lab(s)" that must currently be prescribed to the patient. Up to three other Labs may be specified.
93	Alert Template	Name of the template that defines how to handle an "alert" for this Drug/Lab Search.
94	Description	A user provided description of the ADE Search.
95	Contact	Who should be contacted for questions regarding this ADE Search?

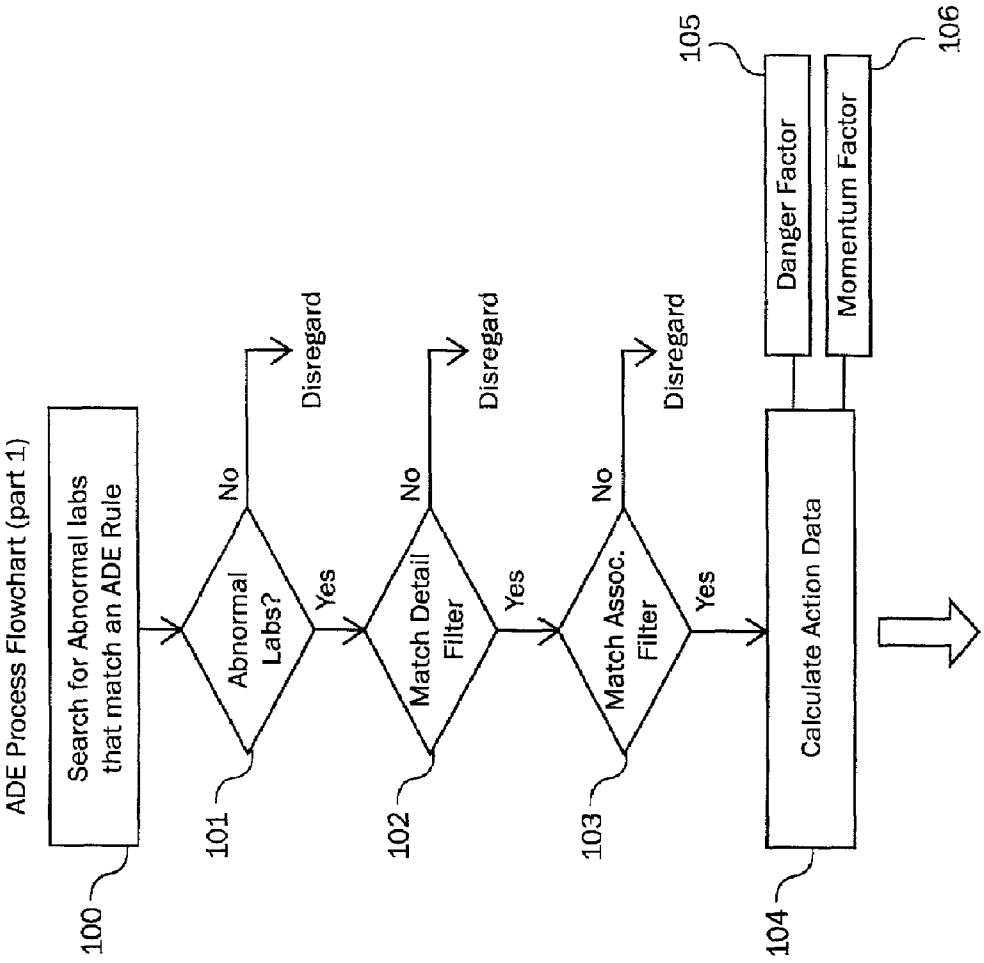

ADE Process Flowchart (part 1)
Search for Abnormal labs that match an ADE Rule
Abnormal Labs?
No
Disregard
Yes
Match Detail Filter
No
Disregard
Yes
Match Assoc. Filter
No
Disregard
Yes
Calculate Action Data
Danger Factor
Momentum Factor
Next Page
100
101
102
103
104
105
106

Fig 8a

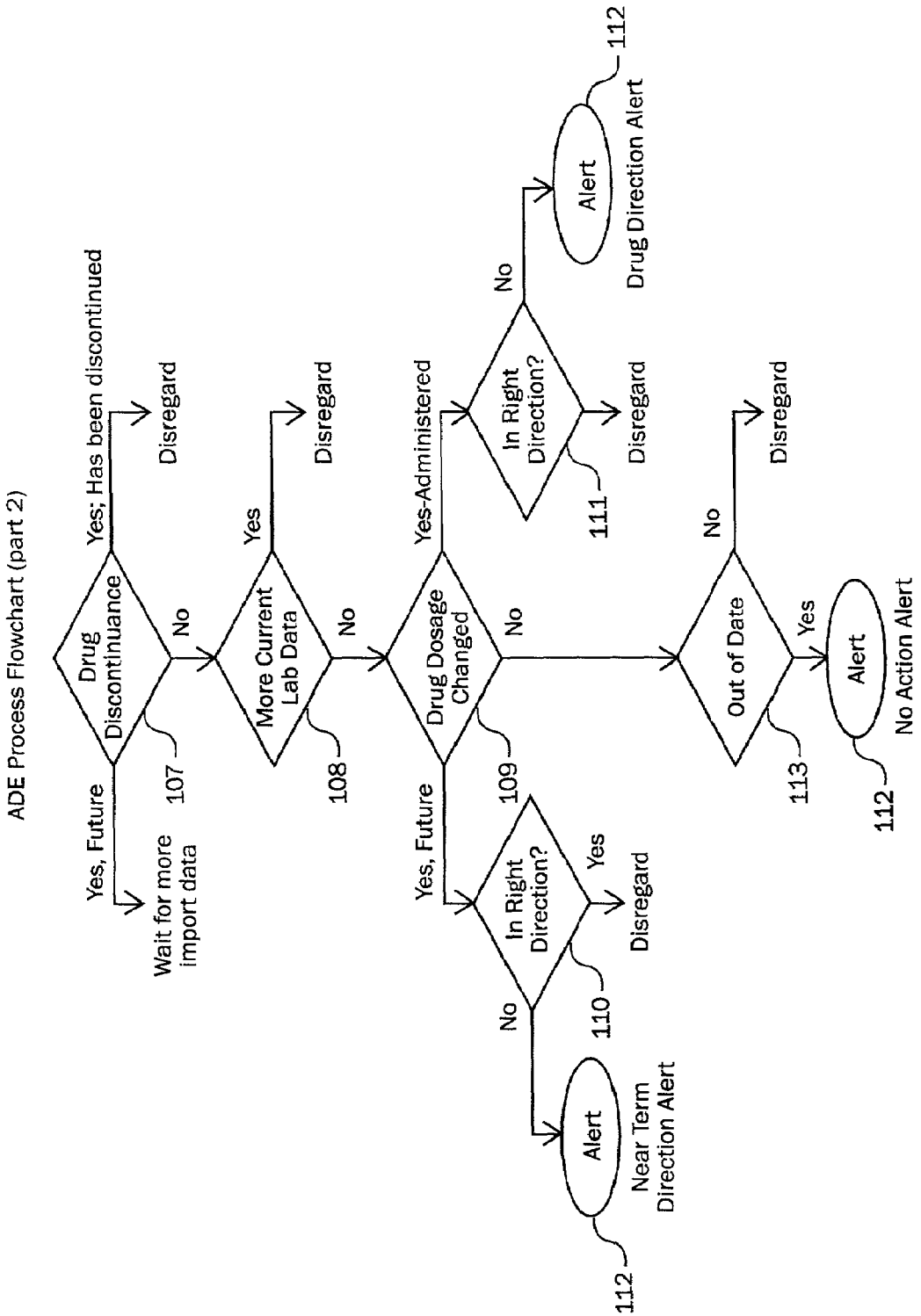

ADE Process Flowchart (part 2)
Drug Discontinuance
Yes; Has been discontinued
Disregard
No
Yes, Future
Wait for more import data
107
More Current Lab Data
Yes
Disregard
No
108
Drug Dosage Changed
Yes-Administered
In Right Direction?
No
Alert
Drug Direction Alert
112
Disregard
111
Yes, Future
In Right Direction?
Yes
Disregard
No
Alert
Near Term Direction Alert
112
110
109
Out of Date
No
Disregard
Yes
Alert
No Action Alert
112
113

Fig 8b

First Abnormal Lab That Match ADE Rule

The Initial process is to use the ADE Rules to identify any abnormal labs.
Each ADE Rule specifies whether it is to look for an "abnormal high" lab level or an "abnormal low" lab level. The ADE Rule then specifies the abnormal lab level value.
The process begins by examining the lab levels for each ADE Rule. If an abnormal lab level is detected, a potential ADE has been identified. Other processes continue with the examination of the potential ADE.

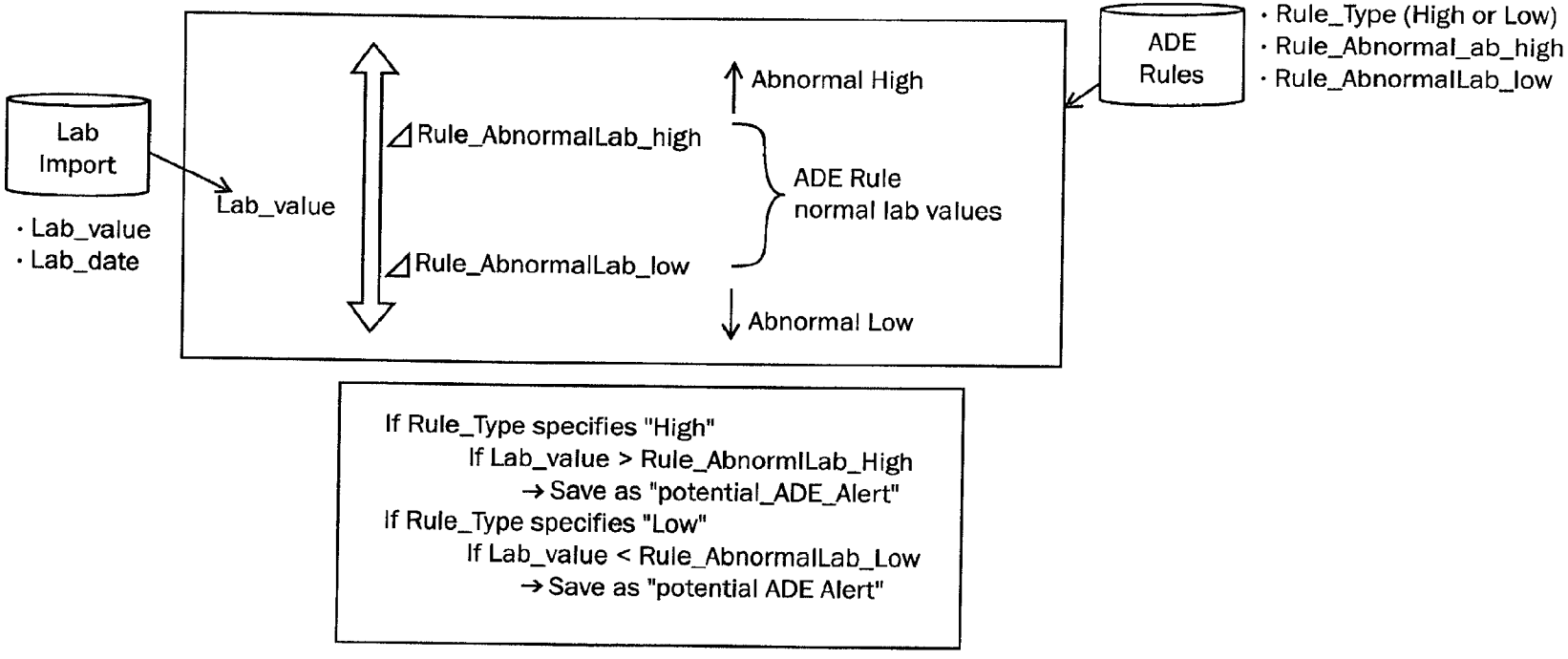


Fig 9

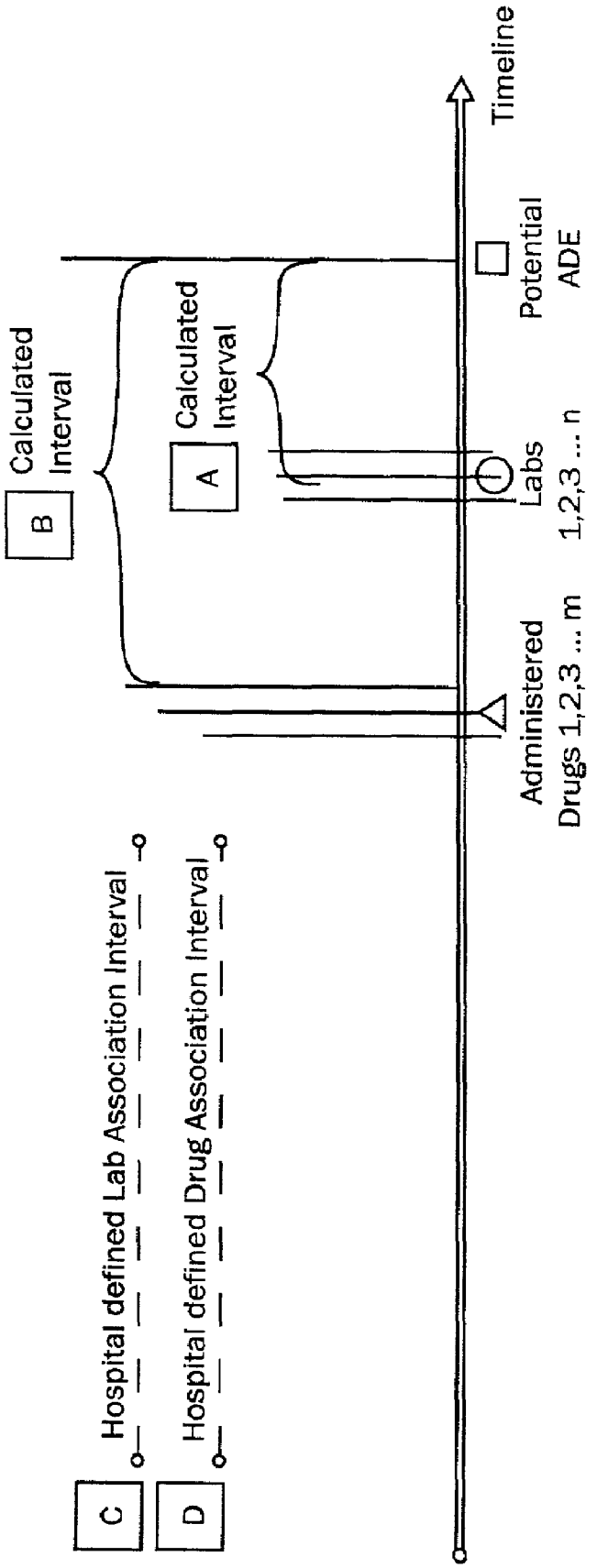

Timeline
Potential ADE
Labs 1,2,3 ... n
Administered Drugs 1,2,3 ... m
A
Calculated Interval
B
Calculated Interval
C
Hospital defined Lab Association Interval
D
Hospital defined Drug Association Interval

Fig 10

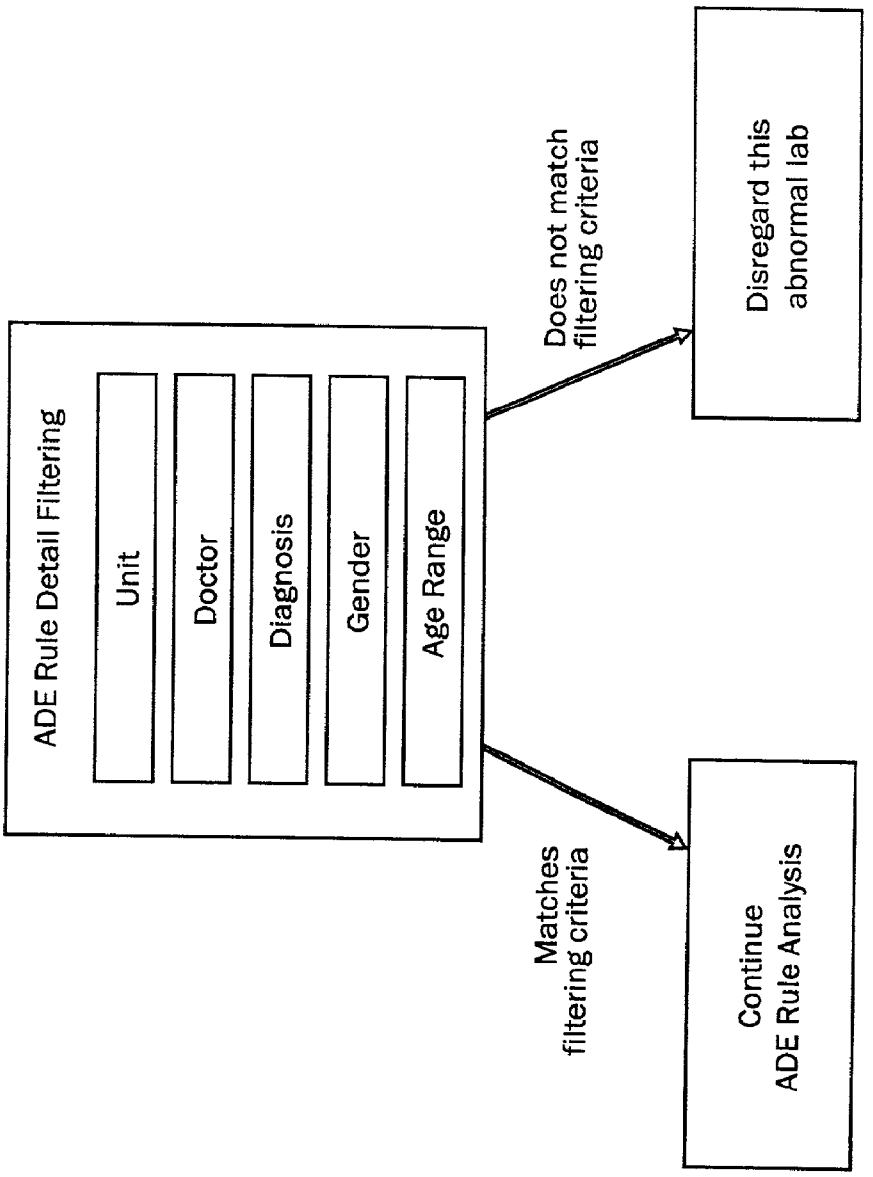

ADE Rule Detail Filtering
Unit
Doctor
Diagnosis
Gender
Age Range
Does not match filtering criteria
Disregard this abnormal lab
Matches filtering criteria
Continue ADE Rule Analysis

Fig 11

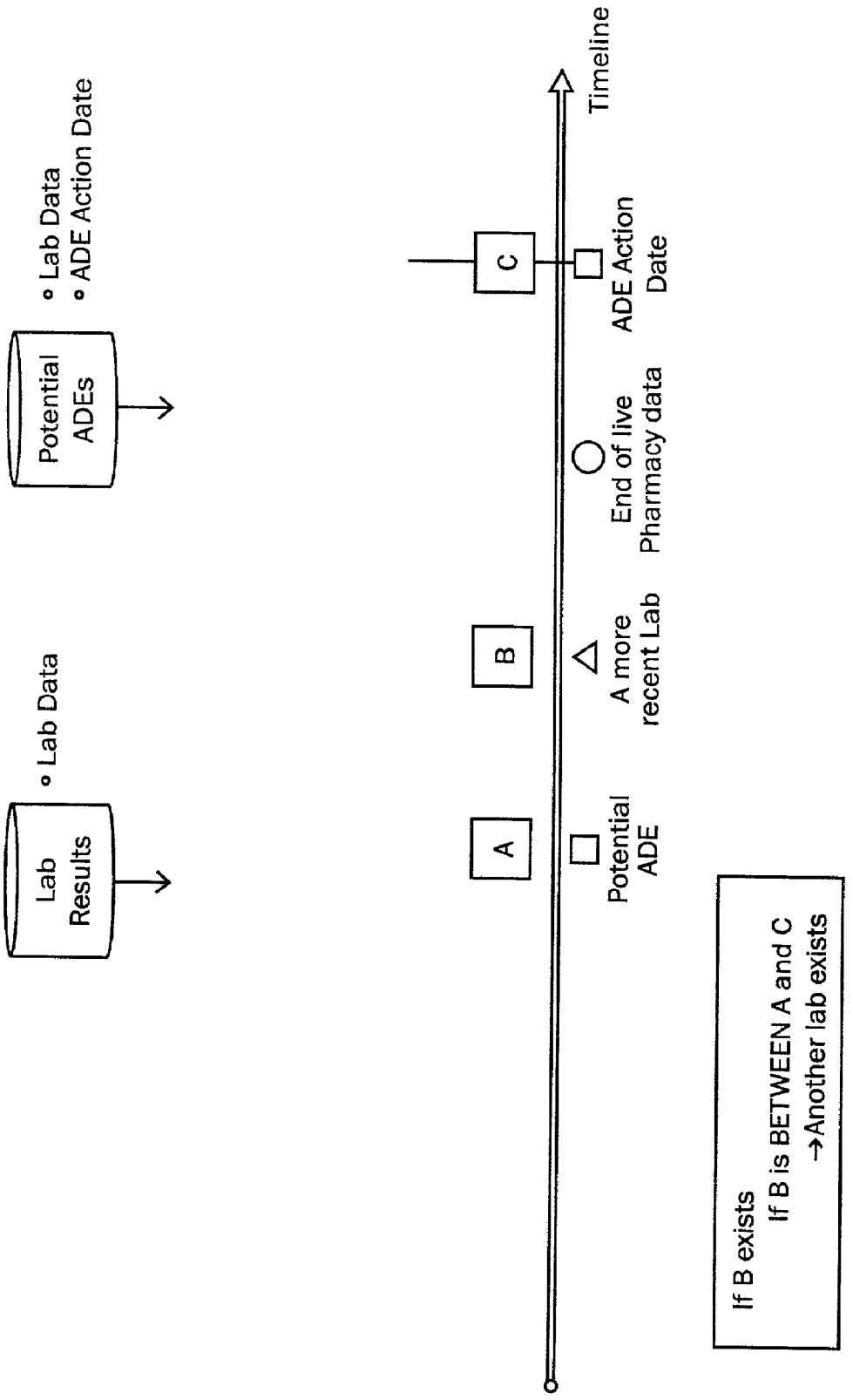

Lab Results
Lab Data
Potential ADEs
Lab Data
ADE Action Date
A
B
C
Potential ADE
A more recent Lab
End of live Pharmacy data
ADE Action Date
Timeline
If B exists
If B is BETWEEN A and C
→Another lab exists

Fig 12a

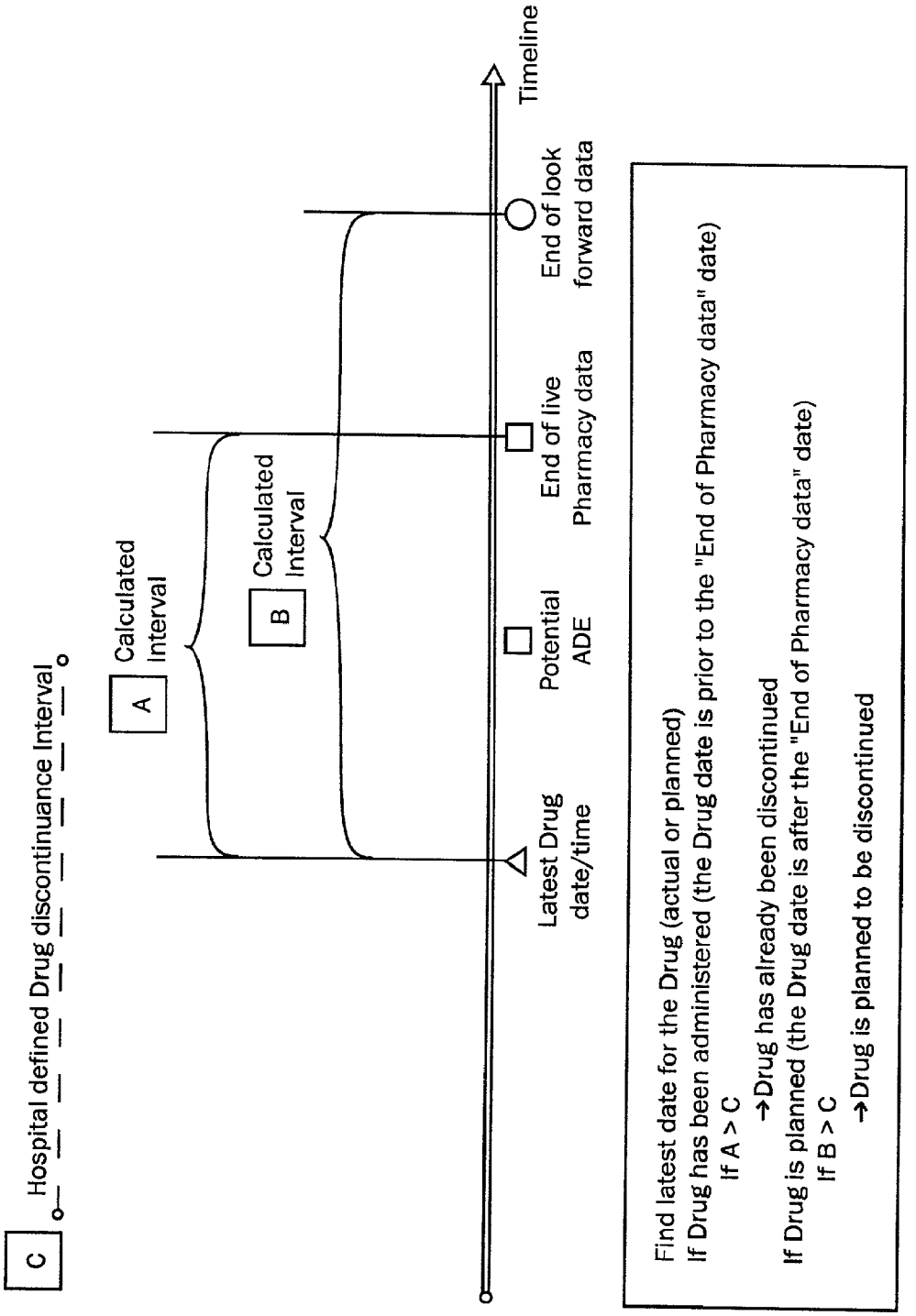

C
Hospital defined Drug discontinuance Interval
A
Calculated Interval
B
Calculated Interval
Timeline
Latest Drug date/time
Potential ADE
End of live Pharmacy data
End of look forward data
Find latest date for the Drug (actual or planned)
If Drug has been administered (the Drug date is prior to the "End of Pharmacy data" date)
If A > C
→Drug has already been discontinued
If Drug is planned (the Drug date is after the "End of Pharmacy data" date)
If B > C
→Drug is planned to be discontinued

Fig 12b

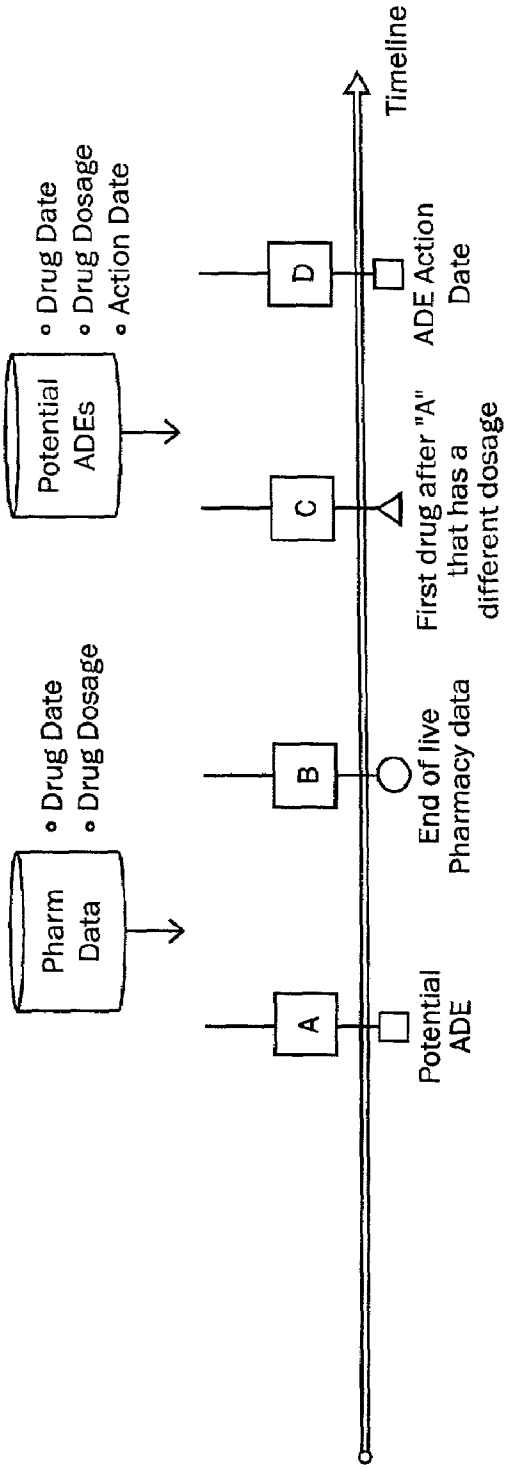

Timeline
Pharm Data
Drug Date
Drug Dosage
Potential ADEs
Drug Date
Drug Dosage
Action Date
A
B
C
D
Potential ADE
End of live Pharmacy data
First drug after "A" that has a different dosage
ADE Action Date
If C exists BETWEEN A and D
If C date <= B date
If C dosage > A dosage
→Administered drug dosage higher
If C dosage < A dosage
→Administered drug dosage lower
If C date > B date
If C dosage > A dosage
→Planned drug dosage higher
If C dosage < A dosage
→Planned drug dosage lower

Fig 12c

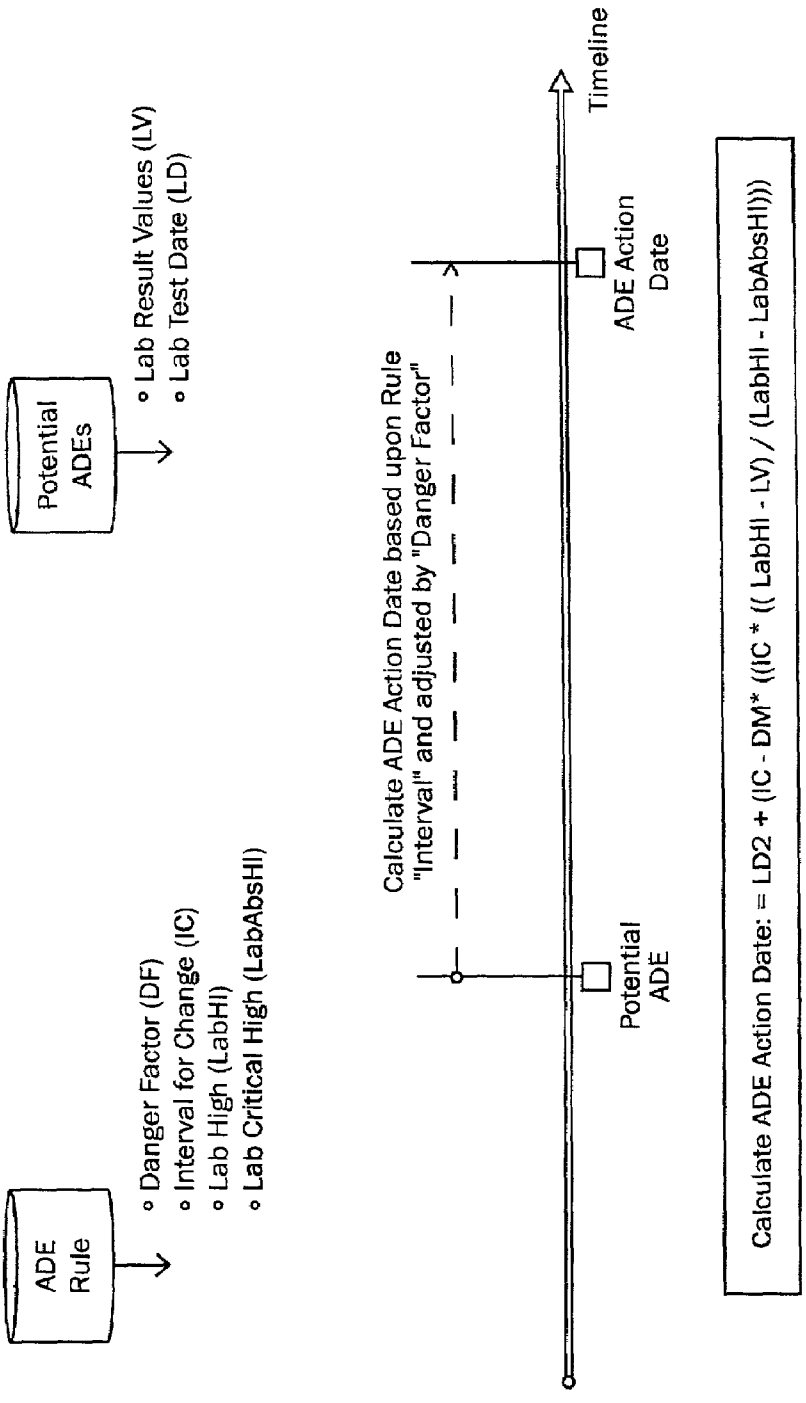

ADE Rule
Danger Factor (DF)
Interval for Change (IC)
Lab High (LabHI)
Lab Critical High (LabAbsHI)
Potential ADEs
Lab Result Values (LV)
Lab Test Date (LD)
Calculate ADE Action Date based upon Rule "Interval" and adjusted by "Danger Factor"
Timeline
ADE Action Date
Potential ADE
Calculate ADE Action Date: = LD2 + (IC - DM* ((IC * ((LabHI - LV) / (LabHI - LabAbsHI)))

Fig 13

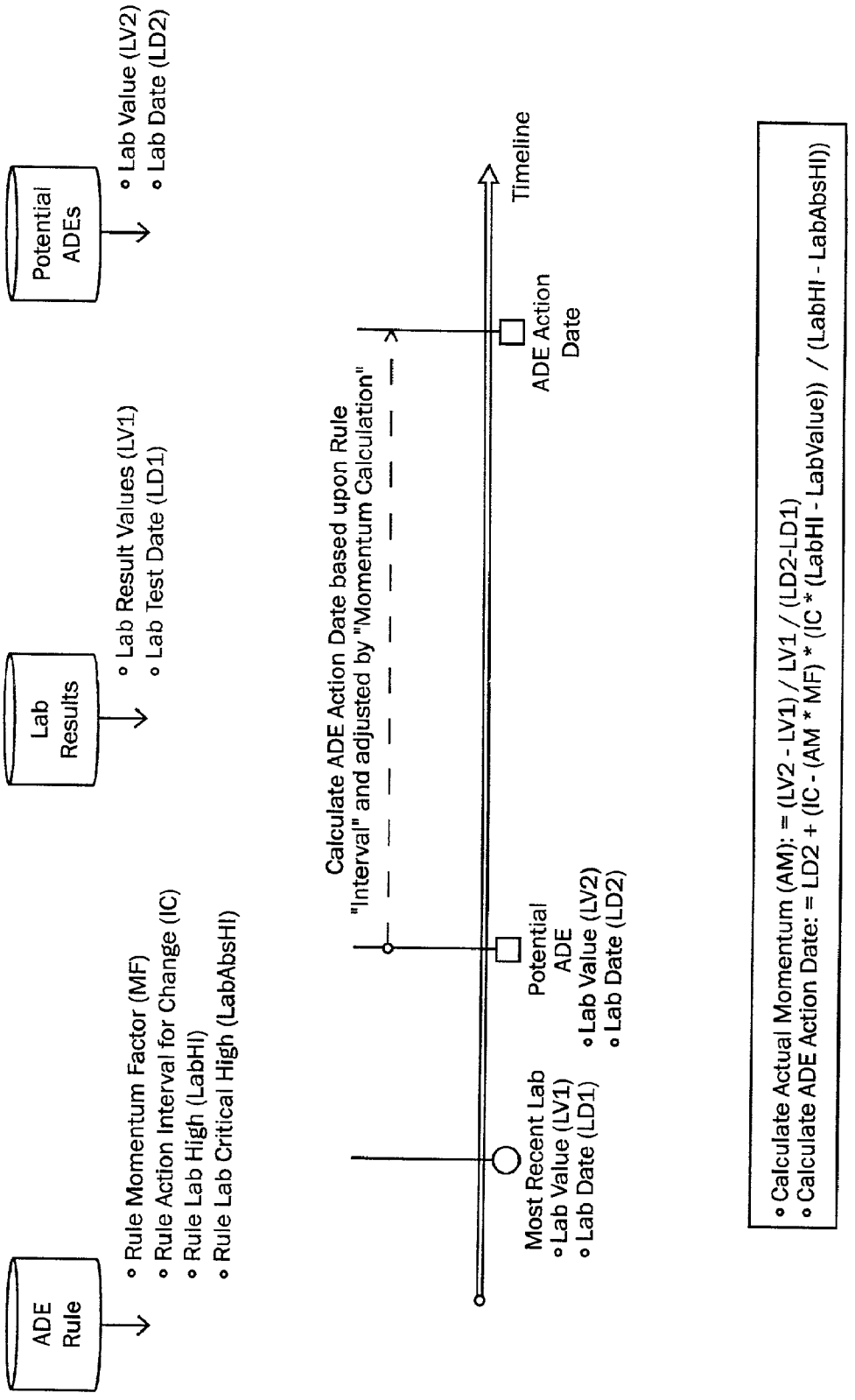

ADE Rule
Rule Momentum Factor (MF)
Rule Action Interval for Change (IC)
Rule Lab High (LabHI)
Rule Lab Critical High (LabAbsHI)
Lab Results
Lab Result Values (LV1)
Lab Test Date (LD1)
Potential ADEs
Lab Value (LV2)
Lab Date (LD2)
Calculate ADE Action Date based upon Rule "Interval" and adjusted by "Momentum Calculation"
Timeline
ADE Action Date
Most Recent Lab
Lab Value (LV1)
Lab Date (LD1)
Potential ADE
Lab Value (LV2)
Lab Date (LD2)
Calculate Actual Momentum (AM): = (LV2 - LV1) / LV1 / (LD2-LD1)
Calculate ADE Action Date: = LD2 + (IC - (AM * MF) * (IC * (LabHI - LabValue)) / (LabHI - LabAbsHI))

Fig 14

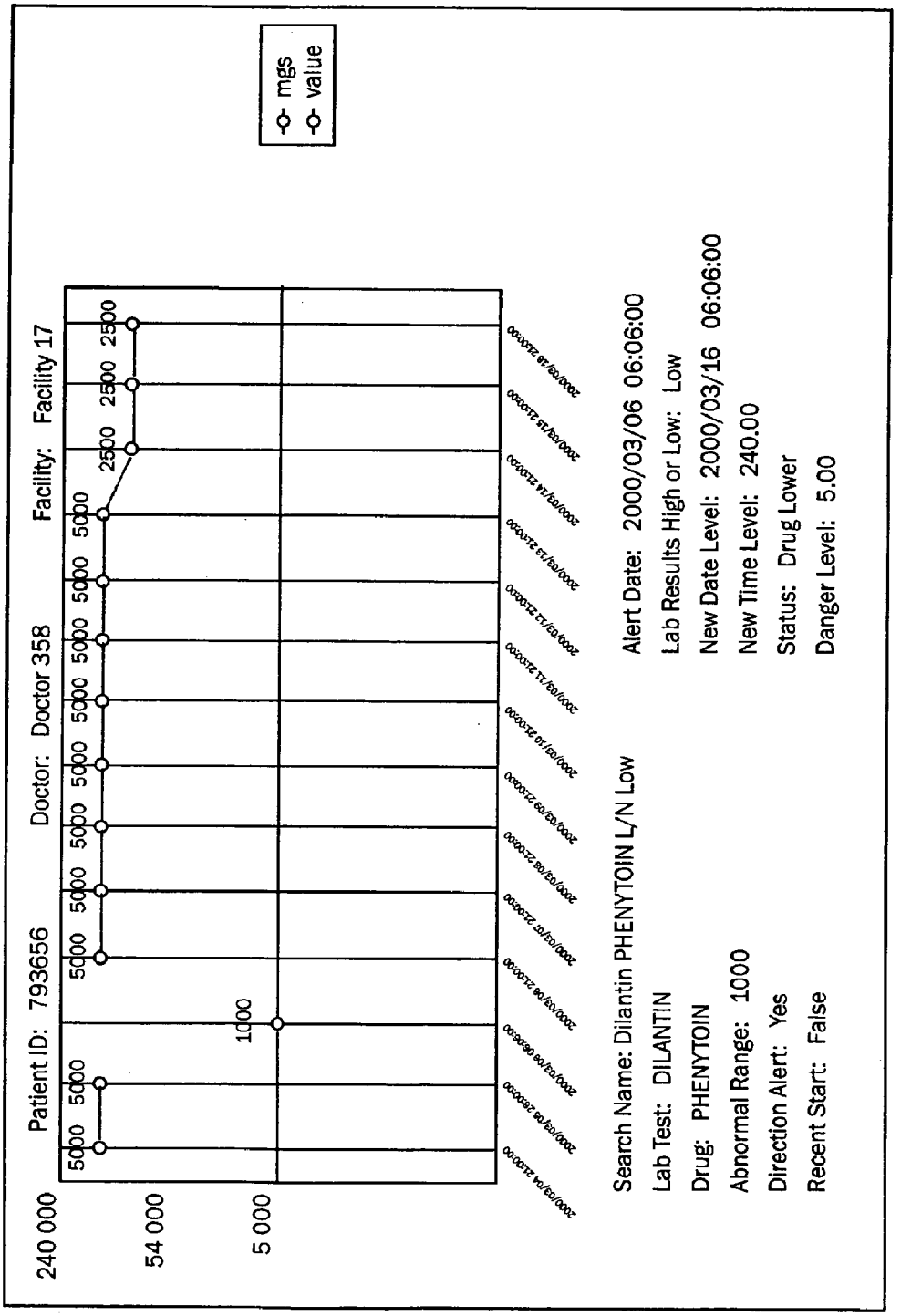

mgs
value
Patient ID: 793656
Doctor: Doctor 358
Facility: Facility 17
240 000
54 000
5 000
5000
1000
2500
Search Name: Dilantin PHENYTOIN L/N Low
Lab Test: DILANTIN
Drug: PHENYTOIN
Abnormal Range: 1000
Direction Alert: Yes
Recent Start: False
Alert Date: 2000/03/06 06:06:00
Lab Results High or Low: Low
New Date Level: 2000/03/16 06:06:00
New Time Level: 240.00
Status: Drug Lower
Danger Level: 5.00

Fig 15a

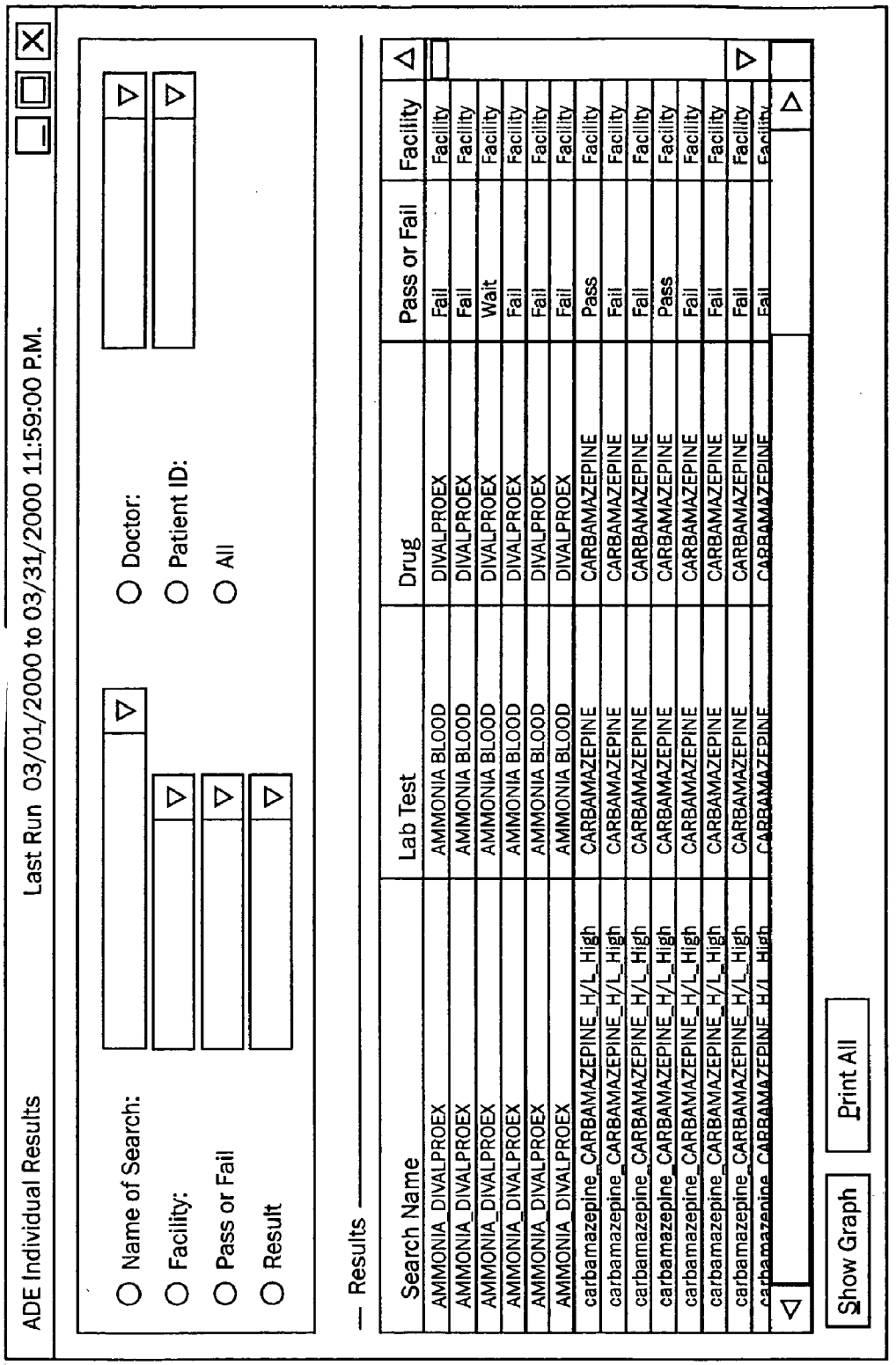

ADE Individual Results
Last Run 03/01/2000 to 03/31/2000 11:59:00 P.M.
Name of Search:
Facility:
Pass or Fail
Result
Doctor:
Patient ID:
All
Results
Search Name
Lab Test
Drug
Pass or Fail
Facility
AMMONIA_DIVALPROEX
AMMONIA BLOOD
DIVALPROEX
Fail
Facility
Wait
Pass
carbamazepine_CARBAMAZEPINE_H/L_High
CARBAMAZEPINE
Show Graph
Print All

Fig 15b

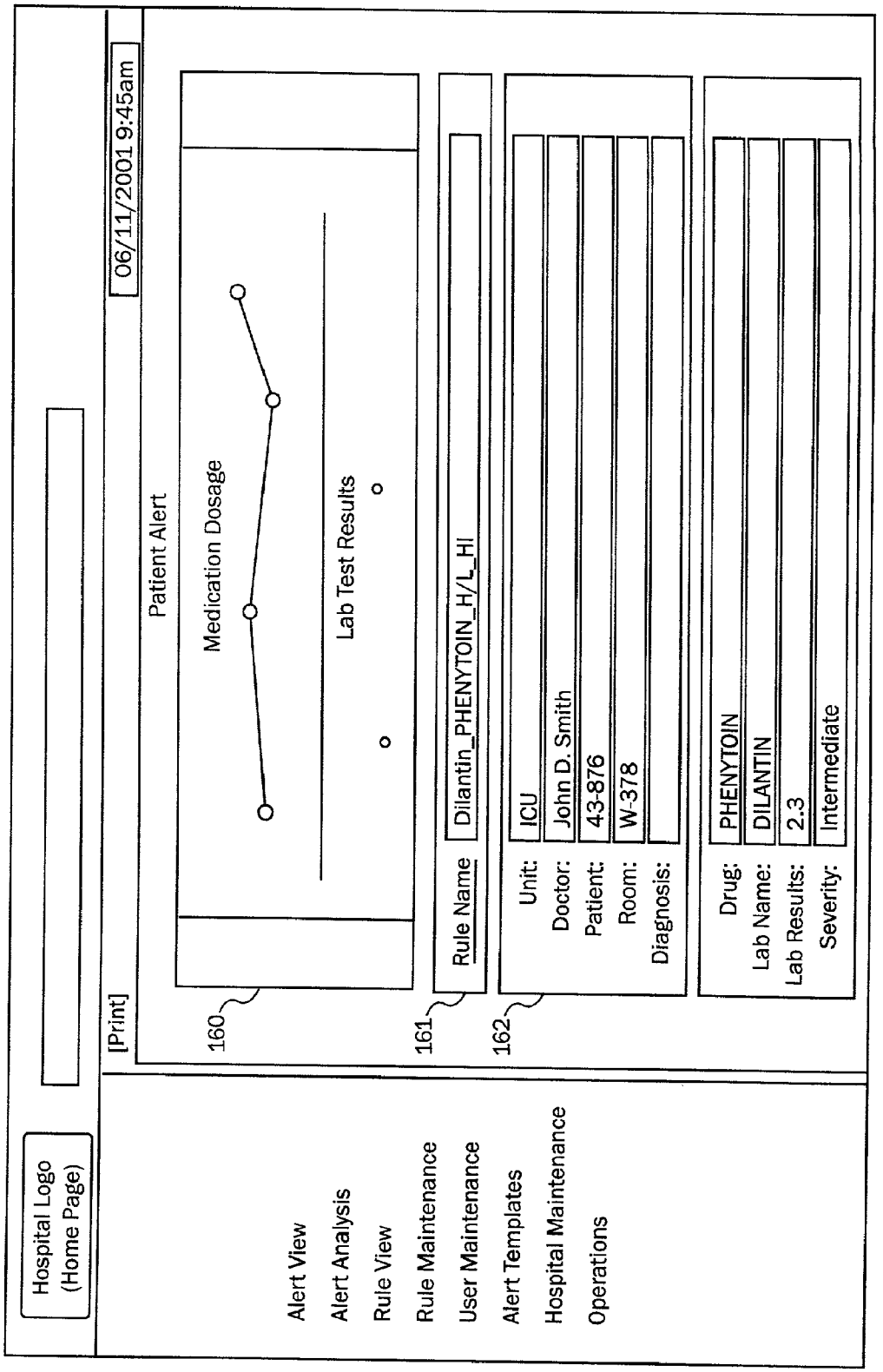

Hospital Logo
(Home Page)
Alert View
Alert Analysis
Rule View
Rule Maintenance
User Maintenance
Alert Templates
Hospital Maintenance
Operations
[Print]
06/11/2001 9:45am
Patient Alert
Medication Dosage
Lab Test Results
160
Rule Name
Dilantin_PHENYTOIN_H/L_HI
161
Unit:
Doctor:
Patient:
Room:
Diagnosis:
ICU
John D. Smith
43-876
W-378
162
Drug:
Lab Name:
Lab Results:
Severity:
PHENYTOIN
DILANTIN
2.3
Intermediate

Fig 16

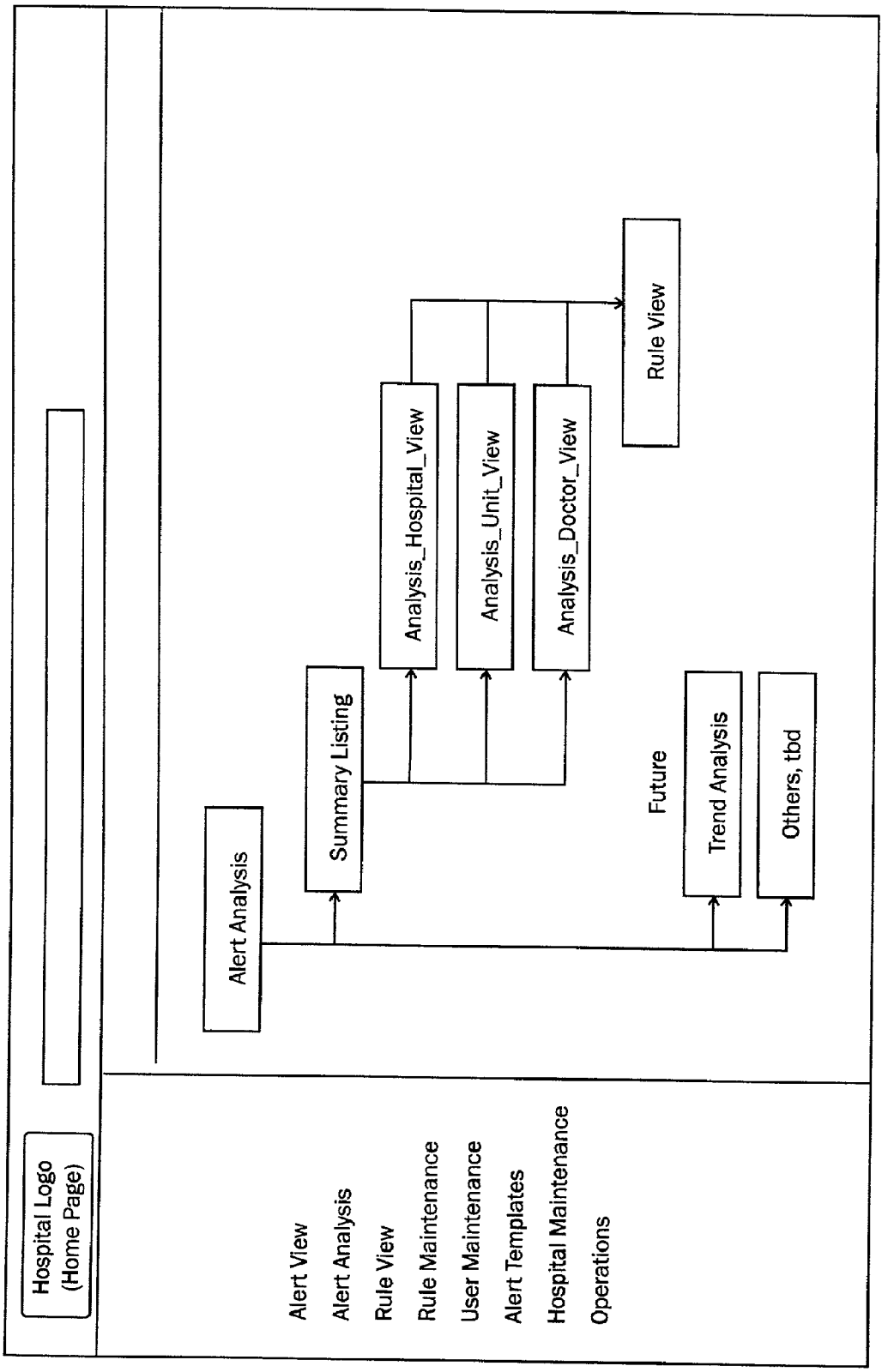

Hospital Logo
(Home Page)
Alert View
Alert Analysis
Rule View
Rule Maintenance
User Maintenance
Alert Templates
Hospital Maintenance
Operations
Alert Analysis
Summary Listing
Analysis_Hospital_View
Analysis_Unit_View
Analysis_Doctor_View
Rule View
Future
Trend Analysis
Others, tbd

Fig 17a

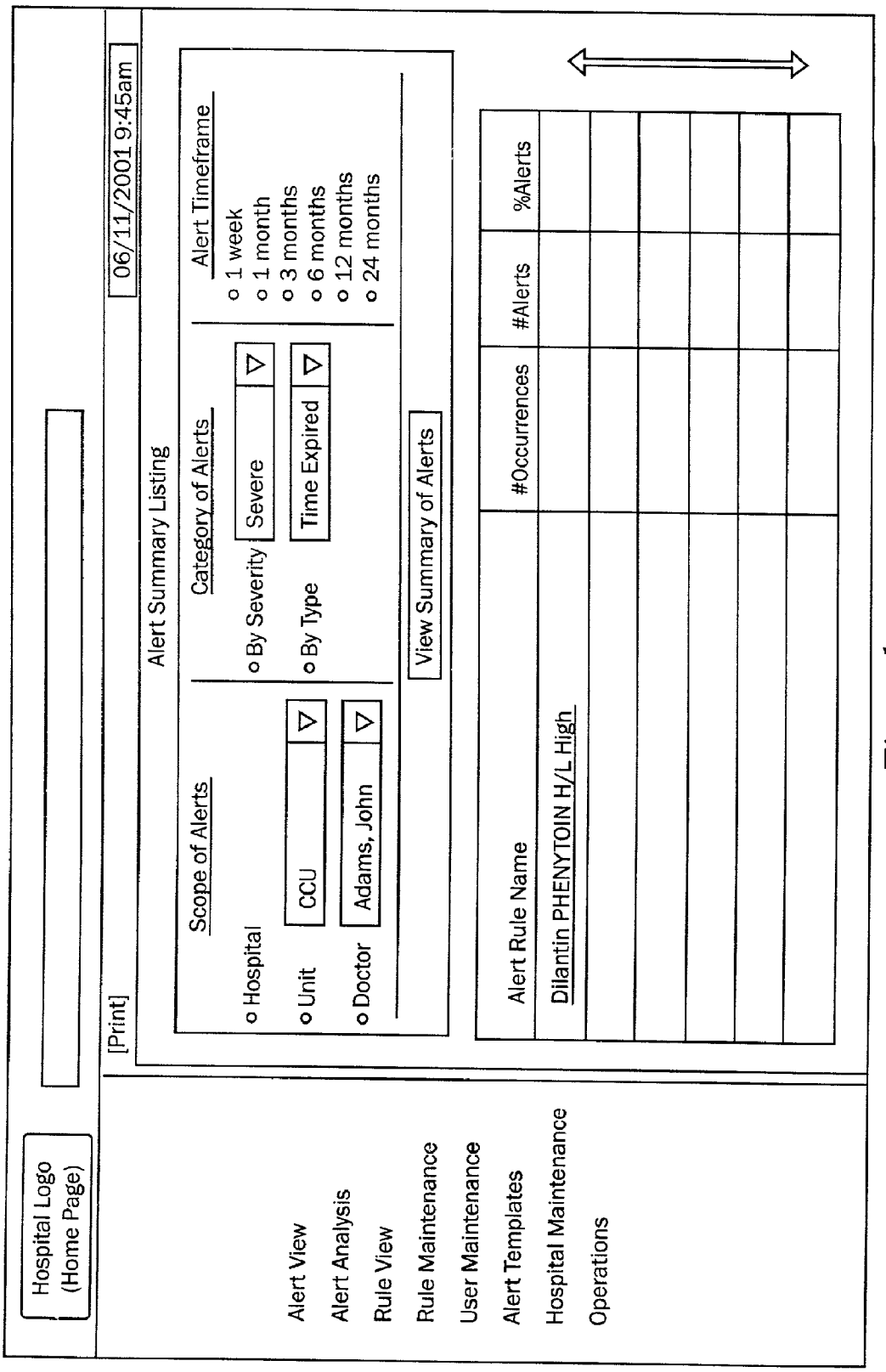
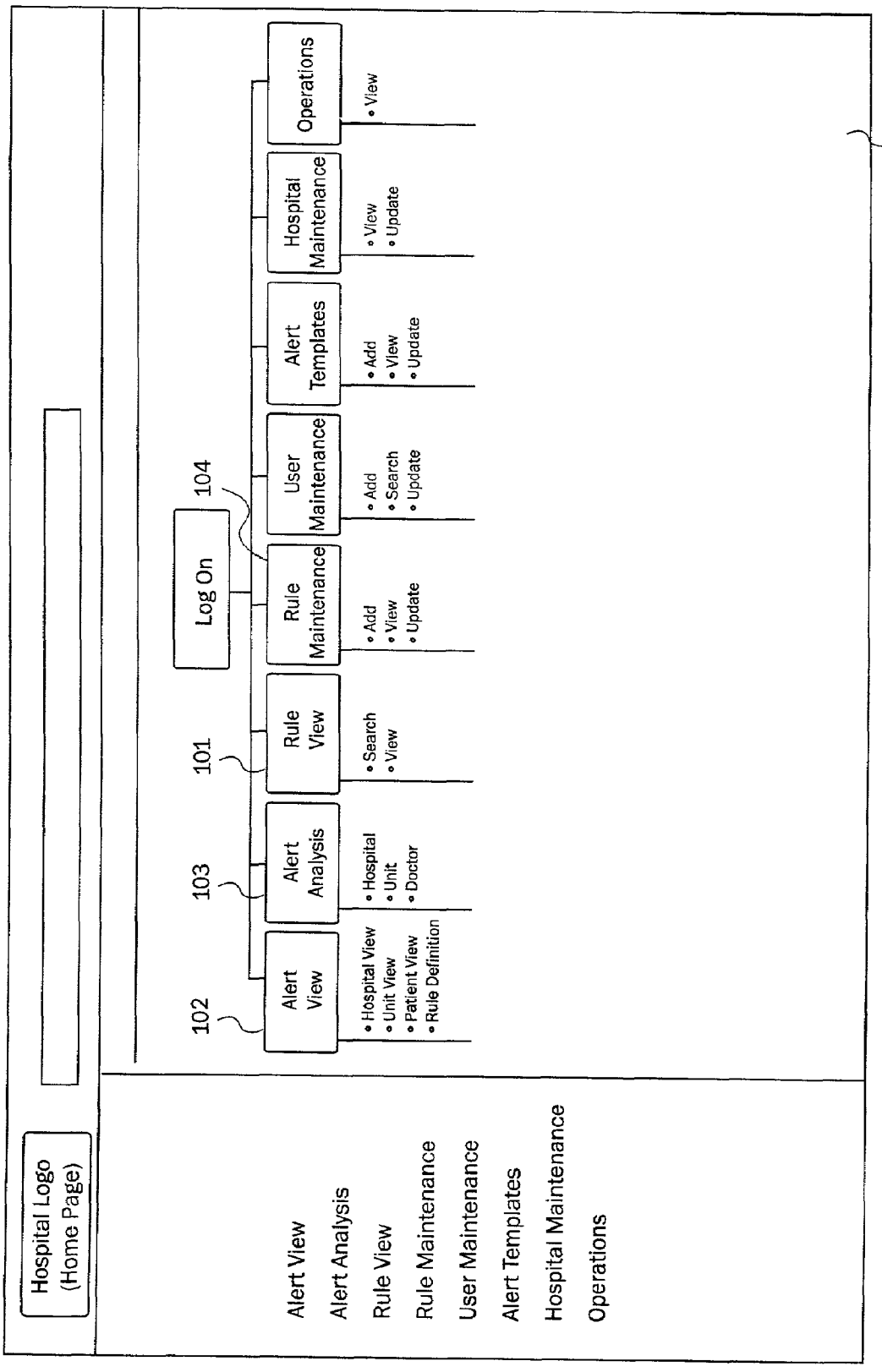

Hospital Logo
(Home Page)
Alert View
Alert Analysis
Rule View
Rule Maintenance
User Maintenance
Alert Templates
Hospital Maintenance
Operations
[Print]
06/11/2001 9:45am
Alert Summary Listing
Scope of Alerts
Hospital
Unit
CCU
Doctor
Adams, John
Category of Alerts
By Severity
Severe
By Type
Time Expired
Alert Timeframe
1 week
1 month
3 months
6 months
12 months
24 months
View Summary of Alerts
Alert Rule Name
#Occurrences
#Alerts
%Alerts
Dilantin PHENYTOIN H/L High

Fig 17b


Hospital Logo
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Alert View
Alert Analysis
Rule View
Rule Maintenance
User Maintenance
Alert Templates
Hospital Maintenance
Operations
Log On
102
103
101
104
10
Alert View
Alert Analysis
Rule View
Rule Maintenance
User Maintenance
Alert Templates
Hospital Maintenance
Operations
• Hospital View
• Unit View
• Patient View
• Rule Definition
• Hospital
• Unit
• Doctor
• Search
• View
• Add
• View
• Update
• Add
• Search
• Update
• Add
• View
• Update
• View
• Update
• View

Fig 18

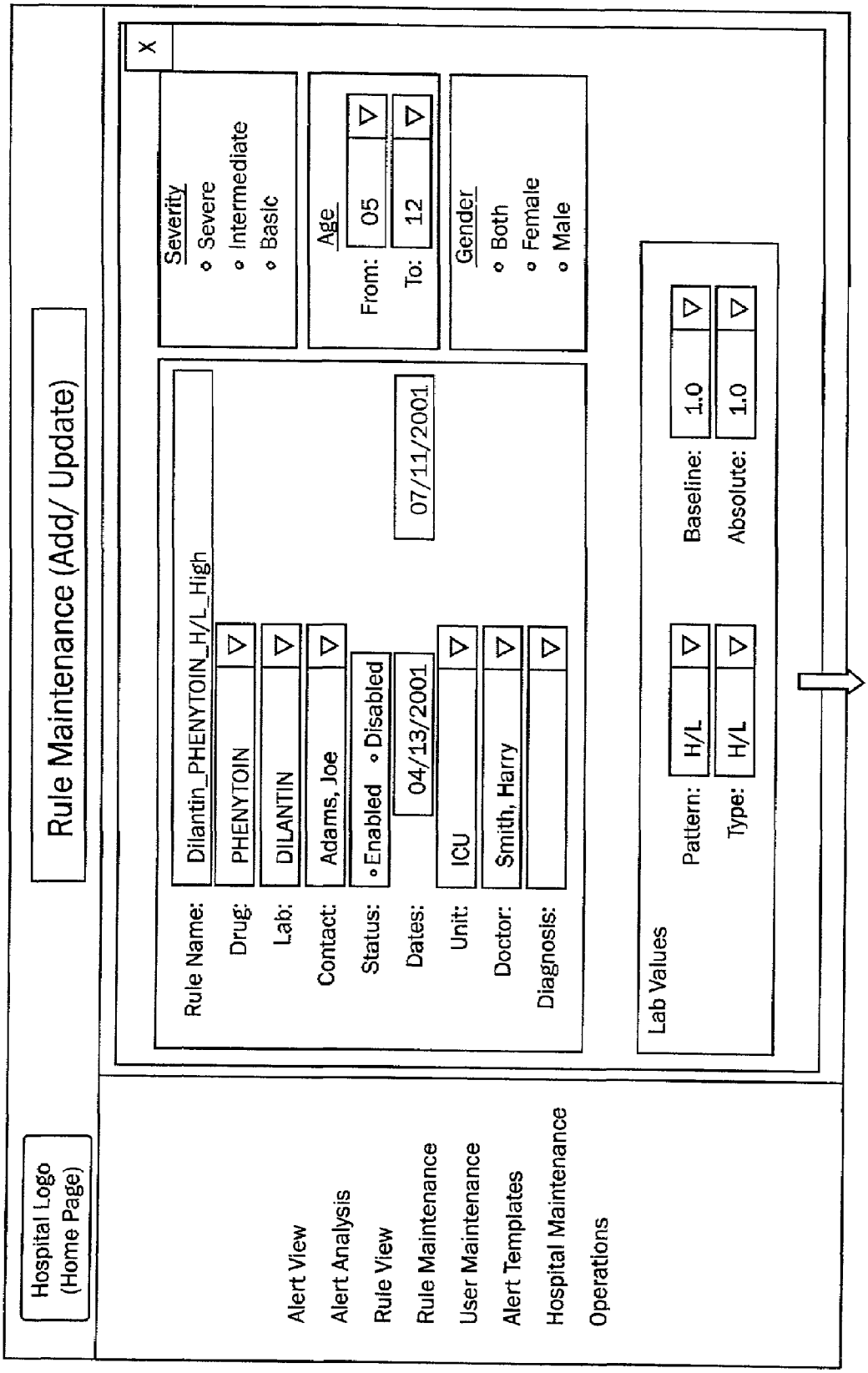
Hospital Logo
(Home Page)
Rule Maintenance (Add/ Update)
Alert View
Alert Analysis
Rule View
Rule Maintenance
User Maintenance
Alert Templates
Hospital Maintenance
Operations
X
Rule Name: Dilantin_PHENYTOIN_H/L_High
Drug: PHENYTOIN
Lab: DILANTIN
Contact: Adams, Joe
Status: Enabled Disabled
Dates: 04/13/2001
07/11/2001
Unit: ICU
Doctor: Smith, Harry
Diagnosis:
Severity
Severe
Intermediate
Basic
Age
From: 05
To: 12
Gender
Both
Female
Male
Lab Values
Pattern: H/L
Type: H/L
Baseline: 1.0
Absolute: 1.0

Fig 19a

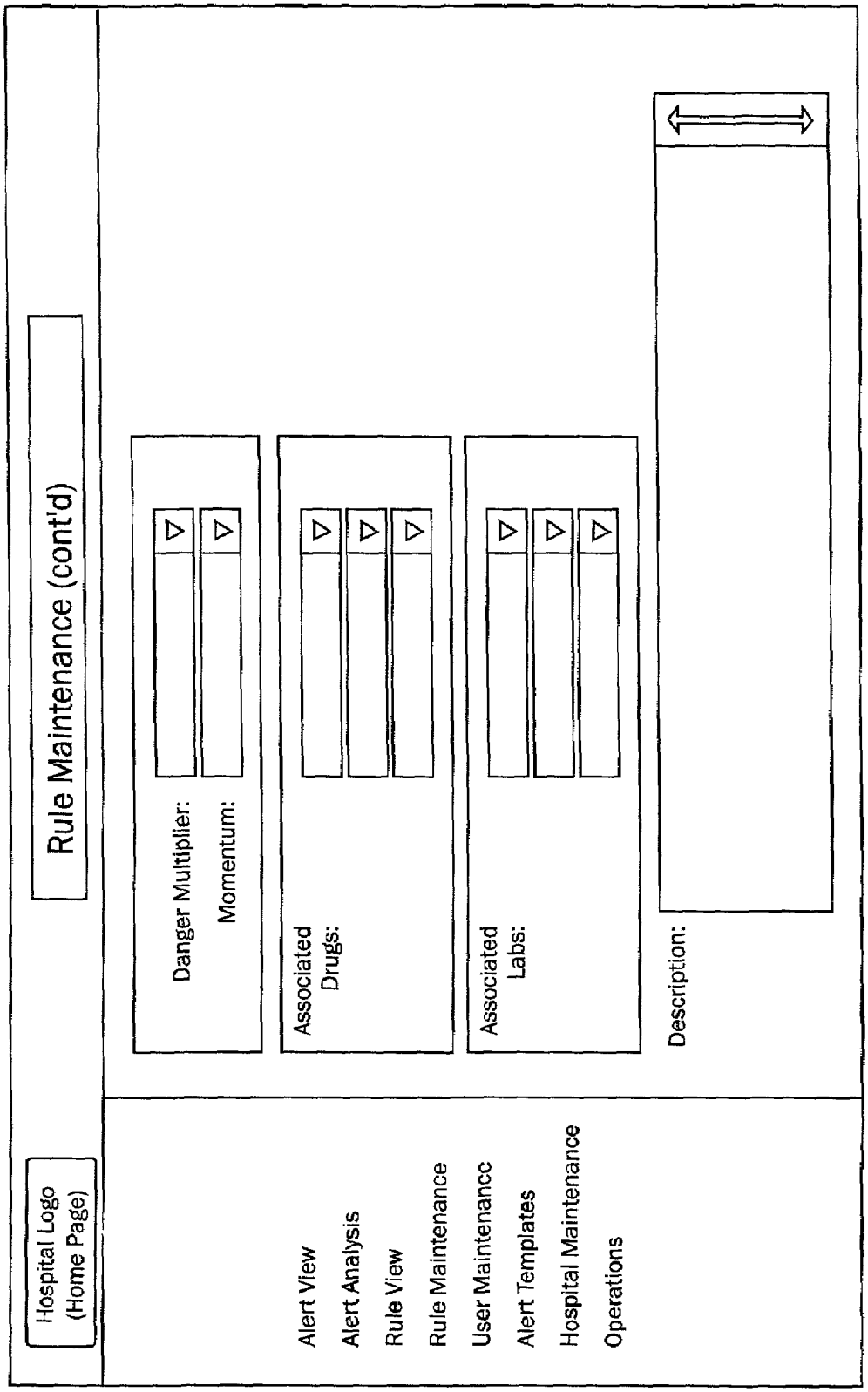
Hospital Logo (Home Page)
Rule Maintenance (cont'd)
Alert View
Alert Analysis
Rule View
Rule Maintenance
User Maintenance
Alert Templates
Hospital Maintenance
Operations
Danger Multiplier:
Momentum:
Associated Drugs:
Associated Labs:
Description:

Fig 19b

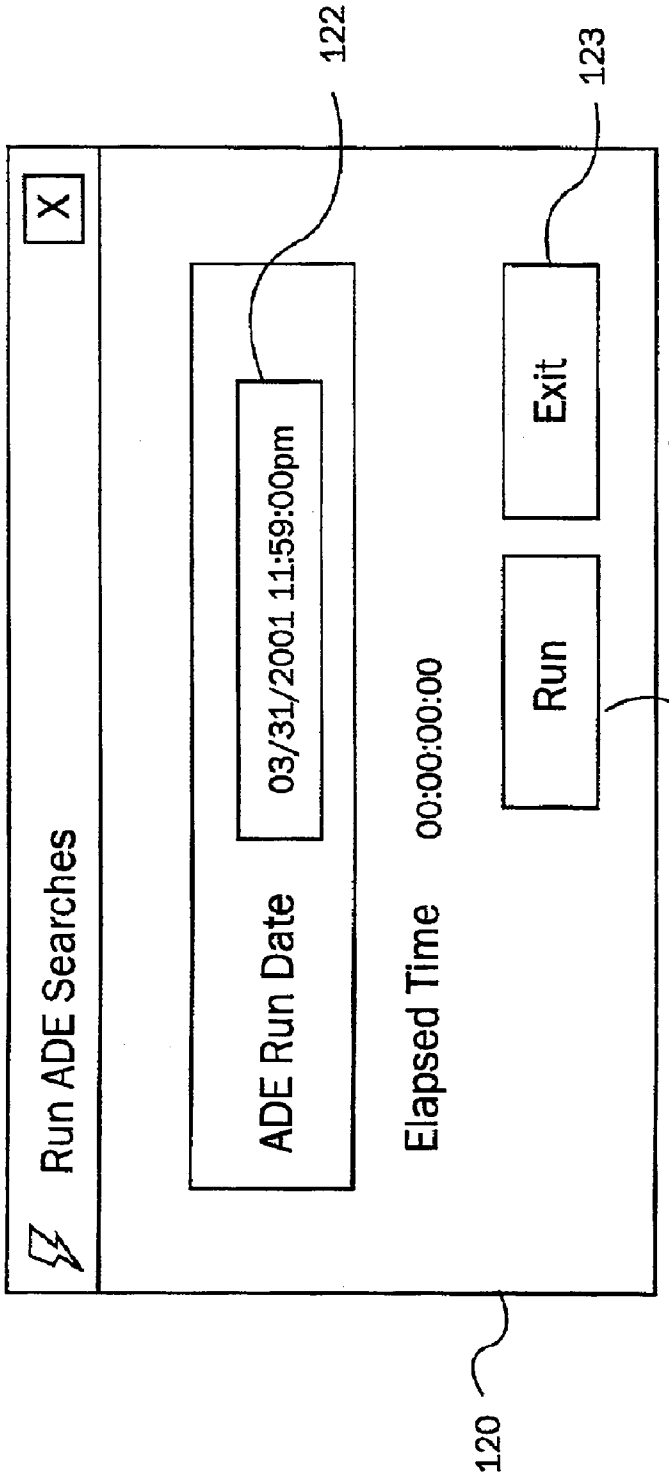
Run ADE Searches
X
ADE Run Date
03/31/2001 11:59:00pm
Elapsed Time
00:00:00:00
Run
Exit
120
121
122
123

Fig 20

METHOD AND SYSTEM FOR IDENTIFYING AND ANTICIPATING ADVERSE DRUG EVENTS

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims priority from U.S. provisional application No. 60/272,019, filed Feb. 28, 2001 the contents of which are incorporated herein in its entirety.

TECHNICAL FIELD

[0002] This invention relates to a method and system for managing and anticipating adverse drug events ("ADE"). More particularly, the invention relates to a method and system for integrating and using data from a medical facility's pharmacy and laboratory information systems to anticipate potential ADEs in a patient's medication regiment.

BACKGROUND OF THE INVENTION

[0003] A number of preventable patient care errors occur because the prescription of medication to a patient is done without first consulting a patient's laboratory results. Some patients have had drugs continuously administered to them for hours or days after toxic levels for that drug are recorded by the lab. Some patients have received particular medication long after the laboratory has documented signs of drug-related side effects. Others have received erroneous laboratory test results because their medication interferes with the laboratory tests they are undergoing. Still others have received medications even after the patient's lab result indicates that it is dangerous to do so. All these errors, and many more not mentioned, could have all been prevented if a patients laboratory results were consulted prior to prescribing or administrating a medication.

[0004] These errors occur for many reasons. At times, a physician is ordering certain medications at a site remote from a medical facility and so is not able to review a patient's chart. At times, the physician isn't even aware of contraindications for certain medication because tests revealing those contraindications have not been performed or had not been recorded in a patient's chart. In some instances, even though contraindications for certain medications are documented, the physician simply fails to detect the contraindications from the patient's chart. Consequently, some oversight is needed in order to determine if mistakes are made or if an ADE might occur in a patient's medication regimen.

[0005] Since a pharmacy department of a medical facility is typically responsible for filling all prescriptions and dispensing all medications to patients, it is often the only means for catching some of these errors. To that extent, some pharmacies have information systems in place that can alert the pharmacist that an ADE would occur between drugs administered to a patient. However, these information systems are typically limited to detecting a potential ADE between drugs administered to a patient These pharmacy information systems are not capable of predicting an ADE based on a patient's physiological condition, because these systems typically do not monitor or have access or have the capability to process a patient's laboratory results.

[0006] A laboratory department of a medical facility typically performs tests and analyzes specimens (such as blood, urine, cell cultures, etc.) received from a patient and stores these results on a laboratory information system. In many instances, the test results and analysis on patient specimens are germane to the administration of medication. However, despite this symbiotic relationship between the laboratory and the pharmacy, these two departments and their work processes, personnel, and particularly their information systems, rarely effectively communicate with each other.

[0007] In many clinical settings, there are a number of factors which prevent the integration of data from the laboratory and the pharmacy. Compatibility issues between the separate information systems is often a major roadblock to integration. The desire of each department to have information systems particularly adapted for their respective needs may be another. The cost of integrating data from both information system is certainly another prohibiting factor. As a result, there is a need for a commercial system that integrates and uses laboratory and pharmacy data to anticipate potential ADEs in a patient's medication regimen.

[0008] Thus, significant improvements in patient care can be achieved by developing a cost effective, commercial, turnkey system that integrates data collected and stored in pharmacy and laboratory information systems and utilizes this data to anticipate potential ADEs in a patient's medication regimen.

BRIEF SUMMARY OF THE INVENTION

[0009] The present invention is a system and method for anticipating potential ADEs in a patient's medication regimen by integrating data typically located in laboratory and pharmacy information systems and filtering the data using predefined criteria. The present invention includes a system for anticipating a possible ADE through the use of a search engine that compares integrated data from laboratory and pharmacy information systems and compares it to predefined ADE rules defining normal ranges for a particular laboratory test. If an abnormal test value is received and a drug in the patient's medication regimen satisfies a drug included in an ADE rule then an alert procedure is triggered which allows for a period of time wherein the patient's lab and pharmacy data is monitored in order to determine if a proper corrective action is undertaken, and if no corrective action or an improper corrective action is taken within that period of time, the healthcare provider is warned of a potential ADE.

[0010] In one embodiment, the ADE monitoring system is utilized in an application service provider environment (ASP) wherein the ADE monitoring system is comprised of at least one server having a communication link to a computer network. In this embodiment, a secure intranet provides the conduit through which data is downloaded from the medical facility, and users access the ADE monitoring system.

[0011] In another embodiment, a method for detecting an ADE is disclosed which includes extracting information within pharmacy and lab data and respectively placing it into a normalized drug table or a normalized lab table. The data within these tables are then filtered by an ADE search engine which searches an ADE rule database to see if it matches any predefined ADE rule. If a match is made an alert procedure is activated.

[0012] While several embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description. As will be realized, the invention is capable of modifications in various obvious aspects, all without departing from the spirit and scope of the present invention. Accordingly, the

drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE ATTACHMENTS

[0013] FIG. **1** is a block diagram representing an embodiment of an ADE monitoring system in an application service provider environment.

[0014] FIG. **2** is a diagram representing the hardware components of the ADE monitoring system of FIG. **1**.

[0015] FIG. **3** is a block diagram representing an alternative embodiment of an ADE monitoring system in a stand-alone environment.

[0016] FIG. **4** is a diagram representing an embodiment of the ADE monitoring system.

[0017] FIG. **5** is a block diagram representing an embodiment of a data import procedure.

[0018] FIG. **6** is a block diagram representing an embodiment of an ADE monitoring procedure.

[0019] FIG. **7** is an embodiment of an ADE rule.

[0020] FIG. **8***a* is flow chart representing the ADE monitoring process.

[0021] FIG. **8***b* is a continuation of FIG. **8***a*.

[0022] FIG. **9** is a diagram depicting detection of an abnormal lab result.

[0023] FIG. **10** is a diagram depicting concurrent lab and drug features.

[0024] FIG. **11** is a diagram depicting filtering for specific details.

[0025] FIG. **12***a* is a timeline depicting a corrective action comprising of a normal lab result.

[0026] FIG. **12***b* is a timeline depicting a corrective action comprising of a discontinuation of a drug.

[0027] FIG. **12***c* is a timeline depicting a corrective action comprising of a change in dosage.

[0028] FIG. **13** is a timeline depicting an adjustment to an action date by a danger multiplier and a formula to calculate the adjustment.

[0029] FIG. **14** is a timeline depicting an adjustment to an action date by a momentum multiplier and a formula to calculate the momentum multiplier and the adjustment to the action date.

[0030] FIG. **15***a* is an embodiment of a patient graph.

[0031] FIG. **15***a* is an embodiment of a patient table.

[0032] FIG. **16** is an embodiment of a patient alert.

[0033] FIG. **17** is an embodiment of a main summary screen.

[0034] FIG. **18** is an embodiment of a main screen.

[0035] FIG. **19***a* is an embodiment of a rule maintenance screen.

[0036] FIG. **19***b* is a continuation of the screen of FIG. **19***a*.

[0037] FIG. **20** is an embodiment of a search screen.

DETAILED DESCRIPTION OF THE INVENTION

[0038] The subject invention is a system and method for monitoring patient drug/lab interactions by integrating data typically located in laboratory and pharmacy information systems and comparing it to predefined ADE rules. It is also contemplated that physiological data (such as blood pressure or heart rate) or patient information, obtainable from computer systems within a health care facility, can also be integrated into the disclosed invention in a manner similar to that described for the pharmacy and laboratory systems.

[0039] As will be explained in greater detail below, the subject invention includes a system configuration which facilitates data transfer, a data import procedure which integrates laboratory and pharmacy data, an ADE monitoring procedure which performs an extensive search for potential ADE, an alert generation procedure for notifying medical facilities of potential ADE, report generating functions for arranging the display of data, and a user interface which allows for simple operation of the ADE monitoring system.

A. System Configuration

[0040] As shown in FIGS. **1** and **2**, an embodiment of an ADE monitoring system **10** in accordance with the subject invention is shown. This embodiment is comprised of a central processor **11** having included therein a number of task oriented applications. The central processor **11** can be any computer known to those skilled in the art, including standard attachments and components thereof (e.g., a disk drive, hard drive, CD/DVD player or network server that communicates with a CPU and main memory, a sound board, a keyboard and mouse, and a monitor). The processor of the CPU in the computer may be any conventional general-purpose single- or multi-chip microprocessor. In addition, the processor may be any conventional special purpose processor such as a digital signal processor or a graphics processor. The microprocessor can include conventional address lines, conventional data lines, and one or more conventional control lines.

[0041] As shown in FIG. **2**, in one embodiment, the ADE monitoring system **20** is utilized in an application service provider environment ("ASP") accessible to a plurality of users and medical facilities through a secure intranet. In this embodiment, the central processor **11** includes a web site hosted by at least one web server **21** in communication with the intranet. The central processor **11** may also include a plurality of web servers **21**, database servers **22**, application servers **23**, or directory servers **24**, and may run on a variety of platforms known in the art, including but not limited to, SQL Server 2000, Windows 2000, Active Directory and IIS.

[0042] As shown in FIG. **3**, in another embodiment, the ADE monitoring system **30** is configured to operate in a stand-alone environment, located within a medical facility. Data from laboratory **41** and pharmacy **42** information systems may be compiled and transmitted by a FTP server **43** through a Local Area Network (LAN).

[0043] As shown in FIGS. **1** and **3**, data from laboratory **31** and pharmacy **32** information systems may be compiled and transmitted to the ADE monitoring system **10** by a File Transfer Protocol ("FTP") server **33** through a router **34** in communication with the ADE monitoring system **30** via a computer network such as a secure intranet or a LAN. In other embodiments, telephonic means or even direct hard wire connections can be utilized for transmitting data to the ADE monitoring system **10**. The data transfers are typically initiated by a medical facility, and can be transmitted periodically or may be transferred dynamically as the data is created. In one embodiment, the data is encrypted prior to transmission to secure the privacy of the information.

[0044] As shown in FIGS. **1**, **2**, and **4**, in one embodiment, the central processor **11** includes software applications or computer instructions located on application servers **23**. As will be explained further below, and more specifically in the sections pertaining to their function, the applications coordinate the functional components of the ADE monitoring system **10**. These applications may include common software

components that are commercially sold, as well as proprietary applications specifically developed to perform specific functions in the ADE monitoring system.

[0045] A Patient Data Import Application **42** is included to receive, validate, and format pharmacy and lab data received from a medical facility. An Adverse Drug Event Application **43** is included to correlate and examine pharmacy and lab data for each patient, and to generate an alert when these criteria do not comply with predefined criteria. A User Access Application **46** may also be included for limiting access to the ADE monitoring system **10** to authorized individuals and for limiting access to information. The User Access Application typically works in conjunction with a User Directory **45** located on a directory server **24**. The User Directory **45** is comprised of a database of authorized users and a level of accessibility allowed for each. An Administration Application may also be included for organizing and maintaining databases pertaining to particular medical facilities and users. A report generation application such as Crystal Reports may also be included.

B. Importing Data

[0046] As shown in FIGS. **5** and **6**, in one embodiment, data records from a healthcare facility is transmitted to the ADE monitoring system through a secure intranet. The ADE monitoring system **10** first subjects the data record to a validation process (block **54**) to verify that the data record is in a known format and to verify that it is complete. Once the data record is verified, it is then reformatted by a reformatting process (block **55**) to be compatible with data structure employed by a database wherein the data is stored.

[0047] If an error occurred in the transmission of the data record or if the data record is improperly formatted, an exception handling procedure (block **58**) is triggered. The exception handling procedure (block **58**) includes the steps of creating an error message and posting it on an error log which notes the time and date of the error. Also, an electronic message, preferably an E-mail, is sent to the healthcare provider sending the data record to notify it of the error.

[0048] A pharmacy information system **51** will typically provide the ADE monitoring system **10** with pharmacy data for each patient and a laboratory information system **52** typically provides information pertaining to lab tests. A data record imported from a pharmacy information system Will typically include information pertaining to a medication prescribed to a patient and the logistics as to how the medication is to be administered. A data record from a lab information system typically provides data pertaining to lab tests for each patient. Lab or pharmacy data is extracted from their respective data records and this data is then correlated with records pertaining to the same patient ID, and stored within a database. In this embodiment, a pharmacy database **56** stores pharmacy data and a laboratory database **57** stores laboratory data.

[0049] The data record can be an ASCII file or it can be formatted in any known manner. A pharmacy data record will typically include data fields containing a patient ID, a doctor ID, the drug administered, a dosage, a time of dosage, a begin date, and a discontinuance date. A lab data record will typically include data fields for a patient ID, a doctor ID, a lab test performed, the test result, the date and time of the test.

[0050] In one embodiment, a normalized table called a daily record is created from data extracted from a pharmacy data record and stored within the pharmacy database **56**. The table is comprised of a chronological sequence of records, with each record having data fields identifying a drug, a drug dosage given or to be given, and a time and date when the drug dosage is administered or will be administered. Each record also includes a data field which represents the total dosage for a particular drug within a 24 hour period from the time the drug is or will be given. A new record is created with each drug dosage given or each drug dosage to be given, and the daily record is updated with each new record.

[0051] A normalized lab table is also created from lab data and stored within the laboratory database **57**. The table is also comprised of a chronological sequence of data records, with each data record having data fields identifying a patient ID, a time of the test, the lab name, and the lab result. A new record is created for every test result, and the lab table is updated after the creation of each new record.

C. ADE Rules

[0052] As shown in FIG. **6**, prior to the use of the ADE monitoring system, ADE rules **64**, **65** are created and stored within the ADE rule database **60**. Each ADE rule contain a plurality of data fields therein which contain information that is used by the ADE monitoring system to determine if an ADE has occurred. The values which are contained in each data field are either defined by or approved by a healthcare provider utilizing the ADE rules. These ADE rules can include some created by a service which provides ADE monitoring **64** and some created by the medical facility **65**.

[0053] As shown in FIG. **7**, an ADE rule is a data record that includes a plurality of fields. In one embodiment, an ADE rule includes data fields for search status **71**, search type **72**, target drug **73**, target lab **74**, drug lab/search name **75**, severity **76**, lab code **77**, pattern **78**, type **79**, baseline **80**, absolute **81**, interval **82**, danger multiplier **83**, momentum multiplier **84**, allergy **85**, hospital unit **86**, doctor(s) **87**, diagnosis **88**, gender **89**, age range **90**, concurrent drugs **91**, concurrent labs **92**, alert template **93**, description **94**, and contact **95**. A precursory explanation of the contents of each field are defined below, the functions of these fields will be expanded further in the specification when needed to describe the functionality of the subject invention.

[0054] Search Status **71** determines if a rule is to be used when performing ADE monitoring. If enabled the rule is used by the subject ADE monitoring system.

[0055] Search Type **72**, Drug/Lab Search Name, and Description **94** are all fields used to classify an ADE Rule. Search Type **72** is used to signify if an ADE rule is a research rule or an alert rule. Alerts are specifically written to produce an alert procedure when satisfied. Research rules are specifically made for research purposes only and do not need to trigger an alert procedure if satisfied. Drug/Lab Search Name **75** is a unique identifier which represents a particular rule.

[0056] Target Drug **73** and Target Lab **74** are the drug and lab combination which is the focus of an ADE rule. Target Drug **73** names the drug which is the basis for the rule. Target Lab **74** names the lab test which is the basis for the rule.

[0057] Severity **76** indicates the severity of the ADE.

[0058] Lab code **77** is a unique identifier for the Target Lab **74**.

[0059] Pattern **78** specifies whether the rule is looking for a high or low lab test, and what is the normal drug response to the lab test (i.e. whether to raise or lower the drug dosage.).

[0060] Type **79** and Baseline **80** are data fields used to determine if a lab value is abnormal. Type **79** specifies

whether the Baseline value **80** defines a high border or a low border of a normal lab result. Baseline **80** represents a value that exceeds or fails to reach either a maximum or minimum normal value, respectively, for the Target Lab **74**.

[0061] Absolute **81**, Interval **82**, Danger Multiplier **83**, and Momentum Multiplier **84** are all used to determine an appropriate waiting period wherein a corrective action is to be taken. Absolute **81** represents a lab test value that is considered dangerous. If the test value in a Drug/Lab data record is equal to or exceeds the Absolute **64** value then the ADE monitoring system treats the situation as a medical emergency. Interval **82** in the ADE rule contains the time interval (in hours) within which the ADE monitoring system expects an action to occur. The Danger Multiplier **83** contains a variable that automatically adjusts how quickly the ADE monitoring system expects a response to an abnormal lab test, based upon how close the lab test is to an Absolute **81** value. Momentum Multiplier **84** includes a factor that takes the previous lab value into consideration and automatically adjusts the Interval accordingly.

[0062] Allergy **85** indicates an allergic reaction to a particular drug. This parameter is simply enabled or disabled. Once enabled and if the baseline value is reached or exceeded, the only action capable of removing an alert would be the discontinuance of the Target Drug **73**. This parameter does not depend on a history of allergy by the patient but is a link with a particular lab test and result that can indicate that the patient is allergic to the drug.

[0063] Hospital Unit **86**, Doctor **87**, Diagnosis **88**, Gender **89** and Age Range **90**, if defined, are additional requirements that must be satisfied if an alert procedure is to be triggered. These parameters are referred to as detail filters and they represent specific conditions which, if present, will override the continued processing of an abnormal lab condition.

[0064] Concurrent Drug **91** and Concurrent Lab **92** are associated conditions which must be present for an alert procedure to be triggered and are referred to as association filters. Concurrent Drug **91** names medications that must have been administered to a patient within a prescribed period of the abnormal lab for an alert condition to exist. Similarly, Concurrent Lab **67** lists additional tests and test values that must be present within a prescribed period of the abnormal lab before an alert procedure is triggered.

[0065] Alert Template **93** and Contact **95** are used in sending an alert to a healthcare provider. The Alert Template **93** contains the name of a template which defines how to handle an alert for the specific ADE rule and Contact **95** lists who should be contacted if an alert is sent.

D. ADE Monitoring

[0066] As shown in FIG. **6**, in one embodiment, ADE monitoring is performed by receiving data from a healthcare provider's laboratory and pharmacy information systems and integrating and correlating the data. This data is then submitted to an ADE search engine **61** which searches an ADE rule database **60** to see if the data satisfies any predefined ADE rule. If a definition is satisfied, an alert procedure is activated to notify the medical facility of a potential ADE.

[0067] ADE monitoring can be done in real time by having the medical facility transmit applicable data as soon as it is received, and by having ADE monitoring activated automatically upon reception of new laboratory and pharmacy data. Real time ADE monitoring allows nearly instantaneous detection of ADE. The ADE monitoring system can also be activated periodically by allowing transmitted pharmacy and lab data to accumulate in pharmacy **56** and laboratory **57** databases and searching for matches at predefined times, or upon activation by a user.

[0068] As shown in FIGS. **8***a* and **9**, in one embodiment, once ADE monitoring is activated, the subject ADE monitoring system will first check to see if an abnormal lab is received (box **100**). This check is done by filtering data located within the pharmacy **56** and lab **57** databases with the plurality of ADE rules stored within the ADE rules database to see if an ADE rule is satisfied by the pharmacy and lab data.

[0069] The filtering process includes using the lab name stored within the Target Drug **73** data field of an ADE rule to filter the drugs listed in the daily record to determine if it was administered or is scheduled to be administered to a patient during a predefined period. If a match exists, the records within the lab table is then filtered using the data located within the Target Lab **74**, Baseline **80**, and Type **79** data fields located in the same ADE rule to determine if an abnormal lab result has been received.

[0070] As shown in FIG. **9**, if a lab name located within the Target Lab **74** data field matches a lab name in the lab table, then the value for the lab is compared with the value within the Baseline **80** database for the same ADE rule. If the lab value is equal to or exceeds (if Type **79** is high) or if it does not exceed (if Type **79** is low) the value in the Baseline **80** data field, then the lab value is an abnormal lab. After an abnormal lab result is detected and absent any additional criteria in the detail filters or association filters, an ADE rule has been satisfied and an alert procedure is triggered.

[0071] As shown in FIG. **11**, the data fields Hospital Unit **86**, Doctor **87**, Diagnosis **88**, Gender **89** and Age Range **90**, comprise a detail filter that, if defined, are additional requirements that must also be satisfied if an alert procedure is to be triggered. If a drug/lab match exists then the patient record is checked to see if the defined detail filters are satisfied (Box **102**). If any defined detail filters are not satisfied, then the drug/lab match is disregarded.

[0072] If a drug/lab match is found and the detail filters are satisfied, the search engine then checks the Concurrent Drug **91** and Concurrent Lab **92** data fields to see if these association filters are defined (Box **103**). As shown in FIG. **10**, if any of the association filters are defined, the search engine filters through the daily record or the lab table, depending on which parameter is defined, to see if the associated drug was administered or if the associate lab result occurred within a predefined period of time prior to the abnormal lab result. If the association filter is satisfied, then the ADE monitoring system can begin an alert procedure. If they are not, then the drug/lab match is disregarded.

E. Alert Procedures

[0073] As shown in FIGS. **8***a* and **8***b*, in one embodiment, an alert procedure includes calculating an action date (box **104**) which defines a waiting period wherein the system allows the problem to be resolved by the medical staff and allows time for additional tests to ensure that a potential ADE does exist (the abnormal lab value being erroneous). The action date is adjusted (boxes **105** and **106**) to take into account a plurality of factors such as the current abnormal lab value, the previous lab value, the amount of time between a previous lab and the current abnormal lab, and the value of a current abnormal lab relative to a potentially dangerous value for the lab.

[0074] During this waiting period prior to the action date, the system monitors incoming pharmacy and laboratory data in order to determine if a proper corrective action is taken. The proper corrective action can be discontinuing a medication or receiving a more recent test result or it can be a response such as raising or lowering a dosage (the appropriate change is listed in the Pattern **78** data field of the matched ADE rule). If the action date is reached without a proper corrective action being taken or if an inappropriate action has been taken (such as raising the drug level when it should be lowered), an alert indicating the existence of a potential ADE is generated and sent to the healthcare provider. If a proper action has been taken then the drug/lab match is disregarded.

[0075] A proper corrective action can be a discontinuation of the medication (box **107**). As shown in FIG. **12***b*, a discontinuation of a medication is detected by the ADE monitoring system by monitoring the period of time starting from the last administration of the medication to be discontinued. A time interval (C) is defined which represents a period sufficient to determine a discontinuance of a particular drug. If the time interval between the last time a drug was administered and the end of the live pharmacy data is greater than (C), and if the drug was not administered between that time, then the drug is effectively discontinued and the drug/lab match is disregarded. If the interval (C) is not satisfied and there is no more data in the pharmacy database, the system will continue to monitor incoming lab results until the interval (C) is satisfied.

[0076] Another proper corrective action may also be receiving a more current result for the same Target Lab **74** (box **108**). As shown in FIG. **12***a*, once an abnormal result (A) is received, subsequent tests are monitored to see if a more recent lab result for the same test (B) is present within the lab table. If a more recent test is present, the lab/drug match is disregarded.

[0077] In some instances, the proper corrective action can also be an adjustment to the dosage given a patient (Box **109**). As shown in FIG. **12***c*, after an abnormal lab result occurs (A) the system monitors subsequent pharmacy data to determine if an actual dosage given or planned dose (B) includes a dosage which is lowered or raised as is required by the Pattern **78** data field in the matching ADE rule. If an actual dosage or a planned dosage is properly adjusted, the drug/lab match is disregarded.

[0078] Absolute **81**, Interval **82**, Danger Multiplier **83**, and Momentum Multiplier **84** are all data fields within a matching ADE rule that are used to determine an appropriate waiting period wherein a corrective action is to be taken. The Interval **82** data field in a matching ADE rule contains the time interval (in hours) within which the ADE monitoring system expects an action to occur, and this time period is adjusted accordingly to take into account a plurality of factors such as the current abnormal lab value, the previous lab value, the amount of time between a previous lab and the current abnormal lab, and the value of a current abnormal lab relative to a potentially dangerous value for the lab. The date wherein the interval expires and an alert is generated is called the action date. The action date is calculated by the formula:

$$\text{Action Date}=I-(DM+(AM*MF))*((I*((HV-LV0/HV-AHV))))$$

[0079] Wherein

[0080] I—value in data field Interval **70** (FIG. **7**)

[0081] DM—represents Danger Multiplier **71**

[0082] AM—actual momentum

[0083] MF—represents a Momentum Multiplier **72**

[0084] HV—represents the Baseline **63** value

[0085] AHV—represents the Absolute **64** value

[0086] LV—represents the recorded lab value

[0087] The Danger Multiplier **71** contains a variable that automatically adjusts how quickly the ADE monitoring system expects a response to an abnormal lab test, based upon how close the lab test is to an Absolute **64** value. The variable is the slope of a linear function that governs how the interval time is adjusted relative to the proximity of a lab test result to the Absolute **71** value. FIG. **13** shows the formula to calculate an action date adjusted for a danger factor. The variables in the formula can be defined as:

[0088] LD**2**—date of abnormal lab value

[0089] IC—value in data field Interval **70** (FIG. **7**)

[0090] DM—represents Danger Multiplier **71**

[0091] LabHI—represents the Baseline **63** value

[0092] LV—abnormal lab value

[0093] LabAbsHi—represents the Absolute **64** value

[0094] Momentum **72** is determined by the value given to the Momentum Multiplier (MF) by the user and the found Actual Momentum (AM). The Momentum Multiplier (MF) is set by the user much like the Danger Multiplier (DM). It acts on the Actual Momentum (AM). Actual Momentum (AM) is calculated by taking the difference in value between the current lab test and the last previous one (LV**2**–LV**1**) and dividing by the time difference between the dates of each (LD**2**–LD**1**). The value of the ratio is then corrected for the absolute value of the lab tests by dividing by the most recent lab value (LV**1**).

[0095] FIG. **14** shows the formula to calculate the actual momentum and an action date adjusted by the momentum multiplier. The variables in the formulas can be defined as:

[0096] LD**2**—date of abnormal lab value

[0097] LV**2**—abnormal lab value (also referred to as Lab Value)

[0098] LV**1**—most recent lab value for same test

[0099] LD**1**—most recent date for same test

[0100] IC—value in data field Interval **70** (FIG. **7**)

[0101] AM—represents the actual momentum

[0102] MF—represents a Momentum Multiplier **72**

[0103] DM—represents Danger Multiplier **71**

[0104] LabHI—represents the Baseline **63** value

[0105] LV—abnormal lab value

[0106] LabAbsHi—represents the Absolute **64** value

[0107] Once an action date is reached without an appropriate action being undertaken, the system makes contact with the healthcare provider in order to alert them of a potential ADE. The matching ADE rule includes the name of an appropriate template in Alert Template **73**, and a destination for the message in the Contact parameter **74**. Preferably, the ADE monitoring system delivers the alert through an electronic messaging system such as an E-mail. It is also contemplated that such alerts can also be transmitted in a known manner through a paging system or a voice mail system to an attending physician. This electronic message may be received at a central point in a healthcare facility, and additionally it may be received at a nursing station located in the medical ward wherein the patient is hospitalized.

[0108] As shown in FIG. **16**, one embodiment of an alert includes a graphical representation of the medication dosage relative to lab test results **160**, a name of the rule satisfied, patient information **162**, and drug/lab information **163**. In this embodiment, the alert is a page which is located within a web

site, but similar information may be transmitted to an email address, a central station within a health care organization, or a pharmacy.

F. Patient Reports

[0109] The ADE monitoring system stores data received from the medical facility as well as the alerts which are generated in a database which is accessible to users for patient care, quality assurance, or medical research. Information within the database can be filtered and compiled by a user to provide specific information relating to a particular patient or to a number of patients within a medical facility. The information can be filtered and compiled via criteria determined through an interactive query or through predefined report parameters. (need more info on report generation capability)

[0110] In one embodiment, an individual patient report is generated utilizing an interactive query. The ADE monitoring system gives the user an option to filter and graph a particular patient's information by defining an ADE rule name, a target lab test, a target drug, an abnormal range, a lab result high or low parameter, a danger level, recent start (instructing the database to consider only recent data), new date look (a feature which enables the computer to estimate what date an action would occur), and new date time (a feature which enables the computer to estimate what time an action would occur). As shown in FIG. **15***a*, an individual patient report can generate a graphical interpretation of the patients data, or as shown in FIG. **15***b* the information can be arranged in a tabular format

[0111] In another embodiment, ADE monitoring system includes a report generation application which can generate predefined reports such as a system report which compiles predefined data for an entire system, an ADE facility report which shows information for a specific facility, a drug management report which breaks out data according to drugs used, ADE reports which performs statistical analysis of ADE's, and an ADE doctor report which shows information for a specific doctor. These reports are predefined and can be generated by simply selecting the function from a menu. As shown in FIG. **15***b*, these reports can include a specific ADE rule name, a total number of occurrences, a total number of alerts, and a percentage of alerts respective of a total number of occurrences. Alerts such as those shown in FIG. **16** can also be accessed and reviewed individually.

G. User Operation

[0112] A user will typically access the ADE monitoring system **10** online by logging onto a web site on a secured intranet. Every authorized user will typically be assigned a unique log on ID and password to enable access. Each user is also typically assigned a security role which limits their ability to access certain information in the ADE monitoring system.

[0113] As shown in FIG. **18**, once logged on, the user is greeted by a primary interface screen **100** which contains selections for navigating to the primary functions of the ADE monitoring system **10**. The primary screen includes menu options which enable a user to run a search **101**, consult ADE results **102**, and **103** and to create and modify ADE rules **104**.

[0114] FIG. **19***a* and **19***b* shows a rule maintenance screen **110** to the ADE monitoring system. The screen is used to create new ADE rules, modify existing ADE rules, check the contents of an ADE rule, and to copy the contents of an ADE rule. The screen includes a plurality of data entry fields which enable a user to enter or change values for data fields of an ADE rule.

[0115] FIG. **20** shows a search screen **120** which is used to run an ADE search. A user may instantaneously activate the ADE monitoring process by selecting the Run button **121**. A status window **122** defines the exact date and time the ADE monitoring was run. After the ADE monitoring process is completed, the exit button **123** is enabled, and the user can then go back to the primary interface screen **100** by selecting it.

[0116] Once back in the primary interface screen **100**, the user can view ADE monitoring results by selecting the Alert View **102** and Alert Analysis **103** options. The ADE monitoring results can then be displayed based on a particular individual or a group of individuals by using the patient reports procedures outlined above.

[0117] While the present invention has been described with reference to several embodiments thereof, those skilled in the art will recognize various changes that may be made without departing from the spirit and scope of the claimed invention. Accordingly, this invention is not limited to what is shown in the drawings and described in the specification but only as indicated in the appended claims, nor is the claimed invention limited in applicability to one type of computer or computer network. Any numbering or ordering of elements in the following claims is merely for convenience and is not intended to suggest that the ordering of the elements of the claims has any particular significance other than that otherwise expressed by the language of the claim.

1. A method of anticipating adverse drug episodes comprising:

defining a plurality of ADE rules having data fields for a lab test name, a value for the lab test, and a drug; and

filtering a patient's lab data and pharmacy data using the plurality of definitions.

2. The method of claim **1**, and further comprising the additional step of creating a normalized drug table from a patient's pharmacy data, the pharmacy table having data fields for each drug administered, a dosage, and a time administered.

3. The method of claim **2**, and further comprising the additional step of creating a normalized lab table from a patient's lab data, the lab table having data fields for a patient id, time of test, name of test, and a test result.

4. The method of claim **3**, wherein the step of filtering includes the steps of extracting a lab name, a result of the lab from the lab table and a drug from the drug table and matching it to a lab name, lab result and drug within an ADE rule.

5. The method of claim **1**, and further comprising the additional step of importing laboratory data and pharmacy data from a healthcare facility.

6. The method of claim **5**, and further comprising the additional step of verifying imported lab data or pharmacy data is formatted in accordance with a predefined format.

7. The method of claim **1**, and further comprising the additional steps of computing a cumulative dosage for a drug within a 24 hour period from a date of administration.

8. The method of claim **1**, wherein the ADE rules also includes a data field containing a waiting period for a proper corrective action.

9. The method of claim **8**, and further comprising the additional steps of filtering subsequent lab data or pharmacy data to determine if a proper corrective action has occurred.

10. The method of claim **9**, and further comprising the additional step of alerting a health care provider when a waiting period for a proper corrective action has expired without a proper corrective action occurring.

11. The method of claim **8**, and further comprising the additional step of adjusting a waiting period based on a test lab value.

12. The method of claim **8** and further comprising the additional step of adjusting a waiting period based on previous lab test values.

13. The method of claim **1**, wherein the lab/data definition includes data fields for associated drugs.

14. The method of claim **13**, further comprising the additional step of filtering a patient's previous pharmacy data for an associated drug.

15. The method of claim **1**, wherein the lab/data definition includes data fields for an associated test lab and result.

16. The method of claim **15**, further comprising the additional step of filtering a patient's lab data for an associated test lab and result.

17. A system for anticipating adverse drug events comprising:

a central processor having a search engine therein; and

an ADE rule database in communication with the server.

18. The system of claim **17**, wherein the central processor is in communication with a computer network.

19. The system of claim **18**, wherein the computer network. is an intranet.

20. The system of claim **17**, and further comprising a laboratory and a pharmacy database.

21. The system of claim **17**, wherein the central processor includes a web server hosting a web site therein and in communication with an intranet.

22. The system of claim **17**, wherein the central processor is in communication with a pharmacy information system and a laboratory information system.

23. The system of claim **17**, wherein the central processor is in communication with a nursing station at a medical facility.

24. The system of claim **17**, wherein the central processor is in communication with a paging system.

25. The system of claim **17**, wherein the central processor includes a web server, an application server, a database server, and a directory server.

26. The system of claim **17** wherein the central processor includes an application for reformatting and integrating pharmacy data and lab data.

27. A method of anticipating adverse drug episodes comprising:

defining a plurality of ADE rules having data fields for a lab test name, a value for the lab test, and a drug;

storing the ADE rules within an ADE rules database;

importing a patient's lab data and pharmacy data;

storing a patient's lab result, the lab test name, and a name of a drug administered to the patient within a database;

matching a patient's lab result, test name, and administered drug with a lab value, lab name and drug within an ADE rule.

28. The method of claim **27**, and further comprising the additional steps of extracting a lab test name, a lab test result from a patient's lab data and extracting a drug name from a patient's pharmacy data.

29. The method of claim **27**, wherein the step of storing includes the steps of storing a patient's lab result and the lab test name within a lab database and storing a name of a drug administered within a pharmacy database.

30. The method of claim **27**, and further comprising the additional steps alerting a health care provider when a match occurs.

31. The method of claim **27**, and further comprising the additional step of storing a patient's hospital unit, doctor, diagnosis, gender, and age within a database.

32. The method of claim **31**, wherein the ADE rule includes a data field for storing a hospital unit, doctor, diagnosis, gender, and age.

33. The method of claim **32**, and further comprising the additional steps of matching a patient's hospital unit, doctor, diagnosis, gender, and age with a respective value in an ADE rule.

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