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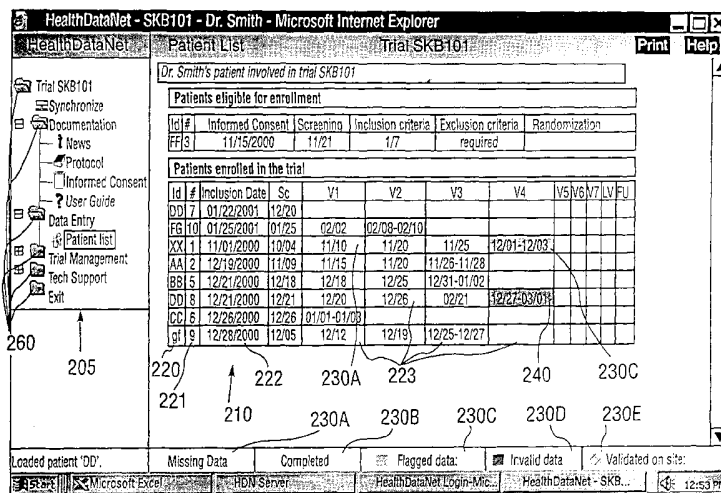
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200

(57) Abstract: A data capture and management system is provided with a plurality of tabular forms (210) that represents a multidimensional database system. Each tabular form contains a plurality of cells (220-223), wherein at least one cell (221-223) of interest can be selected that correspond to another tabular form (21). At least two different means of activating a cell (221-223) of interest are used to display data from the tabular form (210) that corresponds to the cell of interest (221-223). The data from the corresponding tabular form (210). A plurality of descriptors for a cell of interest (221-223) provide status information of the data contained in a corresponding tabular form (210) that enable one to quickly review and interpret large data sets.



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## FIELD OF THE INVENTION

5 This invention relates generally to computer software and the Internet. More particularly, the present invention relates to a data capture and management system.

## BACKGROUND

10 Data management has become not only more involved due to higher data volumes, but also more important in research and development due to a shortened time to market in increasingly demanding and more global markets. This is particularly true in the age of faster computers and the Internet where it has become easier to acquire, exchange and process data. For example, about forty percent of the research and development expenses of pharmaceutical companies is used for clinical trial data capture and management.

15 Clinical trials usually generate a significant amount of data that requires the effort of a large team of people including physicians, clinical data managers, data entry personnel, programmers, and statisticians. Each member of the team performs a specific function vital to the quality of the end database. A system that enables one to concurrently access and process data at the several stages of the database lifecycle enhances the overall work

20 process and accelerates database development.

The use of off-the-shelf database packages will probably be capable of processing all the data captured in, for instance, a clinical trial, product database, or a weather forecast system. However, these packages usually have difficulty being accepted by the various

25 different types of users. One of the reasons is that these packages become too involved and complicated to interact with. It is not uncommon for users to lose track of the status of entered data. In addition, current database management systems commonly lack flexibility, scalability, and performance in order to connect to its users. Therefore, to get a higher

acceptance rate by its users and become a more useful tool, there is a strong demand to develop future data capture and management systems that include better ways to organize data as well as novel techniques to quickly review the status of entered data.

5 Accordingly, there is a need to develop a more practical and useful data capture and management system that facilitates user cooperation and global operability.

### SUMMARY OF THE INVENTION

10 The present invention provides a data capture and management system that is accessible by a computer or the Internet. The system tangibly embodies a program of instructions that are executable by a computer to perform method steps for data capture and management. In accordance with exemplary embodiments, the present invention includes a plurality of tabular forms, thereby representing a multi-dimensional database system. The present  
15 invention could include just one tabular form, however, most applications require several corresponding tabular forms. Each tabular form contains data in a plurality of cells. Other types of data representations could also be included. Each cell could correspond to a corresponding tabular form. The data between corresponding tabular forms could be displayed by activating a cell of interest in a tabular form of interest. A particular cell of  
20 interest is activated by at least two different means of activating. For example, a first means and a second means of activating a cell of interest which need to distinguishable from each other. Means of activating a cell are, for instance, but not limited to, a click, a double-click, roll-over, or other means of activating a cell. The first means of activating a cell of interest in a tabular form of interest is used to display, for instance, a data sheet.  
25 Other types of data representations could also be used. The data sheet displays, for instance, a data summary or a selection of data that corresponds to the data from a corresponding tabular form. The corresponding tabular form is part of the plurality of tabular forms and is associated to the cell of interest. The second means of activating a cell

of interest in a tabular form of interest is used to display, for instance, the corresponding tabular form.

5 In addition, the present invention provides various ways of reviewing the status of the entered data. For instance, it might be important to know that, after data has been entered in, for instance, a tabular form of interest, the form could still require some additional data to be filled out in some of the cells. Other examples that might be of interest for review are, for example, but not limited to, the information that a particular tabular form needs to be verified, statistical parameters need to be calculated, the form contains erroneous data, or  
10 the form contains data exceeding predefined boundaries. The different ways of reviewing the status of the data in a form or data sheet is accomplished by different descriptors, which is accomplished by providing a cell with a descriptor. Examples of descriptors are, for instance, but not limited to, a plurality of signs, a plurality of colors, a plurality of tags, or a plurality of statistical parameters. In case of colors, different color codes are used to  
15 indicate the status of data of a tabular form, which is indicated by that color of a cell.

The data capture and management system could be used on a single computer, but could also be part of an internet-based network that contains a central hub and one or more agents or computers connected to the central hub to perform at least one data capture and  
20 management operation. In this case, the system also provides a web-browser for online communication between a user using one or more agents and the central hub. Besides an online connection, the system, could also be used offline in which a local web-browser is provided for offline communication between a user using one or more agents and a local server. The system also provides mechanisms for synchronizing at least one data capture  
25 and management operation between the local server and the central hub.

In addition, the system includes a manager with a plurality of tools to manage at least one data capture and management operation. The system also includes different mechanisms to

display information of at least one data capture and management operation as well as different mechanisms to manipulate data in the plurality of cells. For instance, these manipulation mechanisms include, but are not limited to, the basic computer data operations such as copy, cut, paste, edit, undo, drag, or delete as well as mathematical operations. In addition, data could be manipulated by the use of, for example, but not limited to, radio buttons, sliders, data menus, click boxes, or the like. Manipulation of data is possible at the tabular form level as well as the data sheet level of the system

In view of that which is stated above, it is the objective of the present invention to provide a data capture and management system with a plurality of tabular forms that represents a multi-dimensional database system.

It is another objective of the present invention to provide a data capture and management system in which each tabular form contains a plurality of cells, wherein at least one cell of interests can be selected that corresponds to another tabular form.

It is yet another objective of the present invention to provide a data capture and management system that contains at least two different means of activating a cell of interest to display data from the tabular form that corresponds to the cell of interest. The data from the corresponding tabular form could be displayed partially as a data sheet or displayed entirely as a corresponding tabular form.

It is still another objective of the present invention to provide a plurality of descriptors for a cell of interest to provide status information of the data contained in a corresponding tabular form.

It is still another objective of the present invention to provide a flexible data capture and management system in which data can be quickly interpreted and manipulated.

It is another objective of the present invention to integrate the data capture and management system in a local as well as a global network connected to a central hub, wherein the system could be used on different computers and act as different agents that interact with the central hub.

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The advantage of the present invention over the prior art is that the system enables one to capture and manage large amounts of multidimensional data, such as, but not limited to, data obtained in clinical trials, by incorporating mechanisms for easy access and review at the different levels of the multidimensional database. Another advantage is that the present invention uses different descriptors that enable one to quickly review and interpret large data sets.

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## BRIEF DESCRIPTION OF THE FIGURES

The objectives and advantages of the present invention will be understood by reading the following detailed description in conjunction with the drawings, in which:

**FIG. 1** illustrates the general concept of a plurality of tabular forms with a plurality of cells according to the present invention;

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**FIG. 2** illustrates a data capture and management system according to the present invention;

**FIG. 3** illustrates a tabular form with a data sheet according to the present invention;

**FIG. 4** illustrates a corresponding tabular form according to the present invention;

**FIG. 5** illustrates a corresponding tabular form with a data sheet according to the present invention;

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**FIG. 6** illustrates a corresponding tabular form of descriptor data including a data sheet according to the present invention;

**FIG. 7** illustrates a corresponding tabular form with a data sheet that allows data manipulation according to the present invention; and

**FIG. 8** illustrates an Internet setup for utilizing the data capture and management system according to the present invention.

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## DETAILED DESCRIPTION OF THE INVENTION

Although the following detailed description contains many specifics for the purposes of illustration, anyone of ordinary skill in the art will readily appreciate that many variations and alterations to the following exemplary details are within the scope of the invention. Accordingly, the following preferred embodiment of the invention is set forth without any loss of generality to, and without imposing limitations upon, the claimed invention.

The present invention provides a data capture and management system that is accessible by a computer or the Internet. The system tangibly embodies a program of instructions that are executable by a computer to perform method steps for data capture and management. In accordance with several exemplary embodiments, the present invention includes a plurality of tabular forms and represents a multi-dimensional database system. **FIG. 1** shows the general concept of a plurality of tabular forms **10**. Each tabular form in **10**, e.g. **100**, **130**, **160**, and **180**, contains a plurality of cells. For instance, tabular form **100** contained cells **110** and tabular form **130** contained cells **140**. The present invention is not limited to a data representation in cells **110**, whereas other forms of data representation could also be used. Cells **110** and **140**, for example, could represent data in terms of number, letters, images, and the like. A cell of interest **120** in a tabular form **100** could correspond to a corresponding tabular form **130** and is a selected cell by the user from cells **110**. The corresponding tabular form **130** also contains a plurality of cells **140**. The present invention could include just one tabular form, however, most applications require several corresponding tabular forms, thereby creating a complex and multidimensional data

capture and management system. The idea is that a cell of interest **120** represents a corresponding tabular form **130**, as is discussed in more detail below. In the most extensive case, all cells **110** of tabular form **100** could represent a corresponding form, thereby creating a complex and multi-dimensional system. For instance, a clinical trial database is such a complex and multi-dimensional system, wherein each cell **110** could represent a particular client or patient and test date. Each cell **110** is then a cell of interest like cell **130** and will then correspond to a corresponding tabular form such as **130** that corresponds to **120**. A corresponding tabular form **130** could then contain, for instance, all the data for a particular client or patient. Another example is that corresponding tabular form **130** could contain specific medical data of that particular client or patient. The present invention is not limited to a clinical trial database systems, which is presented as an exemplary embodiment, as it could also be used for product or inventory data management, weather database systems, pharmaceutical drug database systems, and the like. The present invention is also not limited to the number of cells **110** that correspond to a corresponding tabular form **130**. A single cell **110** or a plurality of cells **110** could be associated to subsequent or corresponding tabular forms. For example, cell **170** could be selected as a cell to correspond to tabular form **180**. Furthermore, the corresponding tabular form **130** could also contain a selected cell of interest **150** that corresponds to yet another level with a corresponding form **160**. Thereby, the system encompasses a cascading mechanism of tabular forms at different levels. The general idea is that this system enables one to manage and capture data from a global to a more specific perspective and level of detail, wherein the first tabular form **100** represents the subsequent and corresponding tabular form **130** in a global sense by just one cell, for instance **120**, whereas the corresponding tabular form **130** provides more detail to the user in its plurality of cells **140**.

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**FIG. 2** shows an exemplary embodiment of a clinical trial data capture and management system **200**. Tabular form **210** contains a plurality of cells. In this particular example, the cells are used for different purposes such as patient ID **220**, patient number **221**, patient



inclusion data **222**, or clinical trial test data **223**. As one skilled in the art might readily acknowledge, many different types of data could be represented in each cell in tabular form **210** as is discussed below in more detail.

5 The present invention provides various ways of reviewing the status of the entered data in a tabular form of interest. For instance, it might be important to know that after data has been entered in, for instance, a tabular form **210**, the form could still require some additional data to be filled out in some cells. Referring back to **FIG. 1**, it is important to realize that the entered data could either be done at the first level, which is tabular form  
10 **100**, or at the subsequent/corresponding level, which is for instance tabular form **130**, **160** or **180**. Other examples that might be of interest for review are, for example, but not limited to, the information that a particular tabular form needs to be verified, statistical parameters need to be calculated, the form contains erroneous data, or the form contains data exceeding predefined boundaries. Referring back to **FIG. 2**, the different ways of reviewing the status of the data in form **210** is accomplished by different descriptors, for  
15 example, and not limited to, **230A**, **230B**, **230C** **230D**, and **230E**, which is accomplished by providing a cell of interest **240** with a descriptor **230D**. As shown in the particular example of **FIG. 2**, the information given by a descriptor could be “missing data” **230A**, “completed” **230B**, “flagged data” **230C**, invalid data” **230D**, and “validated on site” **230E**.  
20 Examples of descriptors are, for instance, but not limited to, a plurality of signs, a plurality of colors, a plurality of tags, or a plurality of statistical parameters. In case of colors, different color codes are used to indicate the status of data of a tabular form, which is indicated by that color of a cell.

25 As shown in **FIG. 2**, the data capture and management system **200** includes a manager **250** with a plurality of tools **260** to manage at least one data capture and management operation. Examples of tools **260** are, for instance, but not limited to, different folders with standard computer software means to manage at least one database, a user guide, technical support,

or the like. The system also includes different tools **260** to display information of at least one data capture and management operation. In addition, as is discussed below, the manager **250** also contains tools **260** to utilize the data capture and management system **200** on either a single computer, as well as part of an internet-based network.

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As discussed above with respect to **FIG. 1**, the data between corresponding tabular forms could be viewed by activating a cell of interest in a tabular form of interest. In fact, a particular cell of interest could be activated by at least two different means of activating. For example, a first means and a second means of activating a cell of interest. The first means of activating a cell is, for instance, but not limited to, a click, a double-click, roll-over, or other means of activating a cell. The activation could be accomplished by a computer mouse, by a touch to a screen, a remote device, or the like. **FIG. 3** shows tabular form **310** which is identical to tabular form **210** in **FIG. 2**. However, tabular form **310** also shows data sheet **320**. Data sheet **320** is displayed by a first means of activating a cell of interest **330** in a tabular form of interest **310**, such as, for instance, a roll-over. The present invention is not limited to the example of a data sheet **320**, since other types of data representations could also be used, such as, for instance, images, buttons, hyperlinks, or the like. The data sheet **320** displays, for instance, a data summary or a selection of data that corresponds to the data from a corresponding tabular form. In this particular embodiment referring to a clinical trial database, cells **340** in data sheet **320** could, for instance, represent and summarize specific data related to visit 1 **350** of patient **360**. The tabular form **310** as well as the data sheet **320** could both contain different descriptors **370** as discussed above to enable a user to quickly review the status of the entered data.

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A second means of activating a cell of interest in a tabular form of interest is used to display, for instance, the corresponding tabular form. The second means of activating a cell is selected from the same group, but not limited to, as the first means of activating the cell of interest with the requirement that first and second means are different and

distinguishable. As an exemplary embodiment, the same cell **330** could be activated by a second means, such as a click, to display the corresponding tabular form. As an exemplary embodiment, as shown in **FIG. 3**, a cell of interest **390** for patient **380** is selected to display a corresponding tabular form **410** as shown in **FIG. 4**. The corresponding tabular form **410** contains more detailed data than the tabular form **310**. According to the specific embodiment of a clinical trial database, corresponding tabular form **410** contains data for patient **420** (same patient as **380** in **FIG. 3**) specific to different visits or tests **430**. Again, the tabular form **410** could contain different descriptors **440**, as discussed above, to enable a user to quickly review the status of the entered data. As mentioned above, in each tabular form, a cell of interest could be selected and activated by a first or second means. Therefore, in corresponding tabular form **410**, cell of interest **450** could be selected and activated to display either a subsequent/corresponding tabular form or a data sheet. **FIG. 5** shows the exemplary embodiment wherein cell of interest **520** in corresponding tabular form **510** is activated. Note that cell of interest **520** in corresponding tabular form **510** is the same as cell of interest **450** in corresponding tabular form **410** in **FIG. 4**.

In addition to a first and a second means of activating a cell of interest, it might in some cases or applications be necessary to provide additional means, e.g. a third means, of activating a cell of interest. In other words, the present invention also includes one or more additional means of activating a cell of interest. The important aspect to consider is that the different means of activating a cell of interest should be distinguishable from each other, as discussed above.

The data sheet **530** displays, for instance, a data summary or a selection of data that corresponds to the data from a subsequent/corresponding tabular form. In this particular embodiment referring to a clinical trial database, cells **540** of data sheet **530** could, for instance, represent and summarize specific data related to vital signs **550** of patient **560**.

The tabular form **510** as well as the data sheet **530** could both contain different descriptors **570**, as discussed above, to enable a user to quickly review the status of the entered data.

**FIG. 6** is yet another example of an embodiment on how tabular forms and data sheets could interact. **FIG. 6** shows tabular form **610**, which classifies descriptor data from a plurality of different tabular forms in cells **620**. The exemplary embodiment shows, for instance, but not limited to, a variety of different clusters of cells according to “confirmed data” **630A**, “flagged data” **630B**, “validated data” **630C**, and “invalid data” **630D**. Again, cells **620** in tabular form **610** could be selected, for example, cell **630** could be selected to display data sheet **640**. In this particular example, data sheet **640** is a form **650** containing cells **660** to display general information about a patient **670** that corresponds to the cell of interest **630**. Again, the tabular form **610**, as well as the data sheet **640**, could both contain different descriptors, as discussed above, to enable a user to quickly review the status of the entered data.

15

The data capture and management system of the present invention also includes different mechanisms to manipulate data in each of the plurality of cells. For instance, these manipulation mechanisms include, but are not limited to, the basic computer data operations such as copy, cut, paste, edit, undo, drag, or delete, as well as mathematical operations. Such operations are utilized at the tabular form level as well as the data sheet level of the system. **FIG. 7** shows an exemplary embodiment in which data could be entered in data sheet **720** in tabular form **710**. In the exemplary embodiment of a clinical trial, **FIG. 7** shows a data sheet **720** with a variety of vital signs **730** of a patient **740**. For instance, cell **750** requests a systolic blood pressure, for which the value could be entered in **760A** and the units in **760B**. As one skilled in the art might readily acknowledge, a wide variety of other techniques of entering data, rather than typing, could be employed, including, but not limited to, predefined radio buttons, sliders, menus, or equivalents thereof. In addition, the embodiment of a clinical trial is presented for exemplary purposes

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only and the present invention is not limited to clinical data as discussed above in which it could used also encompass product or inventory data, weather data, pharmaceutical drug data, and the like.

5 Furthermore, various types of mathematical operations could be carried out before data is displayed in a cell. It might, for instance, be important to convert data to a different unit (e.g. miles to km, cm to inches), change currency (dollars to French francs), perform a calculation based on a model or set of equations, or equivalents thereof. These mathematical operations are not limited to the level of tabular forms or whether the data  
10 concerns a data sheet of tabular form. An example of a calculation related to clinical trials is, for instance, but not limited to, the calculation of body surface area from height and weight. As one skilled in the art might readily appreciate, many different types of calculations can be included.

15 In addition, as is mentioned above, manager **250** in **FIG. 2** also contains tools **260** to utilize the data capture and management system **200** on either a single computer **820A**, now referring to **FIG. 8** , as well as part of an internet-based network **800** that contains a central hub **810** and one or more agents or computers (**820A, 820B ... 820N**) connected to central hub **810** to perform at least one data capture and management operation. In this case, the  
20 system also provides a web-browser for online communication **830** between a user using one or more agents **820A, 820B ... 820N** and the central hub **810**. Online communication is, for instance, provided through a standard Web browser using an Internet service provider, an Intranet network system, or equivalents thereof. Besides an online connection, the system, could also be used offline in which a local web-browser is provided for offline  
25 communication between a user using one or more agents **820A, 820B ... 820N** and a local server stored on each of the agents **820A, 820B ... 820N**. Examples of a local web-browser are, for instance, a Local Area Network (LAN), a local server running on user's computer, or equivalents thereof. The system also provides mechanisms for synchronizing at least

one data capture and management operation between the local server and the central hub. Synchronization is important when more than one user operates on the same database.

5 The present invention has now been described in accordance with several exemplary embodiments, which are intended to be illustrative in all aspects, rather than restrictive. Thus, the present invention is capable of many variations in detailed implementation, which may be derived from the description contained herein by a person of ordinary skill in the art. All such variations are considered to be within the scope and spirit of the present invention as defined by the following claims and their legal equivalents

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## CLAIMS

What is claimed is:

1. A program storage device accessible by a computer, tangibly embodying a program of  
5 instructions executable by said computer to perform method steps for data capture and  
management, said methods steps comprising:
  - (a) providing a plurality of tabular forms, wherein each of said tabular forms contains  
data in a plurality of cells;
  - (b) providing a first means of activating a cell of interest of said plurality of cells in a  
10 tabular form of interest of said plurality of tabular forms to display a data sheet  
with corresponding data from a corresponding tabular form of said plurality of  
tabular forms; and
  - (c) providing a second means of activating said cell of interest of said plurality of  
cells in said tabular form of interest of said plurality of tabular forms to display  
15 said corresponding tabular form.
2. The device as set forth in claim 1, wherein said method steps further comprise  
the step of providing in said cell a plurality of descriptors.
- 20 3. The device as set forth in claim 2, wherein said plurality of descriptors  
comprises a plurality of signs.
4. The device as set forth in claim 2, wherein said plurality of descriptors  
comprises a plurality of colors.
- 25 5. The device as set forth in claim 2, wherein said plurality of descriptors  
comprises a plurality of tags.

6. The device as set forth in claim 2, wherein said plurality of descriptors comprises a plurality of statistical parameters.
- 5 7. The device as set forth in claim 1, wherein said method steps further comprise the step of providing a manager with a plurality of tools to manage at least one data capture and management operation.
- 10 8. The device of claim 7, wherein said method steps further comprise the step of providing means to display information of said at least one data capture and management operation.
9. The device as set forth in claim 1, wherein said method steps further comprise the step of providing means to manipulate said data in said plurality of cells.
- 15 10. The device as set forth in claim 9, wherein said step of providing means to manipulate said data comprises means to copy, cut, paste, edit, undo, drag, or delete.
- 20 11. The device as set forth in claim 1, wherein said method steps further comprise the step of providing means to manipulate said corresponding data in said data sheet.
- 25 12. The device as set forth in claim 11, wherein said steps of providing means to manipulate said data comprises means to copy, cut, paste, edit, undo, drag, or delete.



13. The device as set forth in claim 11, wherein said step of providing means to manipulate said data comprises means to use radio buttons, sliders, data menus, or click boxes.
- 5 14. The device as set forth in claim 1, wherein said method steps further comprise the step of providing one or more additional means of activating said cell of interest.
- 10 15. The device as set forth in claim 1, wherein said method steps further comprise the means to calculate said data.
16. A method of using a database for clinical trial data capture and management, comprising the steps of:
- 15 (a) providing a plurality of tabular forms wherein each of said tabular forms contains data in a plurality of cells;
- (b) providing a first means of activating a cell of interest of said plurality of cells in a tabular form of interest of said plurality of tabular forms to display a data sheet with corresponding data from a corresponding tabular form of said plurality of tabular forms; and
- 20 (c) providing a second means of activating said cell of said plurality of cells in said tabular form of said plurality of tabular forms to display said corresponding tabular form.
- 25 17. The method as set forth in claim 16, further comprising the step of providing in said cell a plurality of descriptors.
18. The method as set forth in claim 17, wherein said plurality of descriptors comprises a plurality of signs.

19. The method as set forth in claim 17, wherein said plurality of descriptors comprises a plurality of colors.
- 5 20. The method as set forth in claim 17, wherein said plurality of descriptors comprises a plurality of tags.
21. The method as set forth in claim 17, wherein said plurality of descriptors comprises a plurality of statistical parameters.
- 10 22. The methods as set forth in claim 16, further comprising the step of providing a manager with a plurality of tools to manage at least one data capture and management operation.
- 15 23. The method of claim 22, further comprising the step of providing means to display information of said at least one data capture and management operation.
24. The method as set forth in claim 16, further comprising the step of providing means to manipulate said data in said plurality of cells.
- 20 25. The method as set forth in claim 24, wherein said step of providing means to manipulate said data comprises means to copy, cut, paste, edit, undo, drag, or delete.
- 25 26. The method as set forth in claim 16, further comprising the step of providing means to manipulate said corresponding data in said data sheet.

27. The methods as set forth in claim 26, wherein said step of providing means to manipulate said data comprises means to copy, cut, paste, edit, undo, drag, or delete.

5           28. The device as set forth in claim 26, wherein said step of providing means to manipulate said data comprises means to use radio buttons, sliders, data menus, or click boxes.

29,       The device as set forth in claim 16, further comprising the step of providing means  
10       to calculate said data.

30.       The device as set forth in claim 16, further comprising the step of providing one or more additional means of activating said cell of interest.

15

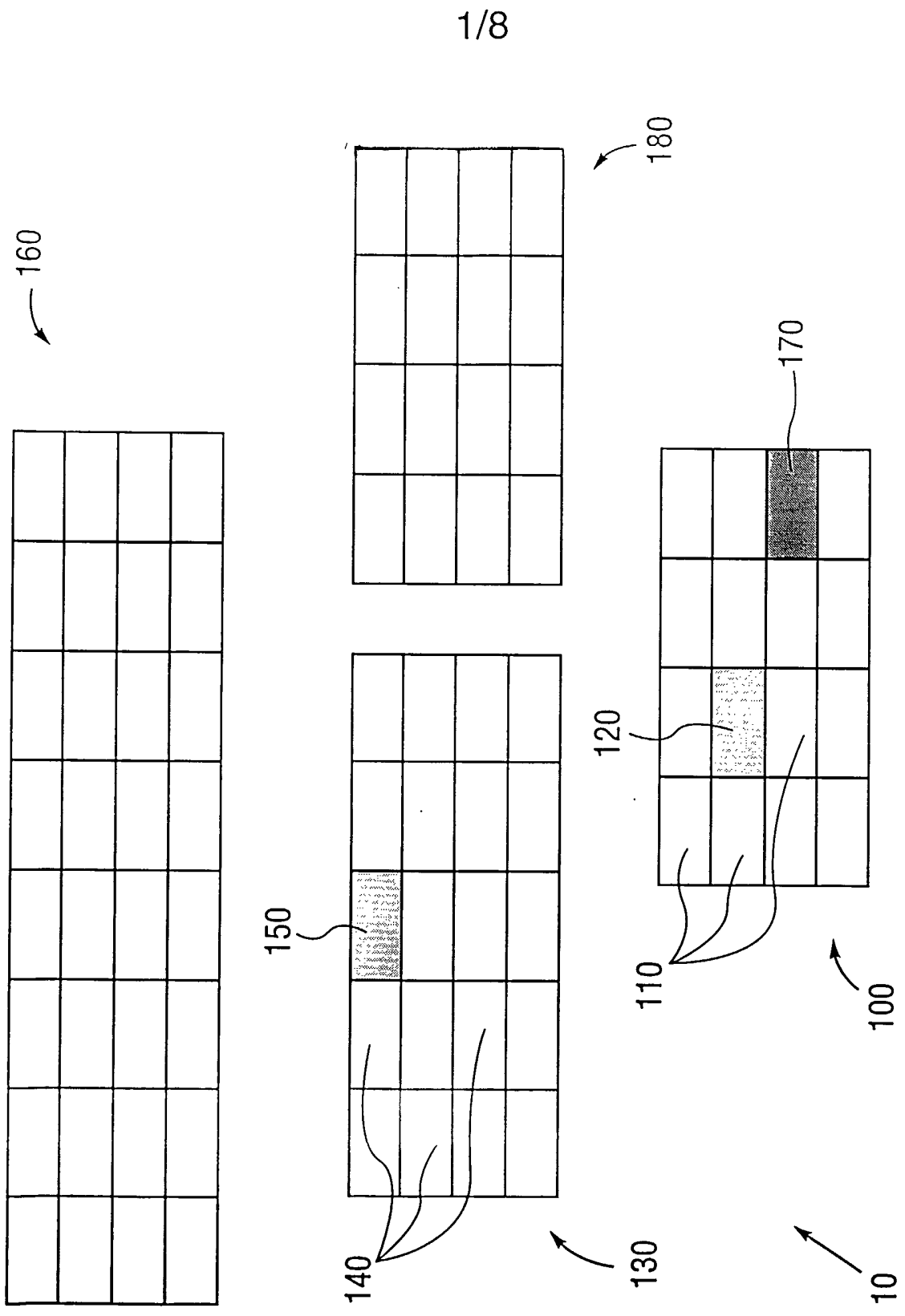


Figure 1

HealthDataNet - SKB101 - Dr. Smith - Microsoft Internet Explorer

HealthDataNet Patient List Trial SKB101 Print Help

Dr. Smith's patient involved in trial SKB101

Patients eligible for enrollment

Id #	Informed Consent	Screening	Inclusion criteria	Exclusion criteria	Randomization
FF13	11/15/2000	11/21	1/7	required	

Patients enrolled in the trial

Id #	Inclusion Date	Sc	V1	V2	V3	V4	V5	V6	V7	LV	FU
DD 7	01/22/2001	12/20									
FG 10	01/25/2001	01/25	02/02	02/08-02/10							
XX 1	11/01/2000	10/04	11/10	11/20	11/25	12/01-12/03					
AA 2	12/19/2000	11/09	11/15	11/20	11/26-11/28						
BB 5	12/21/2000	12/18	12/18	12/25	12/31-01/02						
DD 8	12/21/2000	12/21	12/20	12/26	02/21	12/27-03/01					
CC 6	12/26/2000	12/26	01/01-01/03								
gf 9	12/28/2000	12/05	12/12	12/19	12/25-12/27						

220 ↑ 222 230A 223 240 230C

221 210 230A 230B 230C 230D 230E

260 205

Loaded patient 'DD'. Missing Data Completed Flagged data: Invalid data Validated on site:

Start Microsoft Excel HDN Server HealthDataNet Login-Mic HealthDataNet - SKB... 12:53 PM

Figure 2

200



420

Patient: gf (# 9) Trial: SKB101 430

Initials: gf Number: 9 Status: Included Sex: Female Age: 45

Random #: 556363 Unit #: 122 Consent: 12/06/2000 Inclusion: 12/28/2000 End:

	Screening	Visit1	Visit2	Visit3	Visit4	Visit5	Visit6	Visit7	Last Visit
Date	12/05/2000	12/12/2000	12/19/2000	12/25-12/27	+ [6-8]	+ [6-8]	+ [6-8]	+ [6-8]	+ [6-8]
Inclusion criteria	OK								
Exclusion criteria	OK								
Randomization	#556363								
Medical History	12/28/2000								
Tumor Assessment	4 cm								
Pregnancy test	Negative								
GOG	1								
Physical Exam	12/28/2000		01/24/2001	Brief	Brief	Brief	Brief	Brief	Brief
Vital Signs / BSA	1.74 m <sup>2</sup>	1.66 m <sup>2</sup>	before	before	before	before	before	before	before
CA-125	65 U/ml								
SKB101 infusion	700 mg	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>
CBC	01/25/2001	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
Chem 20	140 nmol/l	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
Toxicity Assessment									
Signoff	[required]	required	required	required	required	required	required	required	required
Adverse events		to check	to check	to check	to check	to check	to check	to check	to check
Other Medications	1	1	1	1	1	1	1	1	1
Other Exams	to check	to check	to check	to check	to check	to check	to check	to check	to check

440

450

410

Figure 4

cbu

**Patient** (gf (#9)) **Trial** SKB101 **Print** **Help** **Back to list**  
 Initials: gf Number: 9 Status: Included Sex: Female Age: 45  
 Random #: 556363 Unit #: 122 Consent: 12/06/2000 Inclusion: 12/28/2000 End:

	Screening	Visit1	Visit2	Visit3	Visit4	Visit5	Visit6	Visit7	Last Visit
Date	12/05/2000	12/12/2000	12/19/2000	12/25-12/27	after infusion	after infusion	after infusion	after infusion	after infusion
Inclusion criteria	OK								
Exclusion criteria	OK								
Randomization	#556363								
Medical History	12/28/2000								
Tumor Assessment	4 cm								
Pregnancy test	Negative								
GOG	1								
Physical Exam	12/28/2000	01/24/2001	Brief	Brief	Brief	Brief	Brief	Brief	Brief
Vital Signs / BSA	1.74 m <sup>2</sup>	1.66 m <sup>2</sup>	before	before	before	before	before	before	before
CA-125									
SKB101 infusion			440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>
CBC			after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
Chem 20			after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
Toxicity Assessment			after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
Signoff			required	required	required	required	required	required	required
Adverse events			to check	to check	to check	to check	to check	to check	to check
Other Medications			to check	to check	to check	to check	to check	to check	to check
Other Exams			to check	to check	to check	to check	to check	to check	to check

**Vital Signs**

Date	12/01/2000
Height	65 in
Weight	145 lb
Temperature	98 F
Temperature site	Oral
Pulse	65
Pulse type	Regular
Respiration	13
Stop	135 mmHg
Dbp	56 mmHg

570 520 540 570 550 530 510

Figure 5



Data validation Trial SKB101 **Print** **Help** **Add Patient**

Validation status of collected forms

Not/ Available Data

Confirmed Data 620

Initials	Patient	Form	Visit
XX	1	Date: 10/04/2000	Screening
AA	2	Date: 11/15/2000	Visit 1
gf	9	SKB101 infusion: 700 mg	Visit 1
DD	8	SKB101 infusion: 800 mg	Visit 1
XX	1	Signoff: 11/09/2000	Screening

Flagged Data 630B 630A

Initials	Patient	Form	Visit
FF	3	CA-125: 14 U/ml	Screening
FF	3	Inclusion criteria: 1/7	Screening
AA	2	SKB101 infusion: 710 mg	Visit 1
XX	1	Vital Signs: 1.71 m <sup>2</sup>	Visit 1
XX	1	Vital Signs: 11/27/2000	Visit 2

Validated Data 630C 630

Initials	Patient	Form	Visit
XX	1	Chem 20: 15mmol/l	Screening
XX	1	Exclusion criteria: ok	Screening
XX	1	GOG: 1	Screening
XX	1	history: 11/20/2000	All Visits
XX	1	history: 11/21/2000	Screening
XX	1	Tumor Assessment: 13 cm	Screening
fg	10	Vital Signs: 1.85 m <sup>2</sup>	Visit 1

Invalid Data 670 630D 650

Initials	Patient	Form	Visit
BB	5		Screening
DD	8		Visit 3
DD	8		Visit 1
DD	8		Screening
DD	8		Visit 3
FG	10		Screening

Forms	
Date	02/02/2001
Height	170 cm
Weight	160 lb
Temperature	99 F
Temperature site	Oral
Pulse	65
Pulse type	Regular
Respiration	45
Sbp	135 mmHg
Dbp	70 mmHg

660

640

610

Figure 6



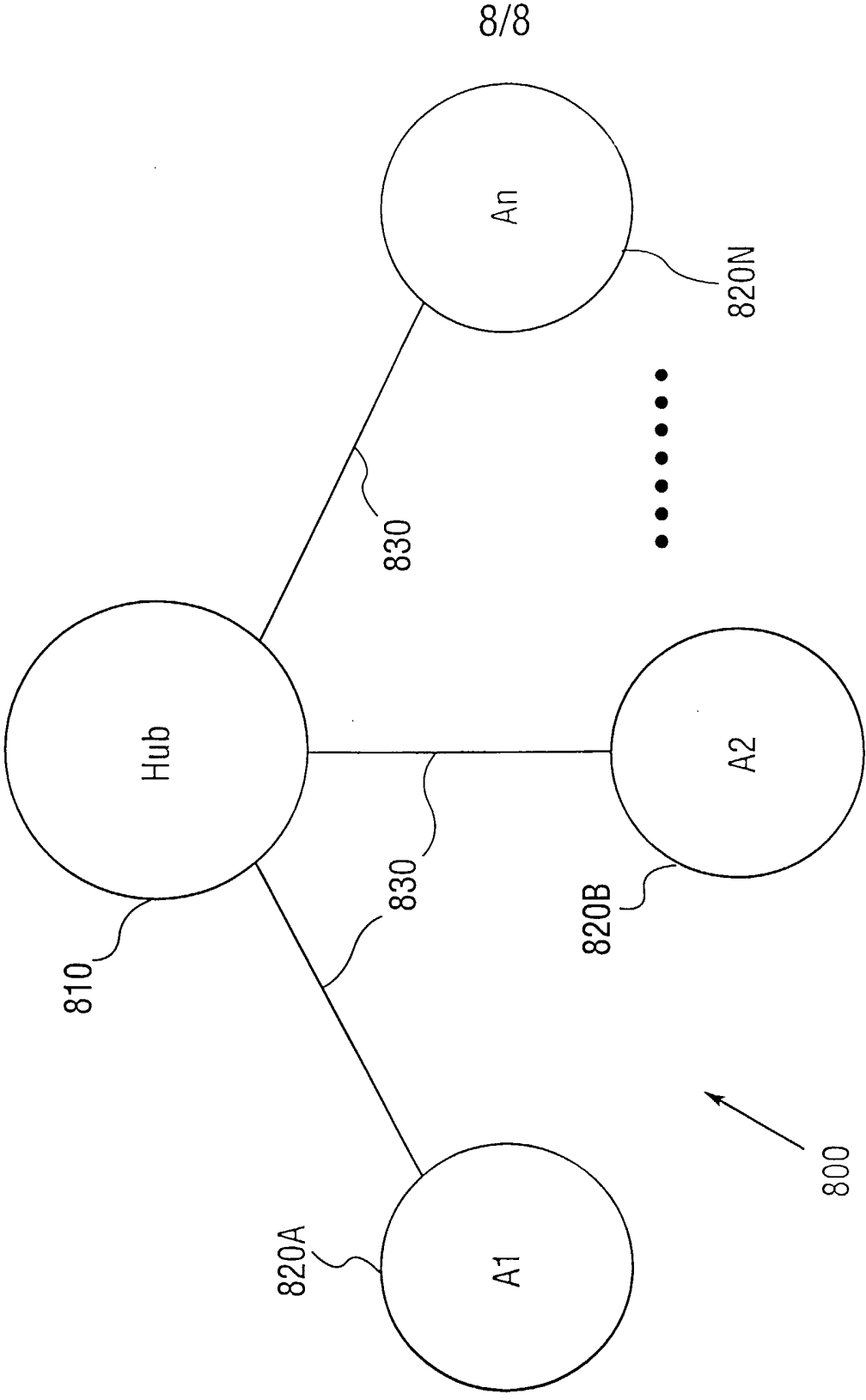


Figure 8

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US02/32547

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
IPC(7) : G06F 7/00 US CL : 715/503-509, 513		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) U.S. : 715/503-509, 513		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) USPAT, USPG-PUB, EPO, JPO, DERWENT, IBM TDB		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,416,895 A (ANDERSON et al) 16 May 1995, column 3, lines 42-67, column 4, lines 1-14.	1-30
A	US 5,623,282 A (GRAHAM et al) 22 April 1997, column 2, lines 20-50	1-30
A	US 6,298,342 B1 (GRAEFE et al.) 02 October 2001, column 3, lines 7-67, column 4, lines 1-12	1-30
A	US 6,292,809 B1(EDELMAN) 18 September 2001, column 2, lines 1-50.	1-30
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search	Date of mailing of the international search report	
27 January 2003 (27.01.2003)	25 FEB 2003	
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer STEPHEN HONG	
Facsimile No. (703)305-3230	Telephone No. (703) 305-3900	