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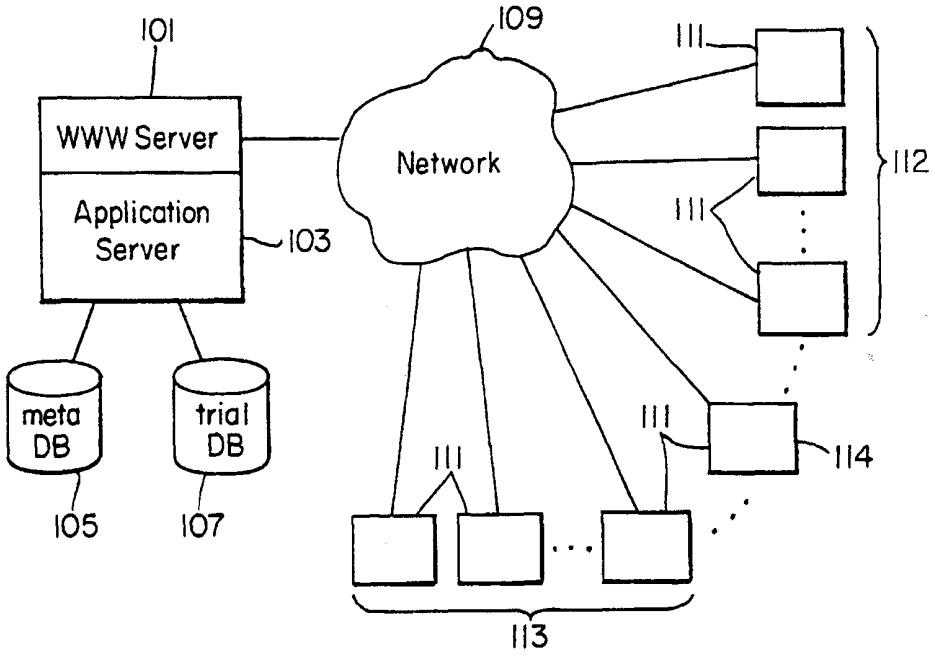
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(54) Title: CLINICAL TRIAL DATA MANAGEMENT SYSTEM AND METHOD

(57) Abstract

A system and method for managing clinical trial data includes dynamically generating, at a server, a data entry form to be displayed at a client. The data entry form is generated dynamically in a SGML–derived language. Control elements within the form comprise images which are used to construct the control elements and larger controls. The form is generated from a protocol database and a context received from the client, is populated from the data database, and is published to the client. Templates based on the protocol database comprise several frames including intermediate frames for displaying frame borders which are non–horizontal and non–vertical. If the trial protocol changes during a trial, the generated form is based on the protocol version active at the time data was entered into the form. Inadvertent use of the application is discouraged requiring an authentication procedure and displaying a picture of the authenticated user. Furthermore, help is provided by creating a link between the text of each question and information about the question. The source of help may be any or all of a protocol document, an investigative brochure, and a study guide. In addition, a user, upon logging in, is presented with a dashboard screen which provides information or links to information such as trial–related news, alerts, statistical information, progress reports and a list of work to be completed.



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INTERNATIONAL SEARCH REPORT

Inte onal Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G06F19/00 G06F9/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G06F

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KIUCHI T ET AL: "Automated generation of a World Wide Web-based data entry and check program for medical applications" COMPUTER METHODS AND PROGRAMS IN BIOMEDICINE, FEB. 1997, ELSEVIER, NETHERLANDS, vol. 52, no. 2, - February 1997 (1997-02) pages 129-138, XP002123139 ISSN: 0169-2607 the whole document --- -/--	1-56

[X] Further documents are listed in the continuation of box C.

[ ] Patent family members are listed in annex.

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Int ional Application No
PCT/US 99/12406

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	KELLY M A ET AL: "The Internet and randomised controlled trials" INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS,IR,ELSEVIER SCIENTIFIC PUBLISHERS, SHANNON, vol. 47, no. 1-2, - 1997 page 91-99 XP004107516 ISSN: 1386-5056 the whole document	1-56
A	"MULTI-STATE BUTTON MANIPULATION USING A SINGLE GRAPHIC" IBM TECHNICAL DISCLOSURE BULLETIN,US,IBM CORP. NEW YORK, vol. 38, no. 4, page 585-587 XP000516262 ISSN: 0018-8689 the whole document	5,24,25, 28-31, 35,36, 43,44, 46,47, 50,53,54
A	ANONYMOUS: "Efficient 3D Buttons in Dynamic Hyper Text Markup Language Pages" IBM TECHNICAL DISCLOSURE BULLETIN, vol. 41, no. 1, pages 695-698, XP002123140 New York, US the whole document	5,24,25, 28-31, 35,36, 43,44, 46,47, 50,53,54
A	GIRGENSOHN A ET AL: "Seamless integration of interactive forms into the Web" COMPUTER NETWORKS AND ISDN SYSTEMS,NL,NORTH HOLLAND PUBLISHING. AMSTERDAM, vol. 29, no. 8-13, page 1531-1542 XP004095347 ISSN: 0169-7552 the whole document	7-17,42
A	NETSCAPE COMMUNICATIONS CORP.: "NetHelp" NETHELP RELEASE 1.0 SDK DOCUMENTATION, 'Online! - August 1996 (1996-08) pages 1-14, XP002071214 USA Retrieved from the Internet: <URL:http://home.nestcape.com/eng/help/sdk 1/sdksite.htm> 'retrieved on 1998-07-10! the whole document	7-17,42

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