(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau





(43) International Publication Date 25 August 2005 (25.08.2005)

PCT

(10) International Publication Number WO 2005/078628 A3

(51) International Patent Classification: *G06F 19/00* (2006.01)

(21) International Application Number:

PCT/EP2005/050602

(22) International Filing Date:

10 February 2005 (10.02.2005)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/545,168 18 February 2004 (18.02.2004) US 10/975.057 28 October 2004 (28.10.2004) US

(71) Applicant (for all designated States except US): SIEMENS AKTIENGESELLSCHAFT [DE/DE]; Wittelsbacherplatz 2, 80333 München (DE).

(72) Inventors; and

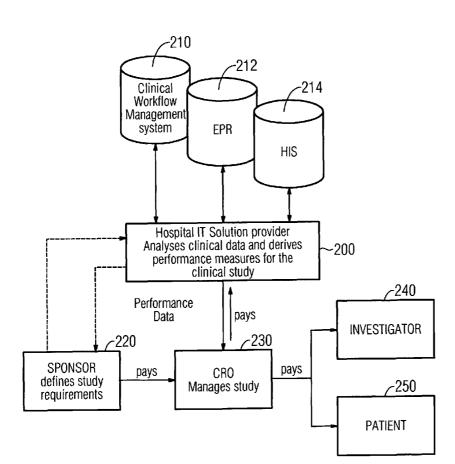
(75) Inventors/Applicants (for US only): ABRA-HAM-FUCHS, Klaus [DE/DE]; Graslitzer Str. 17, 91058 Erlangen (DE). RUMPEL, Eva [DE/DE]; Anton-Bruckner-Str. 16, 91052 Erlangen (DE). SCHMIDT,

Markus [DE/DE]; Bucherstr. 39a, 90419 Nürnberg (DE). SCHNEIDER, Siegfried [DE/DE]; Kulmbacher Str. 33, 91056 Erlangen (DE). SCHREINER, Horst [DE/DE]; Erlanger Str. 63, 90765 Fürth (DE). ZAHLMANN, Gudrun [DE/DE]; Johann-Mois-Ring 15a, 92318 Neumarkt (DE).

- (74) Common Representative: SIEMENS AKTIENGE-SELLSCHAFT; Postfach 22 16 34, 80506 München (DE).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH,

[Continued on next page]

(54) Title: METHOD OF IMPROVING A CLINICAL STUDY



(57) Abstract: A method is proposed for improving a clinical study. The method includes obtaining criteria for the clinical study, and comparing clinical data the obtained criteria using a computer device. Thereafter, using the computer device, performance measures derived based upon comparisons. These derived performance measures then usable to improve the clinical study. For example, these performance measures may be used for ranking, and consequently improving, clinical study.

WO 2005/078628 A3



GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

with international search report

- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report: 9 March 2006

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



International Application No CT/EP2005/050602

		- 1017	£P2005/05000Z		
A. CLASSIF	FICATION OF SUBJECT MATTER G06F19/00				
According to	International Patent Classification (IPC) or to both national classification	ation and IPC			
B. FIELDS S	SEARCHED				
Minimum doo	cumentation searched (classification system followed by classification $G06F$	on symbols)			
	on searched other than minimum documentation to the extent that s				
	ata base consulted during the international search (name of data base ternal, PAJ, INSPEC, COMPENDEX, BIOS		erms usea)		
ELO-III	ternar, PAO, INSPEC, COMPENDEX, BIOS	113			
C. DOCUME	NTS CONSIDERED TO BE RELEVANT		,		
Category °	Citation of document, with indication, where appropriate, of the rele	evant passages	Relevant to claim No.		
	-	-/			
		·			
<u></u>					
X Furth	er documents are listed in the continuation of box C.	X Patent family members	are listed in annex.		
° Special cat	tegories of cited documents :	"T" later document published after	er the international filing date		
conside	nt defining the general state of the art which is not ered to be of particular relevance		onflict with the application but ciple or theory underlying the		
filing da	ate		or cannot be considered to		
which i	nt which may throw doubts on priority claim(s) or is ciled to establish the publication date of another i or other special reason (as specified)	"Y" document of particular releva	nen the document is taken alone ance; the claimed invention olve an inventive step when the		
other n		document is combined with	one or more other such docu- eing obvious to a person skilled		
later th		*&" document member of the sar	ocument member of the same patent family		
	actual completion of the international search	Date of mailing of the interna	ational search report		
20 December 2005		17/01/2006			
Name and m	nailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk	Authorized officer			
	NL - 2200 FM Hijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Barba, M			



International Application No

		C1/EP2005/050602				
C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT						
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.				
X	"THE TRIAL BRIDGE FRAMEWORK" CTIS CONFIDENTIAL, 'Online! 2001, pages 1-16, XP002360334 Retrieved from the Internet: URL:http://www.ctisinc.com> 'retrieved on 2005-12-01! page 1, right-hand column, line 28 - page 2, right-hand column, line 37 - page 4, right-hand column, line 37 - page 4, right-hand column, line 13 page 5, left-hand column, line 11 - line 26 page 6, left-hand column, line 1 - right-hand column, line 31 page 8, left-hand column, line 38 - page 9, left-hand column, line 32 - page 10, right-hand column, line 3 page 13, left-hand column, line 7 - right-hand column, line 7 - right-hand column, line 7 -	1-144				
X	page 15, right-hand column, line 7 - page 16, left-hand column, line 41 ———— M. DESMET ET AL: "THE CHALLENGE OF AUDITING CLINICAL LABORATORIES" DRUG INFORMATION JOURNAL, 'Online! vol. 31, 1997, pages 197-205, XP002360335 USA Retrieved from the Internet: URL:http://www.diahome.org> 'retrieved on 2005-12-01! page 197, left-hand column, line 1 - page 200, left-hand column, line 26 page 200, left-hand column, line 28 - page 201, left-hand column, line 41 page 202, left-hand column, line 45 - page 204, left-hand column, line 43	1-144				
X	US 2003/191664 A1 (BLUMENFELD T H) 9 October 2003 (2003-10-09) paragraph '0005! - paragraph '0014! paragraph '0027! - paragraph '0049! paragraph '0051! - paragraph '0055!	1-144				
X	WO 01/93178 A (FASTTRACK SYSTEMS, INC) 6 December 2001 (2001-12-06) page 3, line 30 - page 4, line 12 page 5, line 10 - page 8, line 9 page 8, line 23 - page 17, line 10 page 20, line 22 - page 21, line 26 page 24, line 8 - page 29, line 28	1-144				
X	US 2003/097291 A1 (FREEDMAN L J) 22 May 2003 (2003-05-22) the whole document	1-144				

International Application No CT/EP2005/050602

		P2005/050602					
C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT							
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.					
A	WO 02/075477 A (ELI LILLY AND COMPANY; CRAWFORD, ANN, MARIE; CRIST, BARRY, DEAN; HADDA) 26 September 2002 (2002-09-26) page 3, line 1 - page 4, line 10 page 6, line 14 - page 7, line 30 page 12, line 5 - line 26 page 22, line 7 - page 23, line 14	1-144					
A	GOUVEIA-OLIVEIRA A ET AL: "A database system for integrated clinical trial management, control, statistical analysis and ICH-compliant reporting." PROCEEDINGS / AMIA ANNUAL SYMPOSIUM. AMIA SYMPOSIUM. 1999, 1999, pages 72-76, XP002360336 ISSN: 1531-605X page 72, left-hand column, line 23 - right-hand column, line 30 page 72, right-hand column, line 35 - page 74, left-hand column, line 28 page 74, right-hand column, line 39 - page	1-144					
	76, left-hand column, line 11						
	•						
		,					
		4					
4							
		,					
•							
		·.					



Information on patent family members

International Application No CT/EP2005/050602

	Publication date	Patent family member(s)			Publication date
A1	09-10-2003	US	2005102162	A1	12-05-2005
Α	06-12-2001	AU EP JP	1364333	A2	11-12-2001 26-11-2003 25-03-2004
A1	22-05-2003	NONE			
Α	26-09-2002	NONE		<u> </u>	
	A A1	A1 09-10-2003 A 06-12-2001 A1 22-05-2003	A1 09-10-2003 US A 06-12-2001 AU EP JP A1 22-05-2003 NONE	A1 09-10-2003 US 2005102162 A 06-12-2001 AU 6520501 EP 1364333 JP 2004509383 A1 22-05-2003 NONE	A1 09-10-2003 US 2005102162 A1 A 06-12-2001 AU 6520501 A