EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 December 2013
EMA/INS/GCP/504197/2013
Compliance and Inspection

Minutes of joint meeting of GCP IWG and eClinical Forum (eCF) representatives on electronic data capture systems and investigator site eSource readiness

11 June 2013 15:00-18:00, meeting room 2D

Chair: Fergus Sweeney

Agenda Item	
1.	Introduction of participants The 11 eClinical forum representatives introduced themselves to the GCP IWG. A list with the participants' affiliation has been included at the end of this document.
2.	Adoption of draft agenda, 11 June 2013 (15:00-18:00) The agenda was adopted with no amendments.
3.	**Electronic data capture systems** The eCF representatives explained the purpose of the meeting which was to clarify the requirements expressed by the EMA GCP IWG in order to ensure that industry is in line with those expectations.
3.1	**Data transcription and hosting models** The eCR representatives gave a presentation on 'EDC data transcription & hosting models'. The presentation covered the following topics: • general background, • rationale for extending the requirement of source data to transcribed data, • contemporaneous independent investigator site copy, • exclusive control by the sponsor. For each topic presented, a list of specific questions was addressed to the GCP IWG for clarification and discussion. The main points highlighted during the discussions are as follows:

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Agenda Item	
	• The requirements mentioned in the GCP IWG reflection paper are set for both source data as well as transcribed data. • The eCRF becomes a source document for data entered directly into it. • It is essential that the principal investigator (PI) maintains an independent (i.e. out of the sponsor's control), contemporaneous copy of the CRF for which he has exclusive control. This could be at the PI site, although, it could also be maintained at an independent site/vendor when assuring the investigator's continuous access. The inspectors expressed their preference for an independent copy of the CRF to be maintained at the investigator's site (print out, solid media memory device, local server etc.), instead of an independent vendor controlling the PI copy in a central database, since the details of the contractual arrangements between the 3rd party and the sponsor (i.e. complete independence from sponsor) and access by the PI in the long term would become a challenge. Nevertheless, the choice remains the sponsor's and either solution is acceptable as long as the requirements detailed in the reflection paper are fulfilled. The responsibility for archiving and maintaining the CRF at the investigator site, regardless of whether it is paper or electronic, is the responsibility of the investigator and not the sponsor. The eCF representatives concluded their presentation by describing 6 EDC models that are in use today, in order to clarify compliance with the requirements of the legislation. The GCP IWG pointed out that the models presented did not seem to fulfil the current requirements and would therefore not be acceptable to the group. The group acknowledged that some solutions could take time to develop; however, in the meantime sponsors should implement mitigating actions since any solution where the server is under the control of the sponsor is not acceptable and has been implemented without ensuring that the systems are in line with current requirements. As a final conclusion, both parties acknowledged the importance of this meeting which has given the opportunity to the GCP IWG to remind the participants of requirements for EDC systems used in clinical trials. In addition, this meeting has assisted the eCF representatives in thinking about further solutions on how EDC vendors could provide the pharmaceutical industry with EDC systems which would be compliant with the current legislation.
4.	**Investigator site eSource readiness**
4.1	Document and tool on investigator site eSource readiness, presentation The eCF eSource sub-team representatives introduced the eClinical forum's Investigator Site eSource-readiness Assessment Project to the GCP IWG. The presentation included the reasons for assessing EHR and the need to develop a standardised assessment tool followed by an overview of the site assessment tool. The tool has been piloted by a total of 14 sites in the EU, US and Canada with positive feedback. The next steps are to further improve the tool based on the feedback received by the pilot sites, EHR vendors and regulators. It is envisaged that the tool will be made available via the eCF website.

Agenda Item	
	The GCP IWG welcomed this initiative and generally felt that this would be a very valuable tool for site selection but pointed out some practical issues that should be taken into consideration such as: • some sites do not use EHR whereas for others (for example Sweden) it is mandatory; • there is a danger of putting additional burden on the PI by having to fill in this form. The PI may not even be the most knowledgeable person to answer this; • it may be better to receive feedback at a hospital/county/country level rather than from individual PIs. The inspectors agreed to review the assessment tool in more detail within the eSource subgroup and provide eCF with their comments. The chair asked the eCF group to continue communicating with the GCP IWG on this topic and provide feedback on the progress of the assessment tool. A similar meeting could be scheduled for the future, if considered necessary.

Table 1. eClinical forum representatives at the GCP IWG meeting

Group	Company
Pharma	Boehringer Ingelheim Pharma GmbH & Co. KG
Pharma	Bristol-Myers Squibb International Corporation
Pharma	Novartis Vaccines and Diagnostics
EDC/Data Processing	Oracle Health Sciences Global Business Unit (HSGBU)
EDC/Data Processing	Pharma Consulting Group AB
Data Management Association	Arnoult.org
Quality & Regulatory Affairs	Medidata Solutions
Consulting	ConSept Consulting
Pharma	Bristol-Myers Squibb International Corporation
Pharma	Eli Lilly
EHR Vendor	iSOFT GmbH, a CSC company