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Compliance and Inspections

Annual report of the Good Clinical Practice Inspectors Working Group 2014

Adopted by the GCP IWG on 05 March 2015

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1. Introduction

This document is the seventh annual report of the GCP IWG¹. This group was established in 1997 under the scope of Article 57(1)(i) of Regulation (EC) No. 726/2004.

The GCP IWG focuses on harmonisation and co-ordination of GCP related activities at EU² level. The group's role and activities are described in more detail in its [mandate](#), which was revised in 2013, the [work plan](#) and also in [volume 10](#), chapter IV, of the Rules Governing Medicinal Products in the European Union.

The group supports the co-ordination of the provision of GCP advice and maintains a dialogue with other groups such as CHMP³, CVMP⁴, CMDh⁵, PhV IWG⁶, GMP/GDP⁷ IWG and other groups, as needed, on areas of common interest.

This annual report is set out in line with the format and objectives of the 2014 [work plan](#).

2. Meetings

The plenary GCP IWG meetings took place on:

- 05-06 March 2014
- 03-04 June 2014
- 16-17 September 2014
- 02-03 December 2014

During 2014, the following GCP inspectors' subgroups/working parties were involved in the discussion of specific topics and drafting documents:

- GCP/CMDh working party (refer to section 7.4);
- GCP/CHMP assessors subgroup (refer to section 4.1);
- GCP TMF⁸ (refer to section 5, 3rd bullet point);
- GCP IWG subgroup, subgroup G, on the preparation of the functional aspects of the EU Portal and database required by the new Clinical Trial Regulation-Reg 536/2014 in relation to inspections, including handling of serious breaches (refer to section 6.1, 3rd bullet point).

¹ Good Clinical Practice Inspectors Working Group

² European Union

³ Committee for Medicinal Products for Human Use

⁴ Committee for Medicinal Products for Veterinary Use

⁵ Coordination Group for Mutual Recognition and Decentralised Procedures - Human

⁶ Pharmacovigilance Inspectors Working Group

⁷ Good Manufacturing Practice/Good Distribution Practice

⁸ Trial Master File

3. Inspections conducted in support of the centralised procedure and under national programmes

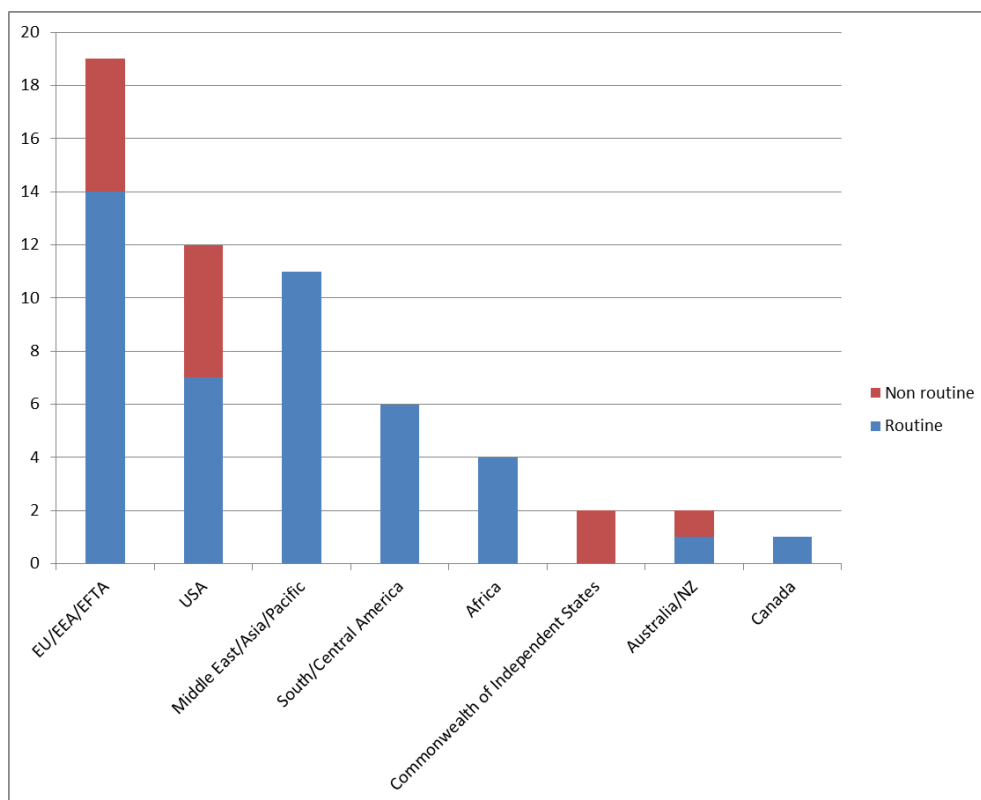
3.1. CHMP requested inspections

3.1.1. General overview

The CHMP requested 66 GCP inspections in 2014. In total, 57 GCP inspections were carried out by the inspectorates of the EU member states in the same year. The number of inspections requested and conducted is not consistent due to the fact that several inspections requested in the last 3 months of the year 2013 were conducted in 2014 and some inspections requested in the last 3 months of 2014 will be carried out in 2015. The data in this report relates to inspections carried out.

In figure 1, the number of inspections carried out in 2014 is shown by region and type of inspection. Most inspections were carried out in the EU/EEA⁹/EFTA¹⁰ (33.3%) followed by inspections in the USA (21.1%) and the Middle East/Asia/Pacific (19.3%).

Figure 1: Inspections conducted per region and type of inspection



⁹ European Economic Area

¹⁰ European Free Trade Association

Table 1: Number of inspections conducted per region and type of inspection.

Region	Non-Routine	Routine	Total
EU/EEA/EFTA	5	14	19
USA	5	7	12
Middle East/Asia/Pacific	-	11	11
South/Central America	-	6	6
CIS	2	-	2
Canada	-	1	1
Africa	-	4	4
Eastern Europe (non EU)	-	-	-
Australia/New Zealand	1	1	2
Total in all regions	13	44	57

Figure 2: Inspections conducted per type of site

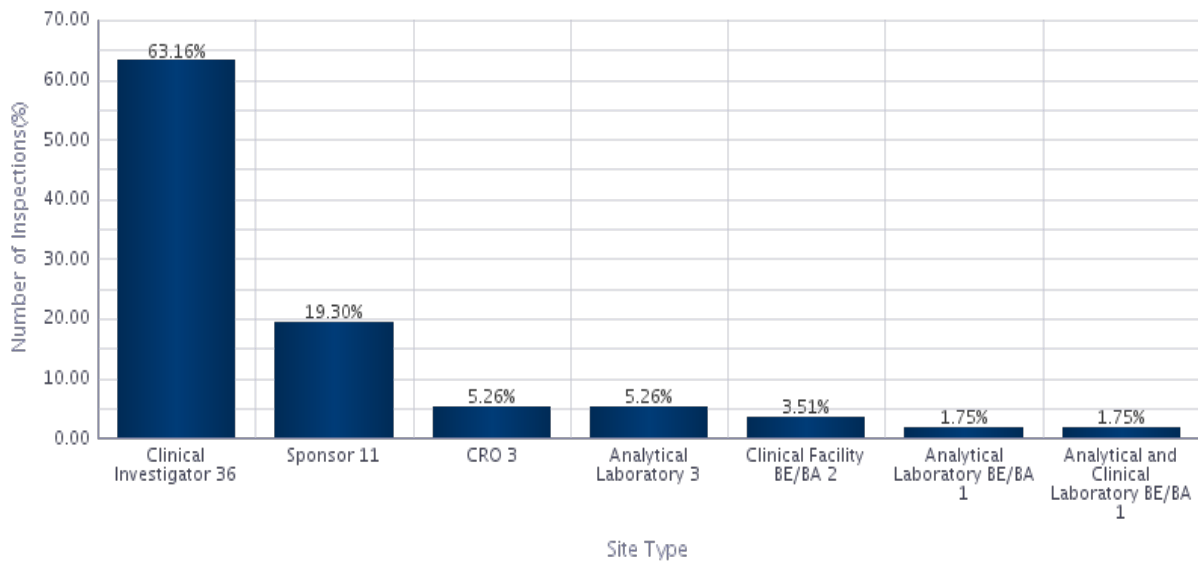


Figure 2 represents the number of inspections conducted in 2014 per type of site. Most inspections were conducted at clinical investigator sites.

3.1.2. Categorisation of findings

A total of 673 deficiencies, comprising 30 critical (4.46%), 290 major (43.09%) and 353 minor (52.45%) were recorded for the 57 CHMP requested inspections conducted in 2014.

The main findings observed in the 2014 inspections are detailed below in accordance with the GCP categorisation of findings agreed by the GCP IWG.

Figure 3: Number of findings with regard to the main categories graded by critical, major and minor

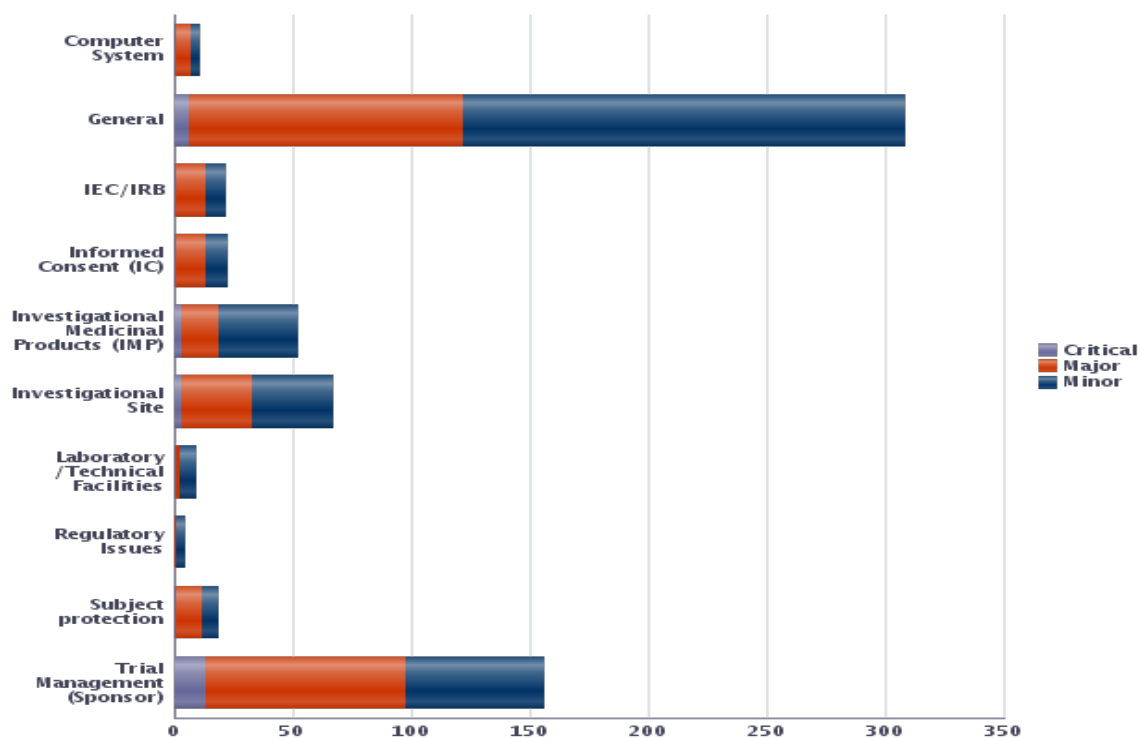


Table 2: Number of findings per sub-category of the top 3 main categories (general, trial management and investigational site) graded by critical, major and minor.

Number of findings per sub-category of the top 3 main categories (general, trial management and investigational site) graded by critical, major and minor					
Deficiency category name	Deficiency sub-category name	# Inspected deficiencies			# Inspected deficiencies total
		Critical	Major	Minor	
General	Contracts/agreements	1	8	8	17
	Direct access to data	-	2	2	4
	Essential documents	4	42	73	119
	Facilities and equipment	-	2	7	9
	Organisation and personnel	-	7	18	25
	Qualification/training	-	12	21	33
	SOPs ¹¹	1	22	22	45
	Source documentation	-	21	36	57
General total		6	116	187	309
Trial management (sponsor)	Audit	-	6	1	7
	CSR ¹²	-	17	10	27
	Data management	4	28	17	49
	Document control	-	4	6	10
	Monitoring	6	20	17	43
	Protocol/CRF ¹³ /diary/questionnaires design	2	7	7	16
	Statistical analysis	1	3	-	4
Trial management (sponsor) total		13	85	58	156
Investigational site	Protocol compliance (assessment of efficacy)	-	-	1	1
	Protocol compliance (others)	1	4	5	10
	Protocol compliance (safety reporting)	1	8	8	17
	Protocol compliance (selection criteria)	-	9	1	10
	Reporting in CRF/diary	1	9	19	29
Investigational site total		3	30	34	67

¹¹ Standard Operating Procedures

¹² Clinical Study Report

¹³ Case Report Form

Examples of cross section (critical, major, minor) findings in the top sub-categories of the main three categories "general", "trial management" and "investigation site" are listed below:

General

Essential documents:

- lack of essential documents e.g. receipt of IMP¹⁴ shipment to site, records of blood samples shipment to the central laboratories;
- incomplete documentation (e.g. incomplete screening list);
- lack of contemporaneous independent copy of the CRF filed on site.

SOPs:

- lack of evidence that sponsor SOPs have been followed and used;
- SOPs not update as required;
- sponsor failure to implement an efficient quality management system.

Source documentation:

- discrepancies between source data and data reported in the CSR;
- missing source documents;
- lack of document specifying location of source data.

Qualification/training:

- incomplete training documentation;
- lack of training of study personnel on trial related procedures.

Organisation and personnel:

- incomplete site personnel signature log;
- tasks performed by staff not authorised to do so.

Trial management

Data management:

- inappropriate system for reporting protocol violations;
- laboratory reports were submitted late to the site;
- data management activities were only undertaken after the clinical conduct of the trial was completed;
- the decisions made by the DMSB¹⁵ were not communicated to the site.

¹⁴ Investigational Medicine Product

¹⁵ Data Monitoring Safety Board

Monitoring:

- monitor has not identified number of deficiencies on site;
- lack of escalation process to resolve issues identified by monitor;
- monitor not following monitoring plan;
- investigator's training was done over the phone.

Document control:

- lack of version/date on the document;
- late introduction of amendments in the study.

Investigational site

Protocol compliance (selection criteria):

- violation of a number of inclusion criteria for some patients;
- final decision about eligibility not always documented in hospital records.

Reporting in CRF/diary:

- several discrepancies between source data such as medical history, concomitant medication etc. and the CRF for a sample of subjects;
- corrections on CRF not signed and dated;
- data not reported in CRF in a timely manner.

Protocol compliance (others):

- IMP and concomitant medication protocol deviations;
- protocol visits were not performed within the visit windows specified in the protocol;
- the sponsor established and used a system of prospectively accepting deviations from the protocol;
- insufficient maintenance of blinding of IMP.

Protocol compliance (safety reporting):

- not all adverse events reported to the sponsor as required per protocol;
- instructions for SAE¹⁶ follow-up reports not followed;
- inadequate SAE documentation and reporting.

Protocol compliance (assessment of efficacy):

- site did not strictly follow the protocol criteria that had to be used to assess the disease status;
- the procedures for the primary end point assessment for patients were not always strictly followed as required by the clinical protocol.

¹⁶ Serious Adverse Event

3.2. GCP inspections performed under national programmes

The CHMP GCP inspections are just a small part of the total number of inspections performed by the EU/EEA inspectors as there are many others performed as part of their national programmes in the following contexts:

- oversight of the conduct of clinical trials in Europe;
- marketing authorisation applications (MRP¹⁷, DCP¹⁸ or national procedures).

The following statistics are based on information obtained from EudraCT¹⁹ and include the CHMP requested inspections.

Table 3: Inspections conducted per region

Region	Number of Inspections conducted in 2014
EU/EEA	300
North America	16
Rest of the world	47
Total in all regions	363

Figure 4: Number of inspections conducted per type of site



* The information has not been provided in EudraCT

¹⁷ Mutual Recognition Procedure

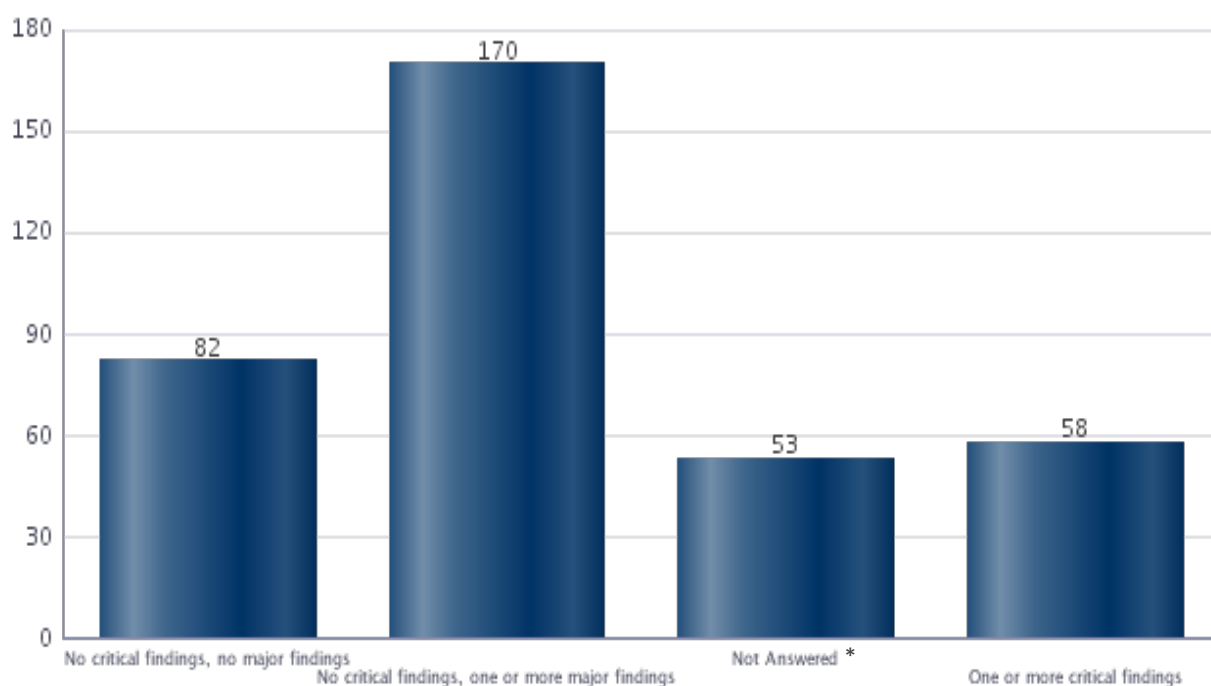
¹⁸ Decentralised Procedure

¹⁹ European Clinical Trials Database

Table 4: Trial specific vs. non-trial specific conducted inspections

Type of inspections	Number of inspections conducted in 2014
Trial specific	175
Non-trial specific	182
Not answered (information not provided in EudraCT)	6
Total	363

Figure 5: Inspection outcome in relation to the number of critical and major findings



* The information has not been provided in EudraCT

4. Harmonisation topics

4.1. Procedures and guidance documents

- The pilot phase of the [“Procedure for Reporting GCP inspections conducted in the context of the Centralised Procedure”](#) ended in 2014. The group began the revision of the procedure based on experience gained during the pilot phase.
- The group published the following document:
 - a revised version of the [“Procedure for coordinating GCP inspections requested by the CHMP”](#).

4.2. Inspection co-operation

- Co-operation between the Member States:
 - in 2014 the majority of the inspections requested by the CHMP were joint inspections involving inspectors from at least two Member States.
- Co-operation with 3rd countries:
 - observers from countries outside the EU have always been invited to observe the EU GCP inspections performed in those countries in the context of the centralised procedure. In 2014, out of the 38 inspections performed outside the EEA, at least 8 GCP inspections requested by the CHMP were observed by 3rd country regulatory authorities including Japan, South Korea and the USA. Three inspections were performed jointly with the USA.

4.3. GCP training and development

4.3.1. 2014 EU GCP Inspectors Working Group Workshop

In 2014 the EU GCP Inspectors' Working Group workshop took place in Paris on 17 – 19 November 2014. Participants included inspectors from the EEA (Austria, Belgium, Bulgaria, Croatia, Denmark, Estonia, Finland, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, United Kingdom), from countries outside the EEA (Brazil, Canada, Ghana, Japan, Republic of Korea, Russian Federation, Kingdom of Saudi Arabia, Serbia, Ukraine, Switzerland, Chinese Taipei, Malaysia, Chinese Taipei, USA).

The following topics were covered:

- The new EMA Question & Answer on data listings:
 - how should inspectors review and use the data listings during inspection preparation;
- Validation of computerised systems in clinical trials:
 - how to conduct an inspection of computer validation,
 - common findings in inspection of validation of computerised systems;
- Inspection of electronic data systems:
 - FDA's²⁰ experience,
 - Europe's experience;
- A practical demonstration on electronic data integrity;
- Categorisation and impact of inspection findings;
- International co-operation on GCP inspections:
 - needs and achievements in the area of GCP inspections,
 - observing EU national inspections- Ghana's experience in Italy,
 - PMDA's²¹ GCP questionnaire.

Break-out sessions were included with discussion points on the different topics covered in the agenda.

²⁰ U.S. Food & Drug Administration

²¹ Pharmaceuticals and Medical Devices Agency of Japan

4.3.2. 2014 EU GCP Bioequivalence Inspections Forum and training course

A BE²² Forum took place in Paris on 19 November 2014 in the afternoon. Participants included BE senior inspectors from EU/EEA, from WHO²³ and from Brazil (via telephone conference).

The following topics were covered:

- problems in the analysis of endogenous substances;
- choice of the internal standard – are there any rules for selection of internal standards (if a radiolabelled analyte is not available);
- smoothing – what is acceptable,
- acceptance and in/exclusion of calibration samples;
- data input – data output – data lock – data release - analytical run inspector expectation;
- data management and risk of data manipulation.

A BE inspections training course took place in Paris on 20 – 21 November 2014. Participants included inspectors from the EU and WHO.

The following topics related to bioequivalence trials were covered:

General aspects and clinical part:

- regulatory context,
- bioequivalence trials: definition, main characteristics,
- inspection of the clinical part of a bioequivalence trial,
- investigational medicinal product,
- ECGs²⁴;

Bioanalytical part:

- bioanalytical part of bioequivalence trials,
- what to inspect,
- chromatography: general considerations,
- examples of findings,
- hints and tips.

4.3.3. On-line GCP Inspectors' Basic Training Course

In 2014, the EMA on-line GCP inspectors' basic training course was published on EudraPortal. Access was also given to observer countries and Switzerland.

A webinar was organised on 27 June 2014 with the participation of more than 40 GCP inspectors from the EU, observer countries and Switzerland. The webinar was organised and chaired by the Agency and 6 senior EU GCP inspectors co-ordinated and led the different sessions. A number of general questions were discussed as well as the specific exercises which were sent to the participants in advance of the

²² Bioequivalence

²³ World Health Organization

²⁴ Electrocardiogram

webinar. Following the webinar the participants were asked to complete a quiz and certificates were issued to those who passed with 70% or more. The course will be repeated at least once in 2015 and is to become accessible to non-EU GCP inspectors.

4.3.4. GCP IWG meetings

During the GCP IWG meetings held in 2014, the following topics were addressed:

- update on the revision of the ICH-E6 GCP guideline and discussion on the new addendum;
- discussion on GCP compliance interpretation and ethical issues identified during inspections;
- discussion and development of peer review of product/company inspection related issues (bioequivalence and non-bioequivalence studies);
- developing and monitoring opportunities for joint inspections;
- discussion and response to queries received from stakeholders;
- how to optimise the use of inspection resources;
- update on EudraCT development.

5. Topics of interest

The GCP IWG published the following:

- Overview of comments received on ['Reflection paper on the use of interactive response technologies \(interactive voice/web response systems\) in clinical trials'](#).
- [Report on CHMP requested GCP inspections and their findings, 2000-2012](#).

The scope of this document is to communicate to the public, details on its inspection activity and provide further information on the inspection outcomes for the centralised procedure. The document provides greater transparency on the inspection process and findings and highlights the areas that require more attention. The analysis of the findings provides support for discussion and harmonisation of findings and their grading at the level of the GCP IWG. Finally, it is hoped that this document may help in prioritising areas for attention in future inspections, either in general or of specific company-types or sites.

- The group published the minutes from the following meetings with stakeholders which took place in 2013:
 - The [minutes of the joint meeting of the GCP IWG and eClinical Forum \(eCF\) representatives on electronic data capture systems and investigator site eSource readiness](#).
 - [Summaries of the presentations of the workshop on risk-based quality management in clinical trials 02-03/12/2013](#).
- A revised version of the TMF reflection paper was prepared and discussed within the group. The comments received during the public consultation were addressed by the members of the TMF subgroup. The group is working on the final version of the reflection paper which will be published in 2015.
- The group also revised the template of the announcement letter to the applicant of a GCP inspection requested by the CHMP.

- A new Question & Answer was published in the Agency external web site on [“How should data be presented when they are sent to the inspection team prior to a GCP inspection request by the CHMP”](#).

6. Collaboration with European Commission

6.1. Clinical Trial legislation and related guidance documents

- The group was regularly updated at its meetings, by the European Commission, on the progress of the draft Clinical Trial Regulation.
- The group has provided its comments on the provisions from Directives 2005/28/EC and 2003/94/EC, not taken up by the Clinical Trials Regulation, and which are to be put forward into an implementing regulation and delegated regulation respectively.
- The group began planning the revision of the GCP guidelines, reflection papers and inspection procedures to reflect the changes brought about by the new legislation.
- GCP IWG subgroup, on the preparation of the functional aspects of the EU Portal and database in relation to inspections (including handling of serious breaches).

The group has met on a regular basis since mid-2014 to gather the requirements for the recording in the EU database of inspection data for inspections planned and conducted by EU Member States. The group has also collected the requirements for the reporting of serious breaches to be notified by the clinical trial sponsors to the affected EU member states.

6.2. EudraCT database

The group was updated, on a regular basis, regarding the development of the EudraCT database. During the June GCP IWG meeting the inspectors were informed about the new features of EudraCT version 10.0 and a status update on the EU portal and database project was also given to the group. The importance to update EudraCT with data on EMA and national GCP inspections in a timely manner, was emphasised at a number of meetings and inspectors were reminded how to fill in the relevant inspection fields in EudraCT.

6.3. EU enlargement

Bosnia and Herzegovina, Kosovo, The Former Yugoslav Republic of Macedonia, Montenegro and Serbia were invited and, in most of the cases, attended the GCP IWG meetings held in 2014 as observers.

6.4. Regulation on advanced therapies

The GCP IWG continues with the monitoring of the implementation of GCP guidelines on ATIMPs²⁵ in clinical trials of advanced therapies.

²⁵ Advance Therapies Investigational Medicinal Products

7. Liaison with other EU groups

7.1. GMP/GDP IWG

The GCP IWG maintains a dialogue with the GMP/GDP Inspectors Working Group on areas of common interest and in particular to provide input to guidelines on GMP for IMP (Annex 13).

7.2. PhV IWG

The GCP IWG maintains a dialogue with the Pharmacovigilance Inspectors Working Group on areas of common interest and in particular concerning pharmacovigilance issues observed in relation to GCP inspections.

7.3. CTFG

The GCP IWG together with the CTFG²⁶ prepared a letter regarding the publication of clinical trial results in scientific journals, without the required authorisation, and sent it to:

- the Council of Science Editors;
- the World Association of Medical Editors.

7.4. CMDh

The GCP IWG and the CMDh, mainly through the GCP/CMDh working party, have contributed to:

- The preparation of the 2014 risk based programme of routine GCP inspections of the CROs²⁷ most often used in the conduct of bioequivalence trials included in a marketing-authorisation application in the mutual recognition and decentralised procedures.
- The revision of the guidance on triggers for inspections on bioequivalence trials and of the guidance on the co-ordination of the GCP inspection and co-operation between GCP inspectors, the reference and concerned Member States and CMDh in the context of the evaluation of the GCP compliance of marketing-authorisation applications for mutual recognition and decentralised .
- The discussion of processes for:
 - CRO inspections co-ordination;
 - exchange of information on BE trials/CRO inspections;
 - communication of inspection findings;
 - improving the exchange of information between inspectors and assessors;
 - selection of trial/sites for inspection.

²⁶ Clinical Trial Facilitation Group

²⁷ Clinical Research Organisation

7.5. HMA

The GCP IWG contributed to the discussion at the level of the HMA[1] on the need to increase the resources for EMA GCP inspections. At the November 2014 HMA meeting the issue of lack of resources for EMA GCP inspections was highlighted by EMA and discussed with Member States. EMA is working on a proposal to be discussed further with the GCP inspectors and to be presented to HMA.

7.6. Joint meetings with interested parties

- On 1 December 2014 the e-source GCP IWG subgroup met with representatives of the e-CF in order to discuss the e-CF's EDC²⁸ hosting team's responses to the discussions that took place during the joint meeting with the EMA GCP inspectors in 2013. Discussion allowed the two sides to better understand requirements, current concerns and potential solutions. A "White Paper" and "Checklist" developed by the e-CF to address compliance concerns was discussed and some initial thoughts for areas of clarification, questions to be addressed, and inconsistencies to fix were identified. The e-CF will produce an updated document incorporating feedback expected from regulators ready for release for review by partners during quarter 1/2 2015. A follow-up meeting is proposed for 2015 with a number of representative stakeholders in this area.
- A joint meeting between the GCP IWG and representatives of the EHR4CR²⁹ Communication Task Force took place on 16 September 2014 in order to inform the inspectors about the EHR4CR project and receive their feedback on the project. Although a number of concerns were expressed by the inspectors and discussed with the EHR4CR representatives, overall the IWG found this initiative interesting and emphasised the importance of a direct dialogue and communication with its developers.

8. Liaison with international partners

8.1. Regulatory agencies from outside the EEA

- EMA-FDA GCP initiative began in September 2009 with a pilot phase and it is now in an established phase. The objectives are to conduct periodic information exchange on GCP-related information, conduct collaborative GCP inspections and share information on the interpretation of GCP.

A report and Question & Answer document on the outcomes of the pilot are available, which detail the success of the information-sharing and collaboration on inspections relating to clinical trials:

- [Announcement of the EMA-FDA GCP initiative.](#)
- [Questions and answers on the EMA-FDA GCP initiative.](#)

In light of the successful implementation of the main initiative the Agency, the FDA and the regulatory authorities in some EU Member States agreed to launch a joint initiative to collaborate on the sharing of information and conduct of inspections of bioequivalence studies. The initiative began in January 2014 with an 18-month pilot phase that will run until June 2015. A report on its outcome will be made available after the pilot phase.

²⁸ Electronic Data Capture

²⁹ Electronic Health Records for Clinical Research

The objectives of this initiative and the list of EU Member States are described in the terms of engagement:

- [Terms of engagement](#).
- [List of EU Member States involved in the initiative](#).
- Two EU GCP inspectors attended the FDA's advanced BIMO³⁰ course during the year.
- PMDA (Japan): two representatives of the PMDA from the Office of Conformity Audit joined the first day of the March GCP IWG meeting and presented a questionnaire prepared by PMDA on the implementation system of clinical trials of different national competent authorities. The questionnaire was circulated to the IWG, who were asked to fill it in and send back to PMDA.
- Health Canada: a representative of Health Canada joined the March GCP IWG meeting by telephone conference in order to present Health Canada's risk-based site selection process.

8.2. International initiatives

- PIC/S³¹ GCP/PhV subgroup was formed with members from a number of countries including Argentina, Switzerland, Slovenia, Italy, Denmark, Belgium, France, Hungary and the UK. The first meeting of the group took place on 2 July 2014. The primary purpose of the PIC/S subgroup is to facilitate technical co-operation and harmonisation of practices, capacity building and information sharing in the area of GCP and GVP³² inspections.
- As part of the commitment of the EMA and EU network of GCP inspectors to contribute to the global GCP inspection capacity building and sharing of best practices, two inspectors from Ghana observed a national GCP inspection performed by AIFA³³ in May 2014.
- Contribution to the "Roadmap to Promote Good Clinical Practice Inspection", a Thai-FDA proposed and APEC³⁴ supported project, continued in 2014 by Agency attendance at the APEC Life Science Innovation Forum Multi Regional Clinical Trials-GCP inspections workshop on 09-10 May in China. This workshop formed part of "Step 2" of the "Roadmap to Promote Good Clinical Practice Inspection" and its main purpose was to provide training on advanced GCP inspections topics, discuss future communication and information sharing and consider "Best Practice Recommendations".
- During the 2014 EU GCP IWG workshop a session was devoted to international co-operation in GCP inspections (refer to section 4.3.1, 6th bullet point). During this session various possibilities offered by the EU GCP IWG to the international network of GCP inspectors were presented.

For details of the activities of the GCP IWG for next year see the [work plan](#) for 2015.

³⁰ Bioresearch Monitoring Program

³¹ Pharmaceutical Inspection Co-operation Scheme

³² Good Vigilance Practice

³³ Italian Medicines Agency

³⁴ Asia-Pacific Economic Co-operation