EUROPEAN MEDICINES AGENCY
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Compliance and Inspections

Annual report of the Good Clinical Practice Inspectors Working Group 2015

Adopted by the GCP IWG on 7 June 2016

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1. Introduction

This document is the eighth annual report of the GCP IWG[1]. This group was established in 1997 under the scope of Article 51(e) of Regulation (EC) No 2309/93 and subsequently Article 57(1)(i) of Regulation (EC) No. 726/2004.

The GCP IWG focuses on harmonisation and co-ordination of GCP related activities at EU[2] 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 CHMP[3], CVMP[4], CMDh[5], PhV IWG[6], GMP/GDP[7] 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 2015 work plan.

2. Meetings

The plenary GCP IWG meetings took place on:

- 04-05 March 2015
- 09-10 June 2015
- 09-10 September 2015
- 01-02 December 2015

A joint meeting on EDC[8] systems and risk based monitoring in clinical trials with the GCP IWG and interested parties took place on 30 November 2015.

During 2015, the following GCP inspectors' subgroups/working parties were involved in the discussion of specific topics and drafting documents:

- GCP IWG/CMDh working party (refer to section 6.4), 2 face to face meetings, 2 routine teleconferences and 2 extraordinary teleconferences to discuss major CRO[9] issues were organised in 2015;
- GCP IWG/CHMP assessors subgroup (refer to section 4.1), 3 teleconferences took place in 2015;
- GCP IWG TMF[10] subgroup(refer to section 5.1, 5th bullet point), 4 Adobe Connect teleconferences were held in 2015;
- GCP IWG subgroup, on the preparation of the functional aspects of the EU Portal and database required by the new Clinical Trial Regulation, Regulation (EC) No 536/2014, in relation to clinical trial supervision including inspections and the handling of serious breaches (refer to section 5.1, 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] Electronic Data Capture
[9] Clinical Research Organisation
[10] Trial Master File

7 T-cons were organised during the first 2Q of 2015 to discuss the business requirements for the inspection module and the procedure to handle serious breaches.

- GCP IWG subgroup on ATMP: Revision of ATMPs GCP guideline in the context of the new Clinical Trials Regulation (refer to section 5.4);

  7 T-cons were organised during 2015 to discuss the revision of the ATMPs guideline;

- GCP EMA inspection reporting procedure subgroup (refer to section 4.1, 2nd bullet point);

10 T-cons were organised during the course of 2015 to work on the revision of the IR[11] template and the reporting procedure INS/GCP/4;

- GCP IWG subgroup on guidance on risk proportionate approaches in clinical trials (refer to section 5.1, 4th bullet point);
  - Two teleconferences were organised in 2015.

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

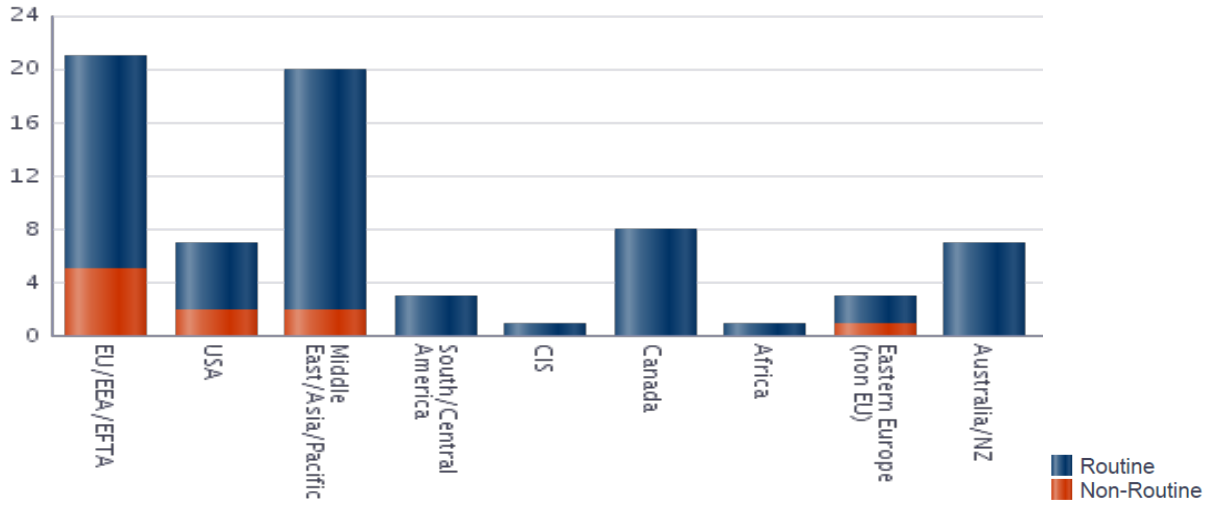
3.1. CHMP requested inspections

3.1.1. General overview

The CHMP requested 78 GCP inspections in 2015. In total, 75 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 2014 were conducted in 2015 and some inspections requested in the last 3 months of 2015 will be carried out in 2016. The data in this report relates to inspections performed in 2015.

In figure 1, the number of inspections finalised in 2015 is shown by region and type of inspection. Most inspections were effectuated in the EU/EEA[12]/EFTA[13] (28%) and the Middle East/Asia/Pacific (27%) followed by inspections in the Canada and USA (11% and 9% respectively).

Figure 1: Inspections conducted per region and type of inspection



[11] Inspection Report
[12] European Economic Area
[13] 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	16	21
Middle East/Asia/Pacific	2	18	20
Canada	0	8	8
Australia/New Zealand	0	7	7
USA	2	5	7
Eastern Europe (non EU)	1	4	5
South/Central America	0	5	5
Africa	0	1	1
CIS	0	1	1
Total in all regions	**10**	**65**	**75**

Figure 2: Inspections conducted per type of site

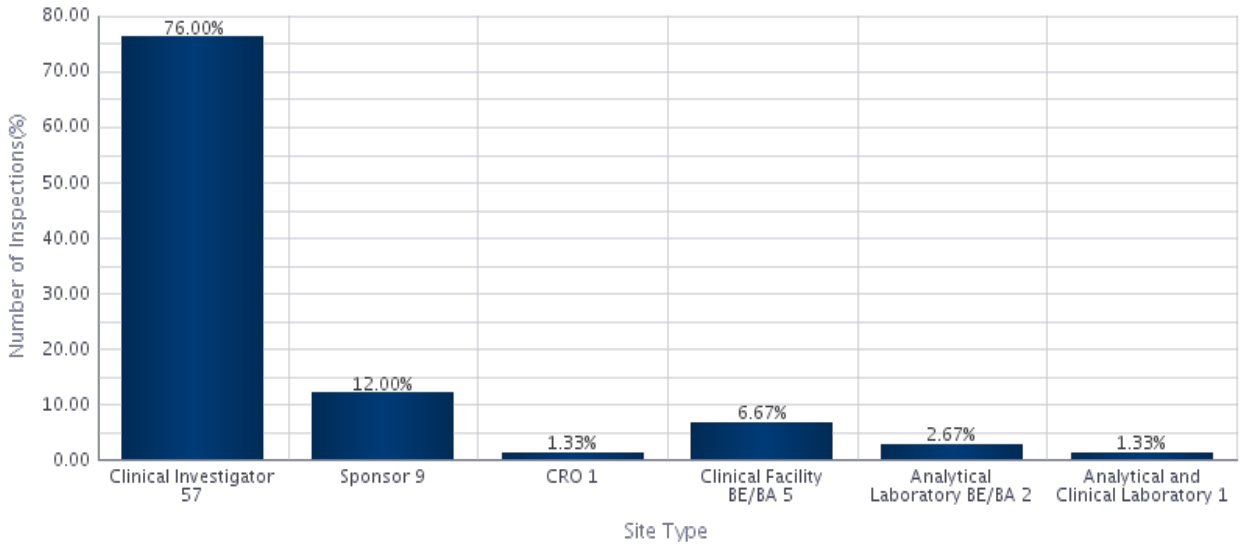


Figure 2 represents the number of inspections conducted in 2015 per type of site. Most inspections were conducted at clinical investigator sites.

3.1.2. Categorisation of findings

A total of 912 deficiencies, comprising 106 critical (11.6 %), 449 major (49.2 %) and 357 minor (39.1 %) were recorded for the 75 CHMP requested inspections conducted in 2015.

The main findings observed in the 2015 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					
		# Inspected deficiencies			# Inspected deficiencies total
Deficiency category name	**Deficiency sub-category name**	**Critical**	**Major**	**Minor**	
General	Contracts/agreements	2	9	7	18
	Direct access to data	1	5	1	7
	Essential documents	6	62	50	118
	Facilities and equipment	-	-	13	13
	Organisation and personnel	6	13	24	43
	Qualification/training	1	17	22	40
	Randomization/Blinding/Codes IMP[14]	-	6	-	6
	SOPs[15]	3	21	17	41
	Source documentation	1	28	20	49
General total		**20**	**161**	**154**	**335**
Trial management (sponsor)	Audit	1	3	1	5
	CSR[16]	5	14	8	25
	Data management	4	18	11	30
	Document control	1	4	8	13
	Monitoring	13	39	9	55
	Protocol/CRF[17]/diary/questionnaires design	-	17	7	23
	Statistical analysis	1	1	1	3
Trial management (sponsor) total		**25**	**96**	**45**	**166**
Investigational site	Protocol compliance (assessment of efficacy)	-	2	1	3
	Protocol compliance (others)	4	17	12	33
	Protocol compliance (safety reporting)	2	29	10	41
	Protocol compliance (selection criteria)	4	11	3	18

[14] Investigational Medicinal Product
[15] Standard Operating Procedures
[16] Clinical Study Report
[17] Case Report Form

Number of findings per sub-category of the top 3 main categories (general, trial management and investigational site) graded by critical, major and minor					
	Reporting in CRF/diary	9	23	42	74
Investigational site total		**19**	**82**	**68**	**169**

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 IMP[18] 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[19] 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[20];
- 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;
- the decisions made by the DMSB[21] were not communicated to the site.

[18] Investigational Medicine Product
[19] Case Report Form
[20] Clinical Study Report

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.

Clinical Study Report (CSR):

- inconsistencies between source data and data reported in the CSR;
- inaccurate information reported in CSR;
- relevant information missing in the CSR.

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 SAE[22] 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;

[21] Data Monitoring Safety Board
[22] Serious Adverse Event

- the procedures for the primary end point assessment for patients were not always strictly followed as required by the clinical protocol.

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 (MRP[23], DCP[24] or national procedures).

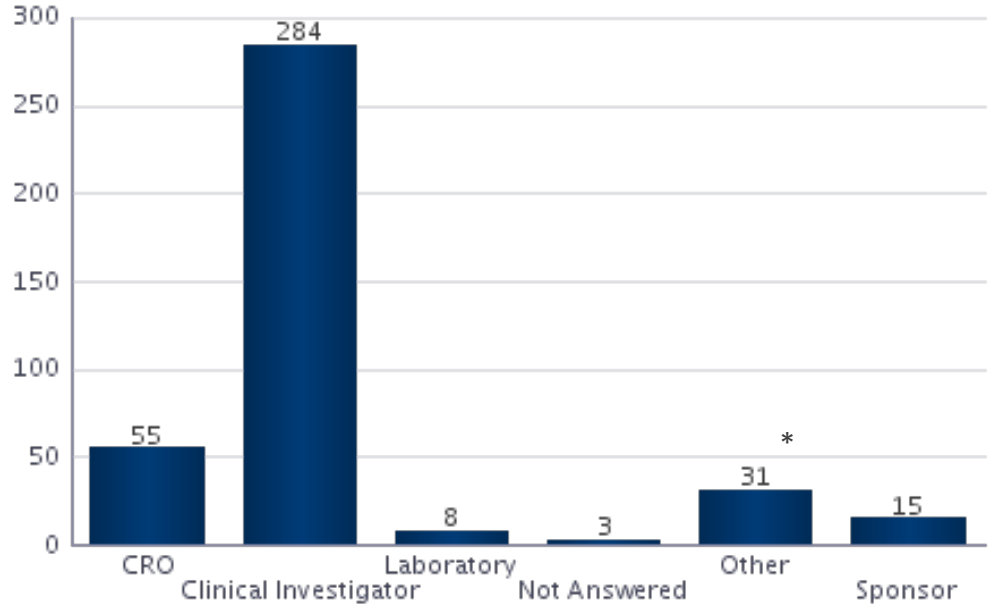
The following statistics are based on information obtained from EudraCT[25] and include the CHMP requested inspections.

Table 3: Inspections conducted per region

Region	Number of Inspections conducted in 2015
EU/EEA	346
North America	8
Rest of the world	42
Total in all regions	**396**

Figure 4: Number of inspections conducted per type of site

* The information has not been provided in EudraCT

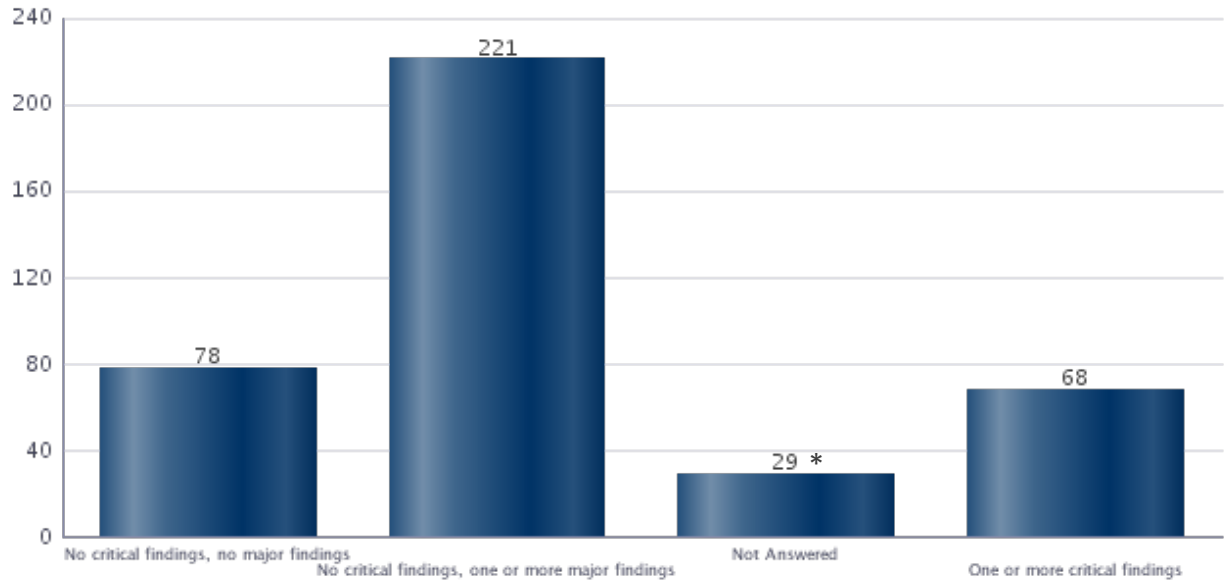


[23] Mutual Recognition Procedure
[24] Decentralised Procedure
[25] European Clinical Trials Database

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

Type of inspections	Number of inspections conducted in 2015
Trial specific	196
Non-trial specific	198
Not answered (information not provided in EudraCT)	2
Total	**396**

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 GCP inspectors/CHMP assessors subgroup carried out a preliminary analysis of the impact of GCP inspection findings on procedural outcomes over a three year period. This analysis is to be extended further and the outcomes reported are to identify potential needs to revise current GCP IWG and/or CHMP procedures.
- 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, and of the inspection reports templates, based on experience gained during the pilot phase.

  A revised template for the individual inspection report has been finalised in 2015 by the group and will be used for another 12 month-pilot phase.

The new template replaces the currently used 3 inspection reports templates, for inspections at the sponsor site, at the clinical investigator site and inspections of BE/BA trials, and now encompasses all the sections for the different type of sites to be completed as applicable. The reporting procedure INS/GCP/4 is also under revision.

Inspection co-operation

- Co-operation between the Member States:
  - in 2015 the majority of the inspections requested by the CHMP were joint inspections involving inspectors from at least two Member States. However, thirteen inspections were carried out by one Member State only.
- 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 2015, out of the 54 inspections performed outside the EEA, at least six GCP inspections requested by the CHMP were observed by 3rd country regulatory authorities, including Bosnia & Herzegovina and the USA. One inspection was performed jointly with the USA.

4.2. GCP training and development

4.2.1. 2015 EU GCP Inspectors Working Group Workshop

In 2015 the EU GCP Inspectors' Working Group workshop took place in London on 12-14 October 2015. Participants included one hundred and fourteen inspectors from the EU/EEA/EFTA and third countries (Austria, Belgium, Bosnia and Herzegovina, Brazil, Canada, Chinese Taipei, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Ghana, Hungary, Iceland, India, Ireland, Italy, Japan, Latvia, Lithuania, Malaysia, Malta, Mexico, Moldova, Montenegro, Netherlands, Nigeria, Norway, Poland, Portugal, Slovak Republic, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Thailand, Turkey, Ukraine, United Kingdom, USA, United Republic of Tanzania and WHO).

This year's workshop included two days on inspection of electronic data integrity covering the following topics:

- GCP Framework and Expectations for Data Integrity;
- management Governance & Quality Culture;
- key principles for inspecting for data integrity:
  - good Documentation Practices for Paper and Electronic (continued)
  - 'critical Thinking' Skills for Data Review
  - reviewing Electronic & Paper Data and 'Metadata'
  - data Life Cycle & Data Governance
  - inspections of Facilities (e.g., Central Labs / CROs) and Quality Management Systems
- validation for Data Integrity:
  - Cloud Computing

During the workshop was also provided an update on new EU Clinical Trial legislation:

- the new Clinical Trial Regulation- what is changing
- overview of the GCP Implementing Act

The final half day of the workshop covered the topics below:

- categorisation and impact of inspection findings;
- Ebola Vaccine Trial Applications.

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

4.2.2. 2015 EU GCP Bioequivalence Inspections Forum and generics workshop

- A BE[26] Forum took place in London on 14 October 2015 in the afternoon. Participants included BE senior inspectors from EU/EEA, from WHO[27] and Brazil, Chinese Taipei, former Yugoslav Republic of Macedonia, India, Malaysia, Mexico, Moldova, South Africa, South Korea, United Republic of Tanzania, United States of America. The following topics were covered:
  - update on the 9th Workshop on Recent Issues in Bioanalysis (9th WRIB),
  - handling of a volunteer management system - inspector expectations for computerised system;
  - level of documentation when setting up a LCMS system (documentation for mobile phases, preparation of subject samples etc.),
  - level of documentation when setting up a LCMS system (documentation for mobile phases, preparation of subject samples etc.),
  - eCRFs in BE trials,
  - source data verification of laboratory values of screening/end of trial values at the clinical laboratory,
  - PK samples and IMPs BE trials,
  - loss of audit trail functionality.
- A workshop on GCP compliance in BE trials/generics took place on 15 October 2015 at the EMA.

Participants included inspectors and assessors from the EU and representatives of stakeholder organisations.

The following topics related to bioequivalence trials were covered:

- proposal regarding common practices by the sponsor for CRO selection criteria and quality assurance and quality control before (selection) and during the conduct of the trial.
- proposal regarding common practices by the MAH for due diligence of licenced-in dossiers (including contractual aspects), (understand the processes in place and discuss best practices) investigational medicinal product.
- proposal regarding common practices by the MAH for due diligence of licenced-in dossiers (including contractual aspects), (understand the processes in place and discuss best practices).

[26] Bioequivalence
[27] World Health Organization

- definition of a common trigger point for the reporting of breaches to competent authorities that were revealed during CRO audits (current situation and future requirements for the notifications of serious breaches in the context of the new CT Regulation).
- CRO closure: mechanisms to ensure data retention for further verification/responsibilities.

4.2.3. On-line GCP Inspectors' Basic Training Course

In 2015, the EMA on-line GCP inspectors' basic training course was announced to inspectors from EU/EEA and third countries. Participants included 67 inspectors from Austria, Brazil, Bulgaria, Chinese Taipei, Croatia, Cyprus, Czech Republic, Finland, Germany, Greece, Italy, Lithuania, Luxembourg, Malta, Netherlands, Norway, Portugal, Republic of Moldova, Russia, Slovenia, Spain, Sweden, Switzerland, Turkey, Uganda, Ukraine and USA.

Two webinars took place on:

- 16 June 2015 with the participation of 32 inspectors from the EU, EEA countries and Switzerland;
- 24 June 2015 with the participation of 23 inspectors from third countries.

These webinars were organised and chaired by the Agency and 5 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 webinar. Following the webinar the participants were asked to complete a quiz and certificates were issued to those who passed. The course will be repeated at least once in 2016 and is to remain accessible to non-EU inspectors.

4.2.4. GCP IWG meetings

During the GCP IWG meetings held in 2015, the following topics were addressed:

- preparing for the implementation of the new Clinical Trials Regulation by providing expert support to the European Commission on GCP related matters and inspections;
- revising the current, and developing new, EMA GCP inspection procedures and guidelines in relation to the implementation of the new Clinical Trials Regulation;
- update on the revision of the ICH-E6 GCP guideline and discussions/provision of comments 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.

5. Topics of interest

The topic on the TMF reflection paper has been moved from this section where it had been included in last year's annual report and this year's GCP IWG work-plan, to the section below as it now forms part of the list of guidance documents to be published in collaboration with the European Commission.

Collaboration with European Commission

5.1. Clinical Trial Regulation and related guidance documents

- The group was regularly updated at its meetings, by the European Commission, on the progress of the following documents:
  - Detailed arrangements for clinical trials inspection procedures including the qualifications and training requirements for inspectors, pursuant to Article 78(7) of Regulation (EU) No 536/2014.
  - Commission Delegated Act on principles and guidelines on good manufacturing practice for investigational medicinal products and on inspection procedures, pursuant to the first subparagraph of Article 63(1) of Regulation (EU) No 536/2014.
  - Detailed Commission guidelines on good manufacturing practice for investigational medicinal products, pursuant to the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014.
  - Good Manufacturing Practice for Advanced Therapy Medicinal Products pursuant to Art 5 of Regulation (EC) No 1394/2007.
- The group began working on the revision of the GCP guidelines, reflection papers and inspection procedures to reflect the changes brought about by the new legislation. A detailed work-plan was prepared and updates were provided throughout the year.
- A GCP IWG subgroup has been involved in the preparation of the functional aspects of the EU Portal and database in particular in relation to gathering the business requirements for the inspection module of the EU portal and database and working on the process to handle serious breaches to be reported by clinical trial sponsors.
- A GCP IWG subgroup on guidance on risk proportionate approaches in clinical trials began developing a new document to provide guidance to commercial and non-commercial sponsors and examples of risk adaptations in clinical trials, with a focus on low-intervention clinical trials, as defined in the Clinical Trials Regulation (EU) No. 536/2014.
- The GCP IWG agreed that the revised version of the draft TMF reflection paper on GCP compliance in relation to trial master files (paper and/or electronic) for management, audit and inspection of clinical trials, will be incorporated into a guidance on TMF as part of the work related to the implementation of the new Clinical Trial Regulation (EU) 536/2014. A GCP inspectors' subgroup began working on this task and the guidance is planned for publication in 2016.

5.2. EudraCT database

At the September GCP IWG meeting the group was informed by the EMA of an error identified in the software used to load summaries of results into the EU Clinical Trial Register. As a consequence, the summary results of clinical trials which have been entered into EudraCT and made public in the EU CTR were removed from the public domain while they were being reviewed and before being returned to the public view. In addition the access for sponsors to enter results or edit existing results was blocked whilst the underlying software error that gave rise to the problem was being resolved.

5.3. EU enlargement

Bosnia and Herzegovina, Kosovo, The Former Yugoslav Republic of Macedonia, Montenegro and Serbia were invited to attend the GCP IWG meetings held in 2015 as observers.

5.4. Regulation on advanced therapies

- The GCP IWG continues with the monitoring of the implementation of GCP guidelines on ATIMPs[28] in clinical trials of advanced therapies.
- The subgroup of GCP inspectors/assessors began working on the revision of the "Detailed guidelines on good clinical practice specific to advanced therapy medicinal products".

6. Liaison with other EU groups

6.1. GMP/GDP IWG

The GCP IWG maintains a dialogue with the GMP/GDP Inspectors Working Group on areas of common interest. The GCP/GMP inspectors subgroup has been re-activated in order to discuss GMP related issues in the new Clinical Trials Regulation.

6.2. 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.

6.3. CTFG

Collaboration on areas of mutual concern in the area of supervision of clinical trials conducted in the Community.

6.4. CMDh

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

- The preparation of the 2015 risk based programme of routine GCP inspections of the CROs[29] most often used in the conduct of bioequivalence trials included in a marketing-authorisation application in the mutual recognition and decentralised procedures.
- 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.

[28] Advance Therapies Investigational Medicinal Products
[29] Clinical Research Organisation

6.5. Heads of Medicines Agencies

See section 6.3

6.6. Joint meetings with interested parties

- A joint meeting on electronic data capture systems (EDC) and risk based monitoring (RBM) in Clinical Trials between the GCP IWG and interested parties took place on 30 November. The following presentations were given:
  - Overview of ICH-E6 Addendum with focus on EDC systems and RBM
  - Cloud Services - A Framework for Adoption in the Regulated Life Sciences Industry
  - Pitfalls sponsors should be aware of when contracting out electronic systems in connection with clinical trials
  - Electronic Data Capture in Clinical Trials using Service Providers
  - Sponsor certification of electronic certified copies and acceptance of electronic copies from other parties (service providers and investigators) as certified copies
  - Regulatory Status of ePRO (eSource) and Site Inspections
  - European Clinical Research Infrastructures Network (ECRIN) Data Centre Certification Programme
  - TransCelerate approach to Risk Based Monitoring
  - CRO experience of Risk Based Monitoring

  The minutes of this meeting will be published on the EMA website in 2016.

6.7. Paediatric Committee (PDCO)

Communication on inspection issues with the PDCO continued in 2015 with the exchange of information on inspections of clinical trials with a paediatric population.

7. Liaison with international partners

7.1. Regulatory agencies from outside the EEA

- The EMA and the FDA have a collaboration initiative since 2009 in the area of GCP[30]. This collaboration was extended to bioequivalence, together with some EU member states[31].
  - During 2015 there were 5 regular T-cons of the EMA-FDA collaboration, 3 as part of the BE EMA-FDA-EU MSs collaboration and 5 product/company specific.
  - As part of the initiative 5 inspections have been observed, 1 has been performed jointly and 3 in a parallel way.
  - Two European Inspectors attended the BIMO training organised by the FDA and 5 FDA representatives attended the training organised by the GCP IWG. One FDA colleague also attended the BE Forum.

[30] Announcement of the EMA-FDA GCP Initiative.
[31] Terms of Engagement

- During 2015 122 documents were exchanged, including 43 Inspection Reports.
- Three FDA CDER representatives took part in the September 2015 GCP IWG meeting and gave presentations on various topics of interest. They also contributed to discussions on GCP and inspection issues during the meeting. In the margins of the IWG meeting, a separate meeting took place between the FDA representatives and EMA to explore further how to progress the collaboration between the two Agencies, including areas for improvement.

- PMDA (Japan):
  - Representatives of the PMDA from the Office of Conformity Audit joined the March GCP IWG meeting via T-con. They presented the outcome of the PMDA's GCP questionnaire, which was circulated to the group last year. A discussion on the interpretation of the questions followed the presentation with the inspectors providing a number of suggestions for further improvement and clarity.
  - In September 2015, a meeting was held at the EMA between representatives of PMDA and EMA during which the two Agencies compared their GCP inspections procedures and explored the possibility to further increase collaboration between the two Agencies in that field.

7.2. International initiatives

- The GCP IWG was informed on a regular basis about the progress of the drafting of the Addendum to ICH E6 and provided its comments both as part of the internal ICH members' consultation as well as part of the public consultation.
- PIC/S[32] GCP/PhV subgroup made up of members from a number of countries including Argentina, Australia, Canada, Switzerland, Slovenia, Italy, Denmark, Belgium, France, Hungary and the UK met on regular basis. During the course of 2015, 4 meetings were organised, including a face to face meeting in November. During these meetings the group mainly discussed about the outcome of the Joint Visit Programme, which foresees a rota of inspections conducted in different countries worldwide. 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 GVP[33] inspections.
- Three PIC/S GCP inspection groups including EU inspectors were active in 2015, conducting a total of five GCP 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, a BE basic training course took place at AIFA[34] on 7th of July with the attendance of three inspectors from Ghana.

  For details of the activities of the GCP IWG for next year see the work plan for 2016.

  http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2016/02/WC500202517.pdf

[32] Pharmaceutical Inspection Co-operation Scheme
[33] Good Vigilance Practice
[34] Italian Medicines Agency