EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Quality and Safety of Medicines

Annual Report of the Good Clinical Practice Inspectors' Working Group 2018

Adopted by the GCP IWG on 12 March 2020

The activities outlined in the annual report for 2018 have been carried out in line with the Agency's business continuity plan and prioritisation of activities for the preparation of the Agency's relocation and are therefore reduced in comparison with the activities carried out by the GCP Inspectors Working Group in previous years.

The delay of the publication of this report is also due to the Agency's business continuity plan and prioritisation of activities for the preparation of the Agency's relocation in 2019.

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1. Introduction

This document is the eleventh annual report of the GCP IWG[1]. This group was established in 1997 under the scope of Article 51(e) of Regulation (EC) No. 2303/93, subsequently amended as Article 57(1)(i) of Regulation (EC) No. 726/2004.

The GCP IWG focuses on harmonisation and coordination 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 publication "The rules governing medicinal products in the European Union".

The group supports the coordination 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 IWG[7] and other groups, as needed, in areas of common interest.

This annual report is set out in line with the format and objectives of the 2018 work plan.

2. Meetings

The plenary GCP IWG meetings took place on:

- 8-9 March 2018;
- 5-6 June 2018;
- 19 September 2018 (teleconference meeting);

Meetings with interested parties:

- A 'Workshop with interested parties on topics regarding (electronic) archiving of study data and related subjects' took place on 08 May 2018.

During 2018, 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 7.5), 2 face to face meetings and 3 teleconferences;
- GCP IWG TMF[8] subgroup (refer to section 4.1), 3 teleconferences were held in 2018 to address the comments received from the public consultation.

[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 Inspectors Working Group
[8] Trial Master File

3. Inspections conducted in support of the centralised procedure

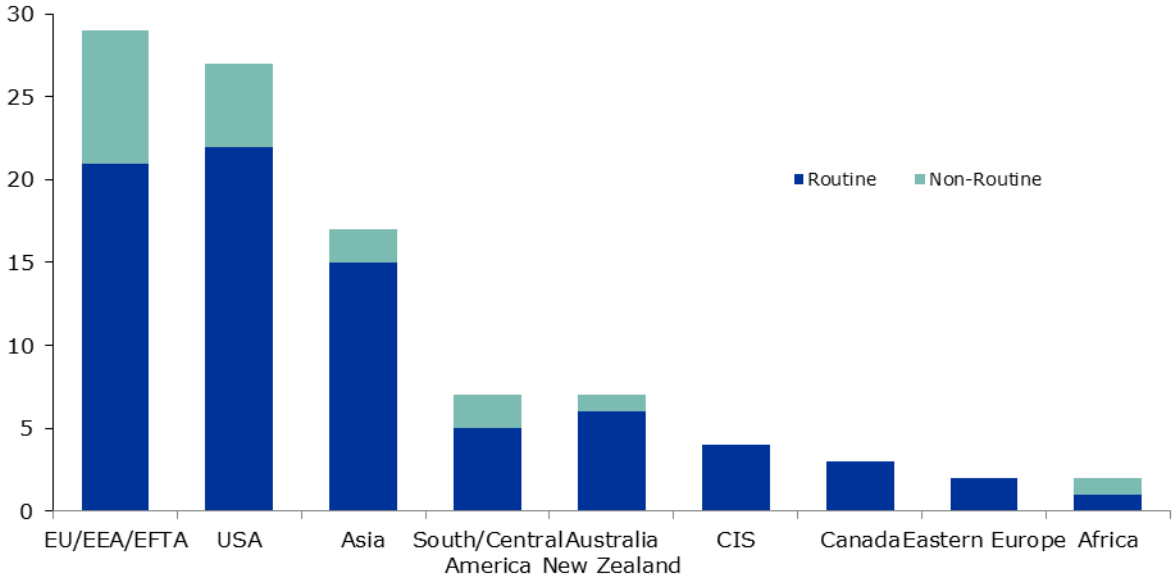
3.1. CHMP requested inspections

3.1.1. General overview

In total, 98 GCP inspections were requested by CHMP and carried out by the inspectorates of the EU Member States in 2018. However, it should be noted that several inspections requested in the last 3 months of the year 2017 were conducted in 2018 and some inspections requested in the last 3 months of 2018 will be carried out in 2019. The data in this report relates to inspections carried out in 2018.

In figure 1, the number of inspections carried out in 2018 is shown by region and type of inspection. Most inspections were carried out in the EU/EEA[9]/EFTA[10] (30%) followed by inspections in the USA (28%) and the Middle East/Asia/Pacific (17%).

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	8	21	29
USA	5	22	27
Middle East/Asia/Pacific	2	15	17
South/Central America	2	5	7
CIS[11]	0	4	4
Canada	0	3	3
Africa	1	1	2
Eastern Europe (non-EU)	0	2	2
Australia/New Zealand	1	6	7
Total in all regions	**19**	**79**	**98**

Figure 2: Inspections conducted per type of site.

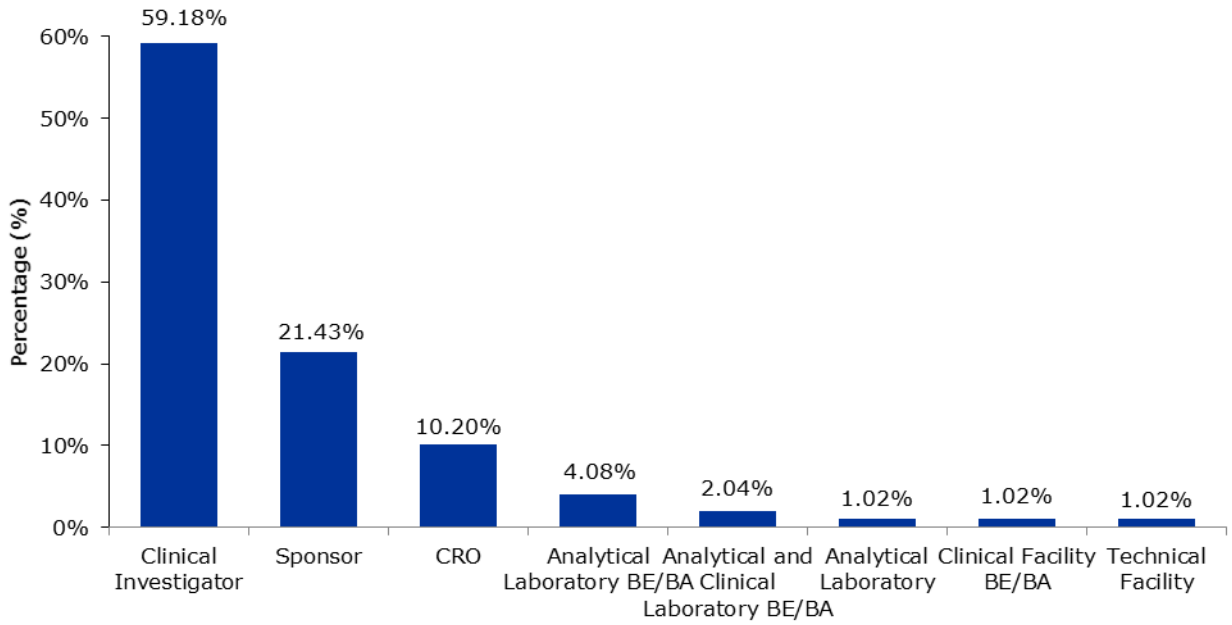


Figure 2 represents the number of inspections conducted in 2018 per type of site. Most of the inspections were conducted at the clinical investigator sites, followed by the sponsor site, CRO, analytical laboratory, clinical facility of BE/BA studies and analytical laboratory of BE/BA.

[11] Commonwealth of Independent States

3.1.2. Categorisation of findings

A total of 1142 deficiencies, comprising 66 critical (6%), 589 major (51.5%) and 487 minor (42.5%) were recorded for the 98 CHMP requested inspections conducted in 2018.

The main findings observed in the 2018 inspections are detailed below in accordance with the GCP categorisation of findings agreed by the GCP IWG.

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

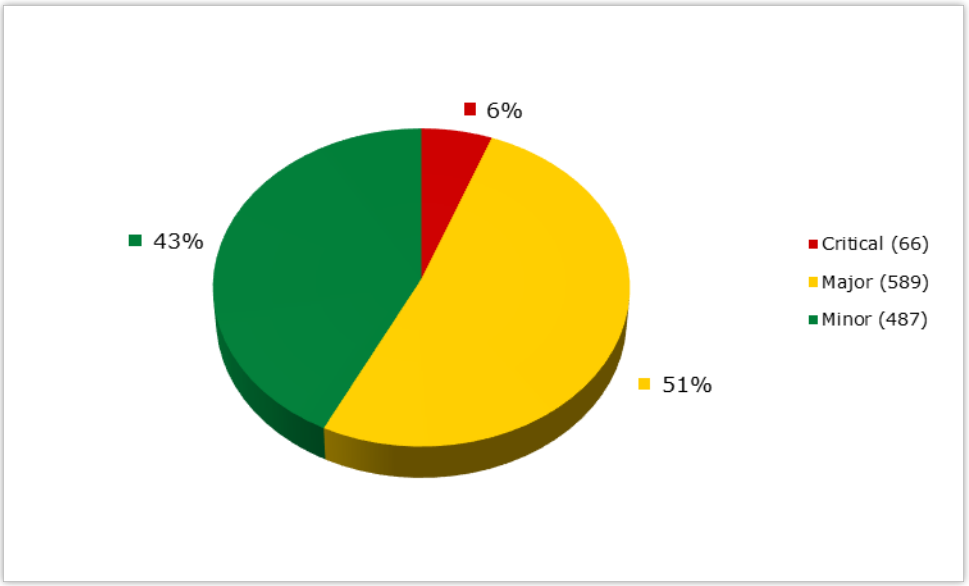


Figure 3.b: Number of findings with regard to the main categories graded by critical, major and minor.

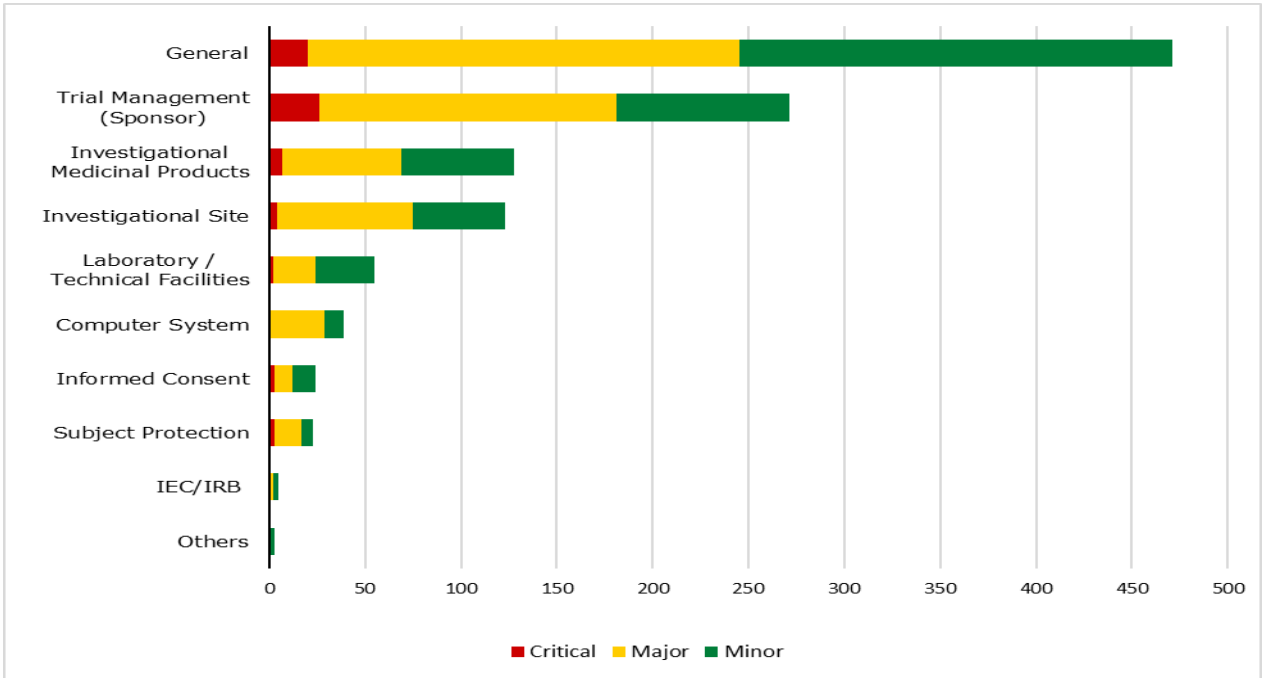


Table 2: Number of findings per sub-category of the top 3 main categories (general, trial management and investigational site) graded by critical, major and minor

		# Inspected deficiencies			# Inspected deficiencies total
Deficiency category name	**Deficiency sub-category name**	**Critical**	**Major**	**Minor**	
General	Contracts/agreements	-	25	19	44
	Direct access to data	-	5	2	7
	Essential documents	9	72	64	145
	Facilities and equipment	-	11	20	31
	Organisation and personnel	2	18	19	39
	Qualification/training	1	18	29	48
	Randomisation/Blinding/Codes IMP[12]	-	5	1	6
	Standard Operating Procedures	5	32	30	67
	Source documentation	3	39	42	84
General total		**20**	**225**	**226**	**471**
Trial management (sponsor)	Audit	1	4	3	8
	Clinical Study Report	3	15	5	23
	Data management	9	51	19	79
	Document control	1	31	27	59
	Monitoring	9	33	26	68
	Protocol/Case Report Form/diary/questionnaires design	1	16	5	22
	Statistical analysis	2	5	5	12
Trial management (sponsor) total		**26**	**155**	**90**	**271**
Investigational medicinal products (IMP)	IMP Accountability	2	3	6	11
	Manufacturing/Packaging/Labelling	-	4	1	5
	Prescription/Administration/Compliance	3	13	13	29
	Supplying/Storage/Retrieving/Destruction	2	42	39	83
Investigational medicinal products total		**7**	**62**	**59**	**128**

[12] Investigational Medicinal Product

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

General

Essential documents:

- the TMF was not ready for inspection and relevant documents were either not filed, or filed late, or located outside the TMF structure;
- lack of essential documents, e.g. receipt of IMP 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[13] filed on site.

Source documentation:

- discrepancies between source data and data reported in the CSR[14];
- 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.

SOPs[15]:

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

Contracts/agreements:

- incomplete contracts in place;
- responsibilities not clearly defined;
- lack of consistency between contract and protocol.

Organisation and personnel:

- incomplete site personnel signature log;

[13] Case Report Form
[14] Clinical Study Report
[15] Standard Operating Procedures

- tasks performed by staff not authorised to do so.

Trial management

Monitoring:

- monitor has not identified number of deficiencies on site;
- inadequate monitoring activities performed at site;
- lack of escalation process to resolve issues identified by monitor;
- monitor not following monitoring plan.

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 DSMB[16] were not communicated to the site.

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.

Protocol/CRF[17]/diary/questionnaires design:

- insufficient design of the study protocol, e.g. no instructions related to concomitant medication or unscheduled visits;
- the design of the CRF is not suitable to accurately collect the data specified within the protocol.

Investigational medicinal products (IMP)

IMP Accountability:

- incomplete inventory log;
- inventory log filled in by unauthorised person;
- inconsistencies between study worksheets and pharmacy records, in dates of IMP returned by subjects.

Manufacturing/Packaging/Labelling:

- lack of labelling of comparator for the specific study;
- lack of evidence of the relabelling conditions of the IMP.

Prescription/Administration/Compliance:

- IMP not administered in the required timeframe after its preparation;
- lack of evidence of IMP compliance calculation;

[16] Data Safety Monitoring Board
[17] Case Report Form

incomplete certificates of compliance signed by the qualified person;

- lack of traceability in records for IMP kits.

Supplying/Storage/Retrieving/Destruction:

- lack of prior approval from sponsor for IMP sent to subject's house;
- insufficient amount of IMP supplied to site by sponsor;
- lack of temperature monitoring of IMP during transport or storage.

Table 3. Findings graded by critical, major and minor per site type.

Inspection Site Type	Critical	Major	Minor	Findings	Findings (%)
Clinical Investigator	2.4%	28.5%	29.3%	**688**	**60.2%**
Sponsor	2.1%	13.9%	6.7%	**260**	**22.8%**
CRO	0.8%	4.0%	2.3%	**81**	**7.1%**
Analytical Laboratory	-	0.4%	0.6%	**12**	**1.0%**
Clinical Facility BE/BA	0.2%	2.0%	0.2%	**27**	**2.4%**
Analytical Laboratory BE/BA	0.4%	1.2%	2.1%	**42**	**3.7%**
Analytical and Clinical Laboratory BE/BA	-	1.2%	1.4%	**30**	**2.6%**
Phase I clinical facility	-	0.2%	-	**2**	**0.2%**
Grand Total	**5.8%**	**51.6%**	**42.6%**	**1142**	**100.0%**

Figure 4: Findings graded by critical, major and minor per site type.

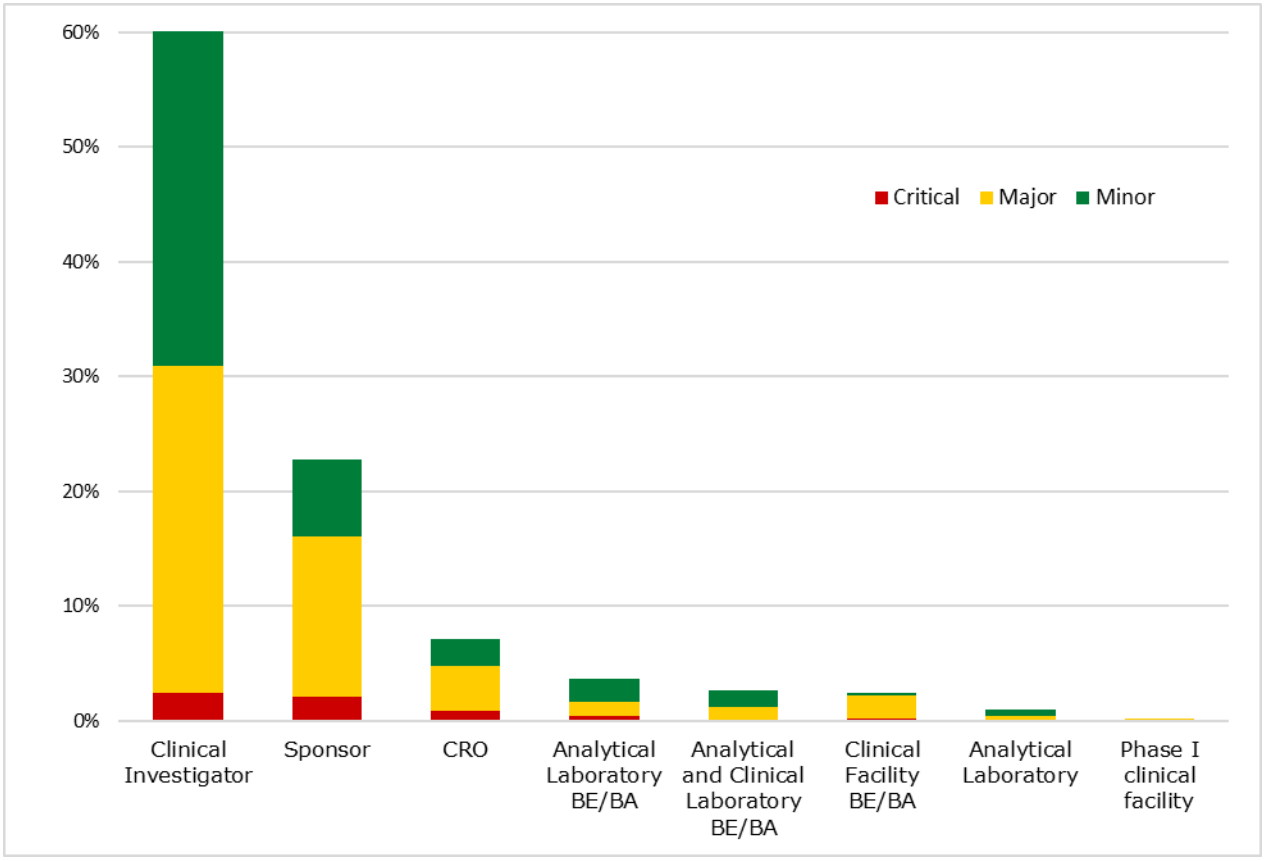


Figure 4.a: Number and categorisation of findings at clinical investigator sites.

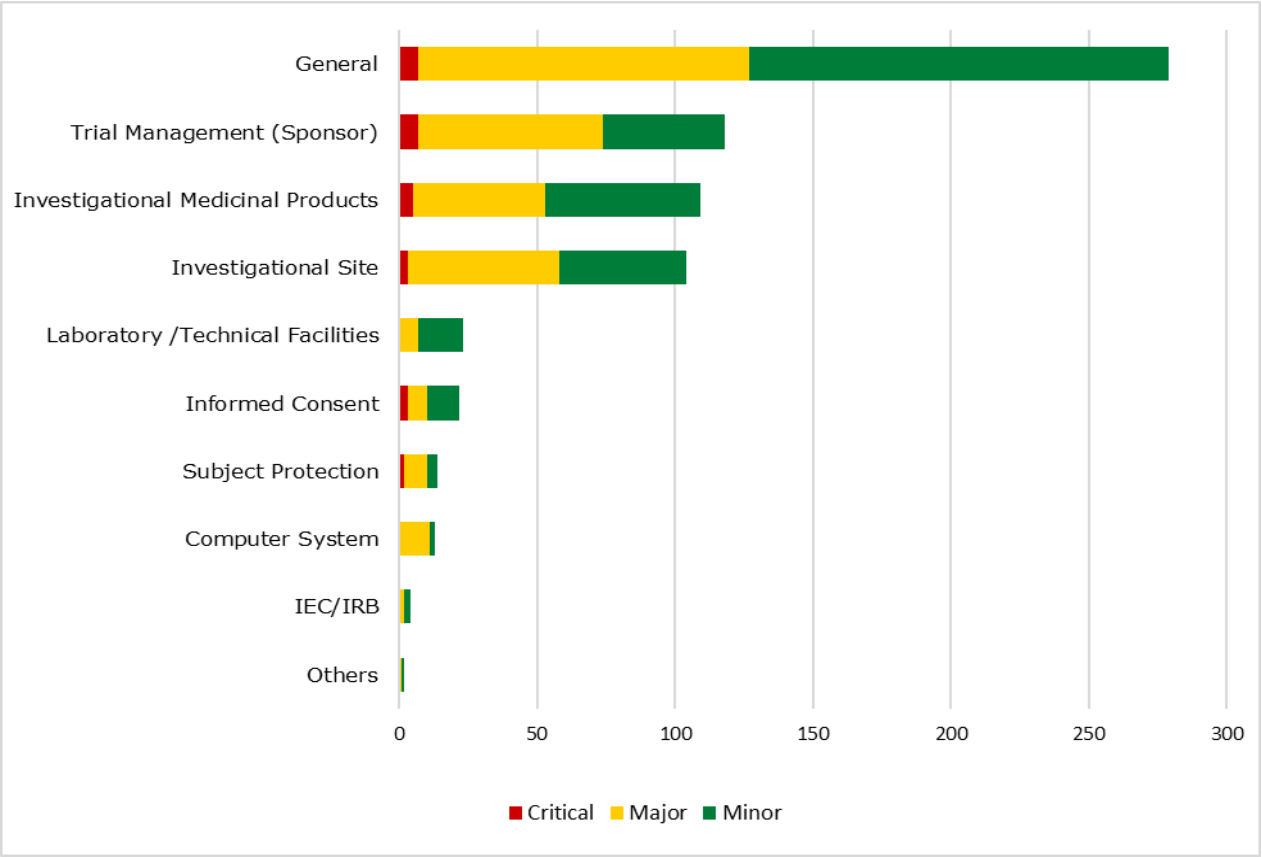


Figure 4.b: Number and categorisation of findings at sponsor site.

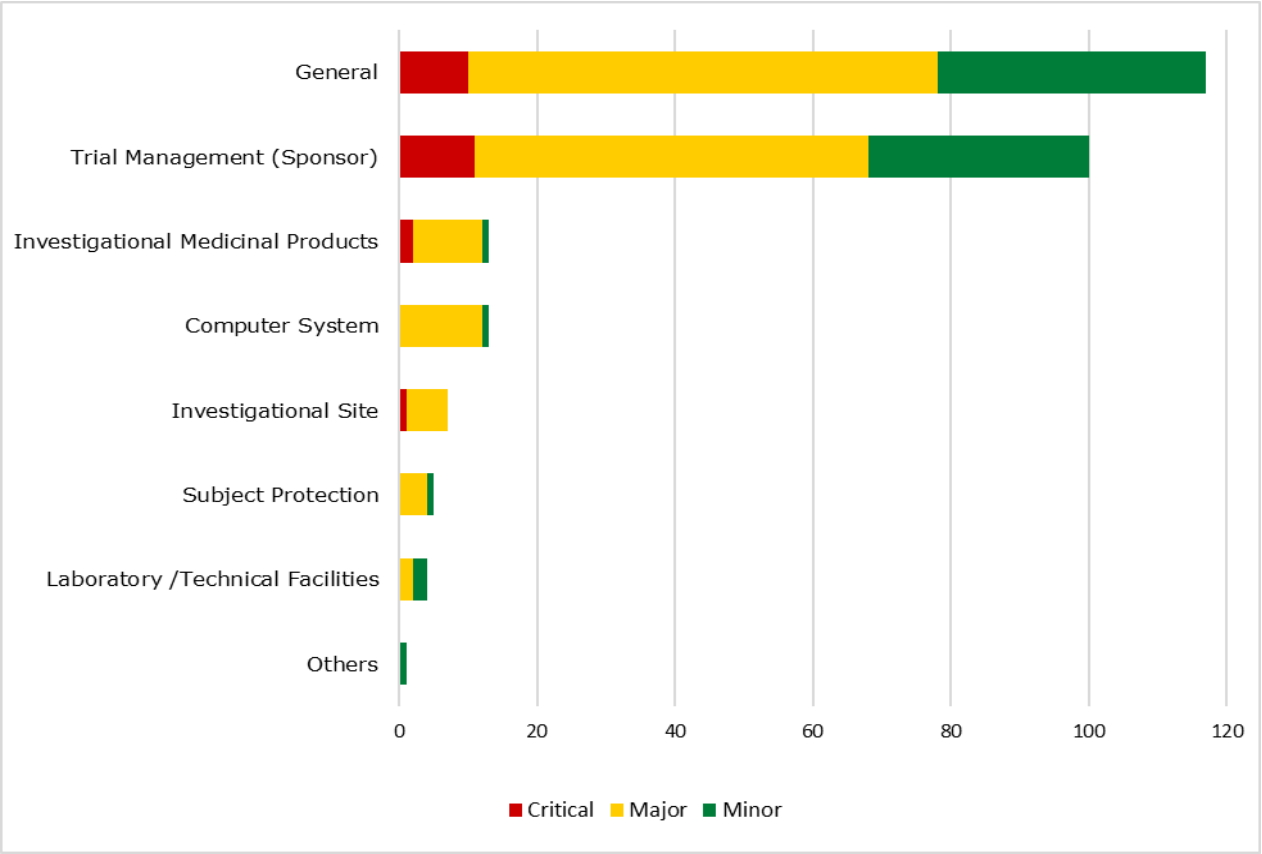
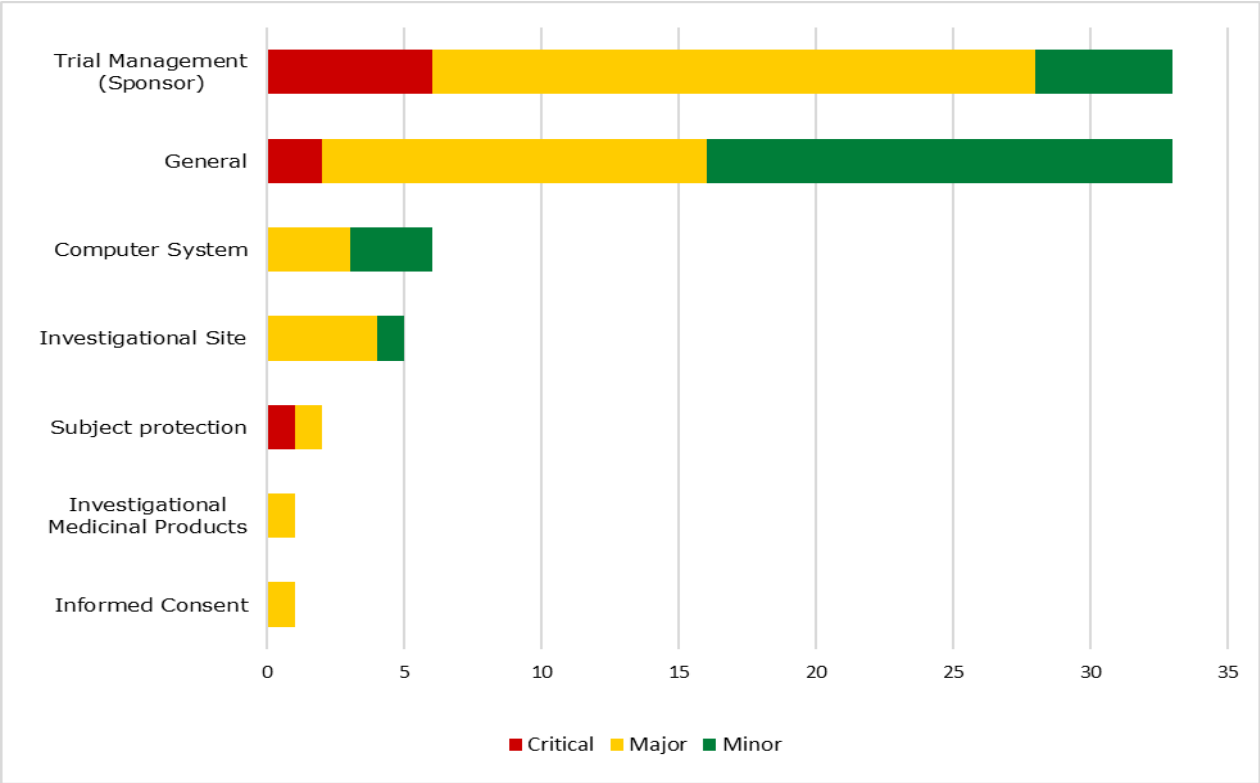


Figure 4.c: Number and categorisation of findings at CRO site.



4. Harmonisation topics

4.1. Procedures and guidance documents

- The GCP inspectors published the final version of the following document after considering the comments from the public consultation:
  - Guideline on GCP compliance in relation to trial master file (paper and/or electronic) for content, management, archiving, audit and inspection of clinical trials.
- The GCP inspectors, in collaboration with the GMDP IWG[18] and the European Commission, published for public consultation the following document:
  - Guideline on the responsibilities of the sponsor with regard to handling and shipping of investigational medicinal products for human use, in accordance with good clinical practice and good manufacturing practice.
- The GCP inspectors continued working on the following document:
  - Guideline on electronic systems and electronic data in clinical trials.

  The GCP inspectors continued working on addressing the comments from the public consultation of the following document:
  - Guideline for the notification of serious breaches of Regulation (EU) No 536/2004 or the clinical trial protocol.

[18] Good Manufacturing Practice/Good Distribution Practice Inspectors Working Group

Note: It was agreed to temporarily suspend the revision of the document on 'Recommendations on the qualification of inspectors verifying compliance in clinical trials with the provisions of good clinical practice' as the main aspects are covered in the Commission Implementing Regulation (EU) 2017/556 of 24 March 2017, on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council.

4.2. Inspection cooperation

- Cooperation between the EU/EEA Member States:

  In 2018, the majority of the inspections requested by the CHMP were joint inspections involving inspectors from at least two Member States. However, 3 inspections were carried out by one Member State only.

- Cooperation with third 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 2018, out of the 98 inspections performed outside the EEA, at least 3 GCP inspections requested by the CHMP were observed by third country regulatory authorities, including Australia, Thailand and Bosnia and Herzegovina. During 2018, 18 inspections were performed collaboratively with the US-FDA[19] and 3 with PMDA.

4.3. GCP training and development

4.3.1. 2018 EU GCP Inspectors Working Group workshop

In 2018 the EU GCP Inspectors' Working Group workshop took place in Bonn (Germany) on 09-11 October 2018. Participants included 129 inspectors from the EU/EEA/EFTA and third countries (Austria, Belgium, Brazil, Canada, Chile, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Kazakhstan, Latvia, Lithuania, Malaysia, Malta, Mexico, Montenegro, The Netherlands, Norway, Poland, Portugal, Republic of Belarus, Slovakia, Spain, Sweden, Switzerland, Thailand, Tunisia, Ukraine, United Kingdom and USA).

The 2018 workshop lasted for two and a half days and covered the following topics:

- Risk proportionate approaches in clinical trials:
  - Clinical Trials Regulation (EU) No 536/2014 and related documents.
  - Risk-based monitoring - Points to consider for GCP inspections.
- A practical view on GCP inspections at sponsor sites:
  - Inspection planning (scope of the inspection, selection of the site/facility to be inspected, aspects to be considered during planning, tools to prepare the inspection).
  - Inspection conduct (procedures and processes, basic principles).
- Clinical and statistical evaluation of trial data:
  - Handling of protocol deviations.
  - Statistical models to handle missing data.
  - Controlling bias in clinical trials.

[19] US Food and Drug Administration

  - Inspection of clinical trials with interim analysis (incl. novel design trials, real world studies).
- Safety reporting in clinical trials:
  - Reporting requirements for SUSARs, medical events of special interest, important medical events, treatment related AEs.
  - Inspections of clinical trials for which data safety monitoring boards (DSMB) have been implemented.
- Electronic media used in clinical trials:
  - Trial Master Files
  - Direct entry of data in e-source, e-CRF Updates on the Clinical Trials Regulation (EU) No 536/2014:

4.3.2. 2018 EU GCP bioequivalence inspections forum

A bioequivalence forum took place in Bonn (Germany) in the afternoon of the 11th of October 2018. 27 participants including mainly BE senior inspectors from EU/EEA and US FDA were present. The following topics were covered:

- Overview of the "Guideline on the management of critical findings identified during bioequivalence inspections".
- Statistical issues on bioequivalence inspections –update on the joint project.
- Monitoring of bioequivalence studies.
- Bioequivalence assessment vs bioequivalence inspection - a matter of perspective?

4.3.3. Online GCP inspectors' basic training course

In 2018, the EMA online GCP inspectors' basic training course was announced to inspectors from EU/EEA and third countries. 173 participants of the online course included inspectors from Argentina, Armenia, Australia, Austria, Belarus, Belgium, Bosnia and Herzegovina, Brazil, Bulgaria, Cabo Verde, Colombia, Denmark, El Salvador, Gambia, Germany, Ireland, Italy, Kazakhstan, Latvia, Lithuania, Malaysia, Malta, Moldova, Montenegro, Nigeria, Norway, Peru, Poland, Portugal, Romania, Russia, Senegal, Sierra Leone, South Africa, Spain, Sweden, Taiwan, Tunisia, Turkey, Uganda, Ukraine, United States, Zambia and Zimbabwe.

Two webinars took place on:

- 28 May 2018 for EU inspectors with 19 participants;
- 4 June 2018 for non-EU inspectors with 48 participants.
  These webinars were organised and chaired by the Agency and 5 senior EU GCP inspectors from AT, BE, FI, PL and ES who coordinated 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 remain accessible to non-EU inspectors.

4.3.4. Online BE inspectors' basic training course

In 2018, the number of active participants was 27 from 12 different EU MS; Bulgaria, Cyprus, Czech Republic, Denmark, Finland, Ireland, Italy, Lithuania, Malta, Poland, Slovakia and Spain.

One webinar was held on 16 May 2018. A total of 29 participants attended the webinar.

This webinar was organised and chaired by the Agency and 3 senior BE GCP inspectors from FR, ES and IT who coordinated 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.

4.3.5. GCP IWG meetings

During the GCP IWG meetings held in 2018, the following topics were addressed:

- Preparing for the implementation of the Clinical Trials Regulation (EU) No 536/2014 by providing expert support to the European Commission on GCP related matters and inspections.
- Developing EMA GCP inspection guidelines in relation to the implementation of the new Clinical Trials Regulation.
- Update on EU portal and database development.
- Modernisation of ICH E8 and the sub-consequent renovation of ICH-E6 and the new ICH E19.
- Developing new questions and answers (Q&A) on GCP.
- Discussion on e-source data/EDC and organisation of the workshop with interested parties.
- Update from GMDP IWG.
- Discussions on EU-FDA joint inspections and outcomes.
- 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.
- Discussion on how to optimise the use of inspection resources.
- Update on EudraCT issues.

5. Topics of interest

- The group discussed the outcome of the following workshop with stakeholders:
  - Workshop with interested parties on topics regarding (electronic) archiving of study data and related subjects took place on 08 May 2018.
- The group finalised the following three Q&As on GCP and published on the EMA website:
  - What is the level of validation/qualification needed to be performed by a sponsor when using an electronic system previously qualified by a provider? What documentation is required to be available for inspections?

  - According to the ICH-GCP and applicable EU laws, is it allowed that some procedures related to the conduct of the clinical trial are performed at the subject's home, instead of a health care establishment?
  - According to the ICH-GCP and applicable EU laws, is it allowed that the Sponsor contract third parties to conduct trial-related duties and functions that are clearly responsibilities of the investigator?
- The group discussed the need for new Q&As on the following topics and which will be included in the group's future workplan:
  - Adjudication committees.
  - Sponsor oversight of activities subcontracted to third parties.
  - Expectations for provision of written information to clinical trial subject in relation to new information requiring re-consent.
  - Inspectors' access to personal data when the access of EEA inspectors to medical information is not clearly stated in the ICF.

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 following texts:
  - Development of the Commission Implementing Regulation (EU) 2017/556 of 24 March 2017, on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014.
  - Delegated Regulation (EU) No 2017/1569 of 23 May 2017, on principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections, 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.
  - The Q&A of the interplay between GDPR and the CT Regulation (EU) No 536/2014.
  - The Q&A document in relation to the CT Regulation (EU) No 536/2014.
- A subgroup of GCP inspectors contributed to the progress of the development of the detailed guidelines on good clinical practice for advanced therapy medicinal products, following the public consultation of the document.

6.2. EudraCT database

The new features of EudraCT result version 10.4 were released during 2018 (13 November 2018) fixing technical issues on results posting. The importance to update EudraCT with data on EMA and national GCP inspections in a timely manner was emphasised at a number of meetings.

6.3. EU portal and database

During the GCP IWG meetings the inspectors were regularly updated on the status of the development of the new EU portal and database. 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 and working on the process to handle serious breaches to be reported by clinical trial sponsors. The inspectors are expected to be involved at a later stage in the testing of the EU Inspection Module.

6.4. EU enlargement

Bosnia and Herzegovina, Kosovo under UNSC Resolution 1244/99, The Former Yugoslav Republic of Macedonia, Montenegro and Serbia did not attend, as observers, the GCP IWG meetings held in 2018.

6.5. Regulation on advanced therapies

The GCP IWG continues with the monitoring of the implementation of GCP guidelines on ATIMPs[20] in clinical trials of advanced therapies.

- A subgroup of GCP inspectors and members of the Committee for Advanced Therapies collaborated in the progress of development and finalisation of the detailed guidelines on good clinical practice for advanced therapy medicinal products, following the public consultation of the document.

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. During 2018 a subgroup of GMP and GCP inspectors discussed the GMP related issues in the Clinical Trials Regulation (EU) No 536/2014 and published for public consultation the 'Guideline on the responsibilities of the sponsor with regard to handling and shipping of investigational medicinal products for human use in accordance with Good Clinical Practice and Good Manufacturing Practice' (section 4.1).

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

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

7.4. CHMP

The GCP IWG maintains a dialogue with the CHMP on areas of common interest and in particular on matters related to good clinical practice and GCP inspections.

[20] Advance Therapies Investigational Medicinal Products

7.5. CMDh

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

- the preparation of the 2018 and 2019 risk-based programme of routine GCP inspections of the CROs 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 coordination,
  - exchange of information on BE trials/CRO inspections,
  - communication of inspection findings,
  - improving the exchange of information between inspectors and assessors,
  - improving the exchange of information with no- EU regulatory authorities (i.e. FDA) including the WHO,
  - selection of trial/sites for inspection,
  - the monitoring of BE trials,
  - new tools and methodology to be used by BE inspectors,
  - management of critical findings identified during bioequivalence inspections.

7.6. Heads of Medicines Agencies

See section 7.3.

7.7. Joint meetings with interested parties

A workshop with interested parties was held on 08 May 2018 on topics regarding (electronic) archiving of study data and related subjects.

7.8. Paediatric Committee (PDCO)

Communication on inspection issues with the PDCO continued in 2018 with the exchange of information on inspections of clinical trials with a paediatric population.

8. Liaison with international partners

8.1. Regulatory agencies from outside the EEA

- The EMA and the FDA have a collaboration initiative since 2009 in the area of GCP[21]. This collaboration was extended to bioequivalence, together with some of the EU Member States[22].
  - During 2018 there were 5 regular teleconferences of the EMA-FDA GCP collaboration, 4 teleconferences as part of the EMA-FDA-MS BE collaboration and 11 teleconferences product/company specific.

[21] Announcement of the EMA-FDA GCP Initiative
[22] Terms of Engagement

- As part of the EMA-FDA GCP initiative 13 inspections have been observed and 5 have been performed jointly.
- A total of 12 teleconferences were held with FDA to discuss two projects on comparison of EMA/FDA GCP inspection outcome and a third one on collaboration in the area of Bioequivalence (also with the participation of Health Canada and WHO).
- Three FDA inspectors attended the Workshop organised by the GCP IWG. Two FDA representatives also attended the BE Forum.
- During 2018, 129 documents were exchanged, including 54 inspection reports.
- Three FDA CDER representatives took part in the June 2018 GCP IWG meeting. They also contributed to the discussions on GCP and inspection issues during the meeting.

- PMDA[23] (Japan):
  - Two PMDA representatives attended the training organised by the GCP IWG.
  - PMDA joined the FDA-EMA initiative as observers in June 2017 for 18-month pilot phase.
  - Three PMDA representatives took part in the June 2018 IWG meeting. They also contributed to the discussions on GCP and inspection issues during the meeting.
- WHO:
  - EMA, WHO and the EU MSs that perform the highest number of BE inspections had several t-cons to understand each other's inspection and regulatory procedures and responsibilities with the view of having a collaboration with regular exchange of inspection information.
  - Since 2018, WHO is an observer of the GCP IWG. Under the EMA, EC DG Santé and the WHO confidentiality arrangement, all documentation and discussions are open to WHO representatives.
- Other regulatory agencies:
  - Provided support in the preparation of the framework for sponsor inspections in Singapore.

8.2. International initiatives

- PIC/S[24] GCP/PhV working group was formed in July 2014 and reports into the PIC/S Sub-Committee on Expert Circles. The primary purpose of the group is to facilitate technical cooperation and harmonisation of practices (including the development of guidance and training material), capacity building and information sharing in the area of GCP and GVP[25] inspections. The group's membership includes representatives from Argentina, Australia, Belgium, Canada, Chinese Taipei, Croatia, Denmark, France, Hungary, Israel, Italy, Slovenia, Spain, Switzerland, the UK and the USA.

  The group also coordinates the PIC/S GCP and GVP joint visit programme, where three visits are carried out by groups of three inspectors from different PIC/S participating authorities over a period of 24 months. The purpose of the visits is to:
  - provide further training for inspectors through the exchange of experience between them;
  - provide the means of harmonising inspection procedures and developing inspection guidance;

[23] Pharmaceuticals and Medical Devices Agency
[24] Pharmaceutical Inspection Cooperation Scheme
[25] Good Pharmacovigilance Practice

- ensure and maintain mutual confidence between inspectors of PIC/S participating authorities.

  Since its formation, 23 joint visit groups have been set up: 11 for GCP, 11 for Human GVP and 1 for Veterinary GVP.

  During 2018, the group held 1 meeting during which the group reviewed the conclusions and recommendations from the joint visit reports to identify future project work.

- Capacity building in non-EU countries
  - Some EU inspectors provided mentorship, in 2018, through participation in training courses organised in countries outside the EU/EEA e.g. South America.

For details of the activities of the GCP IWG for next year see the work plan for 2020.