III Reunión de Coordinadores de Ensayos Clínicos

Lunes, 27 de noviembre de 2023

Racionalizando la burocracia en los ensayos clínicos: Observatorio de Investigación Clínica ESMO

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Organizado por:

GONORTE
Grupo Oncológico

Streamlining Clinical Research

- Introduction and methods
- Recommendations
  - Administrative procedures
    - Essential Documents
    - Document templates
    - Informed consent
    - Delegation log
    - Online platforms
    - Delegation of procedures
    - Monitoring procedures and audits
  - Pharmacovigilance
  - Medical care:
    - Clinical Interference
- Conclusions

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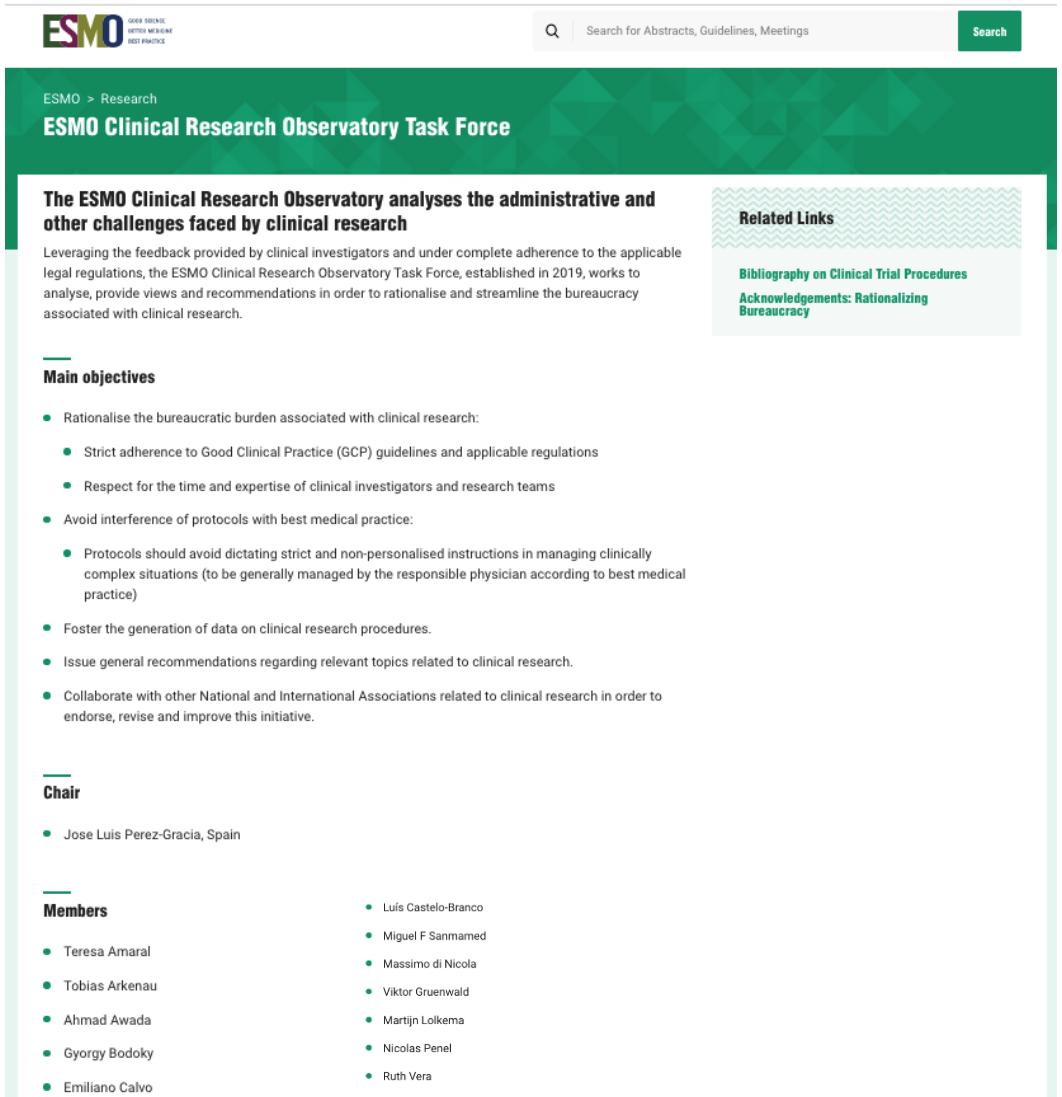
The increased burden of bureaucracy is overwhelming clinical research teams: consequences

- Poor use of the limited time of physicians and research teams:
  - Frustation and loss of motivation of experienced investigators
  - Decreases interest of young physicians towards clinical research careers
- Increased costs:
  - Delays in trial implementation, drug development and patient access to new drugs
  - Especially relevant for academic trials and rare tumors
  - Diverts resources from research to bureaucracy
- No evidence of improving patient well-being or data integrity



https://www.esmo.org/research/esmo-clinical-research-observatory-task-force

ESMO Open
Cancer Horizons

Check for updates

ESMO Clinical Research Observatory (ECRO): improving the efficiency of clinical research through rationalisation of bureaucracy

- Objective: to improve the practice of clinical research by developing communication channels between investigators and sponsors:
  - Rationalize bureaucracy and administrative procedures
  - Improve well-being of patients in clinical trials
- Methods:
  - Full adherence to the Declaration of Helsinky, GCP and regulations
    - **The high burden of bureaucracy is caused by overinterpretation and misinterpretation of guidelines**
  - Generation of data: studies, real examples, surveys, expert panels, etc.
  - Respect to all Clinical Research stakeholders and their responsibilities
  - Full supervision by the ESMO Executive Board

ECRO, ESMO Open 2020

Streamlining clinical research: an ESMO awareness call to improve sponsoring and monitoring of clinical trials

J. L. Perez-Gracia[1*], N. Penel[2], E. Calvo[3], A. Awada[4], H. T. Arkenau[5], T. Amaral[6,7], V. Grünwald[8], M. F. Sanmamed[1], L. Castelo-Branco[9,10], G. Bodoky[11], M. P. Lolkema[12], M. Di Nicola[13], P. Casali[14], R. Giuliani[15] & G. Pentheroudakis[16]

Methods:

- A panel of physicians experienced in clinical research analyzed clinical trial procedures:
  - Administrative workflow
  - Pharmacovigilance
  - Medical care

- The panel:
  - Identified situations that generate debate between investigators and sponsors / CROs
  - Selected real clinical scenarios that exemplify the problems
  - Proposed specific recommendations, based on GCP
    - **Their application depends largely on Investigators and Research Teams**

- The final manuscript was revised and agreed on by all the panel members

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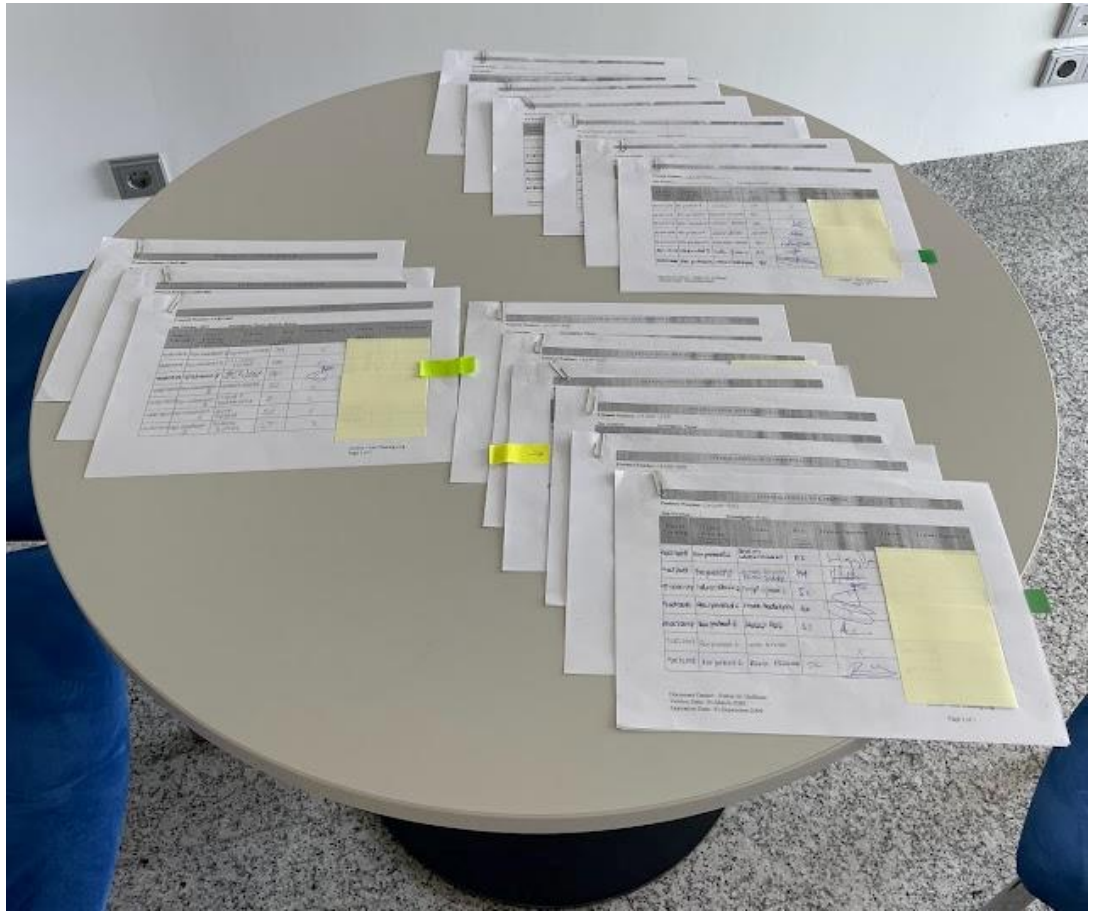
Which documents must be signed?

Overinterpretation of regulations: Superfluous documents



- Examples
  - Informative letters
  - Receipts of documents
  - Trainings
  - Central labs
  - Certificates
  - ...

Training documents to be signed for a study, following a change of procedures of the sponsor. The study was already closed.

GCP 8: ‘Essential documents for the conduct of a clinical trial’

Table 1. Essential documents for the conduct of a clinical trial that need to be signed, according to GCP (GCP, section 8)

1. Protocol, amendments (if any) and sample case report form (CRF): to document investigator and sponsor agreement.
2. Signed agreement between involved parties: to document agreements, e.g.:
   - investigator/institution and sponsor
   - investigator/institution and CROs
   - investigator/institution and authority(ies) (where required)
3. Signed informed consent forms: to document that consent is obtained in accordance with GCP and protocol and dated before participation of each subject in trial.
4. Signed dated and completed CRFs: to document that the investigator or authorized member of the investigator’s staff confirms the observations recorded.
5. Signature sheet: to document signatures and initials of all persons authorised to make entries and/or corrections on CRFs.

GCP, good clinical practice; CRO, contract research organization.

- Panel recommendations:
  - According to GCP, investigators should only sign these documents, as well additional documents required by national or local regulations (e.g. disclosure of conflicts of interest).
  - CROs and sponsors should not request that investigators sign other documents

ESMO Clinical Research Observatory, Annals of Oncology 2023

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How should

documents be signed?

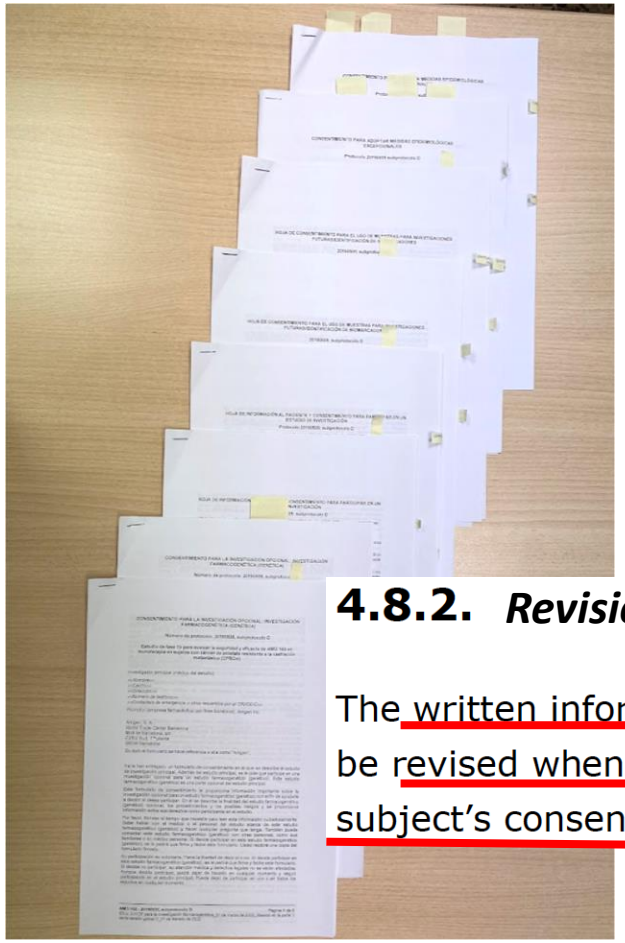
Documentation of informed consent

- *A patient signs the informed consent form. The CRO requests that the investigator adds the following information to the medical records:*
  - *"The version of the informed consent signed by the patient.*
  - *That the patient read it and signed it before any procedures are carried out.*
  - *That the patient was given sufficient time to comfortably read the information contained in the patient information sheet.*
  - *That the patient was given the opportunity to ask questions and all the doubts that arose were resolved (or that the patient did not raise any questions).*
  - *That the patient decided to sign the consent freely and voluntarily.*
  - *That the patient was given a copy of the consent form."*

1.28. Informed consent

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Revision of informed consent

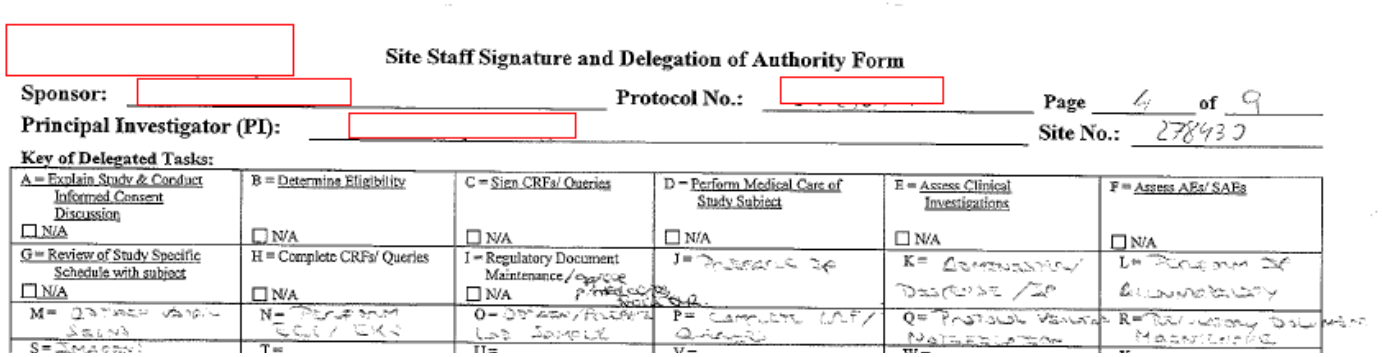


- Different updated informed consent documents to be signed by each patient (and investigator) on one day (main consent, use of samples, ...)
- The patient had abandoned the study one year before
- The institution had included 20 patients in this study

4.8.2. ***Revision of informed consent***

The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent.

Delegation log template



Site Staff Signature and Delegation of Authority Form

Sponsor: [redacted] Protocol No.: [redacted] Page 4 of 9

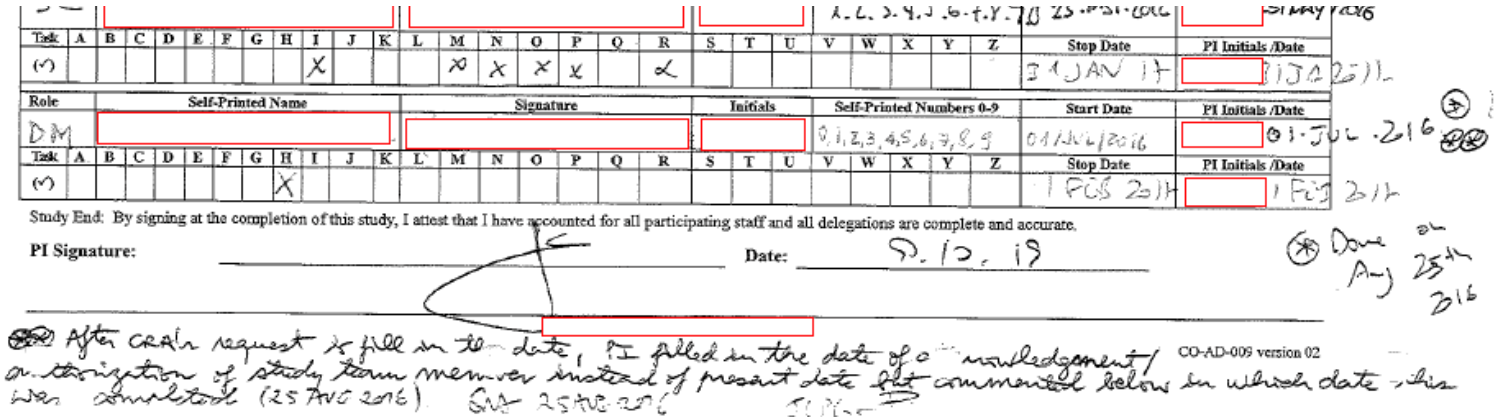
Principal Investigator (PI): [redacted] Site No.: 278430

Key of Delegated Tasks:

A = Explain Study & Conduct Informed Consent Discussion ☐ N/A	B = Determining Eligibility ☐ N/A	C = Sign CRFs/ Queries ☐ N/A	D = Perform Medical Care of Study Subject ☐ N/A	E = Assess Clinical Investigations ☐ N/A	F = Assess AEs/ SAEs ☐ N/A
G = Review of Study Specific Schedule with subject ☐ N/A	H = Complete CRFs/ Queries ☐ N/A	I = Regulatory Document Maintenance ☐ N/A	J = [illegible]	K = [illegible]	L = [illegible]
M = [illegible]	N = [illegible]	O = [illegible]	P = [illegible]	Q = [illegible]	R = [illegible]
S = [illegible]	T =	U =	V =	W =	

4.1.5. *Delegation log*

The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.



Task	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	Stop Date	PI Initials /Date
(M)									X				X	X	X	X		X									31 JAN 17	[redacted] 31 JA 2017

Role	Self-Printed Name	Signature	Initials	Self-Printed Numbers 0-9	Start Date	PI Initials /Date
DM	[redacted]	[redacted]	[redacted]	0,1,2,3,4,5,6,7,8,9	01 JUL 2016	[redacted] 01-JUL-2016

Task	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	Stop Date	PI Initials /Date
(M)								X																			1 FEB 2017	[redacted] 1 FEB 2017

Study End: By signing at the completion of this study, I attest that I have accounted for all participating staff and all delegations are complete and accurate.

PI Signature: [redacted] Date: 5.10.19

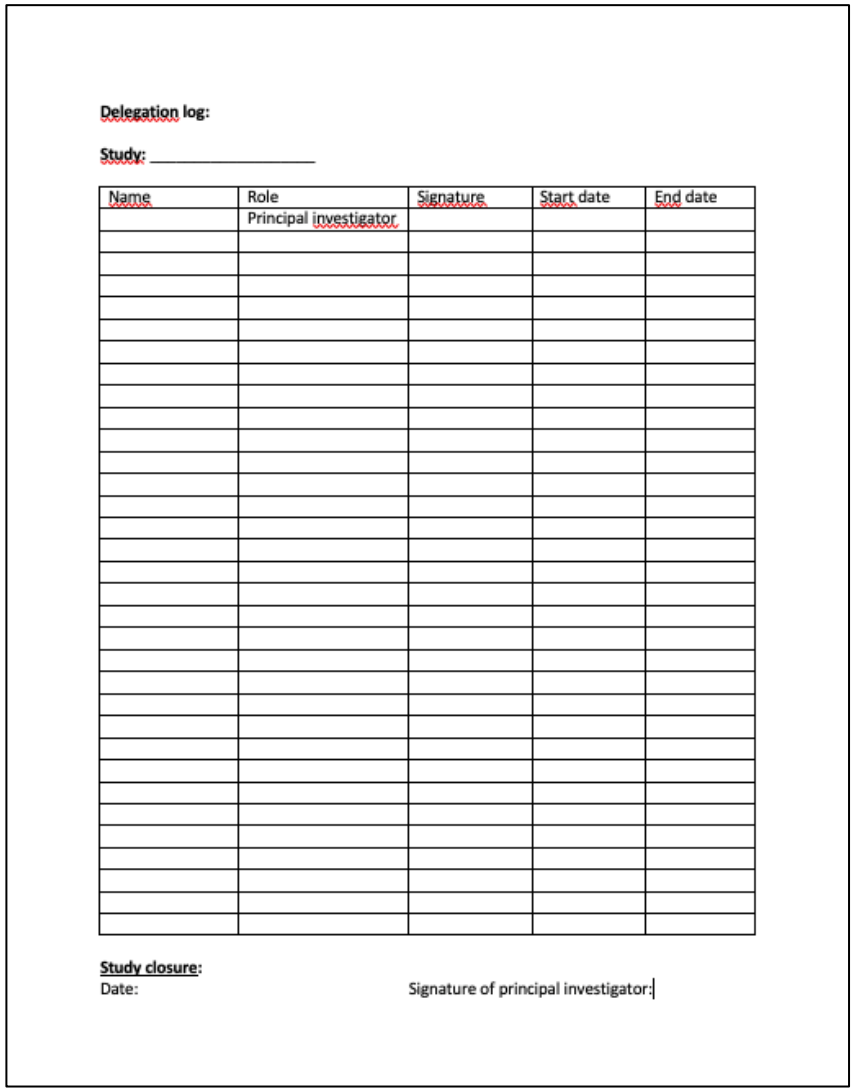
Done on 25th Aug 2016

After CRA's request to fill in the date, PI filled in the date of acknowledgement/ authorization of study team member instead of present date that commenced below on which date this was done/started (25 AUG 2016) GW 25 AUG 2016

CO-AD-009 version 02

One page (out of nine pages) from a delegation log for a study. Formats differ between different sponsors/ CRO

Delegation log template proposed by ECRO



Delegation log:

Study: _____

Name	Role	Signature	Start date	End date
	Principal investigator			

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COVANCE

Investigator Portal

FIRECREST SITE PORTAL

FIRECREST

medidata

PAREXEL Safety Information System

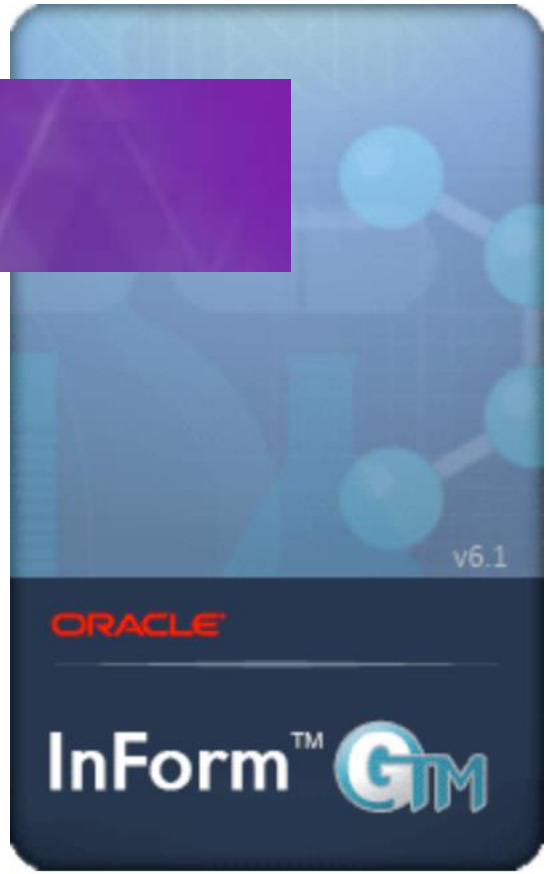
ClinOne

PPD

Interactive Web Response System

epharmasolutions

mystudies.roche.com



SHARED INVESTIGATOR PLATFORM

ORACLE® RDC Onsite

Instructions to reset a password and to unlock an account in an online platform for clinical trials

Effective Date: 02-Nov-2020 GMT-0400
Document Printed On: 31 August 2020

403_ER37_PASSWORD MANAGEMENT JOB AID
User Account Management for (Electronic Data Capture tool)

Change Password for

IMPORTANT: Wait until you receive the InForm trial access notification before attempting to login to InForm

1. Access Password Management Application main menu page by clicking on the following URL: https:// /Password_Reset
2. On the main menu page of Password Management Application, click option for **Site Users**.
3. Enter User ID and click **Continue**.
4. Select one of the three options to **authenticate**
   a. Current PMA Password (previously called CPAC Password) or Activation Code you were emailed by the Helpdesk analyst, or
   b. Answer personal questions, or
   c. Retrieve and Use Email PIN*
   **Clicking on this option will trigger an email to you with a 4-digit PIN.*
5. Enter information in the authentication screen based on the selection you made and click **Authenticate**.
6. Click on **Change Password** option.
7. Select target
8. Enter and confirm a password that meets password rules displayed on the screen, click the **Change Password** button
9. The next screen is a confirmation that your password was successfully changed
10. You can now access via the URLs available on this final confirmation page.

Unlock Account

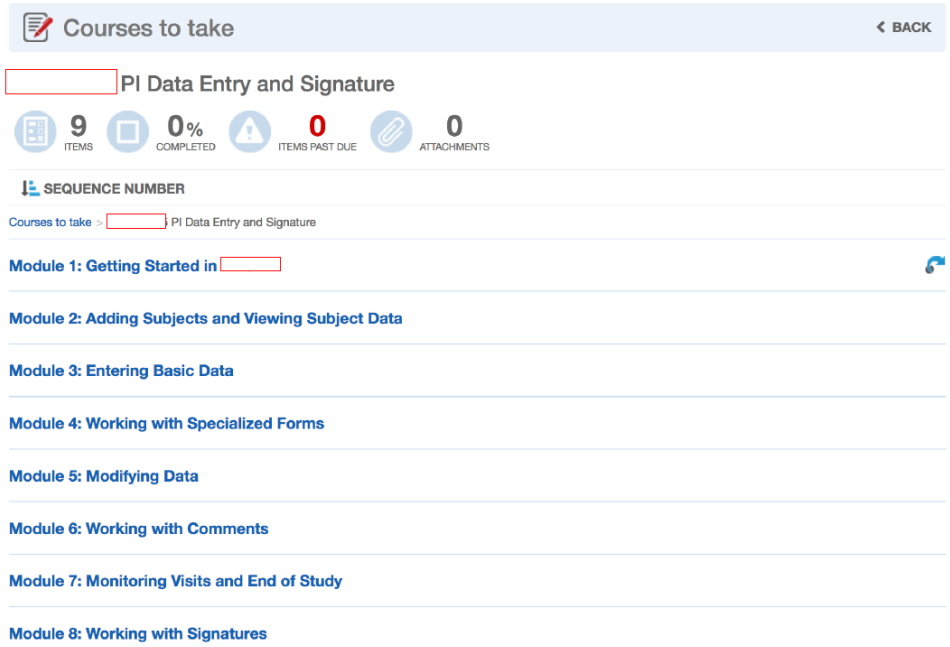
1. Access Password Management Application by clicking on https:// com/ Password_Reset
2. On the main menu page **PMA**, click option for **Site Users**.
3. Enter User ID and click **Continue.**
4. Select one of the three options to **authenticate**
   a. Current PMA Password (previously called CPAC Password) or Activation Code you were emailed by the Helpdesk analyst, or
   b. Answer personal questions, or
   c. Retrieve and Use Email PIN*
   **Clicking on this option will trigger an email to you with a 4-digit PIN.*
5. Enter information in the authentication screen based on the selection you made and click **Authenticate**
6. Click on **Unlock Accounts** option
7. Select the account you want to unlock InForm 4.6 and click **Unlock**.
8. You will now see a confirmation screen saying your account has been unlocked.
9. On this screen, click on the **Home icon** on top right corner to access Home page.
10. Click on **Change password** option.
11. Select the application you want to change password for.
12. Enter and confirm a password that meets password rules displayed on the screen, click the **Change password** button
13. The next screen is a confirmation that your password was successfully changed
14. You can now access InForm 4.6 via the URLs available on this final confirmation page.

IMPORTANT Points/Tips

1. User will have ONE User ID for both PMA and InForm
2. Users will have TWO separate passwords
   i. One to log into PMA (expires every 90 days) and
   ii. One for all trials (expires every 90 days)
   Note: These two passwords must be different.
3. The PMA password was previously called the CPAC password. It is now known as PMA password since CPAC has been retired in 4Q2020.
4. Site User will be sent an email reminder to reset password for InForm every 90 days
5. PMA password also expires every 90 days, but no email reminder will be sent
6. Whenever a user gets access to another the user will need to change their existing password (create new). This new password should be used to log-in to for all your trials
7. **Logging in to** The User ID must be entered in **UPPERCASE** in log-in screen

For additional assistance, please contact MRL Service Desk using the toll-free number provided to you by your CRA or email @ com

Mandatory online courses requested to gain access to an online platform for clinical trials



Panel recommendations:

- Online platforms should be user-friendly, favor a single, rather than multiple access, and compatible with widely used internet browsers and password management applications
- Unnecessary training courses such as those focusing on simple procedures (e.g. signing a document), or that the investigator will not use directly, should be avoided

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Delegation of procedures

- Clinical scenario:
- The investigator must sign personally most documents. No delegation to other team members is allowed, causing administrative overload.
- The investigator is set as default contact for receiving all study documents and materials, which are delivered to the investigators office and e-mail, rather than to the appropriate unit within the site.

- Panel recommendations:
- The high professional training of research teams' members allows them to assume highly complex responsibilities.
- GCP allows delegating CRF signature to authorized members of the investigators staff (GCP 8.3.14).
- Delegation of complex tasks should be favored by sponsors and CROs.
- e-mails, documents, and materials should be addressed to the appropriate persons, avoiding setting the principal investigator as the default contact for every aspect of the study.

Monitoring procedures and audits

- Clinical scenario:
- A protocol requires that patients have received prior standard therapy for advanced urothelial cancer. A patient received prior gemcitabine and carboplatin. The investigator is required to document that this is the standard treatment of this condition (back in 2018).

- Panel recommendation:
- *'Monitors should be appropriately trained and should have the scientific and/ or clinical knowledge needed to monitor the trial adequately.*

A monitor's qualifications should be documented.' (GCP 5.18.2).

- Sponsors and CROs must provide appropriate training to monitors.

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Pharmacovigilance:
38 reports in less than 24 hours …

Safety Letter	**Investigator Safety Letter; MCN 2021-0528304**	Dear Investigator, Attached is a CIOMS of an individual case safety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for exped	6:55
Safety Letter	**Investigator Safety Letter; MCN 2021-0529556**	Dear Investigator, Attached is a CIOMS of an individual case safety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for exped	6:47
Safety Letter	**Investigator Safety Letter; MCN 2021-0529063**	Dear Investigator, Attached is a CIOMS of an individual case safety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	6:35
Safety Letter	**Investigator Safety Letter; MCN 2021-0529420**	Dear Investigator, Attached is a CIOMS of an individual case safety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	
Safety Letter	**Investigator Safety Letter; MCN 2021-0529514**	Dear Investigator, Attached is a CIOMS of an individual case safety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	5:45
Safety Letter	**Investigator Safety Letter; MCN 2021-0529453**	Dear Investigator, Attached is a CIOMS of an individual case safety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	5:32
Safety Letter	**Investigator Safety Letter; MCN 2021-0529043**	Dear Investigator, Attached is a CIOMS of an individual case safety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	5:24
Safety Letter	**Investigator Safety Letter; MCN 2021-052819**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	5:16
Safety Letter	**Investigator Safety Letter; MCN 2021-052892**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	5:06
Safety Letter	**Investigator Safety Letter; MCN 2021-052891**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	4:58
Safety Letter	**Investigator Safety Letter; MCN 2021-052812**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	4:51
Safety Letter	**Investigator Safety Letter; MCN 2021-052921**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	4:43
Safety Letter	**Investigator Safety Letter; MCN 2021-052905**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	4:35
Safety Letter	**Investigator Safety Letter; MCN 2021-052897**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	4:28
Safety Letter	**Investigator Safety Letter; MCN 2021-052895**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	4:21
Safety Letter	**Investigator Safety Letter; MCN 2021-052894**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	4:13
Safety Letter	**Investigator Safety Letter; MCN 2021-052891**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	4:05
Safety Letter	**Investigator Safety Letter; MCN 2021-052824**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	3:57
Safety Letter	**Investigator Safety Letter; MCN 2021-052821**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	3:49
Safety Letter	**Investigator Safety Letter; MCN 2021-052818**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	3:41
Safety Letter	**Investigator Safety Letter; MCN 2021-052814**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	3:27
Safety Letter	**Investigator Safety Letter; MCN 2021-052915**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	1:59
Safety Letter	**Investigator Safety Letter; MCN 2021-052903**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	0:51
Safety Letter	**Investigator Safety Letter; MCN 2021-052896**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	0:38
Safety Letter	**Investigator Safety Letter; MCN 2021-052869**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	23:45
Safety Letter	**Investigator Safety Letter; MCN 2021-052862**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	23:07
Safety Letter	**Investigator Safety Letter; MCN 2021-052830**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	22:56
Safety Letter	**Investigator Safety Letter; MCN 2021-052829**	tor, Attached is a CIOMS of an individua ety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	22:47
Safety Letter	**Investigator Safety Letter; MCN 2021-0528295**	Dear Investigator, Attached is a CIOMS of an individual case safety report (ICSR) utilizing an auto-generated narrative format that meets the criteria for expedited safety reporting to applicable	22:34

Guidance for Industry and Investigators

Safety Reporting Requirements for INDs and BA/BE Studies

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2012
Drug Safety

- *"Reporting individual events for which there is little reason to believe that the drug caused the event is generally uninformative".*

- *"Attempting to evaluate these reports (...) is a drain on resources for FDA, investigators, and institutional review boards (IRBs), diverting them from other activities".*

- *"Such events (...) should not have been reported as IND safety reports".*

- *"Reducing the number of uninformative individual reports will enhance the ability of sponsors, FDA, investigators, and IRBs to focus on safety issues that affect public health".*

FDA, December 2012, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safetyreporting-requirements-inds-investigational-new-drug-applications-and-babe

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Clinical interference

- Situations in which the study protocol, or its interpretation by the sponsor and/or CROs impose a decision regarding patient management which diverges from the best medical judgment, according to the investigators criteria.

- Such (infrequent) situations challenge the principles of the Declaration of Helsinki and GCP, and may be detrimental for the patient.

Clinical interference (I): protocol does not allow radical treatment for oligometastatic disease

- 42 yr-old male, advanced NSCLC, responding to therapy.
- The investigator requests radiosurgery for a single CNS lesion (previously unknown, baseline CNS screening not mandatory)

- Response:

The patient can continue on XXXXX treatment as long as he is clinically stable.
However, patient can not get surgery or radiation therapy for the brain lesion while he is participating in the study.
Please understand that this is to test the efficacy of XXXXX objectively.

Thanks,

Clinical interference (II): patients deteriorates while waiting 3 weeks for central confimation of molecular results

Lung cancer at the intensive care unit: The era of targeted therapy

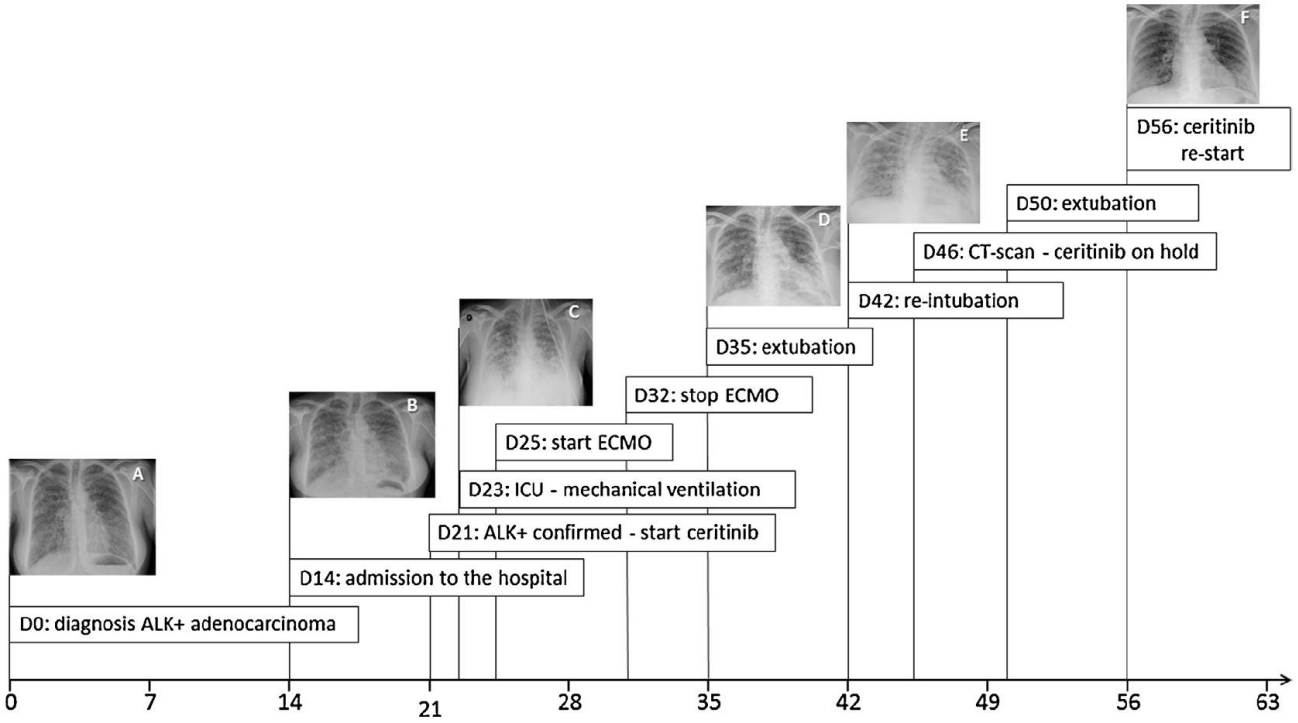

Fig. 1. Schematic time course of the disease, form diagnosis to discharge from the hospital.

21-day delay in treatment initiation due to central confirmation of ALK+ status:

"the question can be raised if the quality of the clinical trial would be harmed if a patient starts therapy based on a validated local positive test"

Adam, Lung Cancer 2015

Clinical interference (III): Treatment discontinuation mandated, based on independent CT review, instead of investigator´s criteria

- E-mail received by investigator:

Dear Dr. XXXXXXXXXXXX

Attached is the report from XXXXXXX on your subject XXXXXXX from the Week 80 scans performed on 11-Apr-2016. XXXXXXX has confirmed metastasis to left para-aortic lymph nodes.

Based on the development of metastasis, the subject should have an end of treatment (EOT) visit (…) The patient should continue to be followed every 4 months for survival.

Please feel free to contact us if you have any questions.

Streamlining clinical research: an ESMO awareness call to improve sponsoring and monitoring of clinical trials

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Table 2. Summary of the proposed framework of principles and recommendations for optimal sponsoring and monitoring of clinical trials

Recommendations for sponsors and CROs:

1. Study procedures: limit the administrative burden to the concepts specifically required by GCP and the applicable regulations.
   - 1.1. Investigators should only sign the documents that are considered essential, and which must be signed by the investigator, according to GCP (GCP section 8; Table 1).
   - 1.2. Use simplified document templates. Avoid including unnecessary ancillary information.
   - 1.3. 'The informed consent should be documented by means of a written, signed and dated informed consent form', as required by GCP (GCP, section 1.28). Duplicating this information in the medical records is not required by GCP, may lead to errors, and does not correctly document the process, since the medical records are not signed by the patient.
     'The written informed consent form (...) should be revised whenever important new information becomes available that may be relevant to the subject's consent' (GCP 4.8.2). Sponsors and CROs should confirm that this criterion is met before requesting patients to re-consent.
   - 1.4. Use simplified delegation log templates. According to GCP, the responsibility of maintaining the delegation log corresponds to the investigator (GCP 4.1.5), who should decide the most appropriate format. We suggest a simplified model in Supplementary Annex 1, available at https://doi.org/10.1016/j.annonc.2022.09.162.
   - 1.5. Develop user-friendly and intuitive electronic resources, which do not require intensive training. Avoid requesting unnecessary training courses.
   - 1.6. Maximize the possibility of delegating tasks from the investigators to other members of the clinical research team.
   - 1.7. Monitoring, audits, and inspections should only request that investigators perform the administrative tasks required by GCP and applicable regulations. Monitors should receive appropriate training in the disease studied.
2. Pharmacovigilance procedures should be focused on improving patient safety. Submitting to investigators individual events which are likely unrelated to the study drugs should be discouraged.
3. Avoid clinical interference of protocols with best medical practice and maximize the options for cross-over in clinical trials, when appropriate.

Recommendations for regulatory authorities

Regulatory authorities may support these principles by considering implementation of the following actions:

1. Ensure that administrative procedures required by clinical research regulations are necessary to guarantee the safety and the rights of patients and the scientific integrity of the data, avoiding an excessive bureaucratic burden.
2. Use wording that prevents overinterpretation of regulations.
3. Include in regulations the concept of clinical interference, and the need to prevent it.
4. Request that pharmacovigilance procedures be directed towards improving patient safety by adequately informing the investigator, following comprehensive and thorough analysis of the safety information by the sponsor.

ESMO Clinical Research Observatory, Annals of Oncology 2023

Conclusions

- Investigators and Sponsors:
  - are committed to following GCP and the applicable regulations
  - should collaborate to rationalize clinical research procedures:
    - avoiding unnecesssary bureaucracy
    - maintaining the high standards of clinical research
  - must develop robust communication channels to streamline clinical research

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Thanks for your time!

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ESMO Clinical Research Observatory (ECRO)

GOOD SCIENCE
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BEST PRACTICE

European Society for Medical Oncology

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Monitoring procedures and audits (II)

- Clinical scenario:
  - The investigator is required to meet with the monitor at each visit even if there are no clinical issues to comment, just administrative procedures.

- Panel recommendations:
  - Unneccessary meetings should be avoided
  - Study meetings should focus on core aspects of protocols, especially on clinical issues, avoiding ancillary administrative procedures.
  - Study monitoring, audits, and inspections should only request administrative procedures covered in GCP and the applicable regulations.
  - Sponsors and CROs frequently consider deviations from the study protocol as ‘major’, without a rigorous assessment, reducing the significance of the term.