KEMENTERIAN KESIHATAN MALAYSIA

PUBLIC CONSULTATION CLOSURE REPORT

TITLE:

MALAYSIAN GUIDELINE FOR GOOD CLINICAL PRACTICE (GCP) INSPECTION 3RD EDITION

National Pharmaceutical Regulatory Agency
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1. INTRODUCTION

1.1. Affected Stakeholder

This Unified Public Consultation (UPC) on Malaysian Guideline for Good Clinical Practice Inspection 3rd Edition involves the following stakeholders:

- Public University
- Private University
- Clinical Research Malaysia (CRM)
- Clinical Research Centre (CRC)
- Pharmaceutical Industries

1.2. Purpose of the UPC.

The guideline has been updated to incorporate an enhanced inspection process, as well as revised terms and definitions in alignment with ICH Good Clinical Practice (GCP) E6 (R3) and the applicable local context.

1.2. Summary of the public consultation results.

The public consultation was originally conducted from 19 September 2025 to 19 October 2025. However, following the migration of the public consultation portal to a new platform on 1 October 2025, technical issues (bugs) were encountered that prevented stakeholders from submitting comments on the proposed guideline.

In light of these issues, the GCPGLP Section extended the consultation period until 28 November 2025. Overall, the public consultation period lasted a total of 71 days.

During the consultation period, the guideline received a total of 54 comments from seven (7) stakeholders.

No questionnaire or survey was conducted during the consultation period for this guideline.

2. GENERAL COMMENTS

2.1. Summary

Overall, the consultation provided constructive feedback on the proposed guideline updates. As the consultation period coincided with the UPC for the SODIP consultation, several stakeholders requested that the guideline be updated in accordance with the forthcoming SODIP Regulations. Nevertheless, as SODIP is still in the drafting stage, alignment with ICH Good Clinical Practice (GCP) E6(R3) was deemed a critical priority for the current update.

Table 1. Comments, suggestions and feedback received for Malaysia Guideline for Good Clinical Practice (GCP) 3rd Edition.

No.	Respondent demography	Significance of comments/feedback	Area	Comments/feedback/query	NPRA Response
1	Government	Significant	Administrative	Routine and For-Cause Inspection should be numbered	Accept the recommendation. Amended according to lines 677 and 686.
2	Government	Significant	Flow Chart of GCP Inspection	Flow chart 3.2- pre-inspection preparation - to rephrase to enhance clarity for e.g 'Submit pre-inspection documents	Accept the recommendation. The examples and conditions of pre-inspection preparation have been included.
3	Government	Not significant	Outcome of Inspection	Section 4.0- outcome of GCP inspection (favourable outcome and non-compliance) may need to be aligned with section 6.0. Critical, major and minor - how does it classified under favourable outcome or non-compliance	Disagree with the comment. This has been addressed in guideline line 805. The categorisation of the finding indicates the severity of the finding but the nature of the finding does not necessarily lead to compliance or non-compliance. The outcome of the inspection, whether it is compliance or non-compliance, depends on how the CAPA is being addressed.

4	Government	Significant	CAPA Evaluation Form	Pg 23 - Appendix A > clinical trials reviewed> should also include CTX	Agree with the recommendation. Amended accordingly in Appendix A.
5	Government	Significant	CAPA Evaluation Form	Pg 24-under the heading facilities and equipment -our inspection is not limited to this also protocol etc, perhaps the heading can be broader	Agree with the recommendation. Amended accordingly in Appendix A.
6	Government	Not Significant	Administrative	Explanation in 'original' is great and should be considered to produce comprehensive guidelines	The comment is unclear, and the specific concern is not evident.
7	Government	Significant	Technical	Must have a clear statement 'inspection' conducted by regulatory authorities whereas 'audit' can be performed by others CRO, sponsors, study site etc	This comment has been addressed in the Glossary. The definition of audit and inspection has been clearly explained in the glossary.
8	Private institution	Not Significant	Administrative	The term CTIL/CTX is still mentioned : line 740 and 741.	The term CTIL/CTX remains in effect under current regulations and guidelines. Until the effectiveness of SODIP is established, the term is still applied.

9	Private institution	Significant	Terms and Condition	inspected party (parties) like inspection can be at CRO , sponsor and site. or organizations . EMA uses personnel	To update the glossary to include a definition of inspected party, which can be used interchangeably with inspectee. The definition of " inspected party" has been included in the terms and conditions section. The inspected party can be used interchangeably with the inspectee.
10	Private institution	Not Significant	Scope of Inspection	2. How about an inspection towards a Clinical Trial approved by MDA? Is the safety of the patients using the interventional medical devices but not in systemic or active compounds?	Medical devices are not under NPRA jurisdiction, and NPRA GCP inspections cover only pharmaceutical products. Therefore, it is not applicable for inclusion in the guideline.
11	Private institution	Not Significant	Law and Regulation	Inspection report: Report prepared by the official representing the Competent Authority, stating whether the company inspected in general complies with the requirements of Directive (EU) 2017/1572, Delegated Regulation (EU) 2017/1569	The EU directive is not applied to the GCP Inspection in Malaysia.

				and/or 91/412/EEC and whether the manufacturer is acceptable for the products in question. The Union report format applies.	
12	Private institution	Not Significant	Law and Regulation	CAPA reporting still has CTIL/CTX	The terms CTIL/CTX are still in effect under the current regulations and guidelines. Until the effectiveness of SODIP is established, the term is still applied.
13	Private institution	Not Significant	Law and Regulation	How Clinical Trial Authorization (CTA) impacted in GCP inspection is that only based on the holders or site or CRO manages the trial.	CTA has yet to be imposed until the enforcement of the relevant regulations.
14	Private institution	Not Significant	Law and Regulation	54-60 - This guideline was issued by the DG of Health under Regulation 29 of CDCR 1984. Will the current SODA be amended to include the wording on the clinical trial?	This comment is not relevant, as the current CDCR 1984 is still effective. Hence, all guidelines will still be issued by the DG of Health under Regulation 29.

15	Private institution	Not Significant	Law and Regulation	105 - Current Malaysian GCP Guideline is still based on ICH E6(R2). Therefore, Malaysian GCP Guideline first need to be updated by adapting/adopting to ICH E6(R3) before Malaysian GCP Inspection Guideline can use ICH E6(R3)	The process of updating the Malaysia GCP Guideline was conducted concurrently with the update on the Malaysia GCP Inspection Guideline by NPRA. By the time the MGCP 5th Edition is released for implementation, the Malaysia GCP Inspection Guidelines will also be available, and aligned with the MGCP 5th edition and ICH E6 R3 Requirements.
16	Private institution	Not Significant	Law and Regulation	184 - Content to be aligned with SODIP that is going to be enforced	The content of this guideline is relevant to the current regulations until the SODIP implementation
17	Private institution	Not Significant	Law and Regulation	740 - Content to be aligned with SODIP that is going to be enforced	The content of this guideline is relevant to the current regulations until the SODIP implementation

18	Private institution	Significant	administrative	771 - We prefer Appendix I to Appendix IV to remain in the Guideline as a single reference	Due to constant upgrades and evolving requirements in the Clinical trial (i.e evolving usage of AI, and requirement of Annex 2, therefore), NPRA decided to address the information available in the Appendix I to IV in the FAQ of the NPRA website.
19	Private institution	Significant	Inspection Report and CAPA	803 - Please specify the timeframe for the inspector to issue the inspection report	To include a timeline for issuance of the inspection report in the narrative (line 803) and flow chart (line 727). Timeline for the issuance of the inspection report by the inspector, included under section 3.4 (Inspection report and CAPA), includes issuance of the report to the inspected party within 30 WD from the last date of the inspection.

20	Private institution	Not Significant	Outcome of GCP Inspection	832 - For non-compliance, we prefer to maintain the description of non-compliance (classification of offence) and the type of action to be taken, whether it is regulatory or legal action	The content of this guideline is relevant to the current regulatory framework. Regulatory action will be decided by the DCA. Therefore, classification of the offence may not be applicable to those listed here. We propose the general term for non-compliance. Further procedures on regulatory or legal action will be updated once SODIP is implemented in future.
21	Private institution	Not Significant	administrative	964 - We prefer Appendices A, B and C to remain in the Guideline as single reference	The appendix A, B, C will be addressed in the FAQ on the website. This allows the NPRA to update the example of the significant finding that was observed during the GCP inspection.

22	Private institution	Significant	Inspection report and CAPA	971 - Please specify the timeframe for CAPA review by Authority for each CAPA	To include a timeline for issuance of CAPA in the narrative (line 803) and flow chart (line 727). Amended accordingly. The CAPA review timeline is included under section 3.4 Inspection report and CAPA. The CAPA correspondence will be reviewed by the inspection team within 30 WD from the date of receipt.
23	Private institution	Significant	CAPA Evaluation Form	972 - Please remove the header (e.g. facilities and equipment) and only list out the findings based on their category	Amended accordingly in Appendix A. Header example to indicate the area of the findings. Inclusion of the area of the finding will assist the NPRA in grouping findings by area for statistical purposes.
24	Private institution	Significant	CAPA Evaluation Form	972- Please remove the second example under the critical finding category to avoid confusion. For each category, one example is sufficient	Amended accordingly in Appendix A.

25	Private institution	Significant	CAPA Evaluation Form	972- What about minor finding	Amended accordingly in Appendix A. The template include the minor finding
26	Private institution	Not Significant	Impact on regulatory timelines	Expanding inspections to include completed clinical trials may risk delaying drug approval timelines. We recommend NPRA prioritise the inspection of pivotal trials intended for near-term registration or allow sponsors to request early inspection scheduling	Not applicable. GCP inspection by NPRA prioritises completed pivotal clinical trials which involve trial participants in Malaysia to support product registration.
27	Private institution	Not Significant	Feasibility of remote/hybrid inspection	Many Malaysian sites have inconsistent internet stability or legacy systems. We request clarification on minimum technical requirements, acceptable platforms, and alternative evidence formats.	Not applicable. The suggestion is not applicable under the scope of this guideline. Technical requirements are usually communicated between the inspection team and the inspected party, and an agreed system or platform is selected that best suits the situation. Therefore, listing the technical requirements may limit the system or specification that works for both parties.

28	Private institution	Not Significant	Operational Clarity on Obstruction	Certain hospital-level processes (e.g., photography restrictions, medical record retrieval delays) may be misinterpreted as obstructing inspection. Clearer definitions would help ensure fairness.	Not applicable. The circumstances included under the refusal of inspection provide a general idea. Anything that is too specific may lead to overinterpretation (Source of the Clause: USFDA).
29	Private institution	Not Significant	Consistency in risk-based inspection selection	More detail would support operational planning, for example, whether product type, study phase, or size are used as criteria.	Not applicable, has been addressed in the guideline under lines 679 - 683. Site selection criteria were applied using a risk-based approach, as explained in Clause 3.1.1 (i.e Pivotal, but not limited to). Details of the selection criteria are not included in the Guideline, as it is an internal procedure on how routine GCP inspections are initiated.

30	Private institution	Not Significant	Categories of Inspection	The expanded inspection scope to include completed trials may directly affect dossier submission timing. Routine inspections should ideally be conducted before regulatory submission to avoid delays. Request: Provide guidelines for prioritising inspections of studies linked to upcoming registrations and define criteria used for risk-based selection.	Please refer to the definition of a routine inspection as outlined on the webpage. A routine GCP inspection conducted by NPRA or other regulatory authorities differs from routine or surveillance inspections performed by accreditation bodies or monitoring authorities under compliance programmes, which are carried out at predetermined intervals. Additionally, risk-based selection is an internal process, and the specific selection criteria should not be disclosed. Only general criteria and overarching statements should be included in the guideline.

31	Private institution	Not Significant	Conduct of GCP Inspection	Not all sites can provide immediate access to all systems or physical records. Request: Clarify acceptable alternative evidence when systems are slow, archived, or require hospital approval.	Not applicable under the scope of this Guideline. It is the sponsor's responsibility to ensure the site's readiness for regulatory inspection . Therefore, the requirement is not applicable to be included in the guideline.
32	Private institution	Not Significant	Availability of key personnel	Ensuring PI, CRC, pharmacist, IT, and QA availability at short notice may be challenging for certain government hospitals. Request: Provide expected response times or "reasonable availability" criteria.	This is not under the scope of the guideline. Based on our experience, this is not an issue.

33	Private institution	Not Significant	Remote Inspection logistic	Clarify acceptable platforms, handling of connectivity limitations, and requirements for PDPA-compliant data sharing.	PDPA 2010 is mandatory for the private sector, and explicitly excludes the Federal and State governments. It is the sponsor's responsibility to ensure that these requirements are met while allowing NPRA and other RA to conduct GCP inspections. Government agencies and government servants are bound by the Official Secrets Act (OSA) 1972 regarding classified information and documents. The comment is not applicable under this guideline.
34	Private institution	Not Significant	Outcome of GCP Inspection	Internal committee review is noted. Request: Provide typical timelines for closure, especially for pivotal trials nearing dossier submission.	Not suitable for inclusion in the GL. Any further clarification (if necessary) should be included in the FAQ, and not in the guideline.
35	Private institution	Significant	outcome of GCP Inspection	The removal of verification inspections puts strong emphasis on CAPA documentation.	Example of findings will be included in the FAQ section on the website

				Request: Include examples of effective CAPA evidence, or define what constitutes sufficient documentation for CAPA verification. Escalation to CPCE/DCA is understood, but clarity on escalation triggers and timelines would help sponsors prepare appropriately.	
36	Private institution	Not Significant	Delay, Deny, limit or refuse inspection	We request further guidance to differentiate genuine site constraints (e.g., restricted areas, patient-sensitive zones, medical records office procedures) from non-compliance, to prevent misclassification.	Examples of findings will be included in the FAQ of the website. Adding the examples of findings in the guideline may limit the list of significant findings.
37	Private institution	Not Significant	Classification of Finding	We request NPRA to publish updated examples of Critical, Major, and Minor findings on its FAQ page for consistent industry interpretation, especially regarding accumulation of minor deviations. Appendix A – CAPA Evaluation Form	Example of finding which was previously included under the Appendix a,b,c will be included as part of the FAQ on the website.

				The standardised CAPA format is welcomed. We suggest NPRA provide anonymised sample CAPA	
38	Private institution	Not Significant	additional consideration	Clarification on expectations for legacy systems lacking full audit trails.	Not applicable to the scope of this guideline. The expectation of the computerised system according to the applicable GCP requirement.
39	Private institution	Not Significant	additional consideration	Whether multi-site inspections will be staggered to avoid overburdening sponsor personnel	No amendment/change needed. LO of inspection will communicate and coordinate with the site/sponsor before finalising the inspection date.
40	Private institution	Not Significant	additional consideration	Additional guidance on boundaries between routine monitoring activities and inspection expectations.	The potential area covered during the GCP inspection will be addressed in the FAQ of the webpage.

41	Private institution	Significant	Abbreviation section	(Line 184 to 186) Consider removing this section — most terms are already defined in Section 2 (Terms and Definitions), and several items are no longer applicable following removal of Appendices I–IV. Abbreviations such as CTIL & CTX can be defined at first use (page #15, line 740)	The suggestion was noted, and the amendment will be made accordingly.
42	Private institution	Not Significant	3.1 Routine inspection	(line 677 to 680) The updated guideline does not mention routine surveillance GCP inspection, does it mean future routine GCP inspection will be triggered by product registration application only?	Please refer to the routine inspection definition (webpage). A routine GCP inspection by NPRA and other RA is unlike a routine/surveillance inspection by the accreditation body or monitoring authority under a compliance program, which is conducted at intervals. Risk-based selection is an internal procedure. Specific selection criteria are not to be exposed. Only the general criteria and

					statements are to be mentioned in the GL.
43	Private institution	Significant	(Flow Chart of GCP Inspection)	Lines 3.2. When further CAPA is evaluated as required, instead of back to the step 'evaluation of CAPA', should the step back to 'CAPA', which means the inspected party need to submit an updated CAPA to the regulatory authority?	The flow chart in section 3.2 has been amended for clarity.
44	Private institution	Significant	Inspection Report and CAPA	There was no calculation start date for the subsequent CAPA responses, is it following the same	The statements are updated for better clarity.

				rule for additional CAPA (from the date of request) or can we further clarify on this?	
45	Private institution	Significant	5. Refusal of inspection	(line 860-863) Denial of inspection NPRA interprets the word deny to include active behaviour by the owner, operator or service provider agent of a medicinal product facility to prevent GCP inspectors from conducting an inspection or to prevent GCP inspectors from completing an inspection.	The suggestion was noted and amended in guideline.
46	Private institution	Significant	5. Refusal to permit entry or inspection (line 888-891	Refusal to permit entry or inspection Refuses to permit entry or inspection includes active and passive behaviour and non-action by the owner, operator or service provider agent e.g: of a drug facility/institution/site that results in GCP inspectors not being able to enter or fully inspect the facility	The suggestion was noted and amended in guideline.

47	Private institution	Not Significant	Classification of Inspection Finding	Suggest allowing flexibility & permit equivalent CAPA Form to be used. "….Responses to inspection findings shall be submitted electronically using the template outlined in Appendix A – CAPA Evaluation Form or an equivalent CAPA form ."	The suggestion is rejected; only the NPRA CAPA template should be used.
48	Private institution	Significant	Terms and Condition	Consider maintaining the word "observation" (per line 535, section 2.0 Terms and definitions) OR "finding" throughout the document.	A definition for "finding" under Section 2.0 Terms and Definitions will be included, and the use of "finding" will be standardised instead of "observation" as part of the narration under the Guideline. The "observation" will be from the guideline.
49	Unknown	Significant		If there is evidence of serious breach of misconduct, will the investigator be blacklisted from conducting a trial?	A general clarification statement will be included in the FAQ.

50	Unknown	Not Significant	Administrative	It may be good to have the inspection checklist as an appendix.	The potential area covered during the GCP inspection will be addressed in the FAQ. The checklist for the inspection is for internal use to guide the inspector and is not suitable for public information.
51	Unknown	Not Significant	Outcome of the GCP Inspection	How come there is no decision tree on whether DCA is going to terminate, suspend, or continue the conduct of research?	Not applicable to the current regulation. This will be covered under the SODIP once it is implemented.
52	Unknown	Not Significant	Scope of guideline	Will there be any clinical audit since it is a clinical matter? I mean there should be a doctor as part of the inspection team.	The clinical audit is under a different scope. NPRA GCP inspection is a regulatory inspection for product registration purposes. For the assessment and monitoring of PI compliance with GCP, the MREC conducts compliance review audits (routine and triggered). The MREC compliance review team comprises

					inspectors/auditors with medical backgrounds.
53	Unknown	Not Significant	Scope of guideline	Outline guidance for conducting verbal and written consent in different languages (dual language consenting).	Not within the scope of this guideline
54	Unknown	Not Significant	Scope of guideline	Specify how investigators should assess and document the patient's understanding of both languages	Not within the scope of this guideline

3. SURVEY FEEDBACK

3.1. Dashboard of Public Consultation

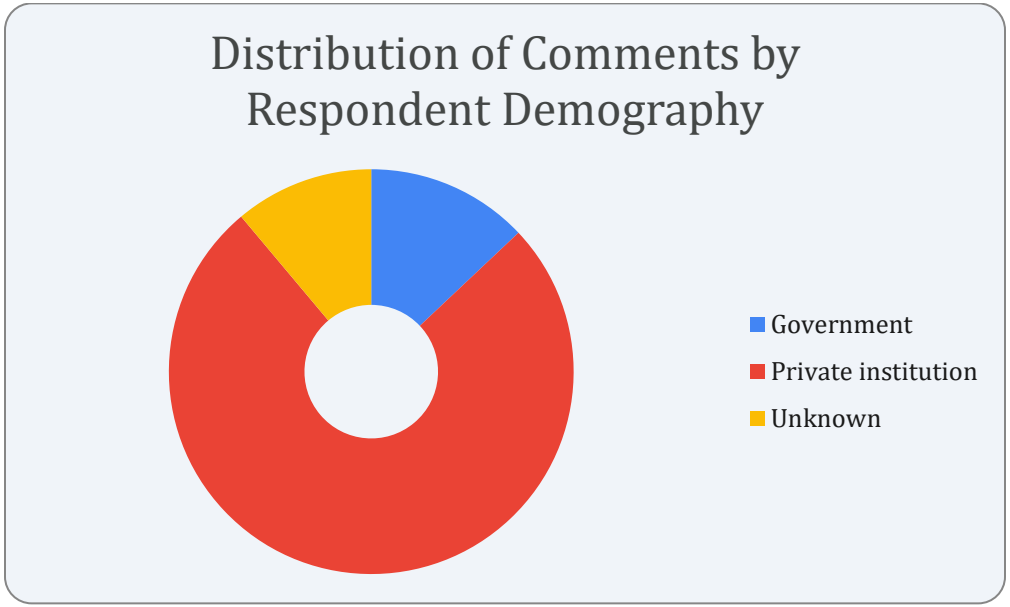

Figure 1. The Pie chart illustrates the Respondent Demographic Distribution.

3.1.1. The distribution of comments by respondent demography is as follows:

Respondent demography	Count	Percentage
Private institution	41	75.90%
Government	7	13.00%
Unknown	6	11.10%

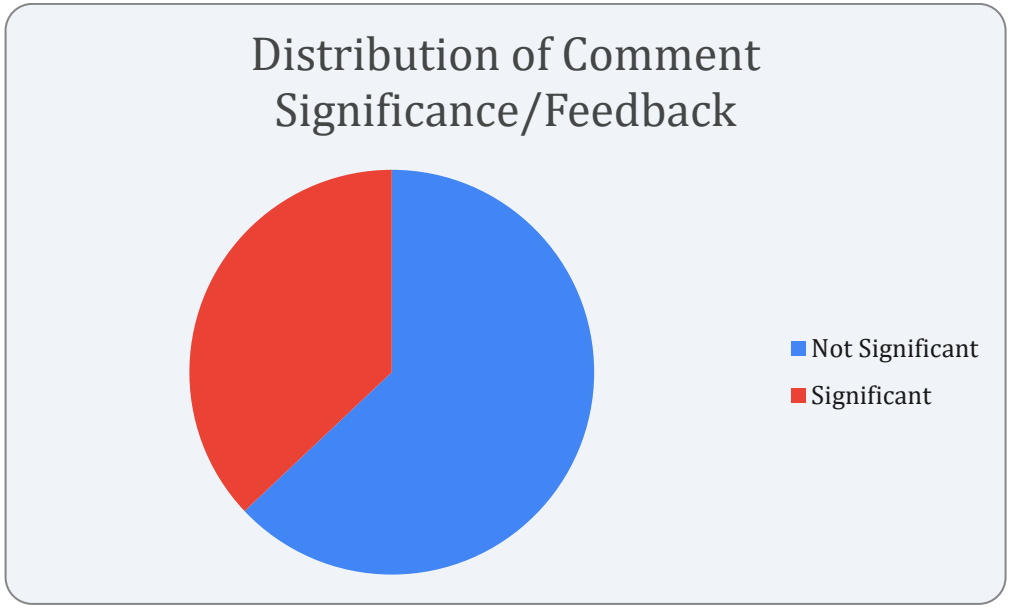

Figure 2. The Pie Chart showing the distribution of Comment Significant vs Not significant

3.1.2. The distribution of comments is as follows:

Comment	Count
Not Significant	34
Significant	20

4. CONCLUSION AND RECOMMENDATION

4.1. Conclusion

Based on the public consultation, no objections were raised to the update, with all respondents expressing their support and providing constructive comments on the draft.

4.2. Recommendation

Relevant comments will be incorporated into the final version of the guideline. Based on the feedback received, editorial revisions will be made to enhance the inspection process flowchart and provide better clarity. Certain recommendations will be addressed in the Frequently Asked Questions (FAQ) section on the NPRA website, as these matters are considered more appropriately clarified through FAQs than included in the guidance document.

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18 December 2025

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