Table S1 List of Delphi review rules revision comparison table

Initial review rules	Final established review rules
X1. If the contract does not contain a section for the signature of the legal representative of Party A, it is deemed non-compliant with the review requirements.	Same as the initial rules.
X2. If the contract text includes a clinical trial budget table, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X3.If the clause "After unblinding a blinded trial, the sponsor should promptly inform the researcher in writing about the trial medication status of the subjects" is not included in the contract, it is deemed non-compliant with the review requirements.	Same as the initial rules.
X4. If the clause "at the end of the project, if a refund is required, Party A (or the sponsor) Sponsor shall bear non-refundable taxes during trial fund reimbursement" is not included in the contract, it is deemed non-compliant with the review requirements.	X4. If the clause "at the end of the project, if a refund is required, Party A (or the sponsor) can initiate a red-letter invoice application in the tax bureau system, and after Party B (or the hospital) receives the application, they should issue a red-letter invoice and simultaneously refund the remaining project funds" is not included in the contract, it is deemed non-compliant with the review requirements.
X5. If the clause "the research institution is responsible for storing the relevant clinical trial data free of charge for 5 years after the termination of the clinical trial in accordance with current laws and regulations, and 3 months before the expiration of the 5-year period, Party A should actively contact Party B to discuss subsequent storage issues. If the sponsor needs the institution to continue storing the data, the applicable fees will be charged according to the institution's current fee standards (currently 6000 yuan/year). If Party A does not contact Party B and more than 1 year passes, the data can be retrieved after paying the annual storage fee; otherwise, it will be considered that the institution has the right to handle the documents on its own." is not included in the contract, it is deemed non-compliant with the review requirements.	Same as the initial rules.
X6. If the names of the parties on the front page of the contract and the signature and seal page do not match, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X7. If the contract does not specify that Party B or Sun Yat-sen University Cancer Center must hold at least two copies, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X8. If the contract does not display page numbers in the header or footer, or if the page numbers are incorrect, or if there are blank pages, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X9. If the bank account name of the hospital (Party B) in the contract does not match the designated name, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X10. If the contract does not have a place for the [legal representative's signature] for Party B, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X11. If the contract does not have a place for the [principal investigator's signature] for Party B, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X12. If the address of Party B in the contract does not match the publicly announced designated address, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X13. If the contract does not include the statement: 'The sponsor/CRO should provide the company's business license to prove its qualification type when submitting the project for approval. If the company's qualification type changes during the contract period, it should be reported to the institution in a timely manner and continue after approval according to regulations. The sponsor/CRO will bear all responsibility for any adverse consequences caused by violating the national human genetic resources management laws and requirements,' it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X14. If the contract does not include the statement: 'The sponsor is primarily responsible for the quality of the clinical trial. 1) Before starting the project or recruiting subjects, the sponsor should organize a project initiation meeting to explain and train on the protocol and implementation details. If a CRO is commissioned, the sponsor should ensure that relevant personnel from both the sponsor and the research team attend the meeting; 2) After enrolling 3 subjects in the project, the sponsor should organize a feedback meeting with the research team to address issues found during prior monitoring, improve and optimize the execution of the project, and keep records of relevant meetings or corrective actions. Projects that do not hold feedback meetings are generally not allowed to continue recruitment; 3) During the trial, if the number of enrolled cases is ≥20 or there are significant/multiple issues, the sponsor should promptly organize inspections; 4) At the conclusion of the project, before submitting the center's summary or final report to the institution's office for stamping, the sponsor should conduct a self-inspection as required by the regulatory authorities and submit the self-inspection report to the institution's office for review as part of the project conclusion process,' it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X15. If the research content section of the contract includes the version number of the protocol, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X16. If the contract does not include a statement similar to 'Research funding will be paid based on the actual number of enrolled subjects,' it will be deemed non-compliant with the review requirements.	X16. If the contract does not include the clauses 'Research funding will be paid based on the actual number of enrolled participants' or 'if the required number of participants is reached and additional participants need to be enrolled, a supplementary agreement to increase the number of participants must be signed,' it will be deemed non-compliant with the review requirements.
X17. If the contract does not clearly specify that the “sponsor” is the“Party A”of the contract, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X18. If the contract does not clearly specify that the “research institution” is the “Party B” of the contract, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X19. If the contract does not include a commitment to immediately destroy all remaining biological samples after testing all blood/urine samples, ensuring they will not be used for any purpose other than this trial, and that Party A is responsible for the proper destruction, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X20. If the responsibility of Party A to cooperate with the drug regulatory authorities' inspection is not clearly stated, it will be deemed non-compliant with the review requirements.	Same as the initial rules.

Table S1 (*continued*)

https://dx.doi.org/10.21037/jmai-2025-1-255

Table S1 (*continued*)

Initial review rules	Final established review rules
X21. If there is no statement such as 'Researchers and clinical trial institutions must allow monitors, auditors, ethics committee reviewers, and inspection personnel from the drug regulatory authorities to directly access the source data and source documents related to the clinical trial,' it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X22. If there is no statement such as 'The monitors assigned by the sponsor should have received appropriate training and possess the knowledge required for clinical trial monitoring in fields such as medicine and pharmacy, and be able to effectively perform monitoring duties,' it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X23. The sponsor may delegate part or all of the work and tasks of its clinical trial to a contract research organization, but the sponsor remains the ultimate responsible party for the quality and reliability of clinical trial data, and should supervise the work undertaken by the contract research organization.	Same as the initial rules.
X24. If there is no statement such as 'The implementation of biological sample testing (e.g., genetics) unrelated to the trial protocol approved by the ethics committee is prohibited,' it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X25. If there is no statement such as 'After the clinical trial ends, the continued storage or potential future use of remaining specimens should be covered by an informed consent form signed by the participants, which should explain the duration of storage, confidentiality of the data, and under what circumstances the data and samples may be shared with other researchers,' it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X26. If there is no statement such as 'The preparation of investigational drugs must comply with the relevant requirements of clinical trial drug production quality management; the packaging labels of investigational drugs must indicate that they are for clinical trial use only, along with clinical trial information and investigational drug information; and the blinding procedure must be maintained in blinded trials,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X27. If there is no statement such as 'The sponsor should clearly specify the storage temperature, transportation conditions (whether light protection is required), storage duration, preparation methods and processes for drug solutions, and requirements for drug infusion devices of investigational drugs. The method of use for investigational drugs should be communicated to all relevant personnel in the trial, including monitors, researchers, pharmacists, and drug storage personnel,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X28. If there is no statement such as 'The packaging of investigational drugs must ensure that the drugs are not contaminated or deteriorated during transportation and storage,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X29. If there is no statement such as 'In blinded trials, the coding system for investigational drugs must include an emergency unblinding procedure, so that in case of an emergency medical condition, the investigational drug can be quickly identified without compromising the blinding of the clinical trial,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X30. If there is no statement such as 'When it is found that the researchers, clinical trial institutions, or personnel of the sponsor do not comply with the protocol, standard operating procedures, this guideline, or relevant laws and regulations during the clinical trial, the sponsor must take immediate corrective actions to ensure good compliance with the clinical trial,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X31. If there is no statement such as 'The sponsor must provide the researchers and clinical trial institutions with legal and financial insurance or guarantees related to the clinical trial, which are appropriate to the nature and degree of the risks involved in the clinical trial. However, this does not include damages caused by the negligence of the researchers or clinical trial institutions,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X32.If there is no statement such as 'The sponsor must bear the diagnostic and treatment costs related to damages or death of the subjects in the clinical trial, as well as the corresponding compensation. The sponsor and researchers must promptly provide the compensation or reimbursement to the subjects,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X33. If there is no statement such as 'Party A is responsible for providing legal and financial guarantees to Party B's medical institution and researchers. This includes damages related to the trial (including damages to the subjects, Party B's medical institution, and researchers) and any disputes arising from the trial, ensuring that Party B is indemnified and compensated (including reasonable legal fees, litigation costs, and expenses, collectively referred to as 'losses').' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X34. If there is no statement such as 'The sponsor must provide the investigational drugs to the subjects free of charge and cover the medical testing costs related to the clinical trial,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X35. If there is no statement such as 'If the sponsor suspends the clinical trial, they must immediately inform the researchers, clinical trial institutions, and the drug regulatory authority, and provide the reasons,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X36. If there is no statement such as 'If the sponsor terminates the clinical trial prematurely, they must immediately inform the researchers, clinical trial institutions, and the drug regulatory authority, and provide the reasons,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X37. If there is no statement such as 'The sponsor must promptly inform the researchers, clinical trial institutions, and the drug regulatory authority of any issues discovered during the clinical trial that may affect the safety of the subjects, may affect the implementation of the clinical trial, or may change the ethical committee's approval,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X38. If there is no statement such as 'The sponsor must rapidly report any suspected and unexpected serious adverse reactions to all researchers and clinical trial institutions participating in the clinical trial, as well as the ethical committee,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X39.If there is no statement such as 'The sponsor's safety update report during the drug development period must include an assessment of the clinical trial's risks and benefits, and the relevant information must be communicated to all researchers, clinical trial institutions, and the ethical committee participating in the clinical trial,' it will be judged as non-compliant with review requirements.	Same as the initial rules.

Table S1 (*continued*)

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Table S1 (*continued*)

Initial review rules	Final established review rules
X40. If there is no statement such as 'The electronic data management system provided by the sponsor for the researchers should undergo reliable system validation, meet the preset technical performance, ensure the integrity, accuracy, and reliability of trial data, and ensure that the system remains in a validated state throughout the entire trial process,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X41. If there is no statement such as 'The sponsor must appoint competent medical experts to provide timely consultation on relevant medical issues in the clinical trial,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X42. If there is no statement such as 'After receiving the trial medication treatment, and for any injuries caused by following the prescribed trial process (even though such injuries may also occur in normal treatment), the subjects will receive appropriate medical treatment, and the sponsor will bear the medical treatment costs for adverse events related to this trial and provide compensation according to Chinese laws and regulations based on specific circumstances,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X43. If there is no statement such as 'The scope of confidentiality, the duration, and breach of contract liabilities,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X44. If there is no statement such as 'The recording, processing, and storage of clinical trial data must ensure the confidentiality of records and subject information,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X45. If there is no statement such as 'All parties involved in the research must sign a conflict of interest declaration and an anti-bribery commitment,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X46. "If there is no statement such as 'During the trial process, if the other party discovers any new uses of investigational products eligible for patenting shall be co-owned,' it will be judged as non-compliant with review requirements.	X46. "If there is no statement such as 'During the trial process, if the other party discovers any technical features or design that meet the criteria for patent application, the patent application rights and patent rights shall be negotiated separately by both parties,' it will be judged as non-compliant with review requirements.
X47. If there is no statement such as 'After the research observation ends, if the sponsor publishes an academic paper related to the research in a public setting, the other party is entitled to authorship of the paper,' it will be judged as non-compliant with review requirements.	Same as the initial rules.
X48. If there is no statement like "After friendly negotiation, the main researchers and researchers of Party B may publish and disclose the trial results of this center for non-commercial purposes, including publishing papers related to this clinical trial in journals or presenting the research at professional or other conferences. Before publishing any research findings, other than those regarding serious adverse events or defects of the trial drug/product, Party B shall inform Party A of the content to be published and obtain Party A's consent. If Party A does not respond within 10 business days after the submission or fails to provide specific reasons for disagreement or modification suggestions, it will be deemed as Party A's consent," then it will be deemed as not meeting the review requirements.	X48. If there is no statement like "After friendly negotiation, the main researchers and researchers of Party B may publish and disclose the trial results of this center for non-commercial purposes, including publishing papers related to this clinical trial in journals or presenting the research at professional or other conferences. Before publishing any research findings, other than those regarding serious adverse events or defects of the trial drug/product, Party B shall inform Party A of the content to be published and obtain Party A's consent. If Party A does not respond within the agreed time period after the submission or fails to provide specific reasons for disagreement or modification suggestions, it will be deemed as Party A's consent," then it will be deemed as not meeting the review requirements.
X49. If there is no statement like "Party B shall arrange to retain the subject documents, other original data, and all documents related to this clinical trial, and store them for at least 5 years after the completion of the clinical trial or 5 years after the registration and marketing of the product, or according to the retention requirements specified in the clinical trial protocol, whichever is longer," then it will be deemed as not meeting the review requirements.	Same as the initial rules.
X50.If there is no statement like "During inspections by the drug regulatory authority, both the research and management teams must send personnel to participate," then it will be deemed as not meeting the review requirements.	Same as the initial rules.
X51.If there is no statement like "In a blinded trial, researchers must implement the unblinding according to the trial protocol. If unblinding occurs unexpectedly or due to an emergency unblinding due to serious adverse events, the researcher must provide a written explanation to the sponsor," then it will be deemed as not meeting the review requirements.	Same as the initial rules.
X52.If there is no statement like "Except for serious adverse events that do not require immediate reporting as stipulated in the trial protocol or other documents (such as the investigator's manual), researchers must immediately report all serious adverse events in writing to the sponsor, and then provide detailed, written follow-up reports in a timely manner," then it will be deemed as not meeting the review requirements.	Same as the initial rules.
X53.If there is no statement like "Researchers must promptly acknowledge and review the safety information provided by the sponsor, consider whether adjustments are needed in the treatment of subjects, and if necessary, communicate with the subjects as soon as possible. They must also report to the ethics committee any suspicious and unexpected serious adverse reactions provided by the sponsor," then it will be deemed as not meeting the review requirements.	Same as the initial rules.
X54. If there is no statement like "Researchers must submit an annual report of the clinical trial to the ethics committee, or provide progress reports as required by the ethics committee," then it will be deemed as not meeting the review requirements.	Same as the initial rules.
X55. If there is no statement like "If any situation arises that may significantly affect the implementation of the clinical trial or increase the risk to the subjects, the researcher must promptly provide a written report to the sponsor, ethics committee, and clinical trial institution," then it will be deemed as not meeting the review requirements.	Same as the initial rules.

Table S1 (*continued*)

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Table S1 (*continued*)

Initial review rules	Final established review rules
X56.If there is no statement such as 'After the clinical trial is completed, the researcher should report to the clinical trial institution; the researcher should provide a summary of the clinical trial results to the ethics committee, and provide the clinical trial-related reports required by the drug supervision and management department to the sponsor,' it will be deemed non-compliant with review requirements.	Same as the initial rules.
X57. If there is no statement such as 'The researcher and the clinical trial institution should appoint qualified pharmacists or other personnel to manage the trial medication,' it will be deemed non-compliant with review requirements.	Same as the initial rules.
X58. If there is no statement such as 'The researcher should ensure that all clinical trial data is obtained from the source documents and trial records of the clinical trial, and that it is accurate, complete, readable, and timely. The source data should have traceability, readability, contemporaneity, originality, accuracy, completeness, consistency, and durability. Modifications to the source data should leave a trace, not conceal the original data, and the reason for the modification should be recorded,' it will be deemed non-compliant with review requirements.	Same as the initial rules.
X59. If there is no statement such as 'The researcher should fill in and modify the case report form according to the guidance provided by the sponsor, ensuring that the data in the various case report forms and other reports are accurate, complete, clear, and timely,' it will be deemed non-compliant with review requirements.	Same as the initial rules.
X60. If there is no statement such as 'The researcher and the clinical trial institution must obtain the sponsor's consent if they authorize an entity outside the clinical trial institution to undertake trial-related duties and functions,' it will be deemed non-compliant with review requirements.	Same as the initial rules.
X61. If there is no statement such as 'The researcher, as a clinical doctor or an authorized clinical doctor, must bear all medical decision-making responsibilities related to the clinical trial,' it will be deemed non-compliant with review requirements	Same as the initial rules.
X62. If there is no statement such as 'The researcher and the clinical trial institution must accept the monitoring and inspection organized by the sponsor and the inspections by the drug supervision and management department,' it will be deemed non-compliant with review requirements.	Same as the initial rules.
X63. If there is no statement such as 'The researcher should use the latest version of the informed consent form and other information provided to the participants, as approved by the ethics committee. If necessary, the participants in the clinical trial should sign the informed consent form again during the process of the trial,' it will be deemed non-compliant with review requirements.	Same as the initial rules.
X64. If there is no statement such as 'The researcher from Party B must have the practice qualification at the clinical trial institution; possess the professional knowledge, training experience, and capability required for clinical trials; and be able to provide the latest work history and relevant qualification documents according to the sponsor, ethics committee, and drug supervision and management department's requirements,' it will be deemed non-compliant with review requirements.	Same as the initial rules.
X65. If there is no statement such as 'The researcher must implement the clinical trial according to the trial protocol approved by the ethics committee,' it will be deemed non-compliant with review requirements.	Same as the initial rules.
X66. If there is no statement such as 'Either party can file a lawsuit in the court where the research institution is located,' it will be deemed non-compliant with review requirements	Same as the initial rules.
X67. If there is no statement such as 'The monitoring frequency should be coordinated with the enrollment progress, and the monitoring frequency should be ≥ 1 time/month,' it will be deemed non-compliant with review requirements.	X67. If there is no statement such as 'The monitoring frequency should be coordinated with the enrollment progress' it will be deemed non-compliant with review requirements.
X68. If there is no statement such as 'Party B is responsible for establishing the management system and record system for trial medication. Provide a storage place for clinical trial drugs that meets the clinical trial protocol's requirements, with dedicated personnel responsible for storage and distribution, and provide drug return records. Unused clinical trial drugs should be returned to Party A after verifying with Party A after the trial is completed,' it will be deemed non-compliant with review requirements	Same as the initial rules.
X69. If there is no statement such as 'Party B has the right to propose the suspension of the clinical trial due to the frequency and severity of SAE, and should promptly notify Party A, the participants, the ethics committee, and the drug supervision and management department, explaining the reason. It should also be reported to the institution's office,' it will be deemed non-compliant with review requirements.	Same as the initial rules.
X70. If there is no statement such as 'Party A promises that even if the insurance policy payout is insufficient to cover the sponsor's compensation responsibilities, the remaining amount will still be paid by Party A. Party A should not use the insurance payout amount or payout time as a reference for compensating the participants. The sponsor should advance the participants' related treatment expenses based on the advance payment principle to ensure their safety and rights. After responsibility is determined, the responsible party shall bear the expenses in accordance with the law,' it will be deemed non-compliant with review requirements.	Same as the initial rules.
X71. "If the statement 'In the event of a compensation dispute or litigation concerning damage to the subject or researcher, the researcher must immediately notify Party A, who must immediately assign a specialist (lawyer or its staff) to fully handle the claim, compensation, or litigation matters, and the research institution or researcher agrees to provide relevant assistance to Party A. Legal liability will be undertaken by both parties according to the determination of responsibility by the medical association and relevant judicial appraisal centers' is not included, it will be deemed non-compliant with the review requirements.	Same as the initial rules.

Table S1 (*continued*)

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Table S1 (*continued*)

Initial review rules	Final established review rules
X72. If the statement 'Notwithstanding the preceding provisions, the sponsor has no obligation or liability to compensate for any loss or damage caused by the following reasons, and the research institution hereby acknowledges and agrees that it will not seek any compensation or other remedies for such loss or damage from the sponsor, its parent company, subsidiaries, affiliates, senior management, directors, agents, or employees' is not included, it will be deemed non-compliant with the review requirements.	X72. If the statement 'Notwithstanding the above provisions, the sponsor will not provide compensation, indemnification, or assume any responsibility for the following situations: 1) The research institution, researchers, or other research staff fail to comply with this agreement, study protocol, the sponsor's written instructions for this study, or applicable laws; 2) The research institution, researchers, or other research staff make unauthorized guarantees or engage in negligent or intentional misconduct (including but not limited to failure to strictly adhere to the study protocol, violation of standard procedures, or improper medical equipment operation); 3) The subject fails to undergo diagnosis and treatment according to the study protocol, fails to comply with the reasonable instructions of the investigator or any research staff, or engages in negligence or intentional misconduct; 4) The natural course or complications of the subject's primary disease, or any other disease or injury the subject may suffer during the study, unless such disease or injury is related to the study (i.e., caused by the activities described in the study protocol, which are different from the treatment the subject would have received had they not participated in the study); 5) Medical accidents; 6) Injury caused by using any drug (including biological materials) or device supplied by a third party' is not included, it will be deemed non-compliant with the review requirements.
X73. If the statement 'Party B and the researcher are responsible for keeping confidential all contents related to the clinical trial, such as the study protocol, case report forms, investigator manual, study progress, and summary reports, and must not disclose them to any third party; all parties must not disclose the personal privacy of the subjects. The confidentiality obligation does not terminate due to the invalidity or termination of this contract, and the confidentiality period is for the duration of the clinical trial and for 5 years after its termination. The confidentiality obligation does not apply to the following information: a) Information that has entered the public domain; b) Information that entered the public domain not due to Party B's fault; c) Information that Party B is required by law to disclose or that Party A has consented to disclose in writing. In any of these cases, the receiving party must notify the disclosing party in writing and obtain its consent before the disclosure applies. If any party has additional confidentiality requirements, the parties may sign a separate confidentiality agreement' is not included, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
X74. If the statement '[Arbitration should be conducted in English as far as possible]' is included, it will be deemed non-compliant with the review requirements.	Same as the initial rules.
None	X75. If the statement 'If either Party A or Party B fails to perform according to the relevant provisions of this agreement, it will be considered a breach of contract. The breaching party must compensate the other party for the losses. Moreover, if Party A breaches the contract, Party B has the right to require Party A to pay the clinical trial fees incurred; if Party B breaches, Party A has the right to recover the clinical trial fees already paid to Party B for the breaching portion and has the right to terminate this agreement and refuse to pay any fees not yet paid to Party B' is not included, it will be deemed non-compliant with the review requirements.
None	X76. If the statement 'If the sponsor, research institution, principal investigator, or CRO is delayed or unable to perform obligations under this agreement due to circumstances beyond their reasonable control (including but not limited to natural disasters, government actions, accidents, strikes, terrorist attacks, biological terrorism, shutdowns, or other forms of industry action) ("force majeure"), and has provided timely notice of the delay or non-performance to the other party, the sponsor, research institution, principal investigator, or CRO will not be held liable for such delay or non-performance. Any force majeure event does not constitute a breach of this agreement, and the performance period will be postponed accordingly; however, if the force majeure event lasts more than thirty (30) days, the parties may discuss how to mitigate the impact of the force majeure event, and if possible, reasonable alternative arrangements may be agreed upon in all circumstances' is not included, it will be deemed non-compliant with the review requirements.

Xn, number of rule items; CRO, Contract Research Organization.

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Table S2 The statistical results of expert evaluations of the rules during three rounds of Delphi process

Round 1					Round 2					Round 3				
Rule number	CV of consensus score	Mean±SD of consensus score	Consensus classification	Percentage of 'critical' or 'important' ratings	Rule number	CV of consensus score	mean±SD of consensus score	Consensus classification	Percentage of 'critical' or 'important' ratings	Rule number	CV of consensus score	mean±SD of consensus score	Consensus classification	Percentage of 'critical' or 'important' ratings
X1	23.90%	4.409±1.054	Moderate	90.91%	X2	23.20%	4.478±1.039	Moderate	91.30%	X4	11.07%	4.773±0.528	high	100%
X2	39.68%	3.455±1.371	Low	90.91%	X3	14.71%	4.522±0.665	High	86.96%	X15	13.11%	4.545±0.596	high	90.91%
X3	16.25%	4.545±0.739	High	77.27%	X4	27.65%	4.217±1.166	Low	78.26%					
X4	31.18%	3.727±1.162	Low	72.73%	X7	11.41%	4.739±0.541	High	91.30%					
X5	9.64%	4.727±0.456	High	100%	X12	11.41%	4.739±0.541	High	95.65%					
X6	4.30%	4.955±0.213	High	100%	X14	20.20%	4.435±0.896	Moderate	91.30%					
X7	8.19%	4.818±0.395	High	77.27%	X15	18.71%	4.522±0.846	Moderate	78.26%					
X8	14.19%	4.636±0.658	High	86.36%	X16	8.03%	4.826±0.388	High	100%					
X9	0.00%	5.000±0.000	High	100%	X27	15.94%	4.565±0.728	High	91.30%					
X10	22.49%	4.500±1.012	Moderate	100%	X41	15.94%	4.565±0.728	High	93.91%					
X11	9.61%	4.864±0.468	High	95.45%	X46	19.34%	4.609±0.891	Moderate	100%					
X12	15.68%	4.636±0.727	High	81.82%	X48	11.90%	4.696±0.559	High	95.65%					
X13	12.53%	4.636±0.581	High	90.91%	X67	9.40%	4.870±0.458	High	100%					
X14	25.21%	4.273±1.077	Low	81.82%	X72	16.66%	4.652±0.775	High	100%					
X15	21.49%	4.136±0.889	Moderate	45.45%	X75	22.62%	4.261±0.964	Moderate	91.30%					
X16	17.61%	4.545±0.800	Moderate	77.27%	X76	15.94%	4.565±0.728	High	95.65%					
X17	11.07%	4.773±0.528	High	95.45%										
X18	11.65%	4.727±0.550	High	95.45%										
X19	18.87%	4.545±0.858	Moderate	90.91%										
X20	13.35%	4.727±0.631	High	95.45%										
X21	8.69%	4.909±0.426	High	95.45%										
X22	10.40%	4.818±0.501	High	95.45%										
X23	7.22%	4.864±0.351	High	100%										
X24	9.61%	4.864±0.468	High	95.45%										
X25	16.58%	4.455±0.739	Moderate	90.91%										
X26	7.22%	4.864±0.351	High	100%										
X27	17.82%	4.500±0.802	Moderate	81.82%										
X28	17.61%	4.545±0.800	Moderate	86.36%										
X29	15.99%	4.591±0.734	High	86.36%										
X30	11.07%	4.773±0.528	High	95.45%										
X31	5.99%	4.909±0.294	High	100%										
X32	5.99%	4.909±0.294	High	100%										

Table S2 (*continued*)

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Table S2 (*continued*)

Round 1					Round 2					Round 3				
Rule number	CV of consensus score	Mean±SD of consensus score	Consensus classification	Percentage of 'critical' or 'important' ratings	Rule number	CV of consensus score	mean±SD of consensus score	Consensus classification	Percentage of 'critical' or 'important' ratings	Rule number	CV of consensus score	mean±SD of consensus score	Consensus classification	Percentage of 'critical' or 'important' ratings
X33	20.06%	4.545±0.912	Moderate	95.45%										
X34	4.30%	4.955±0.213	High	100%										
X35	5.99%	4.909±0.294	High	100%										
X36	5.99%	4.909±0.294	High	100%										
X37	11.07%	4.773±0.528	High	95.45%										
X38	11.65%	4.727±0.550	High	95.45%										
X39	5.99%	4.909±0.294	High	100%										
X40	15.75%	4.773±0.752	High	90.91%										
X41	16.25%	4.545±0.739	High	81.82%										
X42	19.78%	4.591±0.908	Moderate	100%										
X43	5.99%	4.909±0.294	High	100%										
X44	5.99%	4.909±0.294	High	100%										
X45	13.35%	4.727±0.631	High	90.91%										
X46	36.26%	3.727±1.352	Low	77.27%										
X47	16.58%	4.455±0.739	Moderate	100%										
X48	21.89%	4.273±0.935	Moderate	81.82%										
X49	14.86%	4.727±0.703	High	100%										
X50	16.45%	4.500±0.740	Moderate	90.91%										
X51	20.57%	4.636±0.953	Moderate	90.91%										
X52	10.40%	4.818±0.501	High	90.91%										
X53	11.65%	4.727±0.550	High	90.91%										
X54	11.65%	4.727±0.550	High	95.45%										
X55	11.07%	4.773±0.528	High	95.45%										
X56	12.13%	4.682±0.568	High	86.36%										
X57	11.07%	4.773±0.528	High	95.45%										
X58	10.40%	4.818±0.501	High	90.91%										
X59	10.40%	4.818±0.501	High	86.36%										
X60	13.81%	4.682±0.646	High	90.91%										
X61	12.13%	4.682±0.568	High	90.91%										
X62	10.40%	4.818±0.501	High	95.45%										
X63	11.07%	4.773±0.528	High	90.91%										
X64	10.40%	4.818±0.501	High	90.91%										

Table S2 (*continued*)

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Table S2 (*continued*)

Round 1					Round 2					Round 3				
Rule number	CV of consensus score	Mean±SD of consensus score	Consensus classification	Percentage of 'critical' or 'important' ratings	Rule number	CV of consensus score	mean±SD of consensus score	Consensus classification	Percentage of 'critical' or 'important' ratings	Rule number	CV of consensus score	mean±SD of consensus score	Consensus classification	Percentage of 'critical' or 'important' ratings
X65	4.30%	4.955±0.213	High	95.45%										
X66	16.25%	4.545±0.739	High	100%										
X67	27.57%	3.955±1.090	Low	86.36%										
X68	8.69%	4.909±0.426	High	95.45%										
X69	12.13%	4.682±0.568	High	95.45%										
X70	22.49%	4.500±1.012	Moderate	90.91%										
X71	17.35%	4.591±0.796	High	100%										
X72	21.82%	4.227±0.922	Moderate	77.27%										
X73	15.06%	4.455±0.671	Moderate	95.45%										
X74	24.90%	4.409±1.098	Moderate	86.36%										

Xn, number of rule items; CV, coefficient of variation; SD, standard deviation.

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