以患者为中心的药物临床试验实施

技术指导原则（试行）

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I. Overview

(1) Background

"Patient-centered" drug development refers to drug development based on the patient's perspective.

The process of drug development, design, implementation and decision-making, aiming to efficiently develop more suitable for patients

Drugs with clinical value that patients need.

Patients are the direct feelers and experiencers of disease states and drug treatments.

In the entire process of drug development and decision-making, patients should be regarded as active participants.

The patient's experience, opinions, needs and preferences regarding the disease and related treatments

Patient Experience Data (PED), as a tool for drug development and design,

key considerations for implementation and incorporated into a benefit-risk assessment system to

Provide scientific evidence for the development and launch of valuable drugs that researchers need.

The entire process of drug research and development should fully consider patient needs and be patient-centered

Three technical guidelines for drug clinical trial design, trial implementation and benefit-risk assessment

The guiding principle is to systematically conduct

Explain how to fully consider patient needs in the early stages of research and development and incorporate patient experience data

Conduct clinical trial design based on data; how to ensure scientific reliability, subject safety and

Under the premise of privacy and other conditions, optimize the patient experience of participating in clinical trials; and how to

Fully weigh the clinical benefits and risks of drugs from the patient's perspective and make scientific decisions.

Patient-centered drug clinical trial implementation, paying attention to patients during implementation

experience during the process, on the premise of ensuring the reliability of data science, subject safety and privacy

Under the circumstances, improve the convenience of patients participating in clinical trials within the scope of compliance and feasibility,

Reduce the burden on patients to participate in clinical trials and implement more patient-friendly,

And clinical trials that are close to real diagnosis and treatment scenarios.

(2) Purpose and scope of application

This guideline is intended to clarify how to conduct clinical trials in a patient-centered manner.
Including general principles, subject recruitment, informed consent, visits, administration, safety
Consideration factors in sexual monitoring and reporting, data collection, supervision, compensation, etc.
and other considerations when conducting patient-centered clinical trials.
possible risks and related considerations.

This guideline only represents the current views and understanding of the drug regulatory authorities and does not
It is legally binding. With the progress of scientific research, this guideline
The relevant content in the rules will be continuously improved and updated. When applying these guidelines, you should
At the same time, it follows the "Good Clinical Practice (GCP)" and international standards.
ICH and other relevant published guidance
but.

2. General principles

Patient-centered clinical trials should strictly comply with relevant laws and regulations,
GCP and ethics requirements, that is, protecting the rights and safety of subjects and ensuring data and
The results are scientific, true, complete and reliable. Implementing patient-centered clinical
When testing, you should focus on the following three aspects.

(1) Protection of the safety and rights of subjects

When conducting clinical trials with patients as the center, the safety of subjects should be the first priority
and the protection of rights and interests, and take precedence over considerations of scientific and social benefit. In mining
When using some new technologies and new models, you should focus on the impact they may introduce on the recipients.

additional risks of harm to tester safety and rights, such as the use of digital technologies

security risks and personal privacy leakage risks associated with technology.

(2) Improve subject experience and reduce subject burden based on patient needs

Implement clinical trials with patients as the center, striving to improve the subject experience and reduce

Reduce the burden on subjects, such as making informed consent more patient-friendly and reducing

Reduce unnecessary visits, etc. Under the principle of protecting the safety and rights of subjects,

Reliable, predictive

Implement new clinical trials using new technologies and methods that have been established and verified in advance.

test mode. For example, Decentralized Clinical Trial,

DCT) refers to a patient-centered approach that is not limited to traditional clinical trial implementation sites.

A new clinical trial mode with optional scenarios.

(3) Ensure the quality of data

In adopting some new technologies and new models to improve patient experience and reduce patient burden,

When concerned, attention should also be paid to possible challenges and impacts on data quality. For example,

Whether the data collected through remote visits can ensure its authenticity and

Reliability; how to ensure the integrity of the data collected when the data comes from different sources

consistency and completeness, and how to evaluate them.

3. Considerations in the Implementation of Clinical Trials

(1) Consideration of the overall implementation plan

During the epidemic and some special circumstances, sponsors, researchers and clinical trial institutions

When deemed necessary by the agency's assessment, remote informed consent, remote visits, medication

Conduct clinical trials using new models such as direct delivery of goods to patients. Adopt new methods and new models to develop

Clinical trials should comply with relevant laws and regulations and be approved by the ethics committee.

allow. All new methods and models to be used in clinical trials should be documented in the trial protocol

Pre-set in the case, comply with GCP requirements, and ensure electronic data and paper

Data consistency is available for inspection.

In order to avoid blindly pursuing the implementation of new technologies and new models, before starting to implement clinical

Before testing, the research team should fully explore its rationality, necessity and feasibility,

The requirements of relevant laws and regulations on medical treatment and pharmaceuticals should be strictly abided by, and patients can be listened to

opinions to avoid bringing additional burden to the research and affecting the conduct of the trial. Can

According to the characteristics of the subject population, disease characteristics, trial characteristics, drug types, current

There are conditions and uncertainties to explore, as well as future patient acceptance.

For example, the number of rare disease patients is small and geographically dispersed, and the condition is severe and has a long course.

Patient participation in clinical trials is challenging, and new models such as decentralized clinical trials have

May enable patients to participate in appropriate clinical trials regardless of geographical restrictions. And for

For new technologies and models adopted, their risks should be fully assessed and discussed.

certificate.

It is important to note that not all patient-centered clinical trials are suitable

Combined with decentralized clinical trial elements (DCT elements), only in certain

It can be used under specific conditions or in certain links.

(2) Considerations in specific aspects of trial implementation

1. Recruitment based on patient needs

As much as possible, subjects in need should be able to find suitable clinical trials and

Enrollment is guaranteed based on potential subject needs and optimal benefit-risk considerations.

In order to allow patients in need to find suitable clinical trials, consider adopting

Recruitment using Internet platforms, intelligent recruitment based on patient information big data, etc.

Mode. When using Internet platforms for recruitment, the needs of people who do not frequently access the Internet should be considered.

The language of the platform should be easy for patients to understand and ensure that it does not lead to selection of the recruitment population.

bias. At the same time, the content of recruitment advertisements can be diverse to meet the different readings of users.

Reading preferences: pictures, texts, videos, animations, etc., so that patients can read more fully

Understand the research purpose, medication regimen, possible benefits and risks of the project, and should

Avoid being inflammatory and misleading. When using the Internet platform to recruit, apply for

Authors and investigators should evaluate and ensure that the platform accurately reflects the clinical trial

Purpose and requirements. Adopt intelligent recruitment based on patient information big data and other methods

When doing so, the source and use of data on potential subjects should comply with relevant laws and regulations.

The scope of data being recruited and the extent to which these data can be shared should be made clear in advance. by

The personal information of the subjects should be de-identified to a certain extent to prevent the subjects from

Privacy leakage, ensuring data security. Any methods and information used to recruit subjects are

Ethics committee approval should be obtained.

Regardless of the recruitment method used, it should be based on the best possible outcome for potential subjects.

Consider the benefits and risks before joining the group, pay attention to the study and judgment of the admission criteria, and avoid joining the group for the sake of joining the group.

Subjects who enroll quickly but have a poor benefit-risk ratio.

2. Informed consent that is easy for patients to accept

Informed consent is an important step in protecting the rights and interests of subjects. should be viewed from the subject's perspective

Starting from the perspective of safety, using content and methods that are easy for subjects to accept, ensuring that they are fully informed,

Enable subjects to fully understand the benefits and risks of clinical trials and make their own choices

choice and decision.

In order to enable the subjects to fully understand the content of the informed consent, and to protect the subjects'

For rights and interests, electronic notification may be considered. For example, based on subject characteristics,

Click to select the video explanation (enough time should be reserved for two-way communication between the subject and the doctor)

communication) and other multimedia methods. In order to meet the needs of the subjects, not limited by time

and places, consider adopting a remote informed approach.

When trials are conducted electronically or remotely, in order to avoid unfamiliarity

Subjects who are electronically familiar (e.g., older adults) or who do not use electronic

The rights of subjects (e.g., children and persons with disabilities) are compromised in a manner that should

Provide adequate explanations to subjects/guardians in advance and, if necessary, arrangements can be made for on-site

Site staff assist subjects in completing electronic notifications and can also provide traditional methods at the same time

For subjects to choose. When using remote informing methods, researchers should pay attention to

Real-time communication with potential subjects to ensure they fully understand the content under remote conditions,

If subjects have questions about the informed consent form, they should ensure that they can contact their doctor. same

The confidentiality of the informed consent process and the information generated should be ensured. electronic or remote

Records of informed consent should be legal, compliant and traceable. If electronic signature is used

name, and its settings should comply with relevant domestic or international requirements.

For new technologies and methods used in clinical trials (such as digital health

Technology [Digital Health Technology, DHT], electronic clinical outcome assessment

eCOA [electronic Clinical Outcome Assessment], remote monitoring, etc.)

The usage, scope of data collection, benefits and potential risks should be determined with informed consent.

Fully informed. In order to ensure the protection of personal privacy data, informed

Notify in the consent that the subject data collected by its technology or method can be accessed

Permissions and access time range. When these technologies or methods are updated or

When the scope of data collection changes, a new informed consent process should be conducted promptly.

3. Scenario-optional visits

Visits in clinical trials collect efficacy and safety data from subjects

The important aspects of the test should be within the scope of compliance and feasibility to reduce the burden and reduce the burden on the subjects.

Provide convenience and improve subjects' experience.

When considering the content of the visit, in order to reduce the burden on the subject, it should be based on

Subject characteristics, trial design, potential safety risks and other factors, reasonable arrangements

The time point and content of each visit are clearly set in advance in the trial plan.

The optional visit methods and selection criteria should be clearly stated in the trial plan.

pieces. The arrangement of each visit should be based on the potential safety risk of the subject

and the reliability of clinical data and comprehensively consider its rationality and feasibility; before ensuring

The rights and safety of subjects and the data generated during visits are authentic, reliable and traceable.

Under the premise of improving subjects' accessibility and convenience to visits.

The researcher based on the complexity of the interview content and the accuracy of the data obtained, etc.

Appropriate methods should be considered, such as the use of remote visit systems, which should be verified

Remote diagnosis and treatment or visit system to carry out relevant visit activities. When conducting remote visits,

Attention should be paid to protecting the rights and safety of subjects under remote conditions. Researchers should

Take appropriate measures to confirm that the person participating in each visit is the subject himself; apply for the

Researchers and/or investigators should ensure that subjects receive appropriate treatment and care, and should pay attention to

Monitor safety events of subjects under remote conditions, and monitor them in the trial plan in advance.

Conduct risk assessments and establish emergency response plans for security incidents. In order to ensure the number
The quality and completeness of data, the diagnosis and treatment process and the data generated need to be properly and truly
Accurate, complete records and traceability guaranteed.

When medical examination data come from different medical institutions, it may affect
The quality of the data and the consistency of the results should be given special attention. Data should be combined
importance, risks, accuracy requirements (e.g. imaging as a result of efficacy)
The inspection data are critical data and require high accuracy), and the clinical operations required to obtain the data
The complexity of the operation, etc., combined with the trial plan and the evaluation opinions of the researchers and sponsors
Confirm whether to accept data from non-research centers. If you plan to accept research from outside this research center
For medical examination and test data, the sponsor should consult with the researcher and should specify in the trial plan
confirm the criteria for screening and evaluation, and collaborate on screening and evaluation to ensure inspection
ensure consistency of test data with the test facility and ensure data flow and data integrity
and traceability. Sample testing laboratories and medical examination facilities involving medical judgment
The equipment must comply with relevant regulations and possess corresponding qualifications. In order to ensure that the subjects
Security and data authenticity and reliability should ensure that the equipment and personnel used are
Have been appropriately evaluated and qualified.

Regardless of the visit method used, relevant data should be transmitted to the research team in a timely manner
The team can conduct adequate assessments to avoid unnecessary risks for subjects. also,
The privacy of subjects should be ensured to be effectively protected and personal information and data should be prevented from being leaked.
Exposure to ensure the effective preservation and traceability of the original data of the visit. If sampling is involved
Transportation, the quality of the collected samples should be ensured during transportation. Sample collection process
The process and its management must comply with the requirements of current relevant laws and regulations.

4. Drugs reach patients directly

In patient-centered dosing and treatment, the burden on the subject should be minimized.

to provide convenience for subjects and make treatment closer to real medical practice.

Pay attention to medication safety and compliance.

When considering whether to adopt a direct-to-patient approach, in addition to the general considerations

In addition to factors, consideration should also be given to studying the safety profile of the drug (e.g.

Whether it is clear, the risk of serious adverse events, and whether immediate treatment is required after administration

monitor adverse events at all times), storage conditions, administration method (e.g., administration method is

Does it involve complex operations), subject's geographical location, etc. For some oral medicines

medicines or medicines that can be self-administered at home, consider using medicines delivered directly to the patient

(Direct to Patient, DTP) approach, researchers and clinical trial institutions are responsible for

Responsible for delivering the study drugs directly to the subjects, and after the subjects take the medicine,

Retrieve or dispose of remaining medications according to protocol. For some intravenous infusion drugs, etc.

For drugs that require medical staff to operate, direct delivery to patients is generally not recommended.

When using direct drug delivery to patients, you should first pay attention to the safety of the subjects

risk. The researcher should ensure that the subjects have sufficient

Understand how to take medicines and how to store medicines, especially for complex medicines that require

Study drug for additional procedures. In order to reduce the occurrence of safety events in subjects (such as

For safety risks caused by failure to promptly handle such as allergic reactions, the sponsor and/or

Researchers should formulate response plans in advance for safety incidents to ensure that subjects

Subjects can receive appropriate medical care and be informed in advance.

When adopting the direct-to-patient approach, sponsors and researchers should also pay attention to the

Risks associated with reduced subject compliance. It is recommended that researchers conduct regular testing on subjects
Follow up and count the number of returned drugs to ensure that the subjects continue to follow the requirements
Please take medicine. In addition, when adopting the direct-to-patient approach, research should also
The quality of drugs is controlled throughout the entire process to ensure that the drugs are transported and stored
The quality in the process, for example, temperature control should be carried out during transportation, subjects should be guaranteed
Be familiar with the storage conditions and specifications of medicines at home. Usually, for guarantees
For drugs with a long shelf life and can be stored at room temperature, direct delivery of drugs to patients can be considered.
way.

5. Collect data from patients

1) Collection of patient experience data (PED)

Patient experience data provide important insights into clinical trial design and benefit-risk assessment.
The necessary scientific basis (please refer to "Patient-centered drug clinical trial design")
Technical Guiding Principles", "Patient-centered Benefit-Risk Assessment of Drug Clinical Trials"
Technical Guiding Principles for Assessment"). In conducting patient-centered clinical trials, Shen
Sponsors and/or researchers should collect PEDs completely, truthfully, and effectively, and
Real-time feedback helps optimize experimental design. Patients can provide information about disease and treatment needs
Patient experience data, such as summation and experience, may also be provided for use in specific trials.
Clinical Outcome Assessment of Efficacy or Safety Evaluation (Clinical Outcome
Assessment, COAÿÿ

Collection of patient experience data that provides information about patient needs and experiences
Research may collect additional personal information from patients, and attention should be paid to the collection during the process
De-identification and protection of patients' personal privacy data. For collecting patient experiences

For additional considerations in data research, please refer to Patient-Centered Medicines

"Technical Guiding Principles for Clinical Trial Design", "A Guide to Organizing Patients to Participate in Drug Research and Development"

General Consideration Guiding Principles.

For clinical outcome reviews that provide information for evaluating effectiveness or safety in patients

There are the following considerations during the implementation process: First, the evaluation of clinical outcome assessment

The frequency and duration of assessments should be consistent with the natural course of the disease or symptoms, the purpose of the study,

The duration of the study matches. The process design such as assessment time points should be reasonable and minimize

Reduce the burden on subjects, and at the same time, you can set reminders and fill-in functions to reduce the burden on subjects.

Few missing data. Secondly, appropriate options can be selected based on disease indications and population characteristics.

Appropriate clinical outcome assessment method (paper or electronic), device and version. at last,

It should be ensured that clinical outcome assessment results are conducted by researchers with appropriate qualifications.

transcribe and evaluate, but cannot interfere with patient outcome reporting or do anything with the results.

Revise. If different collection methods are used (e.g. electronic and paper, remote and

site), care should be taken to evaluate whether the measurement results collected in different ways are consistent.

sex.

Electronic COA (eCOA) can collect real-time data and transfer data

With advantages such as easy recording, it can be combined with wearable devices or mobile electronic platforms (such as mobile phones).

(machine app) implementation to provide convenience for subjects. Evaluated and verified by the sponsor

Afterwards, the paper-based clinical outcome assessment version can be transferred to the electronic clinical outcome assessment version.

Originally intended to be implemented in clinical trials, effective methods should be implemented to test both

Measurement equivalence of modes. The electronic equipment used should be verified, and the collected

The electronic clinical outcome assessment data should meet the requirements of paper-based clinical outcome assessment.

requirements, operate within the scope of copyright and license, and should ensure compliance with regulatory agencies Requirements for record keeping, maintenance and access. In addition, collected objects should be protected The personal privacy data of the examinee.

2) Digital health technologies (DHT) Applications

Digital medicine is the application of modern computer technology and information technology to the medical process It is a new modern medical treatment method that can apply mobile medical tools (such as such as mobile/wearable devices) or remote patient data collection devices (smart detection/monitoring testing equipment) for subject information (including real-time physical signs, medication compliance, etc.) Perform remote collection. Application of remote digital medical technology equipment can directly collect data from More comprehensive and multi-dimensional data from subjects' real lives, reducing manual input Integrated process, the quality of collected data is high.

When choosing digital health technologies, they should be fit for purpose and suitable for the subjects When using digital medical technology, factors to be considered include disease characteristics, researchers group (including education, language, technical ability, etc. of the study population), experimental design, Characteristics of digital medical technology, etc. In addition, consideration should be given to whether subjects can be used Own digital health technology (e.g., continuous glucose monitor) and/or universal meter Computing platforms (such as mobile phones, tablets) collect data.

Before using digital medical technology, the sponsor needs to conduct thorough research on the clinical research process. computerized system for verification of initial entry of data and any subsequent updates Keep an audit trail. Before starting a clinical trial, ensure that there is evidence that the data The word medical technology is suitable for its purpose in the given context of use. If cannot be obtained

It is necessary to confirm, verify and usable the application of digital medical technology methods.

research, for example by providing evidence confirming that digital health technologies can

Accurately and reliably assess clinical events or characteristics (such as step count or heart rate) in a population.

The use of digital medical technology may bring additional clinical benefits to subjects

risk. Appropriate security testing should be conducted to evaluate the physical properties of digital health technologies

Risk of injury that may arise from physical characteristics (e.g., wristband blocking blood supply, skin

stimulation, etc.). Before using digital medical technology to collect data, personal testing should also be conducted.

Identity identification (such as: exclusive username/password to ensure that the data collected by the device is that of the subject)

The person himself. In order to fully protect the personal privacy data of subjects, it should be ensured that effective

Data security measures are in place.

The adoption of digital medical technology should pay attention to the impact on data quality.

and ensure the traceability of data collected from subjects. Adopt digital health technology

during surgery, such as using different devices or technology platforms (including the subject's own movement

equipment) to collect data, care should be taken to evaluate the consistency of the collected results. digital medicine

Errors in medical technology and general computing platforms (such as involving batteries, sensors, etc.) may

will result in data loss or damage, corresponding contingency plans should be developed. digital medical technology

Technical equipment and technology platforms may also be updated and iterated to ensure consistency and analysis of results.

Analysis brings challenges.

In the digital health technology related materials submitted to the review agency, the sponsor should

Describe the basic information of digital medical technology, including related objects of digital medical technology.

physical characteristics, data output, and how digital health technologies capture clinical events or

Information about features of interest (such as using a pulse meter to count heartbeats). should describe

Characteristics related to usability (e.g., how digital health technology is worn, operated, and charged

electricity), and how to control access to or receive from digital health technologies

Collect data to ensure privacy and security. Sponsors also need information on data management

describe the collection, storage, transmission and archiving of data to demonstrate

Integrity and consistency of data collection during clinical research.

Sponsors should fully evaluate with investigators and ensure that the

The scientific nature and compliance of digital medical technology should be discussed with relevant regulatory agencies when necessary.

Fully communicate and confirm with the organization.

6. Timely safety monitoring and reporting

Safety monitoring and reporting are an important part of ensuring subject safety. pass

The paper diary card allows the subjects to collect safety event information by themselves and display it on the next visit.

The way of communicating with researchers during on-site follow-up usually has low compliance and the collection of

The data is limited. Consider adopting some digital technologies and platforms (e.g.

Through the subject's mobile app or remote visit platform) and/or digital medical technology

(such as wearable devices) to monitor the safety of subjects in real time and

reporting, making it easier for subjects to report safety events in a timely manner and improving compliance

, the collected data can be directly transferred to researchers.

When adopting these technologies, attention should be paid to the additional security risks that may arise

risk. Researchers can receive subject safety information in real time through the platform (e.g.

Such as adverse events), but the researcher will comprehensively consider the safety characteristics of the study drug,

Team resources, etc., reasonably arrange the frequency of viewing and processing of these reports.

Therefore, there will be some time for researchers to receive and evaluate the safety information of subjects.

time delay. In order to prevent the researcher from not checking in time and causing the subjects to suffer

Safety risks, researchers should clearly inform subjects of this situation in advance and inform

Know the circumstances under which the subject is exposed (for example, when a serious adverse event occurs), the subject

The researcher can be contacted directly (e.g., by phone). In addition, when severe

In the event of an incident (such as a serious adverse event), the platform should establish a mechanism to ensure that

The researcher can be directly contacted through the triggering mechanism so that he or she can check within the specified time limit.

Observe the evaluation, promptly and reasonably handle the subjects and report to the sponsor. Finally, pass

Subjects' personal information collected by technology and platforms should be fully protected. like

If different collection methods are used (e.g. electronic and paper), care should be taken to evaluate the different

The measurement results collected by the method are consistent.

7. Remote monitoring

Monitoring is an important part of clinical trial quality management activities. Sponsors can

Adopt multiple risk-based approaches to include decentralized clinical trial models

Clinical trials should be monitored, and the monitoring plan should also be set based on risks. Far

Process monitoring refers to the conduct of clinical research by the sponsor's staff or representatives during the implementation of clinical research.

Review test data in places other than the center, including using source documents to review, etc.

Way. Currently, many clinical trials are implemented using digital systems and platforms.

The data is stored in electronic form, providing the possibility of remote monitoring.

Consider whether to use remote monitoring and review the source documents

When establishing remote access rights, the necessity and rationality should be comprehensively considered, including

Consider (1) the accessibility of subject electronic source data; (2) the relationship between remote monitoring and existing

Compatibility of systems, platforms and processes; (3) Research team's experience and affordability

It depends on the burden and other conditions. Blindly carrying out remote monitoring may bring problems to the research center.

This imposes unnecessary burdens and fails to achieve the purpose of effective supervision.

The primary concern when using remote monitoring is the protection of subjects' personal information.

and data security. Data from various electronic systems such as hospital medical records

When conducting remote monitoring of the source files of the system), relevant parties should follow the "Personal Information

"Information Protection Act" and other relevant laws and regulations, and adopt corresponding measures to protect the personal information of subjects.

information and data security. Access rights and scope of access to each system (such as only

Access to the data of subjects participating in clinical trials, with only readable functions), etc. should be

line regulations. Similarly, in order to ensure data security, the remote

The process monitoring platform should be verified and a login verification process should be set up to ensure progress.

The identity of the person accessing the data in the remote monitoring system. Remote monitors need to go through

Corresponding training should be provided and remote monitoring should be conducted in a confidential and secure network environment.

All inspection records should be kept intact.

8. Compensation of subjects

Regarding the time it takes and the inconvenience caused to subjects to participate in clinical trials,

Compensation should be provided, and the method, amount, and plan of compensation should pass ethical review and

Reflected in the informed consent form or other relevant materials provided to the subjects. for

In order to achieve "timely payment" and effectively protect the rights and interests of subjects, the compensation of subjects

Consider choosing a payment method that combines new technologies to achieve this. If new payment is adopted

The methods should comply with current laws and regulations, paying special attention to the protection of personal information.

4. Other matters needing attention

(1) Strengthen multi-party communication

1. Strengthen communication with subjects

Establishing a good relationship of trust with subjects is the key to patient-centered clinical practice.

The cornerstone of clinical trial implementation, when using remote methods (such as remote visits), should

Particular attention is paid to establishing good researcher-subject relationships. Communication with subjects

and care for the subjects should be throughout the entire process of the trial, and subjects should be listened to in a timely manner.

voice to understand subject needs (e.g., through subject welcome letters and

Inform subjects of clinical data status at the end of the trial, etc.). Encourage patients and

Always report your feelings or encounters to the research doctor, research nurse, or sponsor.

to the problem.

2. Strengthen communication among all parties in the team

Communication between sponsors, researchers, contract research organizations, etc. should be strengthened,

Based on the patient experience data collected in real time during implementation, timely communication and relevant

Trial adjustments or clinical decisions should be made. When adopting new technologies and new models, we should strengthen cooperation with

Communication between authorized researchers ensures smooth implementation of the trial. When there is an

If there are any safety issues, you should communicate with the ethics committee in a timely manner.

3. Communicate with review agencies in a timely manner

When clinical trials adopt new technologies, new models and other related elements, the sponsor should

Explain its necessity, scientificity, and feasibility in the clinical trial plan,

The content involves but is not limited to purpose of use, usage scenarios, basic information, evaluation and

Validation data, comparative trial data with traditional methods, risk assessment and mitigation measures

Implementation, etc., and communicate with the review agency in a timely manner. Sponsors are encouraged to wait for multiple parties to

Continue to explore and develop new technologies that can support patient-centered trial implementation,

New methods and new models will continue to address new risks that continue to emerge with technological development.

Identify, evaluate and manage, and communicate with review agencies.

(2) Education and training

1. Training of researchers

Sponsors and investigators should ensure that researchers involved in trials, especially

New technologies adopted, methods of using new models, precautions, and potential risks

and processing, etc. to ensure that they fully understand the research plan, implementation operations and

potential risks. In addition, training should also be used to improve patient experience data collection and

Feedback is valued. It is recommended to evaluate and monitor the quality and effectiveness of training and encourage the establishment of

Assessment and authorization mechanism after training.

2. Subject training and education

As important trial participants, sponsors and investigators should review subjects in advance

Provide training and education. Subjects should be encouraged to promptly and truthfully express their concerns about the disease and

Opinions and needs for treatment and clinical trial implementation. Subjects should be adequately

Education and training to fully understand the new technologies and technologies used in the implementation of clinical trials

New models (e.g. electronic clinical outcome assessment used in trials, digital health

technology) specific usage methods, precautions, data recording and retention, acquisition

Benefits and potential risks, handling measures when security incidents occur, etc., to ensure

The rights and safety of subjects and improve subject compliance.

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