



Drug Clinical Trials Quality Management and Subject Protection

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Summary

- ◆ The management status of clinical trials institutions
- ◆ Specific measures to enhance the drug clinical trials quality management and subject protection



Achievements of institution construction and management

Situations of clinical trials by institutions:

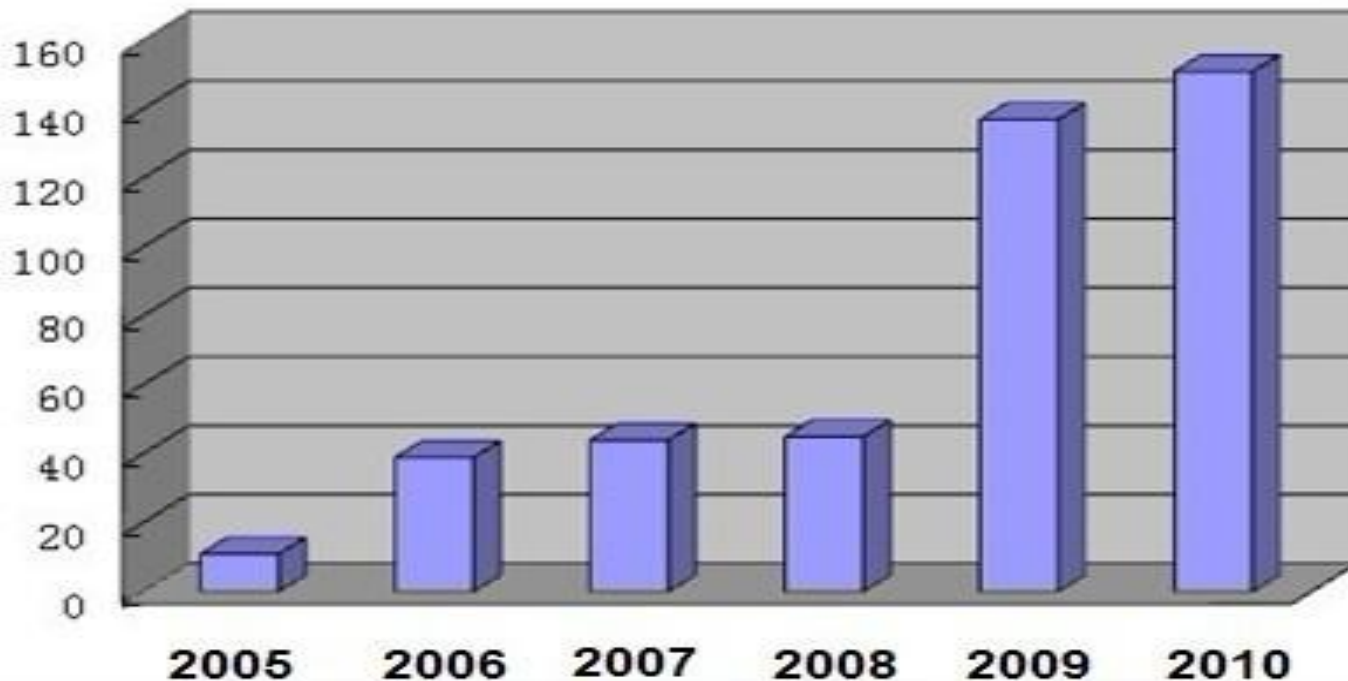
- ❖ 2005-2011, institutions have carried out more than 6,000 clinical trials
- ❖ In recent years, there are about 1500 drug clinical trials in the implementation every year.



Achievements of institution construction and management

Application and approval of the international multi-center drug clinical trial:

2005年至2010年国际多中心临床试验批准量



Time (Year)

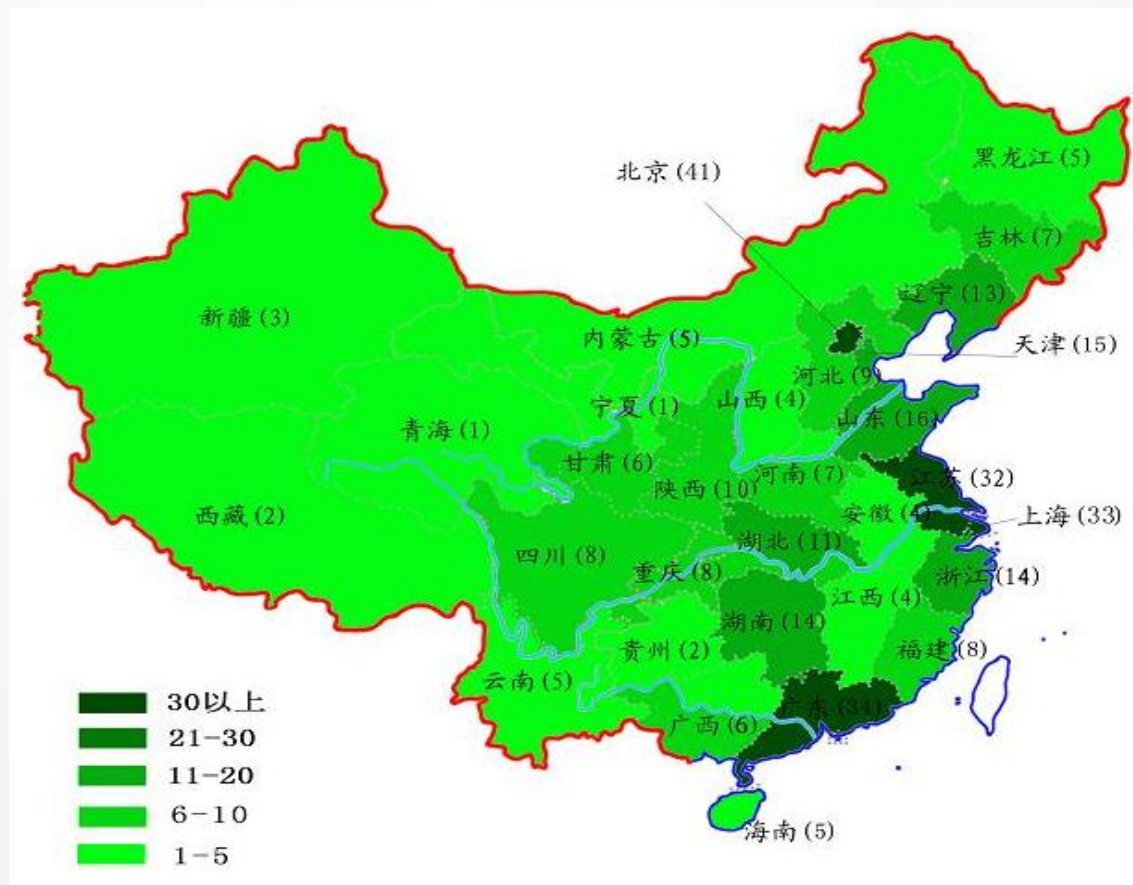


Achievements of institution construction and management

- 333 clinical trials institutions are identified; large number of GCP-trained medical experts participate in the clinical trials work;
- A large number of clinical trials are undertaken, and the quality and level of clinical trials are continuously improved;
- A system of laws, regulations and guidelines are constructed, so clinical trials have a basis for supervision;
- A GCP inspector team with 208 members is trained, with the procedures and standard of supervision and inspection, and the way and the method of supervision and inspection is improved;

Achievements of institution construction and management

Distribution of clinical trials institutions



By the end of 2011, 333 institutions, 2384 specific departments have obtained the qualification identification from the Ministry of Health and SFDA.



Several measures to enhance the quality management of drug clinical trials

- Taking clinical trial Phase I as the breakthrough point, the classification management of drug clinical trials institutions has been implemented.
- Develop the guiding principles and other normative documents, and promote the standardization of clinical trials
- Establish the information system of clinical trials supervision, and improve the efficiency of supervision
- Increase the efforts of the inspection, and ensure the data is reliable.



Implement the classification management to the institutions

- ◆ Taking clinical trials Phase I as the breakthrough point, the classification management of institutions has been progressively implemented
- ◆ Implementation steps
 - Check and correct independently in accordance with the Management Guidelines to the Phase I clinical trial of Drug (Trial)
 - SFDA shall develop The inspection procedures, inspection standards and implementation plans.
 - Check and evaluate the laboratory of drug clinical trial phase I
 - Enhance the training and guiding
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Enhance the guidance, and promote the standardization

◆ Published:

- Management Guidelines of drug clinical trial phase I (Trial)
- Laboratories Management Guidelines to the Biological Samples Analysis of Drug Clinical Trials (Trial)
- Guiding Principles to Ethical Review of Drug Clinical Trials

◆ Under Consultation:

- Guiding Principles to the Management of Drug Clinical Trial Institutions



Enhance the guiding, promote the standardization

Purpose and significance of the Management Guidelines of Drug Clinical Trials Phase I

- According to the complexity, innovation and high-risk of the design and the implementation of the new drug phase I trial
- For the problems that the design level of innovative new drug clinical trials is not high, the experience is not enough, and the risk control is insufficient;
- Guide the construction, operation and management of laboratory of drug clinical trials, and improve the quality of clinical trials and protect the rights and security of subjects.



Enhance the guiding, promote the standardization

Management Guidelines to the Phase I Clinical Trials of Drug
has 14 chapters and 54 clauses in all

- Chapter 1, General Provisions , 2 clauses;
- Chapter 2, Duty Requirements, 6 clauses;
- Chapter 3, Implementation Conditions, 7 clauses;
- Chapter 4, Management Systems and Standard Operating Procedures, 4 clauses;
- Chapter 5 Quality Assurance, 2 clauses;
- Chapter 6, Risk Management, 5 clauses;



Enhance the guiding, promote the standardization

Management Guidelines to the Phase I Clinical Trials of Drug has 14 chapters and 54 clauses in all

- Chapter 7, Contract and Terms of the Agreements, 3 clauses;
- ❖ Chapter 8, Test Plan, 3 clauses;
- ❖ Chapter 9, Subjects Management, 4 clauses;
- ❖ Chapter 10, Test Drug Management, 5 clauses;
- ❖ Chapter 11, Biological Sample Management and Analysis, 4 clauses;
- ❖ Chapter 12, Data Management and Statistical Analysis, 5 clauses;
- ❖ Chapter 13, Final Report, 2 clauses;
- ❖ Chapter 14, Supplementary Provisions, 2 clauses;

Note: the implementation of ethical review is based on the

Guiding Principles of Ethical Review to the Drug Clinical Trial.



Enhance the guiding, promote the standardization

The purpose and significance of the Analysis Laboratory Management Guidelines (Trial):

- The analysis data of biological samples is an important part of new drug registration application, and is an important basis for the technical review of new drug registration by the drug supervision authorities;
- The conditions of biological sample analysis laboratories are uneven, and the development is not balanced;
- **Enhance the quality management of biological sample analysis laboratory, to and improve the analytical ability and level**



Enhance the guiding, promote the standardization

Laboratory Management Guidelines (Trial) has 9 chapters and 47 clauses:

- Chapter 1, General Provisions, 3 clauses
- ❖ Chapter 2, Organization Institutions and Personnel, 5 clauses
- ❖ Chapter 3, Laboratory Facilities, 5 clauses
- ❖ Chapter 4, Instruments and Materials, 3 clauses
- ❖ Chapter 5, Contract Management, 3 clauses
- ❖ Chapter 6, Standard Operating Procedures, 5 clauses
- ❖ Chapter 7, Implementation of Experiment, 8 clauses
- ❖ Chapter 8, Data Management, 10 clauses
- ❖ Chapter 9, Quality Management, 5 clauses



Enhance the guiding, promote the standardization

Guiding Principles to the Management of Drug Clinical Trials Institutions (draft) has 9 chapters and 40 clauses:

- ❖ Chapter 1, General Provisions, 2 clauses
- ❖ Chapter 2, Organization and Personnel Requirements, 4 clauses
- ❖ Chapter 3, Duty Requirements, 10 clauses
- ❖ Chapter 4, Quality Management, 3 clauses
- ❖ Chapter 5, Training and Evaluation, 4 clauses
- ❖ Chapter 6, Management to the Test Drugs, 4 clauses
- ❖ Chapter 7, Standard Operating Procedures, 4 clauses
- ❖ Chapter 8, Document Management, 7 clauses
- ❖ Chapter 9, SAE and Emergency Management, 2 clauses



Enhance the guiding, promote the standardization

Characteristics of the Guiding Principles of Ethical Review to the Drug Clinical Trials

- ❖ Take GCP as the basic framework
- ❖ Take internationally recognized ethical guidelines as the theoretical basis

World Medical Association: Declaration of Helsinki

International Council of Medical Sciences Organizations: International Ethical Guidelines for the Biomedical Research Involving Human

- ❖ Present preliminary plan Ethics Committee about the quality management
- ❖ Present clear requirements to the Ethics Committee about their duties
- ❖ Present the detailed provisions to the Ethics Committee about the system construction, review processes and elements



Enhance the guiding, promote the standardization

Characteristics of the Guiding Principles of Ethical Review to the Drug Clinical Trials

- **As the critical condition of review:**

Complete documents

Statutory number of attendances

Full discussions

During discussion and voting, the applicant and the Committee who conflicts are required to leave.

The committee member who does not participate in the review meeting shall not vote by other members.



Enhance the guiding, promote the standardization

Characteristics of the Guiding Principles of Ethical Review to the Drug Clinical Trials

- Collaborative review of the multi-center clinical trials

The Ethics Committee of the head institution shall be responsible for the review of the scientific and ethical rationality of the trial plan.

Under the premise that the Ethics Committee of the involved institution accepts the review comments of the Ethics Committee of the head institution, they shall review the feasibility to carry out the trial in their institution ... The Ethics Committee of the involved institution has the right to approve or disapprove to carry out the trial in their institution.

The Ethics Committees of each center shall follow up the implementation of the clinical trials conducted in the institution.

The involved institutions shall timely record the follow-up comments of the clinical trials that proposed by the head institution.



Enhance the guiding, promote the standardization

Summary of the ethical review of drug clinical trials

- ❖ Regulating the work of the ethics commission and improving the quality of ethical review, ensure the implementation of clinical trials meets the ethical requirements
- ❖ Besides the ethics committee shall improve its own capacity, it shall enhance the communication with researchers to provide effective advice and guidance
- ❖ High-quality clinical trial is required the multilateral cooperation, and based on discipline, regulation, law, philosophy, organizational structure, process control, best practices and the use of the most advanced technology, but the premise is the personal integrity and the consequent commitment of “to do the right thing.”



Innovate the means, improve the performance

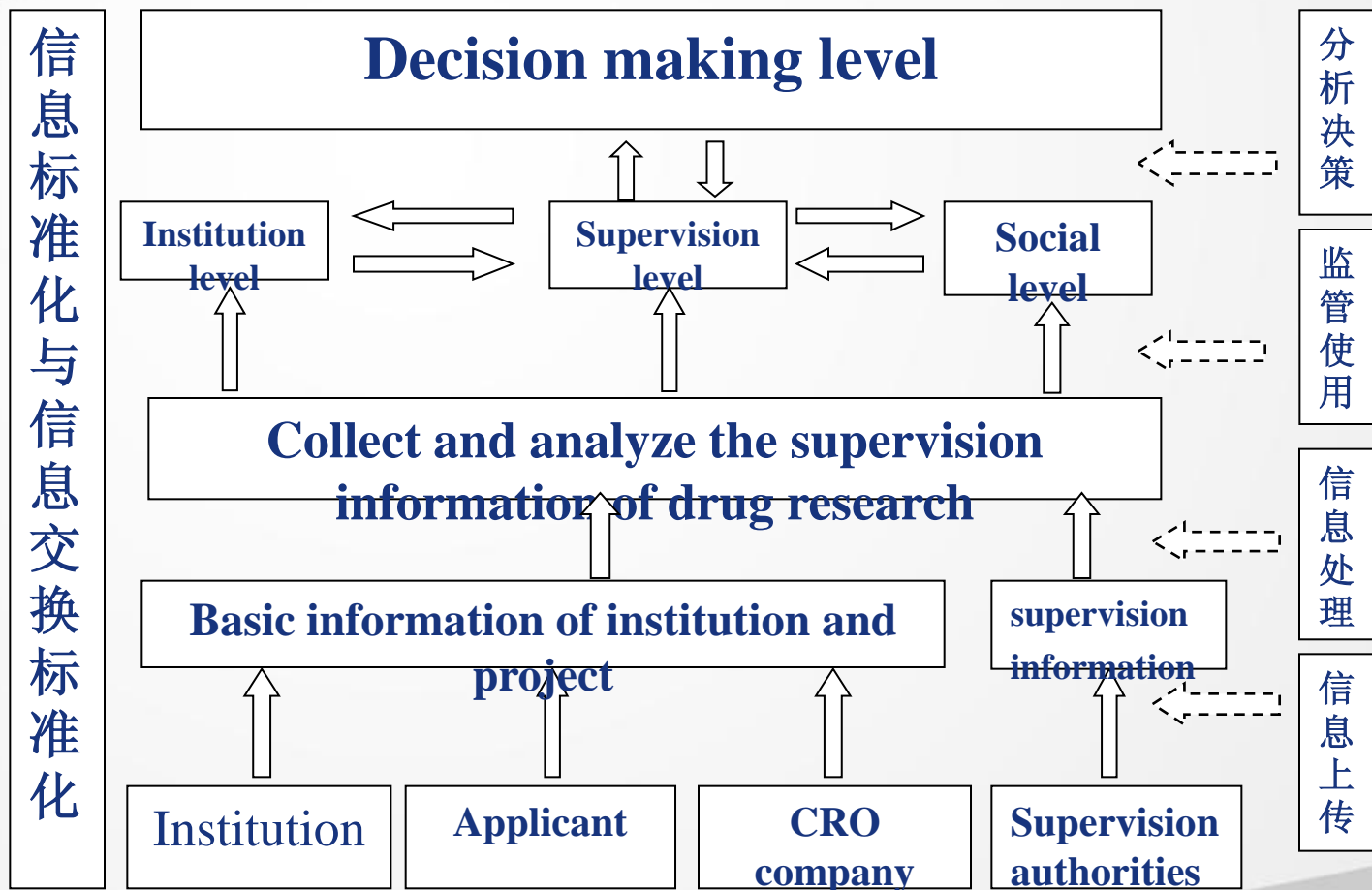
Supervision information system of clinical trials:

- ❖ Take GCP as the basis;
- ❖ Take the critical information of drug clinical trials institution as the basis;
- ❖ Take the safety data of clinical trials as the clues to dynamically supervise;

Includes six major modules: basic information, project record, clinical trials, SAE management, GCP certification, supervision and inspection



Top-level design for the supervision information system





Innovate the means, improve the performance

Supervision information system for drug clinical trials:

- ❖ Dynamically supervise the overall situation of the research institutions
- ❖ Dynamically supervise the implementation and quality management of the clinical trials
- ❖ Dynamically supervise the acceptance to the supervision and inspection and the correction
- ❖ Dynamically manage the daily supervision work
- ❖ Collect information from multi-aspect, strengthen the social supervision



Enhance the efforts of inspection, improve the quality of trail

The purposes of the main means to supervise and inspect the

clinical trials:

- ❖ Improve the compliance of drug clinical trials institutions to the law and regulations (e.g., GCP), the test program and standard operating procedures;
- ❖ Promote the institutions to protect the rights and safety of the subjects;
- ❖ Verify the truth and reliability of the data and information submitted to the supervision authorities.

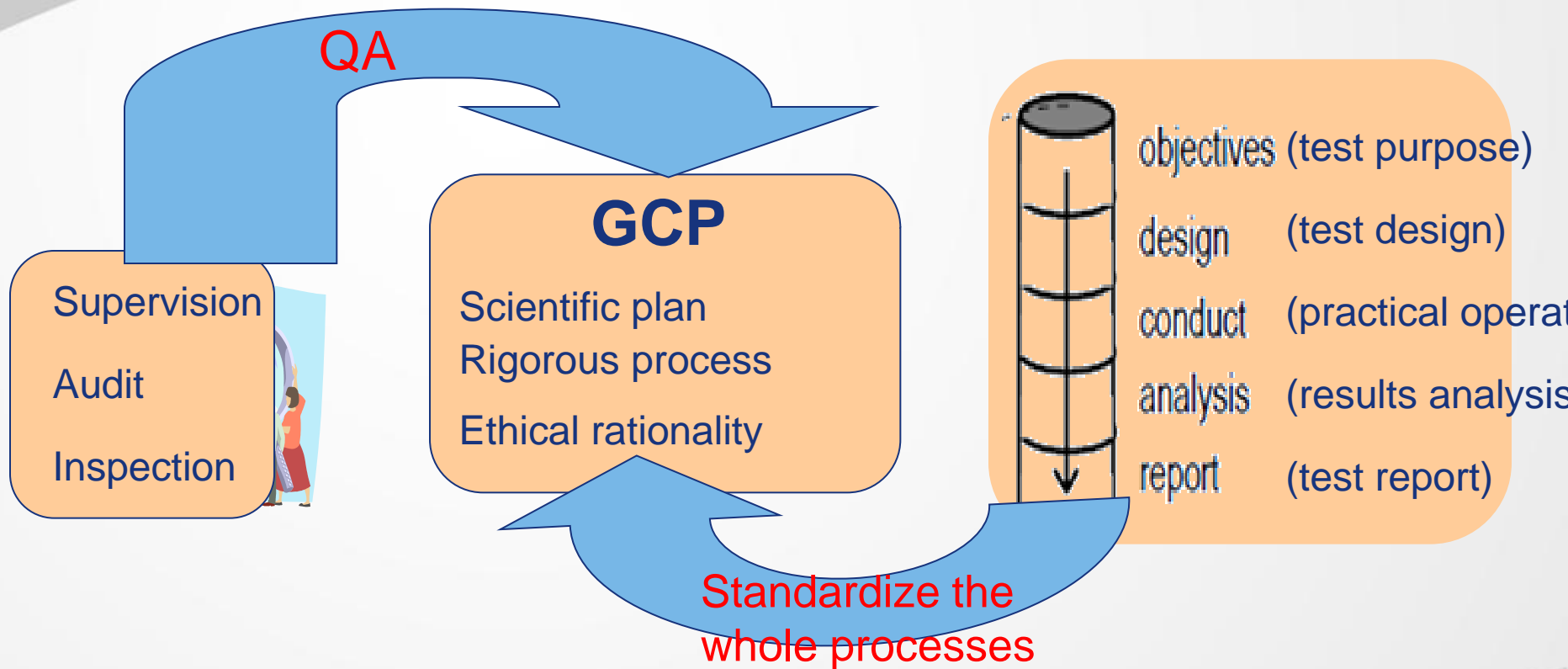


Enhance the efforts of inspection, improve the quality of trail

- ❖ Combine the institution identification, process supervision and project inspection
- ❖ Combine the technical review and on-site inspection
- ❖ Linkage mechanism between the SFDA and the provincial Food and Drug Administration



Conclusion



➤ It's management, standardization and developing of good habit.



The scientific attitude and meticulous work are required.

Good design + good management

+ good data+ good analysis

+ good report + good review

= Good decision

Thanks !

