Evaluation of Education System for Clinical Trial Investigators

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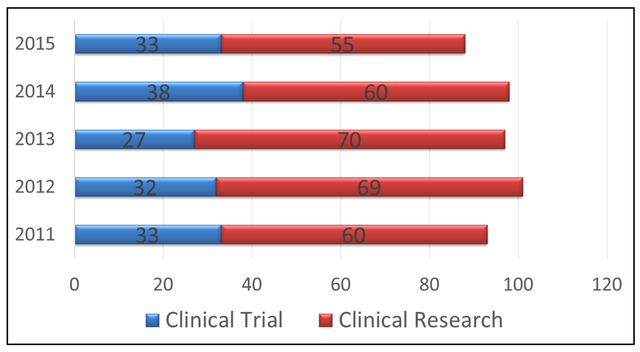
Background

Several cases of misconduct in research have occurred over the years in Japan.

Under new guidelines, measures have been taken to have a researcher's institution assume greater responsibility and create an environment to reduce misconduct. One effort is to enhance researcher integrity by conducting education.

Roles of the Clinical Trial Office of NHO Kure Medical Center/ Chugoku Cancer Center (KMCCCC)

Clinical Trial and Research at KMCCCC



The Clinical Trial Office of KMCCCC is in the position of supporting and educating new investigators and research staff to ensure high data quality.

Objective

To demonstrate the impact of the clinical research education system at KMCCCC on the development of quality management.

It is expected that investigators who initiate clinical trials will ensure high data quality.

Methods

A retrospective review was performed of all clinical trial audits conducted by Pharmaceuticals and Medical Devices Agency(PMDA), Japan Cooperative Oncology Group(JCOG), NRG oncology, and cooperative groups from 2011 to 2015. The audit findings was compared between before and after the implementation of the clinical research education system. Deviation based on GCP, Ethical Guidelines for Clinical Research, and research protocol requirements were categorized as follows:

- ✓Failure to follow the protocol
- ✓Data integrity
- ✓Enrollment of ineligible subject
- ✓IRB submission issue
- ✓Informed consent problem
- ✓Delay in reporting SAE/UAP

Education Systems

- Regularly held 2-3 seminars a year on clinical research at our hospital.
- Since 2013, invited a leading expert in the field to lecture at least once a year.
- Since 2013, provided certificates to seminar attendees.
- Since 2013, required investigators to receive education on the ethics of research and the knowledge and skills necessary to carry out the research.
- If an investigator could not attend the seminars, required them to complete an e-learning course prior to commencing research .

Process to start clinical trial

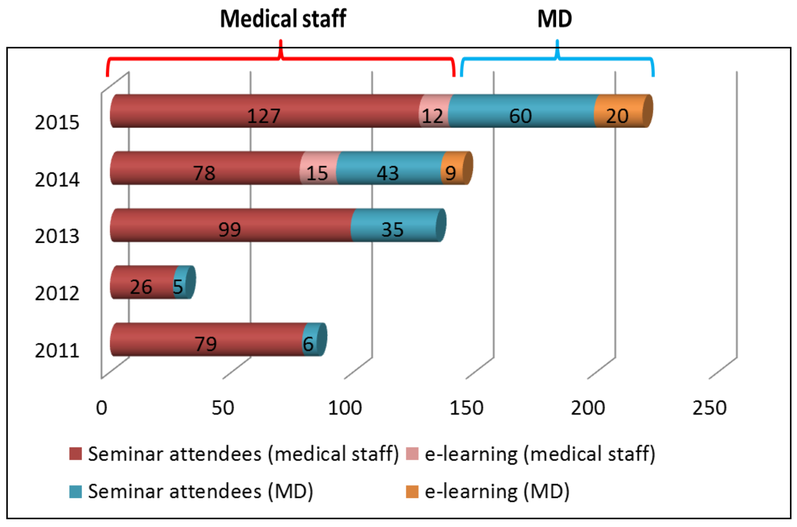
Investigator → Clinical Research Education → IRB (Institutional Review Board) → Clinical Trial Start

Education Contents

- GCP
- Ethical Guidelines for Medical and Health Research Involving Human Subjects
- Responsible Conduct of Research
  - ✓Research Misconduct
  - ✓Data Handling
  - ✓Conflict Of Interest
  - ✓Managing Public Research Funds
- Research Involving Human Subjects
  - ✓Ethical Review Committee
  - ✓Informed Consent
  - ✓Personal Information, etc.

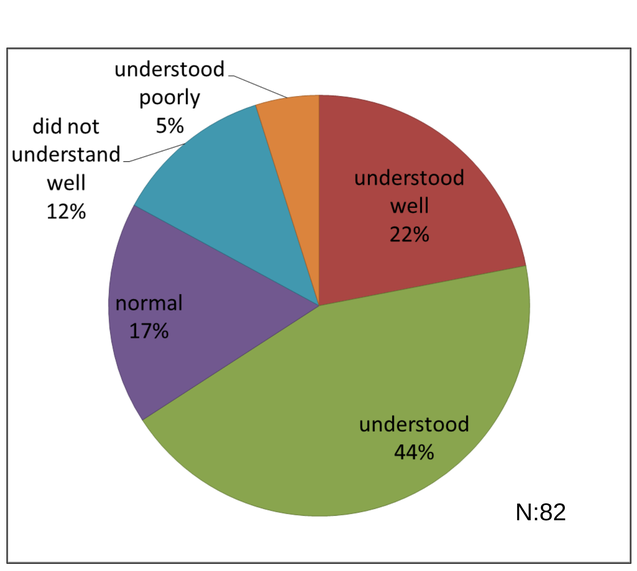
Results

Seminar attendees and investigators who completed the e-learning



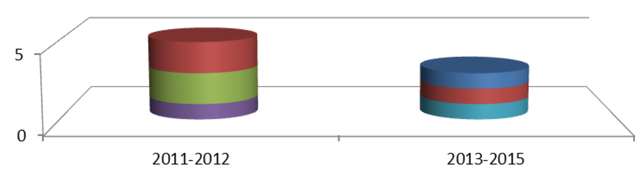
Medical staff; nurse, pharmacist, or others.

Self-reported understanding by seminar attendees in 2015



Audit findings by regulating authority and leading cooperative groups

	2011–2012	2013–2015
Audit	4	5
Deviation	5	3
Deviation / Audit	125%	60%



	2011-2012	2013-2015
Failure to follow the protocol		1
Data integrity	2	1
Enrollment of ineligible subject	2	
IRB submission issue	1	
Informed Consent Problem		1
Delay in reporting SAE/UAP		

Conclusion

Since implementation of the educational system, negative audit findings have been reduced by 65%.
These results indicate that the education system is effective in ensuring high data quality.

NHO KMC CCC